U.S. Department of Veterans Affairs

Veterans Health Administration
VHA FOIA Office (105HIG)
810 Vermont Avenue NW
Washington, DC 20420

In Reply Refer To: **FOIA Request: 19-11256-F**

July 28, 2021

RECEIVED
AUG 20 2021
BY:

Melanie Sloan
American Oversight
1030 15th Street, NW
Washington, DC, 20005
foia@americanoversight.org

Dear Ms. Sloan:

This letter is the second and final partial initial agency decision to your September 4, 2019, request under the Freedom of Information Act (FOIA), 5 U.S.C. § 552, submitted to the Department of Veterans Affairs (VA), Veterans Health Administration (VHA) Central Office FOIA Office requesting the following records:

1. All email communications (including email messages, email attachments, calendar invitations, and calendar invitation attachments) sent by any of the VA officials and employees listed below regarding Spravato (esketamine) nasal spray:

    a. Richard A Stone, Executive in Charge, Veterans Health Administration.
    b. Steven L. Lieberman, Acting Principal Deputy Under Secretary for Health.
    c. Lawrence Connell, Chief of Staff, Veterans Health Administration
    d. Jon M. Jensen, Acting Deputy Chief of Staff
    e. Valerie Mattison Brown, Assistant Deputy Under Secretary for Health, Policy and Planning
    f. Maria Llorente, Acting Assistant Deputy Under Secretary for Health for Patient Care Services (PCS).
    g. Michael A. Valentino, Chief Consultant – Pharmacy Benefit Management Services (PBM), and anyone serving as his assistant or scheduler.
    h. Yasuharu Okuda, Acting Deputy Chief PCS Officer.
    i. Thomas Emmendorfer, Deputy Chief Consultant – PBM.
    j. Joseph Canzolino, Deputy Chief Consultant – Formulary Management.
    k. Timothy Stroup, Deputy Chief Consultant – PBM Strategic Planning.
    l. Virginia Torrise, Deputy Chief Consultant – PBM Professional Practice and Clinical Informatics.
    m. Louis Cobuzzi, Associate Chief Consultant – Planning Analysis and Policy Development.
    n. John Lowe, Associate Chief Consultant – Planning Analysis and Policy Development.
    o. Lynn Sanders, Associate Chief Consultant – Clinical Informatics and Pharmacy Re-engineering.
    p. Vaiyapuri Subramaniam, Associate Chief Consultant – Adverse Drug Events/United States Pharmacopeia 797/Policy.

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q. Matthew A. Fuller, National Clinical Pharmacy Program Manager, PBM.
r. Chester B. Good, Chair, Medical Advisory Panel, PBM.
s. David Carroll, Executive Director, Office of Mental Health and Suicide Prevention.
t. Lynda O'Neill, Contracting Officer, National Acquisition Center.
u. Craig Robinson, Associate Executive Director, National Acquisition Center

American Oversight believes that records containing the terms below are likely to be responsive records, and American Oversight requests that VA, at a minimum, employ these search terms to identify responsive records.
§ Spravato
§ esketamine
§ nasal spray
§ "treatment-resistant" AND depress*
§ stimulant AND suicide
- 4 - VA-19-1109
§ stimulant AND depress*
§ "J&J" AND drug
§ "J&J" AND suicide
§ "J&J" AND depress*
§ "J&J" AND buy
§ "Johnson & Johnson" AND drug
§ "Johnson & Johnson" AND suicide
§ "Johnson & Johnson" AND depress*
§ "Johnson & Johnson" AND buy
§ Janssen AND drug
§ Janssen AND suicide
§ Janssen AND depress*
§ Janssen AND buy

Please note that American Oversight is using the asterisk (*) to designate the standard use of "wildcards" in the search for responsive records. For example, a search for "depress*" would return both depression and depressant. If VA is unable to search for wildcards, please advise so that we may specifically include the variations that we would like searched. Please provide all responsive records from within the following date ranges:
§ March 5–26, 2019
§ June 10–28, 2019
§ August 14–28, 2019.

Your FOIA request was received in my office on September 4, 2019. As stated within the September 5, 2019 letter, line items t. Lynda O'Neill and u. Craig Robinson were referred to the Office of Acquisitions and Logistics, under FOIA tracking number 19-11257-F.

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On April 23, 2021, we requested further clarification regarding your request in which you provided a response to eliminate marketing emails; VA Media Summary and News Clips; Long excel spreadsheets/reports from pharmacy staff or other offices of all medications, that do not directly discuss the key search terms "Spravato, Ekestamine" regarding price and News Alerts from external sources.

At this time VHA is rendering its second and final partial initial agency decision. These documents resulted in an online search conducted by the VA Office of Information and Technology, responsive for Richard Stone, Executive in Charge; Steven L. Lieberman, Acting Principal Deputy Under Secretary for Health; Lawrence Connell, Chief of Staff; Jon M. Jenson, Acting Deputy Chief of Staff; Valerie Mattison Brown, Assistant Deputy Under Secretary for Health, Policy and Planning; Maria Llorente, Acting Assistant Deputy Under Secretary for Health for Patient Care Services (PCS); Michael A. Valentino, Chief Consultant; Thomas Emmendorfer, Deputy Chief Consultant; Virginia Torrise, Deputy Chief Consultant; Lynn Sanders, Associate Chief Consultant; Matthew A. Fuller, National Clinical Pharmacy Program Manager; Chester B. Good Chair, Medical Advisory Panel, PBM; and David Carroll, Executive Director, Office of Mental Health and Suicide Prevention, for the date range of March 5-26, 2019, June 10-28, 2019 and August 14-28, 2019. The search terms used were: Spravato, esketamine, nasal spray, treatment-resistant" AND depress, stimulant AND suicide, 4 - VA-19-1109, stimulant AND depress, J&J" AND drug, "J&J" AND suicide, "J&J" AND depress, "J&J" AND buy, "Johnson & Johnson" AND drug, "Johnson & Johnson" AND suicide, "Johnson & Johnson" AND depress*, "Johnson & Johnson" AND buy, Janssen AND drug, Janssen AND suicide, Janssen AND depress*, Janssen AND buy. Provided within this release is 2,775 pages of responsive records.

Upon my review I have found information protected under the FOIA, specifically, FOIA exemption 5, 5 U.S.C. § 552(b)(5), FOIA exemption 6, 5 U.S.C. § 552(b)(6).

FOIA Exemption 5 [5 U.S.C. § 552 (b)(5)] permits VA to withhold a document or information contained within a document as "pre-decisional" if two requirements are met. First, there must be an identifiable deliberative process. That is, the document must be a direct part of the deliberative process. Second, the agency generated the information or document as part of the agency decision process. Stated another way, VA may withhold information under Exemption 5 where the document or its content makes recommendations or expresses opinions about legal or policy matters during a decision-making process and the document is not the decision document or incorporated into the decision document. Additionally, in accordance with the FOIA Improvement Act of 2016, an agency shall withhold information under the FOIA only if the agency reasonably foresees that disclosure would harm an interest protected by an exemption or disclosure is prohibited by law. Stated another way, if the disclosure is not prohibited by law, the agency must state an articulable, foreseeable harm to the agency or its activities that could occur as a result of release of the document or information.

My review reveals pages that contain information that falls within the protection of Exemption 5. Specifically, information is being withheld under Exemption 5 as the

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documents contain open and frank pre-decisional communications between staff at various levels of the organization. Staff are providing feedback by voicing their opinions. There are several categories of documents that routinely are protected by the deliberative process privilege of Exemption 5. Among the protected documents are advisory opinions, recommendations, and deliberations comprising parts of a process by which governmental decisions and policies are formulated. They are protected because, by their very nature, their release would likely "stifle honest and frank communication within the agency." Materials of this nature go to the very heart of the privilege, for, as the Supreme Court has stated, "the deliberative process privilege rests on the obvious realization that officials will not communicate candidly among themselves if each remark is a potential item of discovery and front page news. Schell, 843 F.2d at 941 "A subordinate who wishes to provide information candidly should not fear that the public will be privy to his views merely because his superiors have not yet acted on his recommendations." In determining whether a document is pre-decisional, an agency does not necessarily have to point specifically to an agency final decision, but merely establish "what deliberative process is involved, and the role played by the documents in issue in the course of that process. Thus, so long as a document is generated as part of such a continuing process of agency decision making, courts have found Exemption 5 can be applicable. In a particularly instructive decision, Access Reports v. DOJ, the Court of Appeals for the District of Columbia Circuit emphasized the importance of identifying the larger process to which a document sometimes contributes. Further, "pre-decisional" documents are not only those circulated within the agency but can also be those from an agency lacking decisional authority that advises another agency possessing such authority. They even can be "documents which the agency decision maker herself prepared as part of her deliberation and decision-making process, or documents that do not end up being considered by the agency decision maker at all. Release of this information would inhibit employees from freely exchanging opinions resulting in harm to deliberative process itself. If employees believed that their open and frank feedback were to become public, staff would be less likely to freely communicate their opinions. See, e.g., Russell v. Dep't of the Air Force, 682 F.2d 1045, 1048 (D.C. Cir. 1982); Coastal States Gas Corp. v. DOE, 617 F.2d 854, 866 (D.C. Cir. 1980); Jordan v. DOJ, 591 F.2d 753, 772-73 (D.C. Cir. 1978) (en banc); Brown v. EEOC, No. 09-111, 2010 U.S. Dist. LEXIS 46466, at *9 (W.D. Ky. May 12, 2010) (holding that Exemption 5 was properly applied to prevent potential chilling effect on agency's discussions and undermining of agency's ability to perform its duties); Morley v. CIA, 699 F. Supp. 2d 244, 255-56 (D.D.C. 2010) (stating that privilege is "intended to prevent chilling future government employees from engaging in frank discussions during the deliberative process" (citing Coastal States, 617 F.2d at 866)), aff'd in pertinent part, vacated and remanded on other grounds, 466 Fed. App'x. 1 (D.C. Cir. 2012).

In addition, releasing the discussions within the emails requested would cause confusion to the public because the information conveyed was not part of final decisions made and therefore would do very little to add to the public's understanding of the operations and activities of the agency. See, AFGE v. HHS, 63 F. Supp. 2d 104, 108

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(D. Mass. 1999) (holding that release of pre-decisional documents "could cause harm by providing the public with erroneous information"), aff'd, No. 99-2208, 2000 U.S. App. LEXIS 10993 (1st Cir. May 18, 2000); Thus exemption 5 is applied to protect against public confusion that might result from disclosure of reasons or rationales that were not in fact ultimately the grounds for the agency's decision.

As emails containing pre-decisional content, the release of this information would cause injury to the deliberative process described in the above paragraphs. The deliberative process privilege of FOIA exemption 5 is invoked as I have determined that the release of this information to the public would negatively impact frank discussions within VHA and would protect against public confusion that might result from disclosure of reasons and rationales that were not consistent with VHA actions. Pages within this document have been withheld both in part and in full and pages have been marked (B5) to annotate the redaction applied.

FOIA Exemption 6 [5 U.S.C. § 552 (b)(6)] covers "personnel and medical files and similar files of which the disclosure would constitute a clearly unwarranted invasion of personal privacy." Stated another way, VA may withhold information under FOIA Exemption 6 where disclosure of the information, either by itself or in conjunction with other information available to either the public or the FOIA requester, would result in an unwarranted invasion of an individual's personal privacy without contributing significantly to the public's understanding of the activities of the federal government.

In United States Department of Justice v. Reporters committee for Freedom of the Press, 489 U.S. 749 (1989), we must determine if a privacy interest is involved, and determine if disclosure of the requested information would serve the public interest, and balance the personal privacy interest against the public interest. In evaluating the public interest in a given case, we must focus on the nature of the requested document and its relationship to the public interest generally. We must consider whether disclosure of the requested document, or portions thereof that have been withheld, would "open agency action to the light of public scrutiny" rather than focus on the particular purpose for which the document is being requested. See Reporters Committee, 489, U.S. at 772.

The coverage of FOIA Exemption 6 is absolute unless the FOIA requester can demonstrate a countervailing public interest in the requested information by demonstrating that the individual is in a position to provide the requested information to members of the general public and that the information requested contributes significantly to the public's understanding of the activities of the Federal government. Additionally, the requester must demonstrate how the public's need to understand the information significantly outweighs the privacy interest of the person to whom the information pertains. Upon consideration of the materials provided, it is recognized that you are in a position to provide the requested information to members of the general public however; I have not been able to identify a countervailing public interest of sufficient magnitude to outweigh the privacy interest in this case. Consequently, the names of non-VA employees, employee email addresses and

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phone numbers have been redacted under Exemption 6. Inserted is (b6) to identify the FOIA Exemption applied.

As noted above, a search for documents responsive to this request was conducted within the VA Office of Information and Technology on September 10, 2019. The following email accounts were not located by the VA OIT office to conduct a search for records responsive to your request: h. Yasuharu Okuda, Acting Deputy Chief PCS Officer, j. Joseph Canzolino, Deputy Chief Consultant – Formulary Management, k. Timothy Stroup, Deputy Chief Consultant – PBM Strategic Planning, m. Louis Cobuzzi, Associate Chief Consultant-Planning Analysis and Policy Development, n. John Lowe, Associate Chief Consultant – Planning Analysis and Policy and p. Vaiyapuri Subramaniam, Associate Chief Consultant – Adverse Drug Events/United States Pharmacopeia 797/Policy. Therefore, we are providing a "no records" response to these portions of your request, as noted above.

If you disagree with my determinations, please be advised you may appeal to:

Office of the General Counsel (024)
Department of Veterans Affairs
810 Vermont Avenue, N.W.
Washington, D.C. 20420
Email: ogcfoiaappeals@va.gov

If you should choose to file an appeal, your appeal must be postmarked or electronically transmitted no later than ninety (90) calendar days from the date of this letter. Please include a copy of this letter with your written appeal and clearly state why you disagree with the determinations set forth in this response.

You may also seek assistance and/or dispute resolution services for any other aspect of your FOIA request, excluding the release determination, from VHA's FOIA Public Liaison and/or Office of Government Information Services (OGIS) as provided below:

VHA FOIA Public Liaison:
Email Address: vhafoia2@va.gov
Phone Number: (877) 461-5038

Office of Government Information Services (OGIS)
Email: ogis@nara.gov
Fax: (202) 741-5769
Mailing address:
Office of Government Information Services
National Archives and Records Administration
8601 Adelphi Road
College Park, MD 20740-6001

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Thank you for your interest in VA. If you have any further questions, please feel free to contact me at (319) 530-7694 or via email at Amber.Heim@va.gov.

Sincerely,

Amber Heim
VHA FOIA Officer

Enclosure: 2,775 pages

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Date: Thursday, Mar 21, 2019, 3:01 PM
To: Boyd, Teresa D. <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>
Cc: Stone, Richard A., MD <(b6) va.gov>
Subject: POC for Spravato clinical implementation

Good Afternoon:
With advance apologies because I am not sure exactly where to address this question. A senior team from J &J was visiting with us to discuss several partnership opportunities. In our meeting, they commented on how quickly the two organizations have moved to make this drug available, and noted that the key Pharmacy leads have connected and an implementation plan is in place. However, given the complex process for administering this product, they asked if we might help identify the VA POC for the clinical implementation. Their field staff is ready to provide training and support, but are not sure what the VA's plans are in general, which locations might be targeted and who they should be interfacing with from the VA.

Dr. Boyd or Dr. Carroll, are either of you the right POC for this effort?

Thank you very much in advance for your assistance,

Deborah
Deborah Lafer Scher
Executive Advisor to the Secretary
Secretary's Center for Strategic Partnerships
US Department of Veterans Affairs
Follow us on Twitter

Sender:	Scher, Deborah L. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FEE3389DFA024F25B96B6D75AC2E7B9F-SCHER, DEBO <(b6) va.gov>
Recipient:	Boyd, Teresa D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6886a7d555a43e0bee23c1e40e1c234-Boyd, Teres <(b6) va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Stone, Richard A., MD /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bd16619615d64adea22e45e63ff6462a-Stone, Rich <(b6) va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>
Sent Date:	2019/03/21 15:50:11
Delivered Date:	2019/03/21 15:50:13

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From:	Torphy, Lisa /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=43AB37387C5C4ED6BAE3006DCDE84582-TORPHY, LIS (b6) va.gov>
To:	Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat <(b6) va.gov>
Subject:	RE: Please edit June F2F minutes
Date:	2019/06/28 13:16:45
Priority:	Normal
Type:	Note

Will do, thanks. ☺

From: Fuller, Matthew A. (PBM)
Sent: Friday, June 28, 2019 11:57 AM
To: Torphy, Lisa <(b6) va.gov>
Subject: RE: Please edit June F2F minutes

Enjoy your weekend. No more edits on my end.

From: Torphy, Lisa
Sent: Friday, June 28, 2019 12:54 PM
To: Fuller, Matthew A. (PBM) <(b6) va.gov>
Subject: RE: Please edit June F2F minutes

Never count on my opinion or notes much. My notes are simply to capture votes and maybe help the presenters recall discussions (b6)). (b6) Or Jenn will likely review once I send them to her after I get everyone's edits. So if you want to tweak a little more, feel free. I'm leaving for the day, so I'll check to see if you made any further edits on Monday. Have a great weekend! ☺

From: Fuller, Matthew A. (PBM)
Sent: Friday, June 28, 2019 10:47 AM
To: Torphy, Lisa <(b6) va.gov>
Subject: RE: Please edit June F2F minutes

Hi Lisa,

Please see edits below. I deleted some of the "red" text and added some "black" text. Otherwise, I think you captured the key points well. What do you think? Thanks.

Matthew

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From: Torphy, Lisa
Sent: Thursday, June 27, 2019 3:05 PM
To: Fuller, Matthew A. (PBM) <(b6) va.gov>
Subject: Please edit June F2F minutes

(b) (5)

(b) (5)

STATUS: Open

(b) (5)

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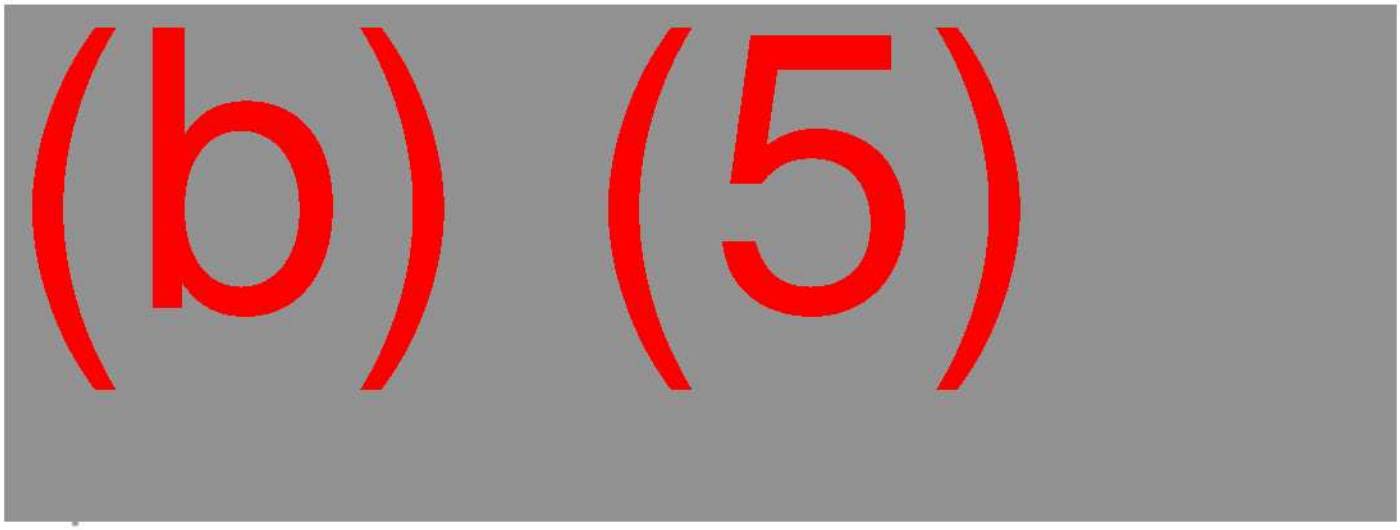

Sender:	Torphy, Lisa /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=43AB37387C5C4ED6BAE3006DCDE84582-TORPHY, LIS <(b6) va.gov>
Recipient:	Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat <(b6) va.gov>
Sent Date:	2019/06/28 13:16:44
Delivered Date:	2019/06/28 13:16:45
Message Flags:	Unread

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From:	Carroll, David (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=95E14EBD3B6745C8952A823B04DABFF5-CARROLL, DA <(b6) va.gov>
To:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>; McGuire, Marsden H. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29e9d648c29f4885828c10446fdd7379-McGuire, Ma <(b6) va.gov>; VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>
CC:	Katz, Ira R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=65f4e28aa7574641932c29fed7c0b4b8-Katz, Ira R <(b6) va.gov>; Drexler, Karen MD (Atlanta) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c456a9bf391415bb4bdb9b6f88bdf45-Drexler, Ka <(b6) va.gov>
Subject:	RE: Planning for access to Spravato across VHA
Date:	2019/03/14 16:11:01
Priority:	Normal
Type:	Note

This is so clear and helpful. My only comment is (b) (5) [redacted] - I replied to your comment in the margin with some ideas. Thank you.

From: Wiechers, Ilse
Sent: Thursday, March 14, 2019 10:24 AM
To: McGuire, Marsden H. <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>
Cc: Katz, Ira R. <(b6) @va.gov>; Drexler, Karen MD (Atlanta) <(b6) va.gov>
Subject: RE: Planning for access to Spravato across VHA

Thanks Marsden –

I've added a bullet as follows:

- (b) (5) [redacted].

I'm going ahead and forwarding it to Tom and Maria for their input now. This will come back around to the group to clear and send up once I've got their input.

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Ilse

From: McGuire, Marsden H.
Sent: Wednesday, March 13, 2019 12:51 PM
To: Wiechers, Ilse (b6) @va.gov>; Carroll, David (VACO) <(b6) va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>
Cc: Katz, Ira R. (b6) @va.gov>; Drexler, Karen MD (Atlanta) <(b6) va.gov>
Subject: RE: Planning for access to Spravato across VHA

This is very clearly laid out, Ilse.

My only question at present has to do with the (b) (5) [redacted].

M

From: Wiechers, Ilse
Sent: Wednesday, March 13, 2019 3:27 PM
To: Carroll, David (VACO) <(b6) va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>
Cc: Katz, Ira R. (b6) @va.gov>; Drexler, Karen MD (Atlanta) <(b6) va.gov>
Subject: RE: Planning for access to Spravato across VHA

Hi everyone –

Attached is a draft 10N memo for your review – please take a look and provide me with some **feedback by tomorrow at 10 AM ET**, when I will send this over to PBM and Maria Llorente for their review &input.

I see this as a 2 part plan: (b) (5) [redacted]

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(b) (5)

Thoughts, feedback, wisdom, guidance, all welcome.

Thanks,
Ilse

From: Wiechers, Ilse
Sent: Tuesday, March 12, 2019 2:47 PM
To: Carroll, David (VACO) <(b6) va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>
Cc: Katz, Ira R. (b6) @va.gov>; Drexler, Karen MD (Atlanta) <(b6) va.gov>
Subject: RE: Planning for access to Spravato across VHA

(b) (5)

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(b) (5)

From: Carroll, David (VACO)
Sent: Tuesday, March 12, 2019 2:36 PM
To: Wiechers, Ilse (b6) @va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>
Cc: Katz, Ira R. (b6) va.gov>; Drexler, Karen MD (Atlanta) <(b6) va.gov>
Subject: RE: Planning for access to Spravato across VHA

Got it – thank you. (b) (5)
Thanks again.

From: Wiechers, Ilse
Sent: Tuesday, March 12, 2019 5:22 PM
To: VHA 10NC5 Action <VHA10NC5Action@va.gov>
Cc: Katz, Ira R. <(b6) @va.gov>; Drexler, Karen MD (Atlanta) <(b6) va.gov>
Subject: Planning for access to Spravato across VHA

Dear Dave &others –

I just finished a call with Tom Emmendorfer and Maria Llorente on our plans moving forward for ensuring access to Spravato across the VHA system. There are 2 main tasks that we (OMHSP) need to address by end of this week, as Jansen reports the medication will be available to the public on 3/18.

1. • Ensure all VA facilities enroll in the Spravato REMS program
2. • Ensure process for signature informed consent is in place for use with Spravato

Pharmacy is working with Jansen on obtaining medication supply, obtaining educational materials developed for patients and providers, and will work with us to develop the back end communications between MH and Pharmacy locally for appropriate/safe dispensing.

I will be asking for quick turn around on draft documents addressing our two tasks in the next 48 hours. Below are my notes from the call, for further context and to start to lay out our proposed plan. I welcome input and feedback – I have a lot of availability in my schedule tomorrow to discuss by phone further, if needed.

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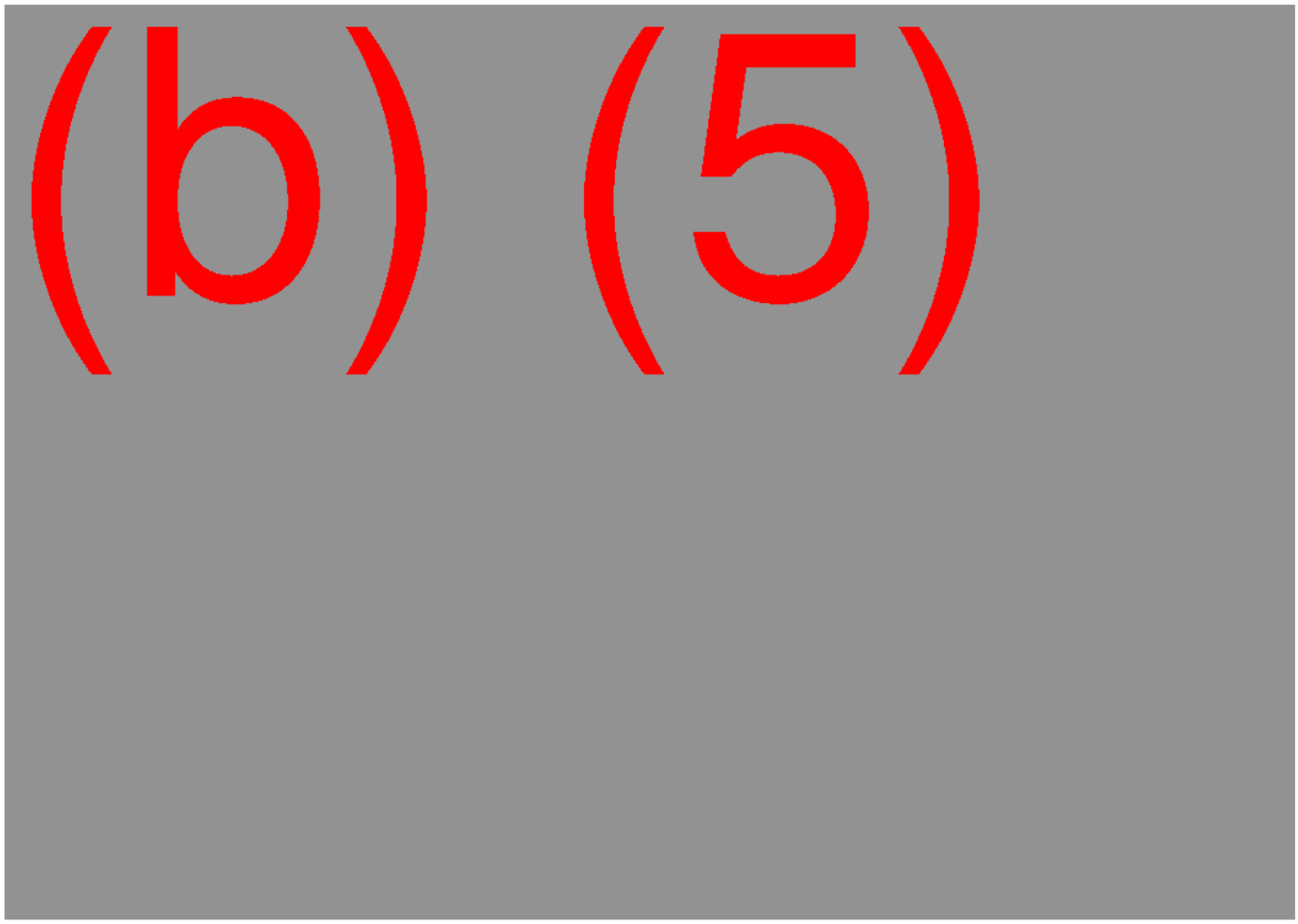
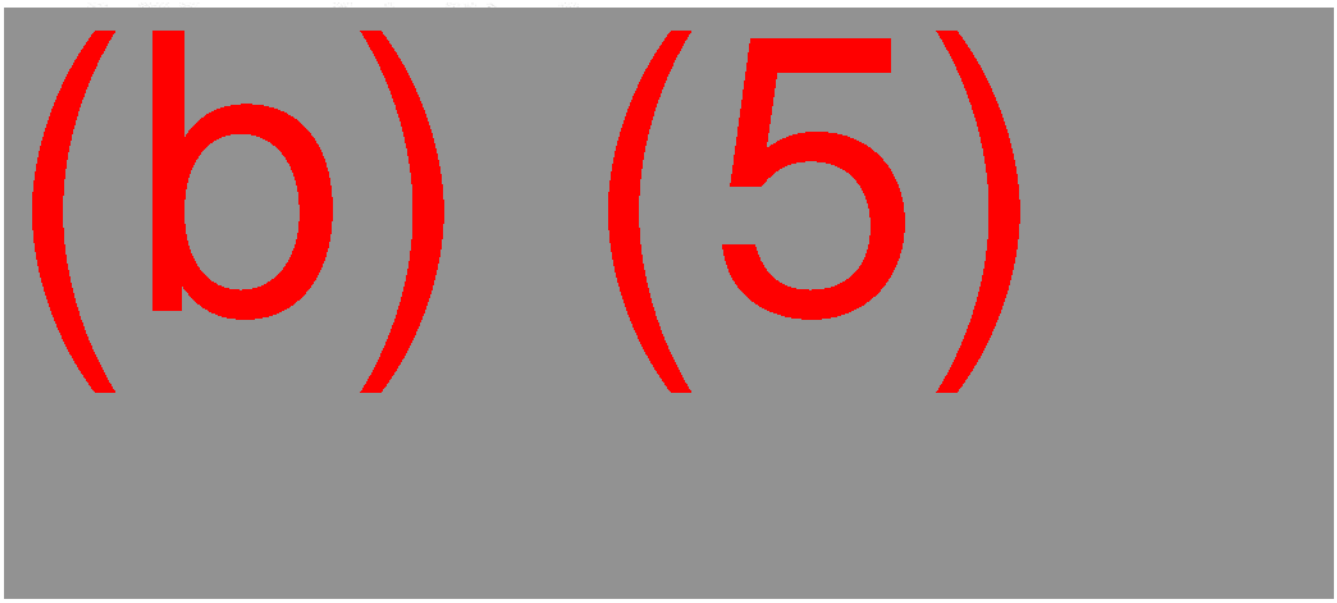
Thanks,
Ilse
***





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Ilse R. Wiechers, MD, MPP, MHS
National Director, Psychotropic Drug Safety Initiative (PDSI)
Co-Director, Care for Patients with Complex Problems (CP)^2
Associate Director, Northeast Program Evaluation Center
Office of Mental Health and Suicide Prevention (10NC5), Department of Veterans Affairs
Assistant Clinical Professor of Psychiatry, Yale University School of Medicine
cell (b6)
email: (b6) @va.gov | (b6) yale.edu

Connect to:
PDSI Home
PDSI Management System
FAQs

Sender:	Carroll, David (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=95E14EBD3B6745C8952A823B04DABFF5-CARROLL, DA <(b6) va.gov>
Recipient:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>; McGuire, Marsden H. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29e9d648c29f4885828c10446fdd7379-McGuire, Ma <(b6) va.gov>; VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>; Katz, Ira R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=65f4e28aa7574641932c29fed7c0b4b8-Katz, Ira R <(b6) va.gov>; Drexler, Karen MD (Atlanta) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c456a9bf391415bb4bdb9b6f88bdf45-Drexler, Ka <(b6) va.gov>
Sent Date:	2019/03/14 16:10:58
Delivered Date:	2019/03/14 16:11:01

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(b5)

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AMERICAN OVERSIGHT

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(b5)

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To:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>; VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>
CC:	Katz, Ira R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=65f4e28aa7574641932c29fed7c0b4b8-Katz, Ira R (b) (6) @va.gov>; Drexler, Karen MD (Atlanta) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c456a9bf391415bb4bdb9b6f88bdf45-Drexler, Ka <(b6) va.gov>
Subject:	RE: Planning for access to Spravato across VHA
Date:	2019/03/12 17:33:01
Priority:	Normal
Type:	Note

Got it – thanks. (b5) [redacted]. Did OGC or the Ethics office weigh in? In any case, the Ethics office

---

From: Wiechers, Ilse
Sent: Tuesday, March 12, 2019 5:22 PM
To: VHA 10NC5 Action <VHA10NC5Action@va.gov>
Cc: Katz, Ira R.(b) (6) @va.gov>; Drexler, Karen MD (Atlanta) <(b6) va.gov>
Subject: Planning for access to Spravato across VHA

Dear Dave &others –

I just finished a call with Tom Emmendorfer and Maria Llorente on our plans moving forward for ensuring access to Spravato across the VHA system. There are 2 main tasks that we (OMHSP) need to address by end of this week, as Jansen reports the medication will be available to the public on 3/18.

1. • Ensure all VA facilities enroll in the Spravato REMS program
2. • Ensure process for signature informed consent is in place for use with Spravato

Pharmacy is working with Jansen on obtaining medication supply, obtaining educational materials developed for patients and providers, and will work with us to develop the back end communications between MH and Pharmacy locally for appropriate/safe dispensing.

I will be asking for quick turn around on draft documents addressing our two tasks in the next 48 hours. Below are my notes from the call, for further context and to start to lay out our proposed plan. I welcome input and feedback – I have a lot of availability in my schedule tomorrow to discuss by phone further, if needed.

Thanks,

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Ilse

(b) (5)



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Ilse R. Wiechers, MD, MPP, MHS
National Director, Psychotropic Drug Safety Initiative (PDSI)
Co-Director, Care for Patients with Complex Problems (CP)^2
Associate Director, Northeast Program Evaluation Center
Office of Mental Health and Suicide Prevention (10NC5), Department of Veterans Affairs
Assistant Clinical Professor of Psychiatry, Yale University School of Medicine
cell (b6)
email: (b) (6) @va.gov | (b6) yale.edu

Connect to:
PDSI Home
PDSI Management System
FAQs

Recipient:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>; VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>; Katz, Ira R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=65f4e28aa7574641932c29fed7c0b4b8-Katz, Ira R <(b6) va.gov>; Drexler, Karen MD (Atlanta) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c456a9bf391415bb4bdb9b6f88bdf45-Drexler, Ka <(b6) va.gov>
Sent Date:	2019/03/12 17:33:05
Delivered Date:	2019/03/12 17:33:01
Message Flags:	Unread Unsent

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To:	Cunningham, Fran /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=613f0d8e535d46af95fed310f100dcbc-Cunningham, <(b6) va.gov>
Subject:	RE: Overlapping FDA Safety Meeting
Date:	2019/06/12 09:36:06
Priority:	Normal
Type:	Note

Parallel

From: Cunningham, Fran
Sent: Wednesday, June 05, 2019 1:48 PM
To: Fuller, Matthew A. (PBM) <(b6) va.gov>
Subject: Overlapping FDA Safety Meeting

Hi Matthew – I didn't realize that the FDA set up a call at 2 today and I have present our vaccine safety data. I will join Ilse's call as soon as I can which should be about 220 or so. If they ask about the MUE while I'm not on can you please update. I'm listing a couple of items below. Thanks!!

1. • Esketamine MUE Draft has been developed and is being internally reviewed. Will submit to Ilse by the end of the week
2. • VAMedSAFE REMS transmission team has been identified and procedures will be put into place. All is still dependent on meeting with Jansen
3. • Meeting with Jansen 6/5 (later this afternoon) to discuss VAMedSAFE submitting REMS for VA providers

Thanks,
Fran

Recipient:	Cunningham, Fran /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=613f0d8e535d46af95fed310f100dcbc-Cunningham, <(b6) va.gov>
Sent Date:	2019/06/12 09:36:10
Delivered Date:	2019/06/12 09:36:06
Message Flags:	Unread Unsent

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From:	Llorente, Maria D. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F5C91F577D894BD9A0F09305DB34DD4F-LLORENTE, M <(b6) va.gov>
To:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Smith, Monica (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=511ea9e77a234375a91a7b34ce23719d-Smith, Moni <(b6) va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; Law, Cassandra M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f888d507d6c54eb5a92fc44199eb5838-Law, Cassan <(b6) va.gov>; Beck, Lucille B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=845480228a8b43e7a5fef5716ded04c2-Beck, Lucil <(b6) va.gov>
CC:	VHA 10P4 Communication Group /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4ba2ff9b4604547be7834a71415253c-VHA 10P4 Co <vha10p4comm@va.gov>
Subject:	RE: News release prenotification: VA to make new nasal spray drug available for treatment-resistant depression
Date:	2019/03/19 15:06:24
Priority:	Normal
Type:	Note

Thank you for catching it!

Sent with BlackBerry Work
(www.blackberry.com)

From: Valentino, Michael (VACO) <(b6) va.gov>
Date: Tuesday, Mar 19, 2019, 2:23 PM
To: Smith, Monica (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Llorente, Maria D. <(b6) va.gov>, Wiechers, Ilse <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>, Law, Cassandra M. <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>
Cc: VHA 10P4 Communication Group <vha10p4comm@va.gov>
Subject: RE: News release prenotification: VA to make new nasal spray drug available for treatment-resistant depression

It's not a naval spray…it's a nasal spray

From: Smith, Monica (VACO)
Sent: Tuesday, March 19, 2019 2:03 PM
To: Carroll, David (VACO) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>;

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Wiechers, Ilse <(b5) @va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>
Cc: VHA 10P4 Communication Group <vha10p4comm@va.gov>
Subject: FW: News release prenotification: VA to make new nasal spray drug available for treatment-resistant depression

Good day, everyone - FYI – this is going out at 3 p.m. today.

From: Christian, Tatjana
Sent: Tuesday, March 19, 2019 1:56 PM
Subject: News release prenotification: VA to make new nasal spray drug available for treatment-resistant depression

Good afternoon,

This news release, attached and cut and pasted below, is scheduled to go out at 3 p.m. today, March 19, and will be posted on VA's news releases webpage.

Please make appropriate notifications.

++++++++++++++++++++++

FOR IMMEDIATE RELEASE
March 19, 2019

VA to make new nasal spray drug available for treatment-resistant depression

WASHINGTON — Today the U.S. Department of Veterans Affairs (VA) announced its health care providers will now be able to offer the newly approved Spravato naval spray for treatment-resistant depression.

The treatment will be made available to Veterans based on their individual medical needs combined with providers' clinical assessments.

The move follows the March 5 Food and Drug Administration (FDA) approval of Spravato (esketamine) nasal spray. Spravato was approved for use in conjunction with an oral antidepressant for the treatment of treatment-resistant depression in adults.

"We're pleased to be able to expand options for Veterans with depression who have not responded to other treatments," said VA Secretary Robert Wilkie. "It reflects our commitment to seek new ways to provide the best health care available for our nation's Veterans."

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Spravato will be available through a restricted distribution system under an FDA-approved Risk Evaluation and Mitigation Strategy (REMS). The purpose of the REMS is to mitigate the risks of serious adverse outcomes and the potential abuse and misuse of Spravato.

VA health care providers will monitor Veterans for serious adverse outcomes, such as sedation and difficulty with attention, judgment and thinking (dissociation), abuse and misuse, worsening of depression and suicidal thoughts and behaviors.

Veterans will self-administer Spravato nasal spray under the direct observation of a health care provider in a certified medical facility, and then must be monitored by a health care provider for at least two hours after receiving their dose. Spravato cannot be dispensed directly to Veterans for use at home.

For additional information on access to Mental Health Support for Veterans, visit VA Mental Health. Veterans in immediate crisis may call the Veterans Crisis Line at 800-273-8255 and press 1, text to 838255 or chat online at Veterans Crisis Line.

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Sender:	Llorente, Maria D. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F5C91F577D894BD9A0F09305DB34DD4F-LLORENTE, M <(b6) va.gov>
Recipient:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Smith, Monica (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=511ea9e77a234375a91a7b34ce23719d-Smith, Moni <(b6) va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; Law, Cassandra M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f888d507d6c54eb5a92fc44199eb5838-Law, Cassan <(b6) va.gov>; Beck, Lucille B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=845480228a8b43e7a5fef5716ded04c2-Beck, Lucil <(b6) va.gov>; VHA 10P4 Communication Group /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4ba2ff9b4604547be7834a71415253c-VHA 10P4 Co <vha10p4comm@va.gov>
Sent Date:	2019/03/19 15:06:23
Delivered Date:	2019/03/19 15:06:24

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From:	Smith, Monica (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=511EA9E77A234375A91A7B34CE23719D-SMITH, MONI <(b6) va.gov>
To:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; Law, Cassandra M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f888d507d6c54eb5a92fc44199eb5838-Law, Cassan <(b6) va.gov>; Beck, Lucille B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=845480228a8b43e7a5fef5716ded04c2-Beck, Lucil <(b6) va.gov>
CC:	VHA 10P4 Communication Group /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4ba2ff9b4604547be7834a71415253c-VHA 10P4 Co <vha10p4comm@va.gov>
Subject:	RE: News release prenotification: VA to make new nasal spray drug available for treatment-resistant depression
Date:	2019/03/19 14:26:04
Priority:	Normal
Type:	Note

Thanks, Mike. I let her know. ☺

From: Valentino, Michael (VACO)
Sent: Tuesday, March 19, 2019 2:23 PM
To: Smith, Monica (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Wiechers, Ilse <Ilse.Wiechers@va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>
Cc: VHA 10P4 Communication Group <vha10p4comm@va.gov>
Subject: RE: News release prenotification: VA to make new nasal spray drug available for treatment-resistant depression

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To: Carroll, David (VACO) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Wiechers, Ilse (b) (6) @va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Law,

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Cassandra M. <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>
Cc: VHA 10P4 Communication Group <vha10p4comm@va.gov>
Subject: FW: News release prenotification: VA to make new nasal spray drug available for treatment-resistant depression

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Sent Date:	2019/03/19 14:26:00
Delivered Date:	2019/03/19 14:26:04

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From:	Fuller, Matthew A. (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=62D9CBB23B184CACB98895776E36A471-FULLER, MAT>
To:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>
Subject:	RE: need input on language for national consult for community care TRD referral (ECT/rTMS/ketamine/Spravato)
Date:	2019/08/23 11:33:00
Priority:	Normal
Type:	Note

☺

From: Wiechers, Ilse
Sent: Friday, August 23, 2019 11:19 AM
To: Fuller, Matthew A. (PBM) <(b6) va.gov>
Cc: Zacher, Jennifer L. (PBM) (b6) va.gov>
Subject: RE: need input on language for national consult for community care TRD referral (ECT/rTMS/ketamine/Spravato)

Ohhhhh exciting/hopeful news! The consult people think they may be able to build a pop out link for the CFU and National protocol! I'll keep you posted.

From: Fuller, Matthew A. (PBM)
Sent: Thursday, August 22, 2019 1:32 PM
To: Wiechers, Ilse (b6) @va.gov>
Cc: Zacher, Jennifer L. (PBM) ((b6) va.gov>
Subject: RE: need input on language for national consult for community care TRD referral (ECT/rTMS/ketamine/Spravato)

Yes, I am sensitive to the issue of double check. In my previous position we would get folks from the community or other VA's requesting transfer for ECT. When they arrived we sometimes found out they really did not meet criteria. I guess we need to do the best we can with what we are given.

From: Wiechers, Ilse
Sent: Thursday, August 22, 2019 4:11 PM
To: Fuller, Matthew A. (PBM) <(b6) va.gov>
Cc: Zacher, Jennifer L. (PBM) (b6) va.gov>
Subject: RE: need input on language for national consult for community care TRD referral (ECT/rTMS/ketamine/Spravato)

I agree – that would be awesome! However, not likely feasible. We will have to front end educate on this point. The consult order will launch via a national memo, and in that we will link directly to CFU/protocol guidance and emphasize inclusion/exclusion criteria. You can help me drafting the

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language for that part. ☺ But I'm going to ask the consult person to what extent we can link to documents or pop up larger documents from inside the consult.

From what I understand in conversations with Community Care thus far, there is – cringing teeth – no way to ensure people actually meet criteria before a consult is entered nor after it is entered and sent out to the community. I continue to search for some sort of double check, but I have yet to find it.

Ilse

From: Fuller, Matthew A. (PBM)
Sent: Thursday, August 22, 2019 1:02 PM
To: Wiechers, Ilse (b6) @va.gov>
Cc: Zacher, Jennifer L. (PBM) (b6) va.gov>
Subject: RE: need input on language for national consult for community care TRD referral (ECT/rTMS/ketamine/Spravato)

Hi Ilse,

For IV ketamine and IN esketamine I think it would be helpful if their respective CFU would "pop up" instead of just asking if they meet criteria (it is easy to "click" yes and proceed without meeting criteria). Otherwise, who will check that the patient meets the approved criteria? Just some quick thoughts.

Matthew

From: Wiechers, Ilse
Sent: Thursday, August 22, 2019 3:26 PM
To: McGuire, Marsden H. <(b6) va.gov>; Katz, Ira R. (b6) @va.gov>; Pomerantz, Andrew <(b6) va.gov>; Drexler, Karen MD (Atlanta) <(b6) va.gov>; Fuller, Matthew A. (PBM) <(b6) va.gov>; Cunningham, Fran <(b6) va.gov>; Czekanski, Elizabeth R <(b6) va.gov>; Myrick, Donald L. (Hugh) <(b6) va.gov>; Krystal, John (b6) @va.gov>; Shiroma, Paulo R. <(b6) va.gov>; Yoon, Gihyun <(b6) va.gov>; Mohamed, Somaia <(b6) va.gov>; Ranganathan, Mohini <(b6) va.gov>; Mathew, Sanjay (HOU) <(b6) va.gov>; Wells, Daina L. <(b6) va.gov>; 'Paul E. Holtzheimer' <(b6) hitchcock.org>; Hauser, Peter <(b6) va.gov>; Yesavage, Jerome <(b6) (b6) va.gov>; 'Jerome A Yesavage' <(b6) stanford.edu>; Martis, Brian <(b6) va.gov>
Cc: Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: need input on language for national consult for community care TRD referral (ECT/rTMS/ketamine/Spravato)

Hi everyone –

I am working on creation of a national consult order that would facilitate referral to care in the community for our newly developed Treatment Resistant Depression (TRD) Standard Episode of Care (SEOC). The TRD SEOC includes language that provides 6 months of care related to TRD and has been

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designed to cover ECT, rTMS, and "medications administered in a healthcare clinical setting" – i.e. IV ketamine and Spravato. This will allow us to ensure tracking and proper referral to community providers who actually have the ability to provide the desired treatment.

I would greatly appreciate your input on the language for this consult by next Wednesday, August 28th. Take a look at the draft language below and keep in mind that the fewer questions asked, the easier to complete and the more likely the information entered is accurate (b6) .

Happy to set up a call to discuss briefly with individuals or a larger group, as people are interested, please just let me know.

Once we finalize language, I will work with the Community Care team to ensure we get this deployed nationally. Updates on that process to follow.

Thanks,
Ilse



Other questions???

***

Ilse R. Wiechers, MD, MPP, MHS
National Director, Psychotropic Drug Safety Initiative (PDSI)

AMERICAN OVERSIGHT

National Lead, Esketamine Clinical Implementation
Associate Director, Northeast Program Evaluation Center
Office of Mental Health and Suicide Prevention (10NC5), Department of Veterans Affairs
Assistant Clinical Professor of Psychiatry, Yale University School of Medicine
cell (b6)
email: (b6) @va.gov | (b6) yale.edu

Sender:	Fuller, Matthew A. (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=62D9CBB23B184CACB98895776E36A471-FULLER, MAT>
Recipient:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>
Sent Date:	2019/08/23 11:33:09
Delivered Date:	2019/08/23 11:33:00

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To:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>
CC:	Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>
Subject:	RE: need input on language for national consult for community care TRD referral (ECT/rTMS/ketamine/Spravato)
Date:	2019/08/22 15:59:43
Priority:	Normal
Type:	Note

Hi Ilse,

(b) (5)
?

From: Wiechers, Ilse
Sent: Thursday, August 22, 2019 3:26 PM
To: McGuire, Marsden H. <(b6) va.gov>; Katz, Ira R.(b6) @va.gov>; Pomerantz, Andrew <(b6) va.gov>; Drexler, Karen MD (Atlanta) <(b6) va.gov>; Fuller, Matthew A. (PBM) <(b6) va.gov>; Cunningham, Fran <(b6) va.gov>; Czekanski, Elizabeth R <(b6) va.gov>; Myrick, Donald L. (Hugh) <(b6) va.gov>; Krystal, John (b6) @va.gov>; Shiroma, Paulo R. <(b6) va.gov>; Yoon, Gihyun <(b6) va.gov>; Mohamed, Somaia <(b6) va.gov>; Ranganathan, Mohini <(b6) va.gov>; Mathew, Sanjay (HOU) <(b6) va.gov>; Wells, Daina L. <(b6) va.gov>; 'Paul E. Holtzheimer' <(b6) hitchcock.org>; Hauser, Peter <(b6) va.gov>; Yesavage, Jerome <(b6) (b6) va.gov>; 'Jerome A Yesavage' <(b6) stanford.edu>; Martis, Brian <(b6) va.gov>
Cc: Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: need input on language for national consult for community care TRD referral (ECT/rTMS/ketamine/Spravato)

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Ilse



Other questions???

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Ilse R. Wiechers, MD, MPP, MHS
National Director, Psychotropic Drug Safety Initiative (PDSI)
National Lead, Esketamine Clinical Implementation
Associate Director, Northeast Program Evaluation Center
Office of Mental Health and Suicide Prevention (10NC5), Department of Veterans Affairs
Assistant Clinical Professor of Psychiatry, Yale University School of Medicine
cell (b6)
@va.gov | (b6) yale.edu

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Recipient:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <{b6} va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <{b6} va.gov>
Sent Date:	2019/08/22 15:58:37
Delivered Date:	2019/08/22 15:59:43
Message Flags:	Unread Unsent

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From:	Fuller, Matthew A. (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=62D9CBB23B184CACB98895776E36A471-FULLER, MAT>
To:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>; Shiroma, Paulo R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cae9fb698bb245669c11a3564784e24e-Shiroma, Pa <(b6) va.gov>; Cunningham, Fran /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=613f0d8e535d46af95fed310f100dcbc-Cunningham, <(b6) va.gov>; Myrick, Donald L. (Hugh) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ffec881db4394259b082b76436cdc904-Myrick, Don <(b6) va.gov>; McGuire, Marsden H. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29e9d648c29f4885828c10446fdd7379-McGuire, Ma <(b6) va.gov>; Drexler, Karen MD (Atlanta) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c456a9bf391415bb4bdb9b6f88bdf45-Drexler, Ka <(b6) va.gov>; Pomerantz, Andrew /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29a9288df9a34e84bddfd00cde79f11b-Pomerantz, <(b6) va.gov>; Katz, Ira R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=65f4e28aa7574641932c29fed7c0b4b8-Katz, Ira R (b6) va.gov>; Yoon, Gihyun /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aec946e46a224f4ea66ce2078a8115d3-Yoon, Gihyu <(b6) va.gov>; Mathew, Sanjay (HOU) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=67422a5cc3904b40bff8fca2b9cd1b48-Mathew, San <(b6) va.gov>; Mohamed, Somaia /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=37831d1786914522b90bb85b2a8e1441-Mohamed, So <(b6) va.gov>; Ranganathan, Mohini /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a929509685bd4ad2895c66775c05d7b5-Ranganathan <(b6) va.gov>; Krystal, John /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3d5500f300d74e0dba7f8b30a5b42f02-Krystal, Jo <(b6) @va.gov>; Czekanski, Elizabeth R /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aee7f346873e4a84a863e6c1d28bac48-Czekanski, <(b6) va.gov>; Wells, Daina L. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2256099a3577421182c5516b56f40815-Wells, Dain <(b6) va.gov>
CC:	Festin, Fe Erlita /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cc0692d6c3fa4d20bd21aade22d20a51-Festin, Fe <(b6) va.gov>; Ma, Demin /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b5cfd22ddd4265b8462d236c50dd7e-Ma, Denim (b6) va.gov>; Dantzler, Anne /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2f5acd16706148918ba6b1552b149061-Dantzler, A <(b6) va.gov>
Subject:	RE: Need input on IV ketamine to IN esketamine conversion guidance
Date:	2019/06/10 15:37:00
Priority:	Normal
Type:	Note

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Hi Ilse,

They are already completing the (b) (5) .

Thanks.

Matthew

From: Wiechers, Ilse
Sent: Monday, June 10, 2019 2:17 PM
To: Shiroma, Paulo R. <(b6) va.gov>; Cunningham, Fran <(b6) va.gov>; Myrick, Donald L. (Hugh) <(b6) va.gov>; McGuire, Marsden H. <(b6) va.gov>; Drexler, Karen MD (Atlanta) <(b6) va.gov>; Pomerantz, Andrew <(b6) va.gov>; Katz, Ira R. (b6) @va.gov>; Yoon, Gihyun <(b6) va.gov>; Mathew, Sanjay (HOU) <(b6) va.gov>; Mohamed, Somaia <(b6) va.gov>; Ranganathan, Mohini <(b6) va.gov>; Krystal, John (b6) l@va.gov>; Fuller, Matthew A. (PBM) <(b6) va.gov>; Czekanski, Elizabeth R <(b6) va.gov>; Wells, Daina L. <(b6) va.gov>
Cc: Festin, Fe Erlita (l(b6) va.gov>; Ma, Demin (l(b6) va.gov>; Dantzler, Anne (l(b6) va.gov>
Subject: RE: Need input on IV ketamine to IN esketamine conversion guidance

Thanks, Paulo.

Is there any additional feedback or suggestions for the most appropriate monitoring plan in this initial case ir(b6) Appreciate your input for the team by end of today.

Best, Ilse

From: Shiroma, Paulo R.
Sent: Friday, June 07, 2019 2:26 PM
To: Wiechers, Ilse (b6) @va.gov>; Cunningham, Fran <(b6) va.gov>; Myrick, Donald L. (Hugh) <(b6) va.gov>; McGuire, Marsden H. <(b6) va.gov>; Drexler, Karen MD (Atlanta) <(b6) va.gov>; Pomerantz, Andrew <(b6) va.gov>; Katz, Ira R. (b6) @va.gov>; Yoon, Gihyun <(b6) va.gov>; Mathew, Sanjay (HOU) <(b6) va.gov>; Mohamed, Somaia <(b6) va.gov>; Ranganathan, Mohini <(b6) va.gov>; Krystal, John <J(b6) @va.gov>; Fuller, Matthew A. (PBM) <(b6) va.gov>; Czekanski, Elizabeth R <(b6) va.gov>; Wells, Daina L. <(b6) va.gov>
Cc: Festin, Fe Erlita <(b6) va.gov>; Ma, Demin <(b6) va.gov>; Dantzler, Anne <(b6) va.gov>
Subject: RE: Need input on IV ketamine to IN esketamine conversion guidance

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(b) (5)
[redacted]

From: Wiechers, Ilse
Sent: Friday, June 07, 2019 4:07 PM
To: Cunningham, Fran <(b6) va.gov>; Shiroma, Paulo R. <(b6) va.gov>; Myrick, Donald L. (Hugh) <(b6) va.gov>; McGuire, Marsden H. <(b6) va.gov>; Drexler, Karen MD (Atlanta) <(b6) va.gov>; Pomerantz, Andrew <(b6) va.gov>; Katz, Ira R. <(b6) @va.gov>; Yoon, Gihyun <(b6) va.gov>; Mathew, Sanjay (HOU) <(b6) va.gov>; Mohamed, Somaia <(b6) va.gov>; Ranganathan, Mohini <(b6) va.gov>; Krystal, John (b6) @va.gov>; Fuller, Matthew A. (PBM) <(b6) va.gov>; Czekanski, Elizabeth R <(b6) va.gov>; Wells, Daina L. <(b6) va.gov>
Cc: Festin, Fe Erlita <(b6) va.gov>; Ma, Demin <(b6) va.gov>; Dantzler, Anne <(b6) va.gov>
Subject: Need input on IV ketamine to IN esketamine conversion guidance
Importance: High

Hello everyone –

Below is a de-identified case summary of the patient (b6) is intending to treat on (b6) as our first IN esketamine patient. The team in (b6) has asked for additional clinical input and guidance from the national workgroup to specifically address the issues of conversion from maintenance IV ketamine to IN esketamine. This is an issue that will come up OFTEN among our early adopters, given they are IV ketamine sites now and will likely have many conversion patients.

The specific question is how best to monitor the patient for safety following the initial IN esketamine dose to ensure it has the same level of efficacy and duration of effect as the IV ketamine did previously. Inpatient? Close outpatient f/up?

Please provide your suggestions and feedback to the (b6) team (cc'd here) by COB Monday. The patient will be coming in for an outpatient appointment on Tue (b6) and they want to be able to discuss treatment plan accordingly.

Thanks so much,
Ilse

From: (b6)
Sent: Friday, June 07, 2019 1:44 PM
To: Wiechers, Ilse (b6) @va.gov>
Cc: Ma, Demin <(b6) va.gov>; Dantzler, Anne <(b6) va.gov>
Subject: IV Ketamine case

Here's the case.

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61 year old white, divorced male who presented for worsening depression and SI with plan to hang himself on (b6) /19 admitted to Inpatient MH.

Since (b6) 2018, (b6) reported that he was isolative in his South End apartment. He reported chronic SI, which worsened in the weeks prior to admission.
PTA, he researched how to hang himself, constructed the noose, hung it and put his head/neck inside of the noose for about 5 seconds.
He stated that he was just "practicing" and once he experienced difficulty breathing, he stopped because "the will to live kicked in." He endorsed persistent poor sleep, anhedonia, and poor energy. He was not interested in ECT because he says that he has tried this before and the benefit did not last beyond 1 month.
Past psychiatric hospitalizations:
-7 prior (b6) admissions, most recently in (b6) 2018
-(b6) (b6) /04
-(b6) x2weeks "I thought he (staff person in detox) wanted me to hit him. That's what my thoughts were telling me."
-(b6) ECT x 2mos "It was probably a mistake. I haven't been right since, with my memory."
-(b6) x1 mo "hallucinations, talking to people that weren't there."
Medication trials:
Zoloft, Duloxetine, Paroxetine, Venlafaxine, Nefazodone, Fluoxetine, Trazodone, Depakote, Lithium, Haldol, Thorazine, Seroquel, and Zyprexa

The patient reported that his last use of drugs was cocaine/benzos once prior to admission. No other substance use. in (b6) . He had positive cocaine on his toxic screen on admission which he acknowledged as he felt so depressed.
DX: Major depression, recurrent, severe.

He was referred by inpatient psychiatrist for IV Ketamine as he was not responding to his usual antidepressants/ECT and was a high suicide risk.
Modified Antidepressant Treatment History Score: 23
PHQ-9 - 14
MADRS score: 39/60
SLUMS - 28

Due to suicidality and refractory depression, IV Ketamine infusion was recommended. He has received 6 index IV Ketamine Infusions and 2 Maintenance IV Ketamine infusions.

POST-KETAMINE ASSESSMENT AFTER #8 KETAMINE INFUSION ON (b6) 2019.
PHQ-9 - 2
Current MADRS score - 3/60
SLUMS - 30
CADSS - 0
HAM-A - 3
He is followed by outpatient psychiatrist and SPC as he is flagged HIGH RISK for suicide.
He is willing to switch to Intranasal Esketamine.
Given the pilot trial, would it be prudent to admit him the day before administration and observe for about a week as inpatient?

(b6)
(b6) ol
Office: (b6)

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VA Cell: (b6) ; Email: (b6) va.gov

Sender:	Fuller, Matthew A. (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=62D9CBB23B184CACB98895776E36A471-FULLER, MAT>
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Sent Date:	2019/06/10 15:37:47
Delivered Date:	2019/06/10 15:37:00

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From:	Wells, Daina L. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2256099A3577421182C5516B56F40815-WELLS, DAIN <(b6) va.gov>
To:	Oslin, Dave (Philadelphia VAMC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45a9248804ff41a195408861537ee66d-Oslin, Dave <(b6) va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b6) @va.gov>; Thase, Michael <(b6) upenn.edu>; Thase, Michael E. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=caef785151044128b74d28545152dd08-Thase, Mich <(b6) va.gov>
CC:	Christopher, Melissa L (VHASDC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a542daad1277489fb77c0b3d08454521-Christopher <(b6) @va.gov>; Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat <(b6) va.gov>
Subject:	RE: need help developing treatment resistant depression training content for VA
Date:	2019/06/12 18:23:48
Priority:	Normal
Type:	Note

Good afternoon,
I'm so happy to hear you are willing to work on this module with us. We will also be working with a Mental Health Clinical Pharmacist who is now a National Program Manager for PBM, Matthew Fuller. I'd like to set up an initial meeting sometime the week of the 24th to discuss plans and timeline. I'll use the scheduling feature in Outlook to find a time that appears to work for everyone. If your Outlook isn't accurate and I select a date and time that doesn't work, please propose a new one. If there are others you'd like me to invite, please let me know.

In the meantime, I'll attach the TRD module our office developed back in 2012 so you can see what we did years ago. Perhaps we can use it as a building block.

Thanks,
Daina

Daina L. Wells, PharmD, MBA, BCPS, BCPP
National Clinical Program Manager
VA Academic Detailing Service, VACO PBM
ADS SharePoint
ADS Inquiry and Request Portal

Suicide Prevention is Everyone's Business.
#BeThere

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Veterans in crisis, or their friends or family, can call the Veterans Crisis Line for confidential support 24 hours a day, seven days a week, 365 days a year at 1-800-273-8255 **and Press 1**, chat online at VeteransCrisisLine.net/Chat, or text to **838255**.

From: Oslin, Dave (Philadelphia VAMC)
Sent: Wednesday, June 12, 2019 3:11 PM
To: Wiechers, Ilse (b6) @va.gov>; Thase, Michael <(b6) upenn.edu>; Thase, Michael E. <(b6) va.gov>
Cc: Christopher, Melissa L (VHASDC) <(b6) @va.gov>; Wells, Daina L. <(b6) va.gov>
Subject: RE: need help developing treatment resistant depression training content for VA

Michael is enthusiastically onboard! I would get someone from one of the current sites but they may all be researchers? Michael might have some thoughts.

From: Wiechers, Ilse
Sent: Tuesday, June 11, 2019 1:54 PM
To: Oslin, Dave (Philadelphia VAMC) <(b6) va.gov>
Cc: Christopher, Melissa L (VHASDC) <(b6) @va.gov>; Wells, Daina L. <(b6) va.gov>
Subject: RE: need help developing treatment resistant depression training content for VA

Hi Dave,

We would welcome Michael's assistance in developing the TRD materials. Voluntell away!

Any suggestions for additional people who aren't as closely connected with Pharma to help balance things out?

Thanks,
Ilse

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(www.blackberry.com)

From: Oslin, Dave (Philadelphia VAMC) <(b6) va.gov>
Date: Monday, Jun 10, 2019, 12:41 PM
To: Wiechers, Ilse (b6) @va.gov>
Cc: Christopher, Melissa L (VHASDC) <(b6) @va.gov>, Wells, Daina L. <(b6) va.gov>
Subject: RE: need help developing treatment resistant depression training content for VA

Can I suggest we use Michael Thase for this? He is much more of an expert and his only vice is he has worked for J&J but I am also a consultant for them so that may be a conflict as well. Let me know if you want me to voluntell Michael.

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Michael is also leading the coop study on esketamine

David W. Oslin, MD
Chief of Behavioral Health
Director, VISN 4 MIRECC
CPL. Michael J. Crescenz VA Medical Center (Philadelphia)
Professor of Psychiatry
Perelman School of Medicine, University of Pennsylvania

(b6)
3900 Woodland Ave
Philadelphia, PA 19104

(b6) (office)
(b6) (cell)

Veterans Crisis Line 800 273 8255 Press 1

From: Wiechers, Ilse
Sent: Monday, June 10, 2019 3:22 PM
To: Oslin, Dave (Philadelphia VAMC) <(b6) va.gov>
Cc: Christopher, Melissa L (VHASDC) (b6) @va.gov>; Wells, Daina L. <(b6) va.gov>
Subject: need help developing treatment resistant depression training content for VA

Hi Dave –

As you may have heard, I've been asked to help VHA stand up clinical implementation of intranasal esketamine. One of the big pieces of this is developing educational content that will be used for training psychiatrists and pharmacists. We are striving to develop VA specific, neutral (i.e. not Pharma created) educational content.

We are currently working on 2 key pieces: 1) an update of the Academic Detailing Treatment Resistant Depression materials, 2) materials describing the REMS requirements for Spravato.

We are seeking subject matter experts to help us work on item #1. Daina Wells (cc'd) from the National Academic Detailing Service will be leading the work on this. Given your leadership with the CPG for MDD, I wanted to reach out to you first and see who you might recommend help serve as a psychiatry SME for TRD material development and review.

I will be working on developing item #2 with the national esketamine implementation workgroup (which includes several of our VA ketamine SMEs).

Appreciate your help and input on this!

Best,

AMERICAN OVERSIGHT

Ilse

***

Ilse R. Wiechers, MD, MPP, MHS
National Director, Psychotropic Drug Safety Initiative (PDSI)
Associate Director, Northeast Program Evaluation Center
Office of Mental Health and Suicide Prevention (10NC5), Department of Veterans Affairs
Assistant Clinical Professor of Psychiatry, Yale University School of Medicine
cell (b6)
(b6) va.gov | (b6) @yale.edu

Suicide Prevention is Everyone's Business. *#BeThere.*



VCL

Sender:	Wells, Daina L. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2256099A3577421182C5516B56F40815-WELLS, DAIN <(b6) va.gov>
Recipient:	Oslin, Dave (Philadelphia VAMC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45a9248804ff41a195408861537ee66d-Oslin, Dave <(b6) va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>; Thase, Michael <(b6) upenn.edu>; Thase, Michael E. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=caef785151044128b74d28545152dd08-Thase, Mich <(b6) va.gov>; Christopher, Melissa L (VHASDC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a542daad1277489fb77c0b3d08454521-Christopher (b6) @va.gov>; Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat <(b6) va.gov>
Sent Date:	2019/06/12 18:23:44
Delivered Date:	2019/06/12 18:23:48

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From:	Pomerantz, Andrew /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=29A9288DF9A34E84BDDFD00CDE79F11B-POMERANTZ, <(b6) @va.gov>
To:	Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; VHA CO 10NC5 EXEC /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3c42d5c2321545dba9a59f4e7c6da358-VHA CO 10NC <VHACO10NC5EXEC@va.gov>
Subject:	RE: Nasal spray depression drug may be riskier than first thought
Date:	2019/06/12 16:03:01
Priority:	Normal
Type:	Note

Seems to be an escalation of papers suggesting caution. Psych news had something Monday.

From: Carroll, David (VACO)
Sent: Wednesday, June 12, 2019 10:11 AM
To: VHA CO 10NC5 EXEC <VHACO10NC5EXEC@va.gov>
Subject: FW: Nasal spray depression drug may be riskier than first thought

FYI

From: Valentino, Michael (VACO)
Sent: Wednesday, June 12, 2019 8:47 AM
To: Llorente, Maria D. <(b6) va.gov>; Wiechers, Ilse (b6) @va.gov>; Boyd, Teresa D. <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>
Subject: FW: Nasal spray depression drug may be riskier than first thought

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From: Emmendorfer, Thomas (PBM)
Sent: Tuesday, June 11, 2019 4:31 PM
To: Valentino, Michael (VACO) <(b6) va.gov>; Narayana, Sampath (VISN1) (b6) @va.gov>
Cc: Zacher, Jennifer L. (PBM) <(b6) va.gov>; Fuller, Matthew A. (PBM) <(b6) va.gov>
Subject: RE: Nasal spray depression drug may be riskier than first thought

I google Sam's title and found the article. Published 7 hours ago.

https://www.nbcnews.com/health/health-news/caution-urged-over-use-fast-acting-version-ketamine-depression-n1016176

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From: Valentino, Michael (VACO)
Sent: Tuesday, June 11, 2019 4:23 PM
To: Narayana, Sampath (VISN1) {b6} @va.gov>
Cc: Emmendorfer, Thomas (PBM) <{b6} va.gov>; Zacher, Jennifer L. (PBM) <{b6} va.gov>; Fuller, Matthew A. (PBM) <{b6} va.gov>
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Hi Sam,

Was this a published article?

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From: Narayana, Sampath (VISN1) {b6} @va.gov>
Date: Tuesday, Jun 11, 2019, 3:29 PM
To: VHAPBM VPE Formulary Committee <VPEFormularyCommittee@va.gov>
Subject: RE: Nasal spray depression drug may be riskier than first thought

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From: Narayana, Sampath (VISN1)
Sent: Tuesday, June 11, 2019 3:27 PM
To: VISN 1 Chiefs of Pharmacy <PharChiefs@med.va.gov>
Subject: Nasal spray depression drug may be riskier than first thought

Esketamine's trajectory to approval shows — step by step — how drugmakers can take advantage of shortcuts in the FDA process with the agency's blessing and maneuver through safety and efficacy reviews to bring a lucrative drug to market.

Step 1: In late 2013, Janssen got the FDA to designate esketamine a "breakthrough therapy" because it showed the potential to reverse depression rapidly — a holy grail for suicidal patients, such as those in an emergency room. That potential was based on a two-day study during which 30 patients were given esketamine intravenously. "Breakthrough therapy" status puts drugs on a fast track to approval, with more frequent input from the FDA.

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Step 2: But discussions between regulators and drug manufacturers can affect the amount and quality of evidence required by the agency. In the case of Spravato, they involved questions like, how many drugs must fail before a patient's depression is considered intractable or "treatment-resistant"? And how many successful clinical trials are necessary for FDA approval?

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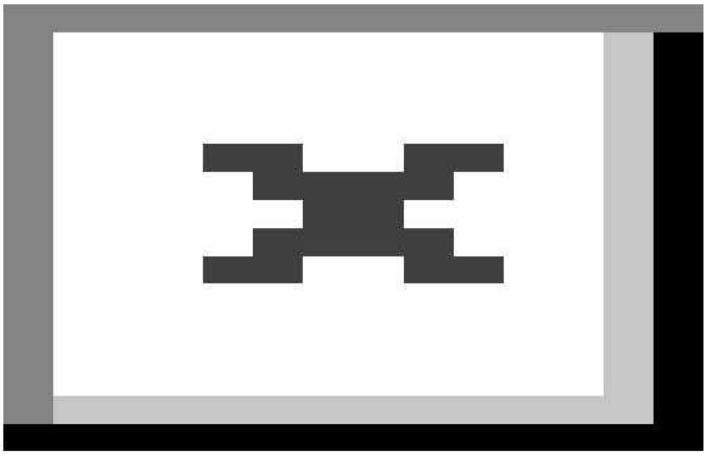

Sender:	Pomerantz, Andrew /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=29A9288DF9A34E84BDDFD00CDE79F11B-POMERANTZ,

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	(b6) @va.gov>
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AMERICAN OVERSIGHT

From:	Fuller, Matthew A. (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=62D9CBB23B184CACB98895776E36A471-FULLER, MAT>
To:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Glassman, Peter A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90608d43ef14423db308fb6c71ed750b-Glassman, P (b(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>
Subject:	RE: Nasal spray depression drug may be riskier than first thought
Date:	2019/06/12 09:57:00
Priority:	Normal
Type:	Note

Thanks. (b6)

From: Valentino, Michael (VACO)
Sent: Wednesday, June 12, 2019 9:48 AM
To: Fuller, Matthew A. (PBM) <(b6) va.gov>; Glassman, Peter A. (b(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>
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"Breakthrough therapy" status puts drugs on a fast track to approval, with more frequent input from the FDA.

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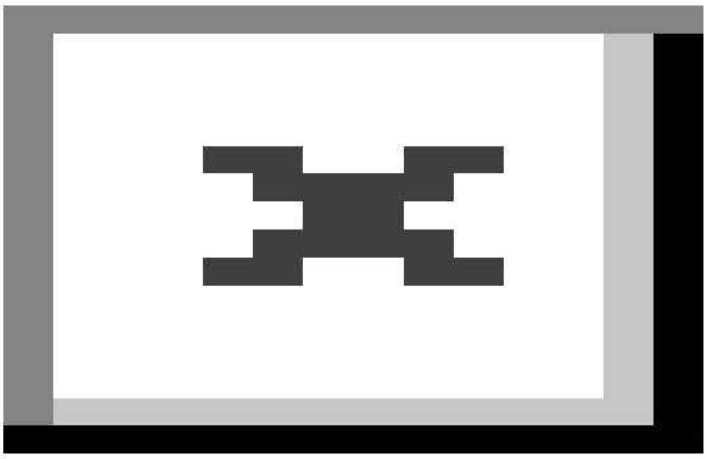

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Sender:	Fuller, Matthew A. (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=62D9CBB23B184CACB98895776E36A471-FULLER, MAT>
Recipient:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Glassman, Peter A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90608d43ef14423db308fb6c71ed750b-Glassman, P <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>
Sent Date:	2019/06/12 09:57:21
Delivered Date:	2019/06/12 09:57:00

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From:	Glassman, Peter A. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90608D43EF14423DB308FB6C71ED750B-GLASSMAN, P <(b6) va.gov>
To:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>
Subject:	RE: Nasal spray depression drug may be riskier than first thought
Date:	2019/06/12 10:34:43
Priority:	Normal
Type:	Note

Interesting article, emphasizing issues that we have identified—and (b6) , and glad that we will be looking at this closely over time.

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From: Valentino, Michael (VACO) <(b6) va.gov>
Date: Wednesday, Jun 12, 2019, 8:48 AM
To: Fuller, Matthew A. (PBM) <(b6) va.gov>, Glassman, Peter A. <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
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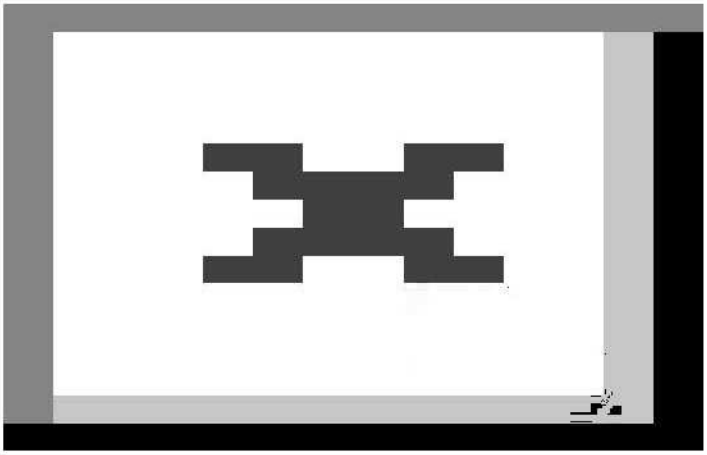
VA-19-1109-B-000053



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Sent Date:	2019/06/12 10:34:39
Delivered Date:	2019/06/12 10:34:43
Message Flags:	Unread

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From:	Capehart, Bruce P. DURVAMC /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6866EFF4E9DF4A48846D056A02044C38-CAPEHART, B (b6) va.gov>
To:	Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat <(b6) va.gov>; Schreiber, Matthew A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=db4d0324bf0945f183f33816c7fd1db0-Schreiber, (b6) .gov>
Subject:	RE: Nasal spray depression drug may be riskier than first thought
Date:	2019/06/17 12:32:59
Priority:	Normal
Type:	Note

(b6) .

Copy of the referenced editorial is attached.

From: Fuller, Matthew A. (PBM)
Sent: Monday, June 17, 2019 9:30 AM
To: Capehart, Bruce P. DURVAMC <(b6) va.gov>; Schreiber, Matthew A. (b6) va.gov>
Subject: FW: Nasal spray depression drug may be riskier than first thought

FYI, in case you haven't seen.

https://www.nbcnews.com/health/health-news/caution-urged-over-use-fast-acting-version-ketamine-depression-n1016176

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Sent Date:	2019/06/17 12:32:58
Delivered Date:	2019/06/17 12:32:59

AMERICAN OVERSIGHT

From:	Zacher, Jennifer L. (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9027C425646E4DE8A7D196908016331B-ZACHER, JEN <(b6) va.gov>
To:	Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat <(b6) va.gov>
Subject:	RE: MoCA
Date:	2019/06/26 14:57:42
Priority:	Normal
Type:	Note

Agree!

From: Fuller, Matthew A. (PBM)
Sent: Wednesday, June 26, 2019 1:55 PM
To: Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: MoCA

Ok. I removed the embedded document but kept our language '(b) (5) [redacted]. Thoughts?

From: Zacher, Jennifer L. (PBM)
Sent: Wednesday, June 26, 2019 2:43 PM
To: Fuller, Matthew A. (PBM) <(b6) va.gov>
Subject: RE: MoCA

(b6) ....correct!!!!

From: Fuller, Matthew A. (PBM)
Sent: Wednesday, June 26, 2019 1:42 PM
To: Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: MoCA

Hi Jenn,

I just got off my call with the Dementia Steering Committee. They announced that makers of the Montreal Cognitive Assessment (MoCA) are now requiring users to complete a one hour training session to be certified to use the instrument. Cost per certification is $125. I bring this up because we have the (b) (5) [redacted] Thoughts?

AMERICAN OVERSIGHT

Matthew

Sender:	Zacher, Jennifer L. (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9027C425646E4DE8A7D196908016331B-ZACHER, JEN <(b6) va.gov>
Recipient:	Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat <(b6) va.gov>
Sent Date:	2019/06/26 14:57:41
Delivered Date:	2019/06/26 14:57:42
Message Flags:	Unread

AMERICAN OVERSIGHT

From:	Lowe, Joette /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2CDA61A196F849548A246B80455099D9-LOWE, JOETT (b6) va.gov>
To:	Slagle, Mark (V9) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b618b365e2e41509ee26c5586e88679-Slagle, Mar <(b6) @va.gov>; Wormuth, Janelle /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=30475070e3ab4f95b2d75040c4e81494-Wormuth, Ja <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>; VHAPBM VPE Operational Advisors /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e82e3cb195934f368f0997bdf33da474-VHAPBH VPE <VPEOperationalAdvisors@va.gov>
Subject:	RE: Memorandum: Certification with SPRAVATO™ Risk Evaluation and Mitigation Strategy (REMS)
Date:	2019/03/19 15:35:56
Priority:	Normal
Type:	Note

(b6)
☺.

Joette S. Lowe, PharmD
VISN 7 Pharmacy Executive (VPE)
3701 Loop Road East
Tuscaloosa, AL 35404
(b6)

Suicide Prevention is Everyone's Business. *#BeThere.*



cid:image009.jpg@01D328A1.8C7B68A0

From: Slagle, Mark (V9)
Sent: Tuesday, March 19, 2019 2:28 PM
To: Wormuth, (b6) (b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Lowe, Joette (b6) va.gov>; VHAPBM VPE Operational Advisors <VPEOperationalAdvisors@va.gov>
Subject: RE: Memorandum: Certification with SPRAVATO™ Risk Evaluation and Mitigation Strategy (REMS)

Jenn has a call with J&J this afternoon to sort out some stuff.

Mark A. Slagle, PharmD, BCPS
VISN 9 Pharmacist Executive
1801 West End Ave., Suite 600

AMERICAN OVERSIGHT

Nashville, TN 37203
(b6)

From: Wormuth, Janelle
Sent: Tuesday, March 19, 2019 2:22 PM
To: Zacher, Jennifer L. (PBM) <(b6) va.gov>; Lowe, Joette (b6) va.gov>; VHAPBM VPE Operational Advisors <VPEOperationalAdvisors@va.gov>
Subject: RE: Memorandum: Certification with SPRAVATO™ Risk Evaluation and Mitigation Strategy (REMS)

Sorry – more questions from the field. So will the guidance from PBM then notify all that the company and the FDA have worked out the REMS program plan?

Thank you
Janelle

Janelle Wormuth, PharmD
VISN23 Pharmacy Executive

From: Zacher, Jennifer L. (PBM)
Sent: Tuesday, March 19, 2019 9:29 AM
To: Lowe, Joette (b6) va.gov>; Wormuth, Janelle (b6) va.gov>; VHAPBM VPE Operational Advisors <VPEOperationalAdvisors@va.gov>
Subject: RE: Memorandum: Certification with SPRAVATO™ Risk Evaluation and Mitigation Strategy (REMS)

Hi,
We talked about this at the meeting… (b6)

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JZ

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To: Wormuth, Janelle (b6) va.gov>; VHAPBM VPE Operational Advisors <VPEOperationalAdvisors@va.gov>
Subject: RE: Memorandum: Certification with SPRAVATO™ Risk Evaluation and Mitigation Strategy (REMS)

(b6) ?

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Joette S. Lowe, PharmD
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From: Wormuth, Janelle
Sent: Tuesday, March 19, 2019 9:15 AM
To: VHAPBM VPE Operational Advisors <VPEOperationalAdvisors@va.gov>
Subject: FW: Memorandum: Certification with SPRAVATO™ Risk Evaluation and Mitigation Strategy (REMS)
Importance: High

In attachment B – it says PBM will provide guidance….. but my VISN already sent this out as an ACTION ITEMS based on the DUSHOM communications…so the pharmacy is asking me about this….
HELP ☺

- Guidance on Spravato® REMS Pharmacy certification will be distributed by Pharmacy Benefits Management (PBM) Services by established communication pathways for all FDA approved REMS.

Janelle Wormuth, PharmD
VISN23 Pharmacy Executive

From: Petti, Jason C
Sent: Monday, March 18, 2019 1:20 PM
To: VHA VISN 23 Action Group <VHAVISN23ActionGroup@va.gov>; Wormuth, Janelle (l(b6) va.gov>; Brown, Larry L. (l(b6) va.gov>; Cohen, Jay L. (b6) @va.gov>
Subject: FW: Memorandum: Certification with SPRAVATO™ Risk Evaluation and Mitigation Strategy (REMS)

Please action and coordinate this via the CMO to VISN PBM, MHSL and PMSL Medical Directors.

Jason C. Petti, MSHA,
Deputy Network Director
VA Midwest Health Care Network (VISN23)
Office: (b6)

AMERICAN OVERSIGHT

From: Office of the DUSHOM Communications
Sent: Monday, March 18, 2019 1:15 PM
To: VHA VISN Directors <VHAVISNDirectors@va.gov>; VHACLE BVAC Group <VHACLEBVACGroup@va.gov>
Cc: VHA VISN Admin Reps <VHAVISNAdminReps@va.gov>; VHA 10NC Action <vha10ncaction@va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>; Wiechers, Ilse <(b6) @va.gov>; VHA CO 10N Support Staff <VHACO10NSS@va.gov>; McCarthy, Brian (b6) @va.gov>
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Good Afternoon,

Please see the attached memorandum "Certification with SPRAVATO™ Risk Evaluation and Mitigation Strategy (REMS)."

1. The purpose of this memorandum and its attachments is to outline the procedures for the use of Spravato® (eskatamine) nasal spray which was approved by the Food and Drug Administration (FDA) on March 5, 2019, to be used in conjunction with an oral antidepressant, for the treatment of depression in adults who have tried other antidepressant medicines but have not benefited from them (see Attachment A for Esketamine Frequently Asked Questions).

2. Because of the risk of serious adverse outcomes resulting from sedation and dissociation caused by Spravato® administration, and the potential for abuse and misuse of the drug, it is only available through a restricted distribution system, under an FDA approved Risk Evaluation and Mitigation Strategy (REMS). Please see and follow instructions in Attachment B for REMS Healthcare Setting Certification Guidance.

3. All medical centers must become a Spravato® REMS certified Healthcare Setting and certified Pharmacy. *Within 30 days of this memorandum*, facilities should report completion of REMS Healthcare Setting certification to their VISN Chief Mental Health Officer, who should then report VISN-wide REMS certification by email to Dr. Ilse Wiechers at (b6) @va.gov.

4. There are resource requirements that facilities must plan to accommodate. Spravato® is intended for patient self-administration under the direct observation of a healthcare provider, and patients are required to be monitored by a healthcare provider for at least 2 hours after Spravato® administration. Spravato® must never be dispensed directly to a patient for home use.

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6. Once educational materials from the manufacturer of Spravato® are made available to VA to review, the review and use of those materials will be consistent

AMERICAN OVERSIGHT

with VHA Directive, 1108.10, Promotion of Drugs and Drug-Related Supplies By Pharmaceutical Company Representatives (PCR) located at: https://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=6435.

7. Please contact Ilse Wiechers, MD, Office of Mental Health and Suicide Prevention at (b6) @va.gov with any questions related to this request.

Renee Oshinski

Attachments

Sender:	Lowe, Joette /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2CDA61A196F849548A246B80455099D9-LOWE, JOETT <(b6) va.gov>
Recipient:	Slagle, Mark (V9) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b618b365e2e41509ee26c5586e88679-Slagle, Mar <(b6) va.gov>; Wormuth, Janelle /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=30475070e3ab4f95b2d75040c4e81494-Wormuth, Ja <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>; VHAPBM VPE Operational Advisors /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e82e3cb195934f368f0997bdf33da474-VHAPBH VPE <VPEOperationalAdvisors@va.gov>
Sent Date:	2019/03/19 15:35:54
Delivered Date:	2019/03/19 15:35:56
Message Flags:	Unread

AMERICAN OVERSIGHT

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Subject:	RE: Memorandum: Certification with SPRAVATO™ Risk Evaluation and Mitigation Strategy (REMS)
Date:	2019/03/20 13:00:57
Priority:	Normal
Type:	Note

(b6)

Sent with BlackBerry Work
(www.blackberry.com)

From: Zacher, Jennifer L. (PBM) <(b6) va.gov>
Date: Wednesday, Mar 20, 2019, 11:05 AM
To: Leslie, Donna M. (b6) @va.gov>, Lowe, Joette (b6) va.gov>, Wormuth, Janelle (b6) va.gov>, VHAPBM VPE Operational Advisors <VPEOperationalAdvisors@va.gov>
Subject: RE: Memorandum: Certification with SPRAVATO™ Risk Evaluation and Mitigation Strategy (REMS)

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Sent: Wednesday, March 20, 2019 11:04 AM
To: Zacher, Jennifer L. (PBM) <(b6) va.gov>; Lowe, Joette (b6) va.gov>; Wormuth, Janelle (b6) va.gov>; VHAPBM VPE Operational Advisors <VPEOperationalAdvisors@va.gov>
Subject: RE: Memorandum: Certification with SPRAVATO™ Risk Evaluation and Mitigation Strategy (REMS)

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AMERICAN OVERSIGHT

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Subject: RE: Memorandum: Certification with SPRAVATO™ Risk Evaluation and Mitigation Strategy (REMS)

(b6) ?

Joette S. Lowe, PharmD
VISN 7 Pharmacy Executive (VPE)
3701 Loop Road East
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(b6)
Suicide Prevention is Everyone's Business. *#BeThere.*



cid:image009.jpg@01D328A1.8C7B68A0

From: Wormuth, Janelle
Sent: Tuesday, March 19, 2019 9:15 AM

AMERICAN OVERSIGHT

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AMERICAN OVERSIGHT

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Renee Oshinski

Attachments

AMERICAN OVERSIGHT

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Recipient:	Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>; Leslie, Donna M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5c658dca625d48eba1d7be8efb4caa5c-Leslie, Don (b6) @va.gov>; Wormuth, Janelle /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=30475070e3ab4f95b2d75040c4e81494-Wormuth, Ja (b6) va.gov>; VHAPBM VPE Operational Advisors /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e82e3cb195934f368f0997bdf33da474-VHAPBH VPE <VPEOperationalAdvisors@va.gov>
Sent Date:	2019/03/20 13:00:56
Delivered Date:	2019/03/20 13:00:57
Message Flags:	Unread

AMERICAN OVERSIGHT

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Subject:	RE: Memorandum: Certification with SPRAVATO™ Risk Evaluation and Mitigation Strategy (REMS)
Date:	2019/03/21 09:31:03
Priority:	Normal
Type:	Note

I sent information from MH – they have pushed back and got it on the agenda for their next call. They do NOT want this.

Joette S. Lowe, PharmD
VISN 7 Pharmacy Executive (VPE)
3701 Loop Road East
Tuscaloosa, AL 35404
(b6)

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From: Leslie, Donna M.
Sent: Wednesday, March 20, 2019 11:11 AM
To: Zacher, Jennifer L. (PBM) <(b6) va.gov>; Lowe, Joette (l(b6) va.gov>; Wormuth, Janelle (l(b6) va.gov>; VHAPBM VPE Operational Advisors <VPEOperationalAdvisors@va.gov>
Subject: RE: Memorandum: Certification with SPRAVATO™ Risk Evaluation and Mitigation Strategy (REMS)

Thanks Jen – I am going to tell my VISN to wait on actioning this out until you have the PBM guidance sent.

AMERICAN OVERSIGHT

From: Zacher, Jennifer L. (PBM)
Sent: Wednesday, March 20, 2019 11:06 AM
To: Leslie, Donna M. <(b6) @va.gov>; Lowe, Joette (l(b6) va.gov>; Wormuth, Janelle (l(b6) va.gov>; VHAPBM VPE Operational Advisors <VPEOperationalAdvisors@va.gov>
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Subject: RE: Memorandum: Certification with SPRAVATO™ Risk Evaluation and Mitigation Strategy (REMS)

Why in the world would Ilse send something like this out?

Joette S. Lowe, PharmD
VISN 7 Pharmacy Executive (VPE)
3701 Loop Road East
Tuscaloosa, AL 35404
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7. Please contact Ilse Wiechers, MD, Office of Mental Health and Suicide Prevention at(b6) @va.gov with any questions related to this request.

Renee Oshinski

Attachments

Sender:	Lowe, Joette /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2CDA61A196F849548A246B80455099D9-LOWE, JOETT (b6) .gov>
Recipient:	Leslie, Donna M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5c658dca625d48eba1d7be8efb4caa5c-Leslie, Don (b6) @va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>; Wormuth, Janelle /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=30475070e3ab4f95b2d75040c4e81494-Wormuth, Ja (b6) va.gov>; VHAPBM VPE Operational Advisors /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e82e3cb195934f368f0997bdf33da474-VHAPBH VPE <VPEOperationalAdvisors@va.gov>
Sent Date:	2019/03/21 09:31:01
Delivered Date:	2019/03/21 09:31:03
Message Flags:	Unread

AMERICAN OVERSIGHT

From:	Wormuth, Janelle /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=30475070E3AB4F95B2D75040C4E81494-WORMUTH, JA (b6) va.gov>
To:	Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>; Lowe, Joette /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2cda61a196f849548a246b80455099d9-Lowe, Joett (b6) va.gov>; VHAPBM VPE Operational Advisors /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e82e3cb195934f368f0997bdf33da474-VHAPBH VPE <VPEOperationalAdvisors@va.gov>
Subject:	RE: Memorandum: Certification with SPRAVATO™ Risk Evaluation and Mitigation Strategy (REMS)
Date:	2019/03/19 10:35:21
Priority:	Normal
Type:	Note

Awesome – thanks Jen.

Janelle Wormuth, PharmD
VISN23 Pharmacy Executive

From: Zacher, Jennifer L. (PBM)
Sent: Tuesday, March 19, 2019 9:29 AM
To: Lowe, Joette (b6) va.gov>; Wormuth, Janelle <(b6) va.gov>; VHAPBM VPE Operational Advisors <VPEOperationalAdvisors@va.gov>
Subject: RE: Memorandum: Certification with SPRAVATO™ Risk Evaluation and Mitigation Strategy (REMS)

Hi,
We talked about this at the meeting… (b6) .

The product still isn't in the supply chain, but sites can get their pharmacies certified now to help streamline the process if/when the product is needed for a patient.

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JZ

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AMERICAN OVERSIGHT

(b6) [redacted]

Joette S. Lowe, PharmD
VISN 7 Pharmacy Executive (VPE)
3701 Loop Road East
Tuscaloosa, AL 35404
(b6) [redacted]
Suicide Prevention is Everyone's Business. *#BeThere.*



cid:image009.jpg@01D328A1.8C7B68A0

From: Wormuth, Janelle
Sent: Tuesday, March 19, 2019 9:15 AM
To: VHAPBM VPE Operational Advisors <VPEOperationalAdvisors@va.gov>
Subject: FW: Memorandum: Certification with SPRAVATO™ Risk Evaluation and Mitigation Strategy (REMS)
Importance: High

In attachment B – it says PBM will provide guidance….. but my VISN already sent this out as an ACTION ITEMS based on the DUSHOM communications…so the pharmacy is asking me about this….
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- Guidance on Spravato® REMS Pharmacy certification will be distributed by Pharmacy Benefits Management (PBM) Services by established communication pathways for all FDA approved REMS.

Janelle Wormuth, PharmD
VISN23 Pharmacy Executive

From: Petti, Jason C
Sent: Monday, March 18, 2019 1:20 PM
To: VHA VISN 23 Action Group <VHAVISN23ActionGroup@va.gov>; Wormuth, Janelle <(b6) [redacted] va.gov>; Brown, Larry L. (l(b6) [redacted] va.gov>; Cohen, Jay L. (b6) [redacted] @va.gov>
Subject: FW: Memorandum: Certification with SPRAVATO™ Risk Evaluation and Mitigation Strategy (REMS)

Please action and coordinate this via the CMO to VISN PBM, MHSL and PMSL Medical Directors.

AMERICAN OVERSIGHT

Jason C. Petti, MSHA,
Deputy Network Director
VA Midwest Health Care Network (VISN23)
Office: (b6)

From: Office of the DUSHOM Communications
Sent: Monday, March 18, 2019 1:15 PM
To: VHA VISN Directors <VHAVISNDirectors@va.gov>; VHACLE BVAC Group <VHACLEBVACGroup@va.gov>
Cc: VHA VISN Admin Reps <VHAVISNAdminReps@va.gov>; VHA 10NC Action <vha10ncaction@va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>; Wiechers, Ilse (b6) @va.gov>; VHA CO 10N Support Staff <VHACO10NSS@va.gov>; McCarthy, Brian (b6) @va.gov>
Subject: Memorandum: Certification with SPRAVATO™ Risk Evaluation and Mitigation Strategy (REMS)

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6. Once educational materials from the manufacturer of Spravato® are made available to VA to review, the review and use of those materials will be consistent with VHA Directive, 1108.10, Promotion of Drugs and Drug-Related Supplies By Pharmaceutical Company Representatives (PCR) located at: https://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=6435.

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Renee Oshinski

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Sent Date:	2019/03/19 10:35:19
Delivered Date:	2019/03/19 10:35:21
Message Flags:	Unread

AMERICAN OVERSIGHT

From:	Emmendorfer, Thomas (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC96BB44E7AE2C94C43B55D094-EMMENDORFER>
To:	Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>
Subject:	RE: Memorandum: Certification with SPRAVATO™ Risk Evaluation and Mitigation Strategy (REMS)
Date:	2019/03/19 10:31:00
Priority:	Normal
Type:	Note

(b6) .

When we get a hard date of when Spravato® is in the supply chain for procurement, could you please send me that date? I want to have that in our April 1st briefing with Dr. Stone that reflects J&J CEO date of 3/18/2019 versus the actual date.

From: Zacher, Jennifer L. (PBM)
Sent: Tuesday, March 19, 2019 10:29 AM
To: Lowe, Joette <(b6) va.gov>; Wormuth, Janelle <(b6) va.gov>; VHAPBM VPE Operational Advisors <VPEOperationalAdvisors@va.gov>
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Why in the world would Ilse send something like this out?

AMERICAN OVERSIGHT

Joette S. Lowe, PharmD
VISN 7 Pharmacy Executive (VPE)
3701 Loop Road East
Tuscaloosa, AL 35404
(b6)
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cid:image009.jpg@01D328A1.8C7B68A0

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Jason C. Petti, MSHA,
Deputy Network Director
VA Midwest Health Care Network (VISN23)

AMERICAN OVERSIGHT

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Renee Oshinski

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Recipient:	Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>
Sent Date:	2019/03/19 10:31:24
Delivered Date:	2019/03/19 10:31:00

AMERICAN OVERSIGHT

From:	Boyd, Teresa D. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F6886A7D555A43E0BEE23C1E40E1C234-BOYD, TERES <(b6) va.gov>
To:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>
Subject:	RE: Media Summary- June 13, 2019
Date:	2019/06/18 05:56:13
Priority:	Normal
Type:	Note

Do we have comms working with you all?
And yes...please let me know once the first patient has been taken care of. Really appreciate it.
Teresa

Sent with BlackBerry Work
(www.blackberry.com)

From: Wiechers, Ilse <(b6) va.gov>
Date: Monday, Jun 17, 2019, 6:50 PM
To: Boyd, Teresa D. <(b6) va.gov>, Valentino, Michael (VACO) <(b6) va.gov>
Subject: RE: Media Summary- June 13, 2019

That's the plan, all systems go as of last round of emails today. I'll confirm as soon as I here from them tomorrow post-dosing.

Sent with BlackBerry Work
(www.blackberry.com)

From: Boyd, Teresa D. <(b6) va.gov>
Date: Monday, Jun 17, 2019, 3:30 PM
To: Wiechers, Ilse <(b6) va.gov>, Valentino, Michael (VACO) <(b6) va.gov>
Subject: RE: Media Summary- June 13, 2019

Just checking to see if Boston is kicking off the first Spravato patient tomorrow?

Thanks!~

Teresa

From: Wiechers, Ilse
Sent: Friday, June 14, 2019 10:54 AM
To: Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO)

AMERICAN OVERSIGHT

<{b6} va.gov>; Llorente, Maria D. <{b6} va.gov>; Boyd, Teresa D. <{b6} va.gov>
Subject: RE: Media Summary- June 13, 2019

Thanks everyone. I think a brief call next Friday after the dust settles from the MAP/VPE meeting would be helpful. I can be available anytime except 10:30-12 pm or 2-3 pm ET.

Ilse

From: Valentino, Michael (VACO)
Sent: Friday, June 14, 2019 5:47 AM
To: Carroll, David (VACO) <{b6} va.gov>; Llorente, Maria D. <{b6} va.gov>; Wiechers, Ilse {b6} @va.gov>; Boyd, Teresa D. <{b6} va.gov>
Subject: RE: Media Summary- June 13, 2019

Agree also.

Many of the field comments we received on the draft monograph and Criteria for Use echoed similar concerns.

That is one of the reasons we couldn't get a formulary decision on our May conference call.

I anticipate a very lively discussion next week at our face-to-face formulary meeting!

Sent with BlackBerry Work
(www.blackberry.com)

From: Carroll, David (VACO) <{b6} va.gov>
Date: Friday, Jun 14, 2019, 6:57 AM
To: Llorente, Maria D. <{b6} va.gov>, Wiechers, Ilse {b6} @va.gov>, Valentino, Michael (VACO) <{b6} va.gov>, Boyd, Teresa D. <{b6} va.gov>
Subject: RE: Media Summary- June 13, 2019

Adding my concurrence on the concerns and the plan. Thanks.

From: Llorente, Maria D.
Sent: Thursday, June 13, 2019 7:26 PM
To: Wiechers, Ilse {b6} @va.gov>; Valentino, Michael (VACO) <{b6} va.gov>; Boyd, Teresa D. <{b6} va.gov>
Cc: Carroll, David (VACO) <{b6} va.gov>
Subject: RE: Media Summary- June 13, 2019

Thank you Ilse. I agree with both your concerns and suggestion to meet next week. I will also discuss with Dr. Beck and ask for her guidance. Completely agree with step-wise and thoughtful implementation as per existing plan. Mike and I will be in Chicago next week Tues-Thurs, but maybe Friday morning?

AMERICAN OVERSIGHT

From: Wiechers, Ilse
Sent: Thursday, June 13, 2019 5:39 PM
To: Valentino, Michael (VACO) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>
Cc: Carroll, David (VACO) <(b6) va.gov>
Subject: RE: Media Summary- June 13, 2019

Hello everyone – adding Dave here as well.

I've spent some more time reading and considering this today. I wanted to email to express my concern directly. (b6) ."

(b6) .

At some point (not urgently, but perhaps next week) I'd like to discuss this with the group further to make sure I am prepared for what is coming next. In the meantime, I will continue to proceed with our step-wise and thoughtful pilot implementation of esketamine that puts Veteran safety first.

Best,
Ilse

From: Valentino, Michael (VACO)
Sent: Thursday, June 13, 2019 9:04 AM
To: Wiechers, Ilse <(b6) @va.gov>; Llorente, Maria D. <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>
Subject: FW: Media Summary- June 13, 2019

1 more

Sent with BlackBerry Work
(www.blackberry.com)

From: Dill, Eric C (b6) @va.gov>
Date: Thursday, Jun 13, 2019, 11:37 AM
To: VHAPBM VPE Formulary Committee <VPEFormularyCommittee@va.gov>
Subject: FW: Media Summary- June 13, 2019

Just FYI, two articles that may get some questions:

AMERICAN OVERSIGHT

From: Cowgill, David E
Sent: Thursday, June 13, 2019 7:24 AM
To: VHA VISN 04 Staff <VIS44Staff@med.va.gov>
Subject: Media Summary- June 13, 2019

...

VA Media

Bloomberg: Trump Offers to Negotiate Price of J&J Anti-Depressant for VA (12 June, Justin Sink, 17.6M uvm; New York, NY)

President Donald Trump offered to help the Department of Veterans Affairs negotiate the acquisition of a new Johnson &Johnson drug to treat depression, a treatment he believes could result in an "incredible" drop in veteran suicide.

"I think they'll be very generous with you," Trump told Veterans Affairs Secretary Robert Wilkie during a Wednesday meeting on opioid abuse at the White House. "And if you like, I'll help you to negotiate."

Trump appeared to be referring to Spravato, a nasal spray sold by Johnson &Johnson that was approved for use treating adults with treatment-resistant depression by the Food and Drug Administration in March. The company said that in short and long-term clinical trials, those who used the drug and a newly initiated oral antidepressant saw sustained improvement in their symptoms compared to adults who received just the oral drug.

The president -- who said he had "read really quite a bit" about the drug -- said he believed it could work well enough to significantly reduce the rates of veteran suicide.

Spravato is a close chemical cousin to the anesthetic ketamine. When it was approved, J&J said it would cost $4,720 to $6,785 in the first month, and then decline in price to $2,360 to $3,540 monthly.

The treatment is the first major breakthrough for depression since Prozac in 1987, and could help usher in a new wave of therapies for a hard-to-treat condition. Existing options typically take weeks to work, and aren't effective for all patients.

"Give it to anybody that has the problem, because you have people calling and our folks do a great job on the phone -- but it's a telephone," Trump said. "You have people calling for help and if those people had that, I'm hearing like instantaneously they're in better shape."

Wilkie said the medicine was "very effective" and that the VA was currently "in the purchasing process" in hopes of having the drug in all VA hospitals by the end of the year.

If you or someone you know is having suicidal thoughts, The National Suicide Prevention Lifeline is: 1 (800) 273-8255.

The White House: Remarks by President Trump in Meeting on Opioids (12 June, Washington, DC)

AMERICAN OVERSIGHT

Roosevelt Room
3:30 P.M. EDT

THE PRESIDENT: Thank you very much. And I think what we do — this is a meeting on opioid and the tremendous effect that's taken place over the last little period of time. And I'm very proud of it and the people working so hard on it.

But I thought what I'd do is ask Secretary Wilkie to give a statement as to what just happened with respect to Choice and the VA, because I think it's a very, very big deal.

Robert?

SECRETARY WILKIE: Thank you, sir. June 6th was a doubly important day. You were celebrating the 75th anniversary of the Normandy landings. And for VA, we began to implement the Mission Act, which you signed last year.

On that day, 44,000 veterans came to us to ask for greater choice in their healthcare on day one. And we began to open up that aperture and provide them, for the first time, with urgent care across the country. So they now have what their fellow citizens have had for many years.

And we expect them to take greater advantage of it as we go along. We've contacted over 9 million veterans to tell them this is now available to them. And it is one of the great transformative steps in the history of our department.

THE PRESIDENT: Yes, it is. It's Choice.

SECRETARY WILKIE: And it's off to a very good — very good start.

THE PRESIDENT: VA Choice.

SECRETARY WILKIE: Yes, sir.

THE PRESIDENT: So, for 44 years, they've been trying to get it, and we got it. And they're loving it, I hear.

SECRETARY WILKIE: Yes. Yes, sir. With that many on the first day, that's a testament to —

THE PRESIDENT: That's a tremendous testament.

SECRETARY WILKIE: Yes, sir.

THE PRESIDENT: Congratulations.

SECRETARY WILKIE: Thank you, sir.

THE PRESIDENT: Come here. I'm proud of you. That's a fantastic job.

SECRETARY WILKIE: Thank you, sir. Thank you very much.

AMERICAN OVERSIGHT

THE PRESIDENT: I'm proud of you. Thank you very much.

Kellyanne?

MS. CONWAY: Mr. President, thank you. The focus that the First Lady and you have placed on the opioid and drug demand, drug supply crisis roiling our nation is starting to produce positive results.

Sender:	Boyd, Teresa D. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F6886A7D555A43E0BEE23C1E40E1C234-BOYD, TERES <(b6) va.gov>
Recipient:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>
Sent Date:	2019/06/18 05:56:12
Delivered Date:	2019/06/18 05:56:13

AMERICAN OVERSIGHT

From:	Boyd, Teresa D. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F6886A7D555A43E0BEE23C1E40E1C234-BOYD, TERES <(b6) va.gov>
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Subject:	RE: Media Summary- June 13, 2019
Date:	2019/06/17 18:57:45
Priority:	Normal
Type:	Note

Fantastic! And thank you!

Sent with BlackBerry Work
(www.blackberry.com)

From: Wiechers, Ilse <(b6) va.gov>
Date: Monday, Jun 17, 2019, 6:50 PM
To: Boyd, Teresa D. <(b6) va.gov>, Valentino, Michael (VACO) <(b6) va.gov>
Subject: RE: Media Summary- June 13, 2019

That's the plan, all systems go as of last round of emails today. I'll confirm as soon as I here from them tomorrow post-dosing.

Sent with BlackBerry Work
(www.blackberry.com)

From: Boyd, Teresa D. <(b6) va.gov>
Date: Monday, Jun 17, 2019, 3:30 PM
To: Wiechers, Ilse <(b6) va.gov>, Valentino, Michael (VACO) <(b6) va.gov>
Subject: RE: Media Summary- June 13, 2019

Just checking to see if Boston is kicking off the first Spravato patient tomorrow?

Thanks!~

Teresa

From: Wiechers, Ilse
Sent: Friday, June 14, 2019 10:54 AM
To: Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Boyd, Teresa D.

AMERICAN OVERSIGHT

<{b6} va.gov>
Subject: RE: Media Summary- June 13, 2019

Thanks everyone. I think a brief call next Friday after the dust settles from the MAP/VPE meeting would be helpful. I can be available anytime except 10:30-12 pm or 2-3 pm ET.

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Agree also.

Many of the field comments we received on the draft monograph and Criteria for Use echoed similar concerns.

That is one of the reasons we couldn't get a formulary decision on our May conference call.

I anticipate a very lively discussion next week at our face-to-face formulary meeting!

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Date: Friday, Jun 14, 2019, 6:57 AM
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Sent: Thursday, June 13, 2019 7:26 PM
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Cc: Carroll, David (VACO) <{b6} va.gov>
Subject: RE: Media Summary- June 13, 2019

Thank you Ilse. I agree with both your concerns and suggestion to meet next week. I will also discuss with Dr. Beck and ask for her guidance. Completely agree with step-wise and thoughtful implementation as per existing plan. Mike and I will be in Chicago next week Tues-Thurs, but maybe Friday morning?

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Hello everyone – adding Dave here as well.

I've spent some more time reading and considering this today. I wanted to email to express my concern directly. (b6)

At some point (not urgently, but perhaps next week) I'd like to discuss this with the group further to make sure I am prepared for what is coming next. In the meantime, I will continue to proceed with our step-wise and thoughtful pilot implementation of esketamine that puts Veteran safety first.

Best,
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Sent: Thursday, June 13, 2019 9:04 AM
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1 more

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From: Dill, Eric C <(b6) @va.gov>
Date: Thursday, Jun 13, 2019, 11:37 AM
To: VHAPBM VPE Formulary Committee <VPEFormularyCommittee@va.gov>
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AMERICAN OVERSIGHT

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"Give it to anybody that has the problem, because you have people calling and our folks do a great job on the phone -- but it's a telephone," Trump said. "You have people calling for help and if those people had that, I'm hearing like instantaneously they're in better shape."

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Roosevelt Room
3:30 P.M. EDT

AMERICAN OVERSIGHT

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THE PRESIDENT: Yes, it is. It's Choice.

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AMERICAN OVERSIGHT

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Sent Date:	2019/06/17 18:57:44
Delivered Date:	2019/06/17 18:57:45

AMERICAN OVERSIGHT

From:	Lowe, Joette /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2CDA61A196F849548A246B80455099D9-LOWE, JOETT <(b6) va.gov>
To:	Dill, Eric C /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c8090e1bf0484cd0ade5e7acea695535-Dill, Eric (b6) @va.gov>; VHAPBM VPE Formulary Committee /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fcba1f4b52e048838d3053091f54eb4e-VHAPBH VPE <VPEFormularyCommittee@va.gov>
Subject:	RE: Media Summary- June 13, 2019
Date:	2019/06/13 12:21:30
Priority:	Normal
Type:	Note

Yes, I read these. This too.

CBS News (Video): Could a simple shot be a breakthrough treatment for PTSD? (12 June, 12.5M uvm; New York, NY)
The first living Marine to win the nation's highest combat decoration since Vietnam was able to have his PTSD symptoms greatly eased. But the experimental treatment Medal of Honor winner Sgt. Dakota Meyer received is only available in 12 of the 172 VA hospitals. Retired Army General Donald Bolduc, who also benefited from stellate ganglion block therapy, is calling for the procedure to be made a part of all PTSD treatments. He speaks to Bill Whitaker for a report about SGB on the next edition of 60 Minutes, Sunday June 16 at 7 p.m. ET/PT on CBS.

Joette S. Lowe, PharmD
VISN 7 Pharmacist Executive
3701 Loop Rd East
Tuscaloosa, AL 35404
(b6)

From: Dill, Eric C
Sent: Thursday, June 13, 2019 10:38 AM
To: VHAPBM VPE Formulary Committee <VPEFormularyCommittee@va.gov>
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Sent Date:	2019/06/13 12:21:24
Delivered Date:	2019/06/13 12:21:30
Message Flags:	Unread

AMERICAN OVERSIGHT

From:	Valentino, Michael (VACO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO,>
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Subject:	RE: Media Summary- June 13, 2019
Date:	2019/06/17 13:12:00
Priority:	Normal
Type:	Note

Will do….also attaching the slides….VERY large file but the first 25 or so slides are for Esketamine…..please consider confidential pre-decisional deliberative information……

From: Wiechers, Ilse
Sent: Monday, June 17, 2019 1:04 PM
To: Valentino, Michael (VACO) <(b6) va.gov>
Subject: RE: Media Summary- June 13, 2019

No – I've not gotten information for that, and I would very much like to be able to listen to the discussion. Please forward and I'll clear my schedule to ensure I can dial in. Thanks!

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Sent: Monday, June 17, 2019 9:49 AM
To: Wiechers, Ilse (b6) @va.gov>
Subject: RE: Media Summary- June 13, 2019

Hi Ilse,

Has anyone from our office contacted you about dialing in for the PBM-MAP-VPE discussion on Esketamine?

If not and this is something you think would be useful, please let me know and I'll get you the dial in number.

Mike

From: Wiechers, Ilse
Sent: Friday, June 14, 2019 10:54 AM
To: Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>
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AMERICAN OVERSIGHT

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[redacted]

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SECRETARY WILKIE: Thank you, sir. Thank you very much.

THE PRESIDENT: I'm proud of you. Thank you very much.

Kellyanne?

MS. CONWAY: Mr. President, thank you. The focus that the First Lady and you have placed on the opioid and drug demand, drug supply crisis roiling our nation is starting to produce positive results.

AMERICAN OVERSIGHT

Sender:	Valentino, Michael (VACO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO,>
Recipient:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>
Sent Date:	2019/06/17 13:13:16
Delivered Date:	2019/06/17 13:12:00

AMERICAN OVERSIGHT

From:	Llorente, Maria D. </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F5C91F577D894BD9A0F09305DB34DD4F-LLORENTE, M>
To:	Beck, Lucille B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=845480228a8b43e7a5fef5716ded04c2-Beck, Lucil <(b6) va.gov>
Subject:	RE: Media Summary- June 13, 2019
Date:	2019/06/14 08:27:00
Priority:	Normal
Type:	Note

Thank you.

From: Beck, Lucille B.
Sent: Thursday, June 13, 2019 9:59 PM
To: Llorente, Maria D. <(b6) @va.gov>
Subject: RE: Media Summary- June 13, 2019

Thanks for letting me know.

(b6) .

I have another comment to share when I see you.

Ku

Lucille B. Beck, Ph.D.
Deputy Under Secretary for Health
for Policy and Services (10P)
VA Central Office
Phone: (b6)
Cell (b6)

Sent with BlackBerry Work
(www.blackberry.com).

From: Llorente, Maria D. <(b6) va.gov>
Date: Thursday, Jun 13, 2019, 7:29 PM
To: Beck, Lucille B. <(b6) va.gov>
Subject: FW: Media Summary- June 13, 2019

Hi Lu. Not sure if you read the Bloomberg article that quoted POTUS re esketamine. I concur with Ilse's comments below and her suggestion to meet. Wanted to make sure that you were aware, and to seek guidance as to approaches. Thank you for your assistance

AMERICAN OVERSIGHT

Maria

From: Wiechers, Ilse
Sent: Thursday, June 13, 2019 5:39 PM
To: Valentino, Michael (VACO) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>
Cc: Carroll, David (VACO) <(b6) va.gov>
Subject: RE: Media Summary- June 13, 2019

Hello everyone – adding Dave here as well.

I've spent some more time reading and considering this today. I wanted to email to express my concern directly. (b6)

At some point (not urgently, but perhaps next week) I'd like to discuss this with the group further to make sure I am prepared for what is coming next. In the meantime, I will continue to proceed with our step-wise and thoughtful pilot implementation of esketamine that puts Veteran safety first.

Best,
Ilse

From: Valentino, Michael (VACO)
Sent: Thursday, June 13, 2019 9:04 AM
To: Wiechers, Ilse (b6) @va.gov>; Llorente, Maria D. <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>
Subject: FW: Media Summary- June 13, 2019

1 more

Sent with BlackBerry Work
(www.blackberry.com)

From: Dill, Eric C (b6) @va.gov>
Date: Thursday, Jun 13, 2019, 11:37 AM
To: VHAPBM VPE Formulary Committee <VPEFormularyCommittee@va.gov>
Subject: FW: Media Summary- June 13, 2019

Just FYI, two articles that may get some questions:

AMERICAN OVERSIGHT

From: Cowgill, David E
Sent: Thursday, June 13, 2019 7:24 AM
To: VHA VISN 04 Staff <VIS44Staff@med.va.gov>
Subject: Media Summary- June 13, 2019

...

VA Media

Bloomberg: Trump Offers to Negotiate Price of J&J Anti-Depressant for VA (12 June, Justin Sink, 17.6M uvm; New York, NY)

President Donald Trump offered to help the Department of Veterans Affairs negotiate the acquisition of a new Johnson &Johnson drug to treat depression, a treatment he believes could result in an "incredible" drop in veteran suicide.

"I think they'll be very generous with you," Trump told Veterans Affairs Secretary Robert Wilkie during a Wednesday meeting on opioid abuse at the White House. "And if you like, I'll help you to negotiate."

Trump appeared to be referring to Spravato, a nasal spray sold by Johnson &Johnson that was approved for use treating adults with treatment-resistant depression by the Food and Drug Administration in March. The company said that in short and long-term clinical trials, those who used the drug and a newly initiated oral antidepressant saw sustained improvement in their symptoms compared to adults who received just the oral drug.

The president -- who said he had "read really quite a bit" about the drug -- said he believed it could work well enough to significantly reduce the rates of veteran suicide.

Spravato is a close chemical cousin to the anesthetic ketamine. When it was approved, J&J said it would cost $4,720 to $6,785 in the first month, and then decline in price to $2,360 to $3,540 monthly.

The treatment is the first major breakthrough for depression since Prozac in 1987, and could help usher in a new wave of therapies for a hard-to-treat condition. Existing options typically take weeks to work, and aren't effective for all patients.

"Give it to anybody that has the problem, because you have people calling and our folks do a great job on the phone -- but it's a telephone," Trump said. "You have people calling for help and if those people had that, I'm hearing like instantaneously they're in better shape."

Wilkie said the medicine was "very effective" and that the VA was currently "in the purchasing process" in hopes of having the drug in all VA hospitals by the end of the year.

If you or someone you know is having suicidal thoughts, The National Suicide Prevention Lifeline is: 1 (800) 273-8255.

The White House: Remarks by President Trump in Meeting on Opioids (12 June, Washington, DC)

AMERICAN OVERSIGHT

Roosevelt Room
3:30 P.M. EDT

THE PRESIDENT: Thank you very much. And I think what we do — this is a meeting on opioid and the tremendous effect that's taken place over the last little period of time. And I'm very proud of it and the people working so hard on it.

But I thought what I'd do is ask Secretary Wilkie to give a statement as to what just happened with respect to Choice and the VA, because I think it's a very, very big deal.

Robert?

SECRETARY WILKIE: Thank you, sir. June 6th was a doubly important day. You were celebrating the 75th anniversary of the Normandy landings. And for VA, we began to implement the Mission Act, which you signed last year.

On that day, 44,000 veterans came to us to ask for greater choice in their healthcare on day one. And we began to open up that aperture and provide them, for the first time, with urgent care across the country. So they now have what their fellow citizens have had for many years.

And we expect them to take greater advantage of it as we go along. We've contacted over 9 million veterans to tell them this is now available to them. And it is one of the great transformative steps in the history of our department.

THE PRESIDENT: Yes, it is. It's Choice.

SECRETARY WILKIE: And it's off to a very good — very good start.

THE PRESIDENT: VA Choice.

SECRETARY WILKIE: Yes, sir.

THE PRESIDENT: So, for 44 years, they've been trying to get it, and we got it. And they're loving it, I hear.

SECRETARY WILKIE: Yes. Yes, sir. With that many on the first day, that's a testament to —

THE PRESIDENT: That's a tremendous testament.

SECRETARY WILKIE: Yes, sir.

THE PRESIDENT: Congratulations.

SECRETARY WILKIE: Thank you, sir.

THE PRESIDENT: Come here. I'm proud of you. That's a fantastic job.

SECRETARY WILKIE: Thank you, sir. Thank you very much.

AMERICAN OVERSIGHT

THE PRESIDENT: I'm proud of you. Thank you very much.

Kellyanne?

MS. CONWAY: Mr. President, thank you. The focus that the First Lady and you have placed on the opioid and drug demand, drug supply crisis roiling our nation is starting to produce positive results.

Sender:	Llorente, Maria D. </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F5C91F577D894BD9A0F09305DB34DD4F-LLORENTE, M>
Recipient:	Beck, Lucille B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=845480228a8b43e7a5fef5716ded04c2-Beck, Lucil <(b6) va.gov>
Sent Date:	2019/06/14 08:27:51
Delivered Date:	2019/06/14 08:27:00

AMERICAN OVERSIGHT

From:	Valentino, Michael (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO, <(b6) va.gov>
To:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b6) @va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>
Subject:	RE: MAP call
Date:	2019/06/20 12:35:29
Priority:	Normal
Type:	Note

Sent with BlackBerry Work
(www.blackberry.com)

From: Valentino, Michael (VACO) <(b6) va.gov>
Date: Thursday, Jun 20, 2019, 11:34 AM
To: Valentino, Michael (VACO) <(b6) va.gov>
Subject: RE: MAP call

Our current Handbook allows promotion of drugs as long as it is consistent with our formulary objectives, so making this drug non-promotable is an additional restriction.
The rationale is that your office and my office reserve the right to educate VA staff about how this drug will be used in VA and how staff will be educated about that.
(b6)

Sent with BlackBerry Work
(www.blackberry.com)

From: Valentino, Michael (VACO) <(b6) va.gov>
Date: Thursday, Jun 20, 2019, 11:30 AM
To: Wiechers, Ilse <(b6) va.gov>
Cc: Llorente, Maria D. <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: MAP call

Non-promotable means that the manufacturer can't lobby VA clinical staff to use the product. However, if a VA clinician reaches out to the manufacturer for information, they are permitted to work with the local Chief of Pharmacy to provide it.

AMERICAN OVERSIGHT

Adding Jenn to clarify I have this right

Sent with BlackBerry Work
(www.blackberry.com)

From: Valentino, Michael (VACO) <(b6) va.gov>
Date: Thursday, Jun 20, 2019, 11:26 AM
To: Wiechers, Ilse <(b6) va.gov>
Cc: Llorente, Maria D. <(b6) va.gov>
Subject: RE: MAP call

Thanks Ilse....Matt is presenting now. I'll ask him to e-mail the CFU so you can take a careful look.

Sent with BlackBerry Work
(www.blackberry.com)

From: Wiechers, Ilse <(b6) va.gov>
Date: Thursday, Jun 20, 2019, 11:24 AM
To: Valentino, Michael (VACO) <(b6) va.gov>
Cc: Llorente, Maria D. <(b6) va.gov>
Subject: RE: MAP call

Mike –

I take the blame for the call mix up – I had things turned around in my head. You all had made clear you were meeting in Chicago. I'm going to try to hop back on when you bring the issue back to a vote and I've scheduled time to touch base with Jen tomorrow afternoon for a full debrief.

I think I'm okay with everything I heard, and suspect any additional revisions were all added to the caution/safety concerns, which as far as I'm concerned is warranted at this point. I'll just need to take a look at the final version once Matt has it available so we can start to planning accordingly with Early Adopter sites.

My only question is trying to discern how the not promotable by the manufacturer status differs from the existing directive 1108.10. I think I had already interpreted the directive to mean pharma reps couldn't be on VA campuses or talking with VA staff while on tour of duty. Clarity on that would be helpful so I can educate the field accordingly.

I very much appreciate the close partnership we've had on this work thus far. Looking forward to our continued work together!

Best,
Ilse

AMERICAN OVERSIGHT

From: Valentino, Michael (VACO)
Sent: Thursday, June 20, 2019 8:50 AM
To: Wiechers, Ilse (b6) @va.gov>
Cc: Llorente, Maria D. <(b6) va.gov>
Subject: MAP call

Hi Ilse, my apologies for the mix up on the time for the MAP call. I suspect we neglected to tell you it was central time not eastern time.

Please let me know if you have any concerns with the decisions made by the Committee (I.e., non-formulary, not promotable by the manufacturer, CFU with slight revisions pending and data collection for ketamine and esketamine)

Thanks for joining us and for all the hard work on this drug.

Mike

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(www.blackberry.com)

Sender:	Valentino, Michael (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO, <(b6) va.gov>
Recipient:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>
Sent Date:	2019/06/20 12:35:28
Delivered Date:	2019/06/20 12:35:29

AMERICAN OVERSIGHT

From:	Zacher, Jennifer L. (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9027C425646E4DE8A7D196908016331B-ZACHER, JEN <(b6) va.gov>
To:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b6) @va.gov>
CC:	Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) va.gov>
Subject:	RE: MAP call
Date:	2019/06/20 12:31:32
Priority:	Normal
Type:	Note

Correct!

From: Valentino, Michael (VACO)
Sent: Thursday, June 20, 2019 11:30 AM
To: Wiechers, Ilse <(b6) @va.gov>
Cc: Llorente, Maria D. <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: MAP call

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From: Valentino, Michael (VACO) <(b6) va.gov>
Date: Thursday, Jun 20, 2019, 11:26 AM
To: Wiechers, Ilse (b6) @va.gov>
Cc: Llorente, Maria D. <(b6) va.gov>
Subject: RE: MAP call

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AMERICAN OVERSIGHT

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(www.blackberry.com)

From: Wiechers, Ilse (b6) va.gov>
Date: Thursday, Jun 20, 2019, 11:24 AM
To: Valentino, Michael (VACO) <(b6) va.gov>
Cc: Llorente, Maria D. <(b6) va.gov>
Subject: RE: MAP call

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Best,
Ilse

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Sent: Thursday, June 20, 2019 8:50 AM
To: Wiechers, Ilse (b6) @va.gov>
Cc: Llorente, Maria D. <(b6) va.gov>
Subject: MAP call

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Mike

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Recipient:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) @va.gov>
Sent Date:	2019/06/20 12:31:31
Delivered Date:	2019/06/20 12:31:32
Message Flags:	Unread

AMERICAN OVERSIGHT

From:	Lieberman, Steven </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=25138F5D2E734AFA81397F0B357CBCC1-LIEBERMAN,>
To:	Oshinski, Renee /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=56925a4f59df47d19fcceb5e7c270bc0-Oshinski, R (b6) va.gov>; Boyd, Teresa D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6886a7d555a43e0bee23c1e40e1c234-Boyd, Teres <(b6) va.gov>
Subject:	RE: Leadership Requesting: Talking Points and Data Need for VA Mental Health Clinicians on Stellate Ganglion Block Procedure
Date:	2019/06/20 21:06:00
Priority:	Normal
Type:	Note

Glad ur there! (b6)

From: Oshinski, Renee
Sent: Thursday, June 20, 2019 9:05 PM
To: Lieberman, Steven <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>
Subject: RE: Leadership Requesting: Talking Points and Data Need for VA Mental Health Clinicians on Stellate Ganglion Block Procedure

Just touched down, flight was only delayed about a half hour but made it out — was worried about storms. Now to try and find a gate!!

(b6) –
(b6) –

Sent with BlackBerry Work
(www.blackberry.com)

From: Lieberman, Steven (l(b6) va.gov>
Date: Thursday, Jun 20, 2019, 7:28 PM
To: Boyd, Teresa D. <(b6) va.gov>, Oshinski, Renee (l(b6) va.gov>
Subject: RE: Leadership Requesting: Talking Points and Data Need for VA Mental Health Clinicians on Stellate Ganglion Block Procedure

Thanks. I was unaware, although Teresa, was this the procedure that a group wanted to meet with us about that Dave recently declined in an email as he said he wanted to wait for more data?

Renee, hope your flight wasn't delayed and you are home as I am typing this

---

From: Boyd, Teresa D.
Sent: Thursday, June 20, 2019 10:26 AM
To: Oshinski, Renee <(b6) va.gov>; Lieberman, Steven (l(b6) va.gov>

AMERICAN OVERSIGHT

Subject: RE: Leadership Requesting: Talking Points and Data Need for VA Mental Health Clinicians on Stellate Ganglion Block Procedure

I do know that MH team has put together information for MH teams re both. In addition, the CPG's for both are upcoming and our stance on such.

I do not believe any of us in VACO were aware of the 60-minutes release.

From: Oshinski, Renee
Sent: Thursday, June 20, 2019 10:24 AM
To: Lieberman, Steven (b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>
Subject: FW: Leadership Requesting: Talking Points and Data Need for VA Mental Health Clinicians on Stellate Ganglion Block Procedure

Wasn't sure if you guys saw this. (b6)

Sent with BlackBerry Work
(www.blackberry.com)

From: RICKS, TARA (b6) va.gov>
Date: Thursday, Jun 20, 2019, 10:21 AM
To: Cunningham, Kristin (b6) va.gov>, Diamond, Sue OSI (b6) .gov>, Poff, Susan <(b6) va.gov>, Pedene, Paula L. (b6) va.gov>, Burden, Rachael (b6) va.gov>, VACO 80E1 <vaco80e1@mail.va.gov>, Greilsamer, Alan (b6) va.gov>, Small, Stephanie T. <(b6) va.gov>, Eason, William J. (b6) va.gov>, Ackerman, William (b6) va.gov>, Andringa, Elizabeth D. (b6) ov>, Baum, Robert (b6) va.gov>, Bennett, Jennifer (Jenna) <(b6) @va.gov>, Boyd, Teresa D. <(b6) va.gov>, Bucsko, Daniel <(b6) va.gov>, Chesney, Colin (b6) va.gov>, Davidson, Benjamin C. (ERPi) (b6) va.gov>, Goldsberry, Wilmya (b6) va.gov>, Gore, Ohm J. (Booz Allen Hamilton) (b6) va.gov>, Gramlick, Debbie (b6) va.gov>, Greenstone, Clinton (b6) va.gov>, Hayes, Terrence (b6) va.gov>, Heard, Maureen (b6) a.gov>, Jaastad, Derrick (b6) va.gov>, Jenkins, Matthew A (b6) .gov>, Kelley, Kimberly (b6) va.gov>, MacDonald, Jennifer E. (Physician) <(b6) a.gov>, Oshinski, Renee (b6) va.gov>, Paige, Paula (b6) va.gov>, Roberts, Kirsten L. (ERPI) (b6) va.gov>, Scanlon, Aimee B. (b6) va.gov>, Sommers, Evelyn (b6) va.gov>, Subbu, Sankalpa (b6) va.gov>, VHA 10D Action <VHA10DAction@va.gov>, VHA 10N Action <VHA10NAction@va.gov>, VHA 10NG Action <VHA10NGAction@va.gov>, VHA Healthcare Operations Center <VHAHOC@va.gov>, Warner, Debra L. (b6) va.gov>, White, Crystal M. <(b6) va.gov>, Williams, Joseph A (OSI) (b6) va.gov>, Smith, Clifford A. (b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Daniels, Lindsay (b6) .gov>, Gavin, Stacy (b6) va.gov>, McGuire, Marsden H. <(b6) va.gov>, Miller, Matthew (VCL Director) (b6) va.gov>, Pollack, Stacey (b6) gov>, Pomerantz, Andrew <(b6) va.gov>, Strmiska, Jon G. (b6) va.gov>

AMERICAN OVERSIGHT

Cc: Ackerman, William (b6) va.gov>, Andringa, Elizabeth D. (b6) a.gov>, Bagchi, Kaushiki M. (APTIVE Resources LLC) (b6) va.gov>, Boccia, Alexis L (b6) va.gov>, Galagaza, Geraldine (b6) va.gov>, Heard, Maureen (b6) va.gov>, Kelley, Kimberly (b6) @va.gov>, Parker, Ginger (b6) va.gov>, Pedene, Paula L. (b6) .gov>, Screen, Gina (b6) a.gov>, Seekins, DeAnne (b6) va.gov>, Hutchins, Anne C SAMVAMC (b6) va.gov>, Buyck, David W SAMVAMC (b6) va.gov>
Subject: RE: Leadership Requesting: Talking Points and Data Need for VA Mental Health Clinicians on Stellate Ganglion Block Procedure

Thank you Ms. Cunningham. We will await guidance.

Adding my ND, COS, and Mental Health Chief since the visibility of this request is moving beyond the public affairs arena.

From: Cunningham, Kristin
Sent: Thursday, June 20, 2019 10:17 AM
To: RICKS, TARA (b6) va.gov>; Diamond, Sue OSI (b6) va.gov>; Poff, Susan (b6) va.gov>; Pedene, Paula L. <(b6) va.gov>; Burden, Rachael (b6) va.gov>; VACO 80E1 <vaco80e1@mail.va.gov>; Greilsamer, Alan (b6) va.gov>; Small, Stephanie T. (b6) va.gov>; Eason, William J. (b6) va.gov>; VHA MISSION Act Core Team <VHAMISSIONActCoreTeam@va.gov>; Smith, Clifford A. (b6) va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>
Cc: Ackerman, William (b6) va.gov>; Andringa, Elizabeth D. (b6) va.gov>; Bagchi, Kaushiki M. (APTIVE Resources LLC) (b6) a.gov>; Boccia, Alexis L (b6) va.gov>; Galagaza, Geraldine (b6) va.gov>; Heard, Maureen <(b6) va.gov>; Kelley, Kimberly (b6) va.gov>; Parker, Ginger (b6) va.gov>; Pedene, Paula L. (b6) a.gov>; Screen, Gina <(b6) va.gov>; Cunningham, Kristin (b6) va.gov>
Subject: RE: Leadership Requesting: Talking Points and Data Need for VA Mental Health Clinicians on Stellate Ganglion Block Procedure

Adding Dr Smith and 10NC5 action. They are working on guidance for the SGB.

Kristin J. Cunningham, PMP
Executive Officer to the Deputy Under Secretary
for Health for Community Care
Office of Community Care
P – (b6)
(b6) va.gov

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<(b6) va.gov>; Eason, William J. <(b6) va.gov>; VHA MISSION Act Core Team <VHAMISSIONActCoreTeam@va.gov>
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Subject: RE: Leadership Requesting: Talking Points and Data Need for VA Mental Health Clinicians on Stellate Ganglion Block Procedure

Thank you Ms. Diamond.

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Adding the MISSION Act Core Team to assist with getting you a response.

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Subject: Leadership Requesting: Talking Points and Data Need for VA Mental Health Clinicians on Stellate Ganglion Block Procedure
Importance: High

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Good morning everyone,

I wasn't sure who would be the best POC for this request – so I am emailing everyone.

VISN 6 is experiencing a significant up-tick in service request from Veterans regarding the stellate ganglion block procedure, to include request to use 'Mission Act resources' if the facility doesn't offer the procedure.

Our VISN COS and VISN Mental Health Chief understand that a lot of these request are being driven by the 60 minutes segment, and that this story offered our Veterans and family members hope that relief is on the way for their persisting nightmares, anger, and fear (PTSD). Veterans are now actively calling their mental health doctors wanting this procedure within our region – and our doctors don't know what to say or how to move forward with these requests. Our clinicians are wanting specific guidance **before** Veterans go out on their own and get this procedure that VA considers 'experimental.'

In addition to SGB, Leadership would also like talking points for Spravato after the results of today's national formulary meeting. The focus of these talking points would be for our mental health doctors and what they should tell patients.

Links to the story's for quick reference.

1. • The stellate ganglion block procedure LINK
2. • Spravato (Ketamine-like drug) LINK

Just to reiterate this is not a request for media talking points. This is a request for talking points for our mental health teams to communicate with patients. (b) (5) [redacted] ices.

Thank you in advance.

Tara Ricks-Edger
Director of Communications
VISN 6 – U.S. Department of Veterans Affairs

"It is not the critic who counts; not the man who points out how the strong man stumbles, or where the doer of deeds could have done them better. The credit belongs to the man who is actually in the arena…who strives valiantly; who errs, who comes short again and again, because there is no effort without error and shortcoming; but who does actually strive to do the deeds; who knows great enthusiasms, the great devotions; who spends himself in a worthy cause; who at the best knows in the end the triumph of high achievement, and who at the worst, if he fails, at least fails while daring greatly, so that his place shall never be with those cold and timid souls who neither know victory nor defeat." - Theodore Roosevelt

Sender:	Lieberman, Steven </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=25138F5D2E734AFA81397F0B357CBCC1-LIEBERMAN,>
Recipient:	Oshinski, Renee /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=56925a4f59df47d19fcceb5e7c270bc0-Oshinski, R ((b6) [redacted] ov>; Boyd, Teresa D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6886a7d555a43e0bee23c1e40e1c234-Boyd, Teres <(b6) [redacted] va.gov>

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Sent Date:	2019/06/20 21:06:19
Delivered Date:	2019/06/20 21:06:00

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From:	Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd.SPDLT)/CN=RECIPIENTS/CN=7A84364F6DC744019C31FCC7070AC372-HOLTZHEIMER (b6) va.gov>
To:	Gavin, Stacy /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4017313de0a84f8e8ceade280f77d235-Gavin, Stac (b6) a.gov>
CC:	Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Schnurr, Paula P. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac4e0f62f679499c913976fdc7b9defc-Schnurr, Pa (b6) va.gov>; VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>; VHA CO 10NC5 EXEC /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3c42d5c2321545dba9a59f4e7c6da358-VHA CO 10NC <VHACO10NC5EXEC@va.gov>; (b6) <(b6) hitchcock.org>
Subject:	RE: Leadership Requesting: Talking Points and Data Need for VA Mental Health Clinicians on Stellate Ganglion Block Procedure
Date:	2019/06/20 14:47:40
Priority:	Normal
Type:	Note

Sorry: these look very good to me, and I have no edits.

Paul E. Holtzheimer, MD
Deputy Director, Research
National Center for PTSD , Executive Division (116D)
White River Junction VA Medical Center
215 North Main Street - Bldg 65
White River Junction VT 05009
(b6)
)

Associate Professor, Psychiatry and Surgery
Geisel School of Medicine at Dartmouth
Dartmouth Hitchcock Medical Center
One Medical Center Drive
Lebanon, NH 03756

From: Paula P. Schnurr (b6) @dartmouth.edu>
Sent: Thursday, June 20, 2019 2:43 PM
To: Gavin, Stacy (b6) va.gov>
Cc: Carroll, David (VACO) <(b6) va.gov>; Schnurr, Paula P. (b6) va.gov>; Holtzheimer, Paul (b6) va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>; VHA CO 10NC5 EXEC <VHACO10NC5EXEC@va.gov>; Paul Holtzheimer <(b6) hitchcock.org>

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Subject: [EXTERNAL] Re: Leadership Requesting: Talking Points and Data Need for VA Mental Health Clinicians on Stellate Ganglion Block Procedure

Stacy, I misunderstood and thought this had been settled, so I told Paul you did not need input from us. I do not have anything to add but I will make sure he looks at this ASAP.

Sent from my iPhone.

On Jun 20, 2019, at 2:33 PM, Gavin, Stacy (b6) a.gov>wrote:

Paul/Paula,

Are you still adding to these? This task is past due. Thanks.

Stacy

From: Carroll, David (VACO)
Sent: Thursday, June 20, 2019 11:20 AM
To: Schnurr, Paula P. (b6) va.gov>; Paula P. Schnurr (b6) @dartmouth (b6) .edu) (b6) @dartmouth.edu>; Holtzheimer, Paul (b6) va.gov>
Cc: VHA 10NC5 Action <VHA10NC5Action@va.gov>; VHA CO 10NC5 EXEC <VHACO10NC5EXEC@va.gov>
Subject: FW: Leadership Requesting: Talking Points and Data Need for VA Mental Health Clinicians on Stellate Ganglion Block Procedure

Here is our most recent iteration.

From: Carroll, David (VACO)
Sent: Thursday, June 20, 2019 11:01 AM
To: VHA 10NC5 Action <VHA10NC5Action@va.gov>; VHA CO 10NC5 EXEC <VHACO10NC5EXEC@va.gov>
Subject: RE: Leadership Requesting: Talking Points and Data Need for VA Mental Health Clinicians on Stellate Ganglion Block Procedure

How's this for proposed talking points? It combines the OCE and our response.

- • Thank you for contacting the Department of Veterans Affairs (VA) Veterans Health Administration (VHA) regarding the Stellate Ganglion Block (SGB) procedure.

- • VA is building a proactive and personalized health care system that honors Veterans' service and empowers them to achieve their greatest level of health and well-being. VA care is both patient-centered and patient-driven; we recommend Veterans speak to their providers about treatment options.

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- • SGB is an injection of an anesthetic medication into the neck that is most often used to treat pain in the head, neck and upper extremities. SGB is a generally safe procedure but serious complications can occur. The procedure is performed at several VA facilities by experienced anesthesiologists, primarily to treat chronic pain conditions. Specialized pain clinics are found at many VA facilities.

- • SGB is not considered an established, evidenced-based treatment for PTSD. Although there are reports of the potential effectiveness of SGB for PTSD, it's use for PTSD is still experimental.

- • Veterans with questions about PTSD treatment are encouraged to talk to a health care provider to learn about potential treatment options. VA-enrolled Veterans can contact their provider via secure message through My HealtheVet, by calling their provider's office, or by making an in-person appointment.

- • VA's National Center for PTSD continuously monitors the published literature and disseminates information rapidly to honor VA's commitment to provide Veterans treatments with proven effectiveness and safety.

- • Visit www.ptsd.va.gov for information about PTSD and its treatment.

From: Dudley, Tracy
Sent: Thursday, June 20, 2019 10:34 AM
To: VHA 10NC5 Action <VHA10NC5Action@va.gov>
Cc: VHA CO 10NC Front Office HSSs <VHACO10NCFOHSSs@va.gov>
Subject: FW: Leadership Requesting: Talking Points and Data Need for VA Mental Health Clinicians on Stellate Ganglion Block Procedure

Good Morning 10NC5

Please see request below and, if your Program Office is responsive, please provide your response by **2pm today.**

Thank You!
Tracy

Tracy L. Dudley
Health System Specialist
ADUSH for Clinical Operations (10NC)
(b6)
)

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From: RICKS, TARA
Sent: Thursday, June 20, 2019 10:21 AM
To: Cunningham, Kristin (b6) va.gov>; Diamond, Sue OSI <(b6) va.gov>; Poff, Susan (b6) va.gov>; Pedene, Paula L. <(b6) va.gov>; Burden, Rachael <(b6) va.gov>; VACO 80E1 <vaco80e1@mail.va.gov>; Greilsamer, Alan <(b6) va.gov>; Small, Stephanie T. <(b6) va.gov>; Eason, William J. <(b6) va.gov>; Ackerman, William (b6) va.gov>; Andringa, Elizabeth D. <(b6) va.gov>; Baum, Robert (b6) @va.gov>; Bennett, Jennifer (Jenna) (b6) .gov>; Boyd, Teresa D. <(b6) va.gov>; Bucsko, Daniel (b6) .gov>; Chesney, (b6) (b6) va.gov>; Davidson, Benjamin C. (ERPi) (b6) va.gov>; Diamond, Sue OSI <(b6) va.gov>; Goldsberry, Wilmya (b6) .gov>; Gore, Ohm J. (Booz Allen Hamilton) <(b6) va.gov>; Gramlick, Debbie <(b6) va.gov>; Greenstone, Clinton <(b6) va.gov>; Hayes, Terrence <(b6) va.gov>; Heard, Maureen <(b6) va.gov>; Jaastad, Derrick <(b6) va.gov>; Jenkins, Matthew A <(b6) va.gov>; Kelley, Kimberly <(b6) va.gov>; MacDonald, Jennifer E. (Physician) <(b6) va.gov>; Oshinski, Renee <(b6) va.gov>; Paige, Paula <(b6) va.gov>; Roberts, Kirsten L. (ERPI) <(b6) va.gov>; Scanlon, Aimee B. <(b6) va.gov>; Sommers, Evelyn <(b6) va.gov>; Subbu, Sankalpa <(b6) va.gov>; VHA 10D Action <VHA10DAction@va.gov>; VHA 10N Action <VHA10NAction@va.gov>; VHA 10NG Action <VHA10NGAction@va.gov>; VHA Healthcare Operations Center <VHAHOC@va.gov>; Warner, Debra L. <(b6) va.gov>; White, Crystal M. <(b6) va.gov>; Williams, Joseph A (OSI) <(b6) va.gov>; Smith, Clifford A. <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Daniels, Lindsay <(b6) va.gov>; Gavin, Stacy (b6) va.gov>; McGuire, Marsden H. <(b6) va.gov>; Miller, Matthew (VCL Director) (b6) 3@va.gov>; Pollack, Stacey <(b6) va.gov>; Pomerantz, Andrew <(b6) va.gov>; Smith, Clifford A. <(b6) va.gov>; Strmiska, Jon G. <(b6) va.gov>
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Subject: RE: Leadership Requesting: Talking Points and Data Need for VA Mental Health Clinicians on Stellate Ganglion Block Procedure

Thank you Ms. Cunningham. We will await guidance.

Adding my ND, COS, and Mental Health Chief since the visibility of this request is moving beyond the public affairs arena.

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2. • Spravato (Ketamine-like drug) LINK

Just to reiterate this is not a request for media talking points. This is a request for talking points for our mental health teams to communicate with patients. Leadership is concerned if we do not get ahead of this it will ulitmately turn into an access or care issue especially for the health and well-being of our Veterans receiving mental health and suicide prevention services.

Thank you in advance.

Tara Ricks-Edger
Director of Communications
VISN 6 – U.S. Department of Veterans Affairs

"It is not the critic who counts; not the man who points out how the strong man stumbles, or where the doer of deeds could have done them better. The credit belongs to the man who is actually in the arena…who strives valiantly; who errs, who comes short again and again, because there is no effort without error and shortcoming; but who does actually strive to do the deeds; who knows great enthusiasms, the great devotions; who spends himself in a worthy cause; who at the best knows in the end the triumph of high achievement, and who at the worst, if he fails, at least fails while daring greatly, so that his place shall never be with those cold and timid souls who neither know victory nor defeat." - Theodore Roosevelt

Sender:	Holtzheimer, Paul /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7A84364F6DC744019C31FCC7070AC372-HOLTZHEIMER <(b6) va.gov>
Recipient:	Paula P. Schnurr (b6) @dartmouth.edu>; Gavin, Stacy /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4017313de0a84f8e8ceade280f77d235-Gavin, Stac <(b6) va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Schnurr, Paula P. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac4e0f62f679499c913976fdc7b9defc-Schnurr, Pa <(b6) a.gov>; VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>; VHA CO 10NC5 EXEC /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3c42d5c2321545dba9a59f4e7c6da358-VHA CO 10NC <VHACO10NC5EXEC@va.gov>; Paul Holtzheimer <(b6) hitchcock.org>
Sent Date:	2019/06/20 14:47:37
Delivered Date:	2019/06/20 14:47:40

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From:	Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd.SPDLT)/CN=RECIPIENTS/CN=29A9288DF9A34E84BDDFD00CDE79F11B-POMERANTZ, (b6) @va.gov>
To:	Schnurr, Paula P. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac4e0f62f679499c913976fdc7b9defc-Schnurr, Pa (b6) va.gov>; Paula P. Schnurr <(b6) @dartmouth.edu>; Gavin, Stacy /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4017313de0a84f8e8ceade280f77d235-Gavin, Stac (b6) a.gov>
CC:	Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Holtzheimer, Paul /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7a84364f6dc744019c31fcc7070ac372-Holtzheimer (b6) va.gov>; VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>; VHA CO 10NC5 EXEC /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3c42d5c2321545dba9a59f4e7c6da358-VHA CO 10NC <VHACO10NC5EXEC@va.gov>; Paul Holtzheimer <(b6) hitchcock.org>
Subject:	RE: Leadership Requesting: Talking Points and Data Need for VA Mental Health Clinicians on Stellate Ganglion Block Procedure
Date:	2019/06/20 15:44:44
Priority:	Normal
Type:	Note

Even better.

From: Schnurr, Paula P.
Sent: Thursday, June 20, 2019 3:03 PM
To: Pomerantz, Andrew <(b6) va.gov>; Paula P. Schnurr (b6) @dartmouth.edu>; Gavin, Stacy (b6) va.gov>
Cc: Carroll, David (VACO) <(b6) va.gov>; Holtzheimer, Paul (b6) va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>; VHA CO 10NC5 EXEC <VHACO10NC5EXEC@va.gov>; Paul Holtzheimer <(b6) hitchcock.org>
Subject: RE: Leadership Requesting: Talking Points and Data Need for VA Mental Health Clinicians on Stellate Ganglion Block Procedure

Andy, I think your text should be integrated into the bullet in which we say Veterans should talk to their providers. We should not tell Veterans to do this in two separate bullets.

Sent with BlackBerry Work
(www.blackberry.com)

From: Pomerantz, Andrew <(b6) va.gov>
Date: Thursday, Jun 20, 2019, 3:00 PM
To: Paula P. Schnurr (b6) @dartmouth.edu>, Gavin, Stacy (b6) va.gov>

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Cc: Carroll, David (VACO) <(b6) va.gov>, Schnurr, Paula P. <(b6) va.gov>, Holtzheimer, Paul (b(b6) va.gov>, VHA 10NC5 Action <VHA10NC5Action@va.gov>, VHA CO 10NC5 EXEC <VHACO10NC5EXEC@va.gov>, Paul Holtzheimer <(b6) hitchcock.org>
Subject: RE: Leadership Requesting: Talking Points and Data Need for VA Mental Health Clinicians on Stellate Ganglion Block Procedure

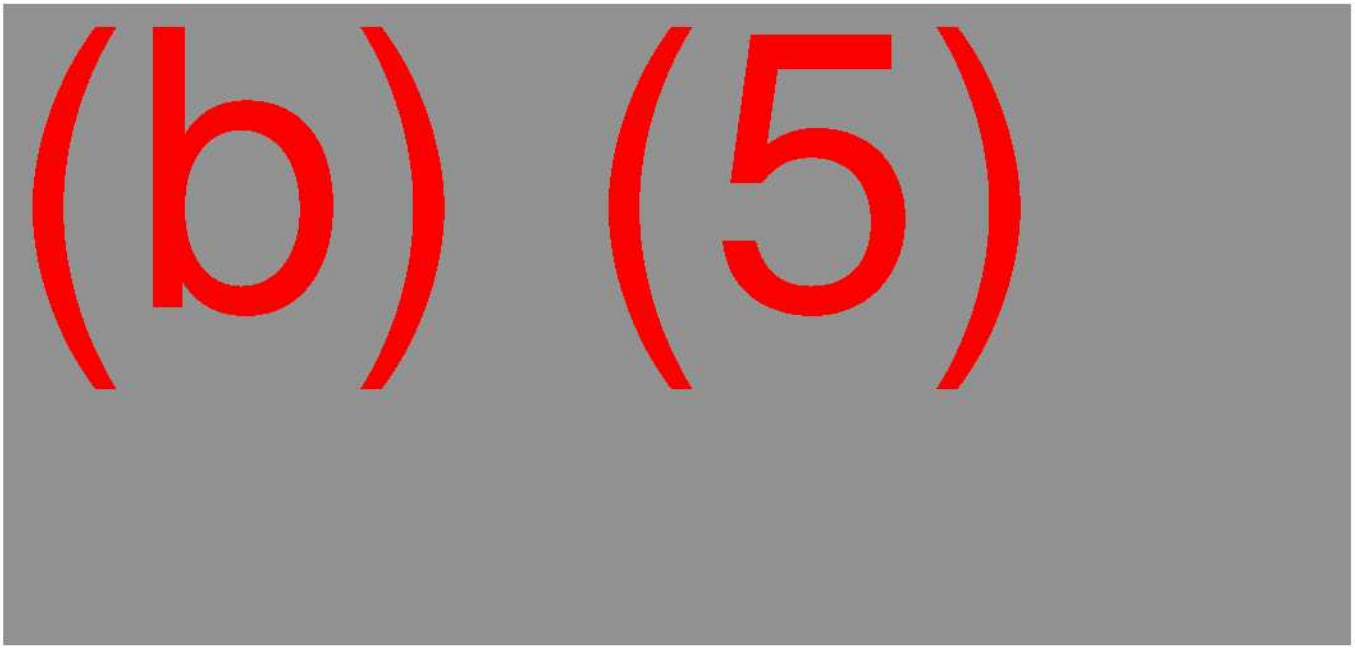
I have had some thoughts about this. inserted below in bold

From: Carroll, David (VACO)
Sent: Thursday, June 20, 2019 11:20 AM
To: Schnurr, Paula P. (t(b6) va.gov>; Paula P. Schnurr
(b6)
>; Holtzheimer, Pau (b(b6) va.gov>
Cc: VHA 10NC5 Action <VHA10NC5Action@va.gov>; VHA CO 10NC5 EXEC <VHACO10NC5EXEC@va.gov>
Subject: FW: Leadership Requesting: Talking Points and Data Need for VA Mental Health Clinicians on Stellate Ganglion Block Procedure

Here is our most recent iteration.

From: Carroll, David (VACO)
Sent: Thursday, June 20, 2019 11:01 AM
To: VHA 10NC5 Action <VHA10NC5Action@va.gov>; VHA CO 10NC5 EXEC <VHACO10NC5EXEC@va.gov>
Subject: RE: Leadership Requesting: Talking Points and Data Need for VA Mental Health Clinicians on Stellate Ganglion Block Procedure

How's this for proposed talking points? It combines the OCE and our response.



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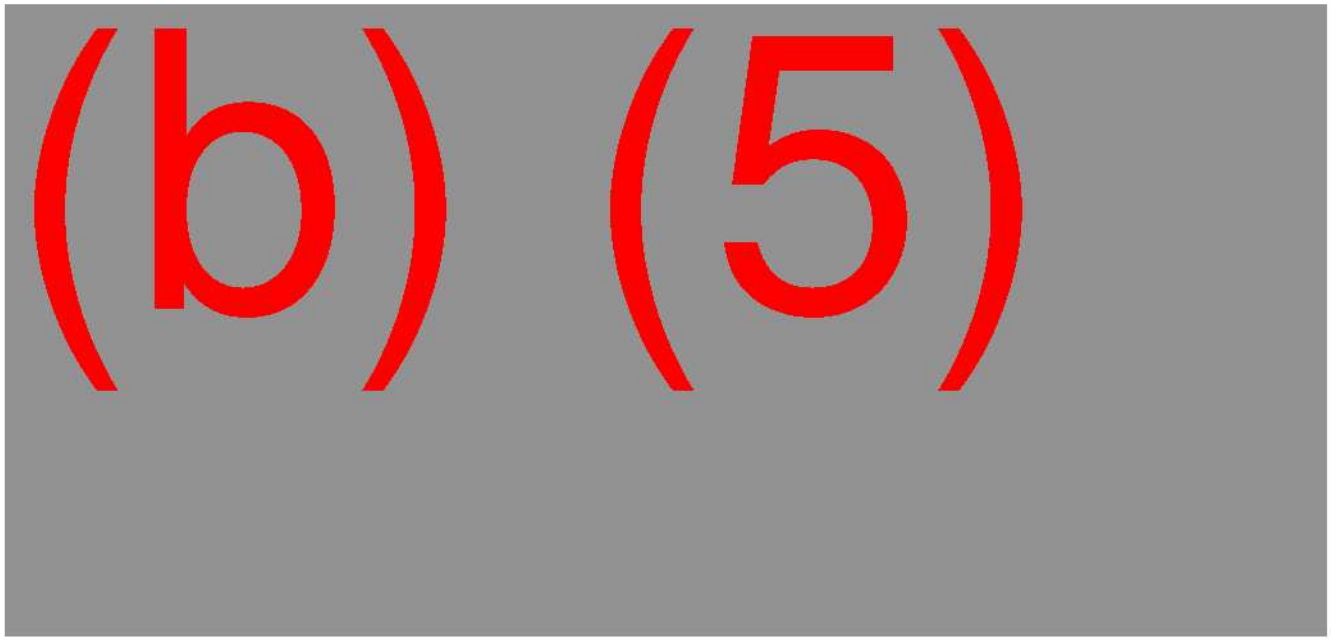

From: Dudley, Tracy
Sent: Thursday, June 20, 2019 10:34 AM
To: VHA 10NC5 Action <VHA10NC5Action@va.gov>
Cc: VHA CO 10NC Front Office HSSs <VHACO10NCFOHSSs@va.gov>
Subject: FW: Leadership Requesting: Talking Points and Data Need for VA Mental Health Clinicians on Stellate Ganglion Block Procedure

Good Morning 10NC5

Please see request below and, if your Program Office is responsive, please provide your response by **2pm today.**

Thank You!
Tracy

Tracy L. Dudley
Health System Specialist
ADUSH for Clinical Operations (10NC)
202.461.5687 (Direct)
(202) 257-9264 (iPhone)

From: RICKS, TARA
Sent: Thursday, June 20, 2019 10:21 AM
To: Cunningham, Kristin <(b6) va.gov>; Diamond, Sue OSI <(b6) va.gov>; Poff, Susan <(b6) va.gov>; Pedene, Paula L. <(b6) va.gov>; Burden, Rachael

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<(b6) va.gov>; VACO 80E1 <vaco80e1@mail.va.gov>; Greilsamer, Alan <(b6) va.gov>; Small, Stephanie T. <(b6) va.gov>; Eason, William J. <(b6) va.gov>; Ackerman, William <(b6) va.gov>; Andringa, Elizabeth D. <(b6) va.gov>; Baum, Robert <Robert.Baum@va.gov>; Bennett, Jennifer (Jenna) <Jennifer.Bennett3@va.gov>; Boyd, Teresa D. <(b6) va.gov>; Bucsko, Daniel <(b6) va.gov>; Chesney, Colin <(b6) va.gov>; Davidson, Benjamin C. (ERPi) <(b6) va.gov>; Diamond, Sue OSI <(b6) va.gov>; Goldsberry, Wilmya <(b6) va.gov>; Gore, Ohm J. (Booz Allen Hamilton) <(b6) va.gov>; Gramlick, Debbie <(b6) va.gov>; Greenstone, Clinton <(b6) va.gov>; Hayes, Terrence <(b6) va.gov>; Heard, Maureen <(b6) va.gov>; Jaastad, Derrick <(b6) va.gov>; Jenkins, Matthew A <(b6) va.gov>; Kelley, Kimberly <(b6) va.gov>; MacDonald, Jennifer E. (Physician) <(b6) va.gov>; Oshinski, Renee <(b6) va.gov>; Paige, Paula <(b6) va.gov>; Roberts, Kirsten L. (ERPI) <(b6) va.gov>; Scanlon, Aimee B. <(b6) va.gov>; Sommers, Evelyn <(b6) va.gov>; Subbu, Sankalpa <(b6) va.gov>; VHA 10D Action <VHA10DAction@va.gov>; VHA 10N Action <VHA10NAction@va.gov>; VHA 10NG Action <VHA10NGAction@va.gov>; VHA Healthcare Operations Center <VHAHOC@va.gov>; Warner, Debra L. <(b6) va.gov>; White, Crystal M. <(b6) va.gov>; Williams, Joseph A (OSI) <(b6) va.gov>; Smith, Clifford A. <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Daniels, Lindsay <(b6) va.gov>; Gavin, Stacy <(b6) va.gov>; McGuire, Marsden H. <(b6) va.gov>; Miller, Matthew (VCL Director) <(b6) @va.gov>; Pollack, Stacey <(b6) va.gov>; Pomerantz, Andrew <(b6) va.gov>; Smith, Clifford A. <(b6) va.gov>; Strmiska, Jon G. <(b6) va.gov>
Cc: Ackerman, William <(b6) va.gov>; Andringa, Elizabeth D. <(b6) va.gov>; Bagchi, Kaushiki M. (APTIVE Resources LLC) <(b6) va.gov>; Boccia, Alexis L <(b6) va.gov>; Galagaza, Geraldine <(b6) va.gov>; Heard, Maureen <(b6) va.gov>; Kelley, Kimberly <(b6) va.gov>; Parker, Ginger <(b6) va.gov>; Pedene, Paula L. <(b6) va.gov>; Screen, Gina <(b6) va.gov>; Seekins, DeAnne <(b6) va.gov>; Hutchins, Anne C SAMVAMC <(b6) va.gov>; Buyck, David W SAMVAMC <(b6) va.gov>
Subject: RE: Leadership Requesting: Talking Points and Data Need for VA Mental Health Clinicians on Stellate Ganglion Block Procedure

Thank you Ms. Cunningham. We will await guidance.

Adding my ND, COS, and Mental Health Chief since the visibility of this request is moving beyond the public affairs arena.

From: Cunningham, Kristin
Sent: Thursday, June 20, 2019 10:17 AM
To: RICKS, TARA <(b6) va.gov>; Diamond, Sue OSI <(b6) va.gov>; Poff, Susan <(b6) va.gov>; Pedene, Paula L. <(b6) va.gov>; Burden, Rachael <(b6) va.gov>; VACO 80E1 <vaco80e1@mail.va.gov>; Greilsamer, Alan <(b6) va.gov>; Small, Stephanie T. <(b6) va.gov>; Eason, William J. <(b6) va.gov>; VHA MISSION Act Core Team <VHAMISSIONActCoreTeam@va.gov>; Smith, Clifford A. <(b6) va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>

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Cc: Ackerman, William <(b6) va.gov>; Andringa, Elizabeth D. <(b6) va.gov>; Bagchi, Kaushiki M. (APTIVE Resources LLC) <(b6) va.gov>; Boccia, Alexis L <(b6) va.gov>; Galagaza, Geraldine <(b6) va.gov>; Heard, Maureen <(b6) va.gov>; Kelley, Kimberly <(b6) va.gov>; Parker, Ginger <(b6) va.gov>; Pedene, Paula L. <(b6) va.gov>; Screen, Gina <(b6) va.gov>; Cunningham, Kristin <(b6) va.gov>
Subject: RE: Leadership Requesting: Talking Points and Data Need for VA Mental Health Clinicians on Stellate Ganglion Block Procedure

Adding Dr Smith and 10NC5 action. They are working on guidance for the SGB.

Kristin J. Cunningham, PMP
Executive Officer to the Deputy Under Secretary
for Health for Community Care
Office of Community Care
P (b6)
Email: (b6) va.gov

From: RICKS, TARA
Sent: Thursday, June 20, 2019 10:15 AM
To: Diamond, Sue OSI <(b6) va.gov>; Poff, Susan <(b6) va.gov>; Pedene, Paula L. <(b6) va.gov>; Burden, Rachael <(b6) va.gov>; VACO 80E1 <vaco80e1@mail.va.gov>; Greilsamer, Alan <(b6) va.gov>; Small, Stephanie T. <(b6) va.gov>; Eason, William J. <(b6) va.gov>; VHA MISSION Act Core Team <VHAMISSIONActCoreTeam@va.gov>
Cc: Ackerman, William <(b6) va.gov>; Andringa, Elizabeth D. <(b6) va.gov>; Bagchi, Kaushiki M. (APTIVE Resources LLC) <(b6) va.gov>; Boccia, Alexis L <(b6) va.gov>; Galagaza, Geraldine <(b6) va.gov>; Heard, Maureen <(b6) va.gov>; Kelley, Kimberly <(b6) va.gov>; Parker, Ginger <(b6) va.gov>; Pedene, Paula L. <(b6) va.gov>; Screen, Gina <(b6) va.gov>
Subject: RE: Leadership Requesting: Talking Points and Data Need for VA Mental Health Clinicians on Stellate Ganglion Block Procedure

Thank you Ms. Diamond.

From: Diamond, Sue OSI
Sent: Thursday, June 20, 2019 10:07 AM
To: RICKS, TARA (b6) va.gov>; Poff, Susan <(b6) va.gov>; Pedene, Paula L. <(b6) va.gov>; Burden, Rachael <(b6) va.gov>; VACO 80E1 <vaco80e1@mail.va.gov>; Greilsamer, Alan <(b6) va.gov>; Small, Stephanie T. <(b6) va.gov>; Eason, William J. <(b6) va.gov>; VHA MISSION Act Core Team <VHAMISSIONActCoreTeam@va.gov>
Cc: Ackerman, William <(b6) va.gov>; Andringa, Elizabeth D.

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<(b6) va.gov>; Bagchi, Kaushiki M. (APTIVE Resources LLC) <(b6) va.gov>; Boccia, Alexis L <(b6) va.gov>; Galagaza, Geraldine <(b6) va.gov>; Heard, Maureen <(b6) va.gov>; Kelley, Kimberly <(b6) va.gov>; Parker, Ginger <(b6) va.gov>; Pedene, Paula L. <(b6) va.gov>; Screen, Gina <(b6) va.gov>
Subject: RE: Leadership Requesting: Talking Points and Data Need for VA Mental Health Clinicians on Stellate Ganglion Block Procedure

Adding the MISSION Act Core Team to assist with getting you a response.

From: RICKS, TARA
Sent: Thursday, June 20, 2019 10:01 AM
To: Poff, Susan <(b6) va.gov>; Pedene, Paula L. <(b6) va.gov>; Burden, Rachael <(b6) va.gov>; VACO 80E1 <vaco80e1@mail.va.gov>; Greilsamer, Alan <(b6) va.gov>; Small, Stephanie T. <(b6) va.gov>; Eason, William J. <(b6) va.gov>
Cc: Ackerman, William <(b6) va.gov>; Andringa, Elizabeth D. <(b6) va.gov>; Bagchi, Kaushiki M. (APTIVE Resources LLC) <(b6) va.gov>; Boccia, Alexis L <(b6) va.gov>; Diamond, Sue OSI <(b6) va.gov>; Galagaza, Geraldine <(b6) va.gov>; Heard, Maureen <(b6) va.gov>; Kelley, Kimberly <(b6) va.gov>; Parker, Ginger <(b6) va.gov>; Pedene, Paula L. <(b6) va.gov>; Screen, Gina <(b6) va.gov>
Subject: Leadership Requesting: Talking Points and Data Need for VA Mental Health Clinicians on Stellate Ganglion Block Procedure
Importance: High

Good morning everyone,

I wasn't sure who would be the best POC for this request – so I am emailing everyone.

VISN 6 is experiencing a significant up-tick in service request from Veterans regarding the stellate ganglion block procedure, to include request to use 'Mission Act resources' if the facility doesn't offer the procedure.

Our VISN COS and VISN Mental Health Chief understand that a lot of these request are being driven by the 60 minutes segment, and that this story offered our Veterans and family members hope that relief is on the way for their persisting nightmares, anger, and fear (PTSD). Veterans are now actively calling their mental health doctors wanting this procedure within our region – and our doctors don't know what to say or how to move forward with these requests. Our clinicians are wanting specific guidance **before** Veterans go out on their own and get this procedure that VA considers 'experimental.'

In addition to SGB, Leadership would also like talking points for Spravato after the results of today's national formulary meeting. The focus of these talking points would be for our mental health doctors and what they should tell patients.

Links to the story's for quick reference.

1. • The stellate ganglion block procedure LINK

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2. • Spravato (Ketamine-like drug) LINK

Just to reiterate this is not a request for media talking points. This is a request for talking points for our mental health teams to communicate with patients. Leadership is concerned if we do not get ahead of this it will ulitmately turn into an access or care issue especially for the health and well-being of our Veterans receiving mental health and suicide prevention services.

Thank you in advance.

Tara Ricks-Edger
Director of Communications
VISN 6 – U.S. Department of Veterans Affairs

"It is not the critic who counts; not the man who points out how the strong man stumbles, or where the doer of deeds could have done them better. The credit belongs to the man who is actually in the arena…who strives valiantly; who errs, who comes short again and again, because there is no effort without error and shortcoming; but who does actually strive to do the deeds; who knows great enthusiasms, the great devotions; who spends himself in a worthy cause; who at the best knows in the end the triumph of high achievement, and who at the worst, if he fails, at least fails while daring greatly, so that his place shall never be with those cold and timid souls who neither know victory nor defeat." - Theodore Roosevelt

Sender:	Pomerantz, Andrew /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=29A9288DF9A34E84BDDFD00CDE79F11B-POMERANTZ, (b6) va.gov>
Recipient:	Schnurr, Paula P. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac4e0f62f679499c913976fdc7b9defc-Schnurr, Pa <(b6) va.gov>; Paula P. Schnurr <Paula.P.Schnurr@dartmouth.edu>; Gavin, Stacy /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4017313de0a84f8e8ceade280f77d235-Gavin, Stac <(b6) va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Holtzheimer, Paul /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7a84364f6dc744019c31fcc7070ac372-Holtzheimer <(b6) va.gov>; VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>; VHA CO 10NC5 EXEC /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3c42d5c2321545dba9a59f4e7c6da358-VHA CO 10NC <VHACO10NC5EXEC@va.gov>; Paul Holtzheimer <(b6) hitchcock.org>
Sent Date:	2019/06/20 15:44:41
Delivered Date:	2019/06/20 15:44:44

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From:	Carroll, David (VACO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=95E14EBD3B6745C8952A823B04DABFF5-CARROLL, DA>
To:	Boyd, Teresa D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6886a7d555a43e0bee23c1e40e1c234-Boyd, Teres <(b6) va.gov>
Subject:	RE: Leadership Requesting: Talking Points and Data Need for VA Mental Health Clinicians on Stellate Ganglion Block Procedure
Date:	2019/06/20 10:30:00
Priority:	Normal
Type:	Note

Yes – an initial version should be ready today, and then need to work on a longer-term FAQ about SGB, and about how to manage off-label, novel requests for care. We will need other offices involved in that, including Whole Health. It is putting local leaders in an awkward place – needing to make decisions on community care referrals (or not) for novel procedures without clear guidance from VACO overall.

From: Boyd, Teresa D.
Sent: Thursday, June 20, 2019 10:28 AM
To: Carroll, David (VACO) <(b6) va.gov>
Subject: FW: Leadership Requesting: Talking Points and Data Need for VA Mental Health Clinicians on Stellate Ganglion Block Procedure

Good Happy Thursday!

Never a dull moment! I suspect your team is working on guidance for the field on the use of both the below. Thanks for keeping me in the loop as well. We need to broadly socialize the VHA practice guidelines on the use of both. Thanks so much,

Teresa

From: RICKS, TARA (l(b6) va.gov>
Date: Thursday, Jun 20, 2019, 10:21 AM
To: Cunningham, Kristin <(b6) va.gov>, Diamond, Sue OSI <(b6) va.gov>, Poff, Susan <(b6) va.gov>, Pedene, Paula L. <(b6) va.gov>, Burden, Rachael <(b6) va.gov>, VACO 80E1 <vaco80e1@mail.va.gov>, Greilsamer, Alan <(b6) va.gov>, Small, Stephanie T. <(b6) va.gov>, Eason, William J. <(b6) va.gov>, Ackerman, William <(b6) va.gov>, Andringa, Elizabeth D. <(b6) va.gov>, Baum, Robert (b6) @va.gov>, Bennett, Jennifer (Jenna) (b6) va.gov>, Boyd, Teresa D. <(b6) va.gov>, Bucsko, Daniel <(b6) va.gov>, Chesney, Colin <(b6) va.gov>, Davidson, Benjamin C. (ERPi) <(b6) va.gov>, Goldsberry, Wilmya <(b6) va.gov>, Gore, Ohm J. (Booz Allen Hamilton) (b6) @va.gov>, Gramlick, Debbie <(b6) va.gov>, Greenstone, Clinton <(b6) va.gov>, Hayes, Terrence <(b6) va.gov>, Heard, Maureen <(b6) va.gov>, Jaastad, Derrick <(b6) va.gov>, Jenkins, Matthew A

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<(b6) va.gov>, Kelley, Kimberly <(b6) va.gov>, MacDonald, Jennifer E. (Physician) <(b6) va.gov>, Oshinski, Renee <(b6) va.gov>, Paige, Paula <(b6) va.gov>, Roberts, Kirsten L. (ERPI) <(b6) va.gov>, Scanlon, Aimee B. <(b6) va.gov>, Sommers, Evelyn <(b6) va.gov>, Subbu, Sankalpa <(b6) va.gov>, VHA 10D Action <VHA10DAction@va.gov>, VHA 10N Action <VHA10NAction@va.gov>, VHA 10NG Action <VHA10NGAction@va.gov>, VHA Healthcare Operations Center <VHAHOC@va.gov>, Warner, Debra L. <(b6) va.gov>, White, Crystal M. <(b6) va.gov>, Williams, Joseph A (OSI) <(b6) va.gov>, Smith, Clifford A. <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Daniels, Lindsay <(b6) va.gov>, Gavin, Stacy <(b6) va.gov>, McGuire, Marsden H. <(b6) va.gov>, Miller, Matthew (VCL Director) <(b6) @va.gov>, Pollack, Stacey <(b6) va.gov>, Pomerantz, Andrew <(b6) va.gov>, Strmiska, Jon G. (b6) va.gov>

Cc: Ackerman, William <(b6) va.gov>, Andringa, Elizabeth D. <(b6) va.gov>, Bagchi, Kaushiki M. (APTIVE Resources LLC) <(b6) va.gov>, Boccia, Alexis L <(b6) va.gov>, Galagaza, Geraldine <(b6) va.gov>, Heard, Maureen <(b6) va.gov>, Kelley, Kimberly <Kimberly.Kelley1@va.gov>, Parker, Ginger <(b6) va.gov>, Pedene, Paula L. <(b6) va.gov>, Screen, Gina <(b6) va.gov>, Seekins, DeAnne <(b6) va.gov>, Hutchins, Anne C SAMVAMC (l(b6) a.gov>, Buyck, David W SAMVAMC (l(b6) va.gov>

Subject: RE: Leadership Requesting: Talking Points and Data Need for VA Mental Health Clinicians on Stellate Ganglion Block Procedure

Thank you Ms. Cunningham. We will await guidance.

Adding my ND, COS, and Mental Health Chief since the visibility of this request is moving beyond the public affairs arena.

From: Cunningham, Kristin
Sent: Thursday, June 20, 2019 10:17 AM
To: RICKS, TARA (b6) va.gov>; Diamond, Sue OSI <(b6) va.gov>; Poff, Susan <(b6) va.gov>; Pedene, Paula L. <(b6) va.gov>; Burden, Rachael <(b6) va.gov>; VACO 80E1 <vaco80e1@mail.va.gov>; Greilsamer, Alan <(b6) va.gov>; Small, Stephanie T. <(b6) va.gov>; Eason, William J. <(b6) va.gov>; VHA MISSION Act Core Team <VHAMISSIONActCoreTeam@va.gov>; Smith, Clifford A. <(b6) va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>
Cc: Ackerman, William <(b6) va.gov>; Andringa, Elizabeth D. <(b6) va.gov>; Bagchi, Kaushiki M. (APTIVE Resources LLC) <(b6) va.gov>; Boccia, Alexis L <(b6) va.gov>; Galagaza, Geraldine <(b6) va.gov>; Heard, Maureen <(b6) va.gov>; Kelley, Kimberly <(b6) va.gov>; Parker, Ginger <(b6) va.gov>; Pedene, Paula L. <(b6) va.gov>; Screen, Gina <(b6) va.gov>; Cunningham, Kristin <(b6) va.gov>
Subject: RE: Leadership Requesting: Talking Points and Data Need for VA Mental Health Clinicians on Stellate Ganglion Block Procedure

Adding Dr Smith and 10NC5 action. They are working on guidance for the SGB.

Kristin J. Cunningham, PMP

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Executive Officer to the Deputy Under Secretary
for Health for Community Care
Office of Community Care
P – (b6)
Email: (b6) va.gov

From: RICKS, TARA
Sent: Thursday, June 20, 2019 10:15 AM
To: Diamond, Sue OSI <(b6) va.gov>; Poff, Susan <(b6) va.gov>; Pedene, Paula L. <(b6) va.gov>; Burden, Rachael <(b6) va.gov>; VACO 80E1 <vaco80e1@mail.va.gov>; Greilsamer, Alan <(b6) va.gov>; Small, Stephanie T. <(b6) va.gov>; Eason, William J. <(b6) va.gov>; VHA MISSION Act Core Team <VHAMISSIONActCoreTeam@va.gov>
Cc: Ackerman, William <(b6) va.gov>; Andringa, Elizabeth D. <(b6) va.gov>; Bagchi, Kaushiki M. (APTIVE Resources LLC) <(b6) va.gov>; Boccia, Alexis L <(b6) va.gov>; Galagaza, Geraldine <(b6) va.gov>; Heard, Maureen <(b6) va.gov>; Kelley, Kimberly <(b6) va.gov>; Parker, Ginger <(b6) va.gov>; Pedene, Paula L. <(b6) va.gov>; Screen, Gina <(b6) va.gov>
Subject: RE: Leadership Requesting: Talking Points and Data Need for VA Mental Health Clinicians on Stellate Ganglion Block Procedure

Thank you Ms. Diamond.

From: Diamond, Sue OSI
Sent: Thursday, June 20, 2019 10:07 AM
To: RICKS, TARA <(b6) va.gov>; Poff, Susan <(b6) va.gov>; Pedene, Paula L. <(b6) va.gov>; Burden, Rachael <(b6) va.gov>; VACO 80E1 <vaco80e1@mail.va.gov>; Greilsamer, Alan <(b6) va.gov>; Small, Stephanie T. <(b6) va.gov>; Eason, William J. <(b6) va.gov>; VHA MISSION Act Core Team <VHAMISSIONActCoreTeam@va.gov>
Cc: Ackerman, William <(b6) va.gov>; Andringa, Elizabeth D. <(b6) va.gov>; Bagchi, Kaushiki M. (APTIVE Resources LLC) <(b6) va.gov>; Boccia, Alexis L <(b6) va.gov>; Galagaza, Geraldine <(b6) va.gov>; Heard, Maureen <(b6) va.gov>; Kelley, Kimberly <(b6) va.gov>; Parker, Ginger <(b6) va.gov>; Pedene, Paula L. <(b6) va.gov>; Screen, Gina <(b6) va.gov>
Subject: RE: Leadership Requesting: Talking Points and Data Need for VA Mental Health Clinicians on Stellate Ganglion Block Procedure

Adding the MISSION Act Core Team to assist with getting you a response.

From: RICKS, TARA
Sent: Thursday, June 20, 2019 10:01 AM
To: Poff, Susan <(b6) va.gov>; Pedene, Paula L. <(b6) va.gov>; Burden, Rachael <(b6) va.gov>; VACO 80E1 <vaco80e1@mail.va.gov>; Greilsamer, Alan

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<(b6) va.gov>; Small, Stephanie T. <(b6) va.gov>; Eason, William J. <(b6) va.gov>
Cc: Ackerman, William <(b6) va.gov>; Andringa, Elizabeth D. <(b6) va.gov>; Bagchi, Kaushiki M. (APTIVE Resources LLC) <(b6) va.gov>; Boccia, Alexis L <(b6) va.gov>; Diamond, Sue OSI <(b6) va.gov>; Galagaza, Geraldine <(b6) va.gov>; Heard, Maureen <(b6) va.gov>; Kelley, Kimberly <(b6) va.gov>; Parker, Ginger <(b6) va.gov>; Pedene, Paula L. <(b6) va.gov>; Screen, Gina <(b6) va.gov>
Subject: Leadership Requesting: Talking Points and Data Need for VA Mental Health Clinicians on Stellate Ganglion Block Procedure
Importance: High

Good morning everyone,

I wasn't sure who would be the best POC for this request – so I am emailing everyone.

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In addition to SGB, Leadership would also like talking points for Spravato after the results of today's national formulary meeting. The focus of these talking points would be for our mental health doctors and what they should tell patients.

Links to the story's for quick reference.

1. • The stellate ganglion block procedure LINK
2. • Spravato (Ketamine-like drug) LINK

Just to reiterate this is not a request for media talking points. This is a request for talking points for our mental health teams to communicate with patients. Leadership is concerned if we do not get ahead of this it will ulitmately turn into an access or care issue especially for the health and well-being of our Veterans receiving mental health and suicide prevention services.

Thank you in advance.

Tara Ricks-Edger
Director of Communications
VISN 6 – U.S. Department of Veterans Affairs

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"It is not the critic who counts; not the man who points out how the strong man stumbles, or where the doer of deeds could have done them better. The credit belongs to the man who is actually in the arena…who strives valiantly; who errs, who comes short again and again, because there is no effort without error and shortcoming; but who does actually strive to do the deeds; who knows great enthusiasms, the great devotions; who spends himself in a worthy cause; who at the best knows in the end the triumph of high achievement, and who at the worst, if he fails, at least fails while daring greatly, so that his place shall never be with those cold and timid souls who neither know victory nor defeat." - Theodore Roosevelt

Sender:	Carroll, David (VACO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=95E14EBD3B6745C8952A823B04DABFF5-CARROLL, DA>
Recipient:	Boyd, Teresa D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6886a7d555a43e0bee23c1e40e1c234-Boyd, Teres <(b6) va.gov>
Sent Date:	2019/06/20 10:30:51
Delivered Date:	2019/06/20 10:30:00

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From:	Carroll, David (VACO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=95E14EBD3B6745C8952A823B04DABFF5-CARROLL, DA>
To:	Gavin, Stacy /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4017313de0a84f8e8ceade280f77d235-Gavin, Stac <(b6) va.gov>
Subject:	RE: Leadership Requesting: Talking Points and Data Need for VA Mental Health Clinicians on Stellate Ganglion Block Procedure
Date:	2019/06/20 15:32:43
Priority:	Normal
Type:	Note

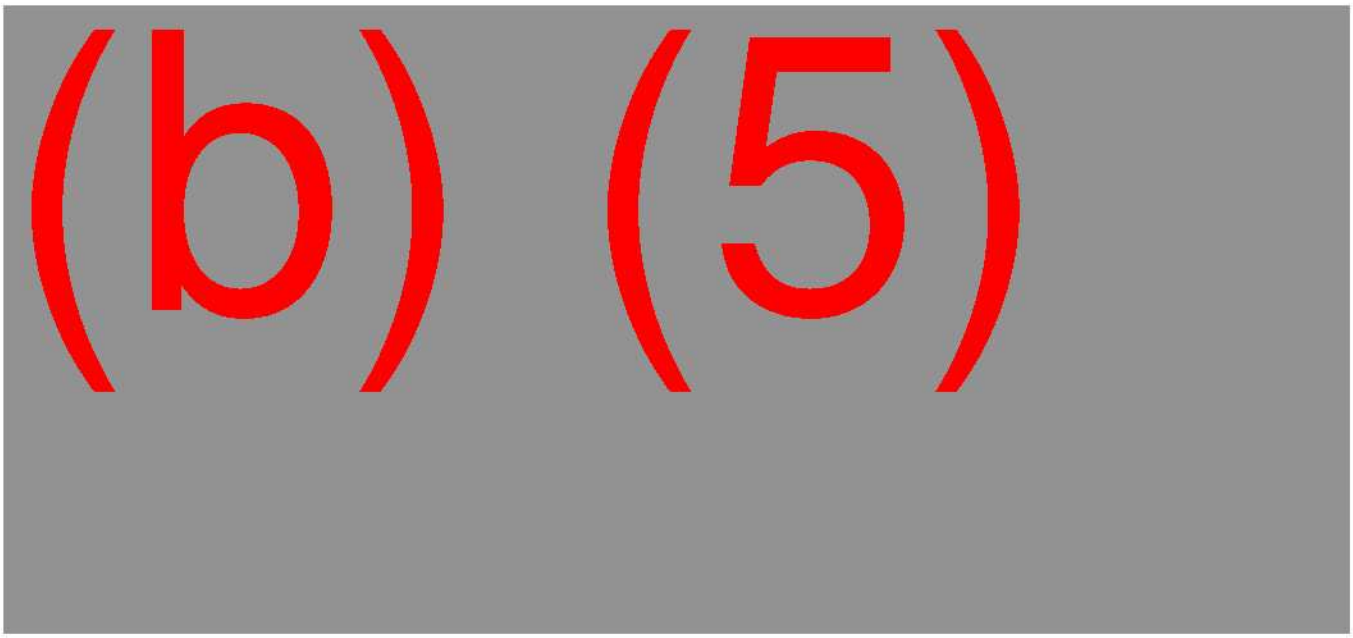
Thanks. Pls share w Tracy and Christine in Community Engagement.
Dentist running behind.

Sent with BlackBerry Work
(www.blackberry.com)

From: Gavin, Stacy <(b6) va.gov>
Date: Thursday, Jun 20, 2019, 2:57 PM
To: VHA CO 10NC Front Office HSSs <VHACO10NCFOHSSs@va.gov>
Cc: VHA 10NC5 Action <VHA10NC5Action@va.gov>, Schnurr, Paula P. <(b6) va.gov>, Holtzheimer, Paul <(b6) va.gov>
Subject: FW: Leadership Requesting: Talking Points and Data Need for VA Mental Health Clinicians on Stellate Ganglion Block Procedure

Good afternoon,

With apologies for the delay, please see the talking points below:



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(b) (5)

From: Dudley, Tracy
Sent: Thursday, June 20, 2019 10:34 AM
To: VHA 10NC5 Action <VHA10NC5Action@va.gov>
Cc: VHA CO 10NC Front Office HSSs <VHACO10NCFOHSSs@va.gov>
Subject: FW: Leadership Requesting: Talking Points and Data Need for VA Mental Health Clinicians on Stellate Ganglion Block Procedure

Good Morning 10NC5

Please see request below and, if your Program Office is responsive, please provide your response by **2pm today.**

Thank You!
Tracy

Tracy L. Dudley
Health System Specialist
ADUSH for Clinical Operations (10NC)
(b6)
(iPhone)

From: RICKS, TARA
Sent: Thursday, June 20, 2019 10:21 AM
To: Cunningham, Kristin <(b6) va.gov>; Diamond, Sue OSI <(b6) va.gov>; Poff, Susan <(b6) va.gov>; Pedene, Paula L. <(b6) va.gov>; Burden, Rachael <(b6) va.gov>; VACO 80E1 <vaco80e1@mail.va.gov>; Greilsamer, Alan <(b6) va.gov>; Small, Stephanie T. <(b6) va.gov>; Eason, William J. <(b6) va.gov>; Ackerman, William <(b6) va.gov>; Andringa, Elizabeth D. <(b6) va.gov>; Baum, Robert <(b6) @va.gov>; Bennett, Jennifer (Jenna)

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Subject: RE: Leadership Requesting: Talking Points and Data Need for VA Mental Health Clinicians on Stellate Ganglion Block Procedure

Thank you Ms. Cunningham. We will await guidance.

Adding my ND, COS, and Mental Health Chief since the visibility of this request is moving beyond the public affairs arena.

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Sent: Thursday, June 20, 2019 10:17 AM
To: RICKS, TARA <(b6) va.gov>; Diamond, Sue OSI <(b6) va.gov>; Poff, Susan <(b6) va.gov>; Pedene, Paula L. <(b6) va.gov>; Burden, Rachael <(b6) va.gov>; VACO 80E1 <vaco80e1@mail.va.gov>; Greilsamer, Alan <(b6) va.gov>; Small, Stephanie T. <(b6) va.gov>; Eason, William J. <(b6) va.gov>; VHA MISSION Act Core Team <VHAMISSIONActCoreTeam@va.gov>; Smith, Clifford A. <(b6) va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>
Cc: Ackerman, William <(b6) va.gov>; Andringa, Elizabeth D. <(b6) va.gov>; Bagchi, Kaushiki M. (APTIVE Resources LLC) <(b6) va.gov>; Boccia, Alexis L <(b6) va.gov>; Galagaza, Geraldine <(b6) va.gov>; Heard, Maureen <(b6) va.gov>; Kelley, Kimberly <(b6) va.gov>; Parker, Ginger

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<(b6) va.gov>; Pedene, Paula L. <(b6) va.gov>; Screen, Gina <(b6) va.gov>; Cunningham, Kristin <(b6) va.gov>
Subject: RE: Leadership Requesting: Talking Points and Data Need for VA Mental Health Clinicians on Stellate Ganglion Block Procedure

Adding Dr Smith and 10NC5 action. They are working on guidance for the SGB.

Kristin J. Cunningham, PMP
Executive Officer to the Deputy Under Secretary
for Health for Community Care
Office of Community Care
P (b6)
Email: (b6) va.gov

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Cc: Ackerman, William <(b6) va.gov>; Andringa, Elizabeth D. <(b6) va.gov>; Bagchi, Kaushiki M. (APTIVE Resources LLC) <(b6) va.gov>; Boccia, Alexis L <(b6) va.gov>; Galagaza, Geraldine <(b6) va.gov>; Heard, Maureen <(b6) va.gov>; Kelley, Kimberly <(b6) va.gov>; Parker, Ginger <(b6) va.gov>; Pedene, Paula L. <(b6) va.gov>; Screen, Gina

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<(b6) va.gov>
Subject: RE: Leadership Requesting: Talking Points and Data Need for VA Mental Health Clinicians on Stellate Ganglion Block Procedure

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VISN 6 – U.S. Department of Veterans Affairs

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Recipient:	Gavin, Stacy /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4017313de0a84f8e8ceade280f77d235-Gavin, Stac <(b6) va.gov>
Sent Date:	2019/06/20 15:32:42
Delivered Date:	2019/06/20 15:32:43

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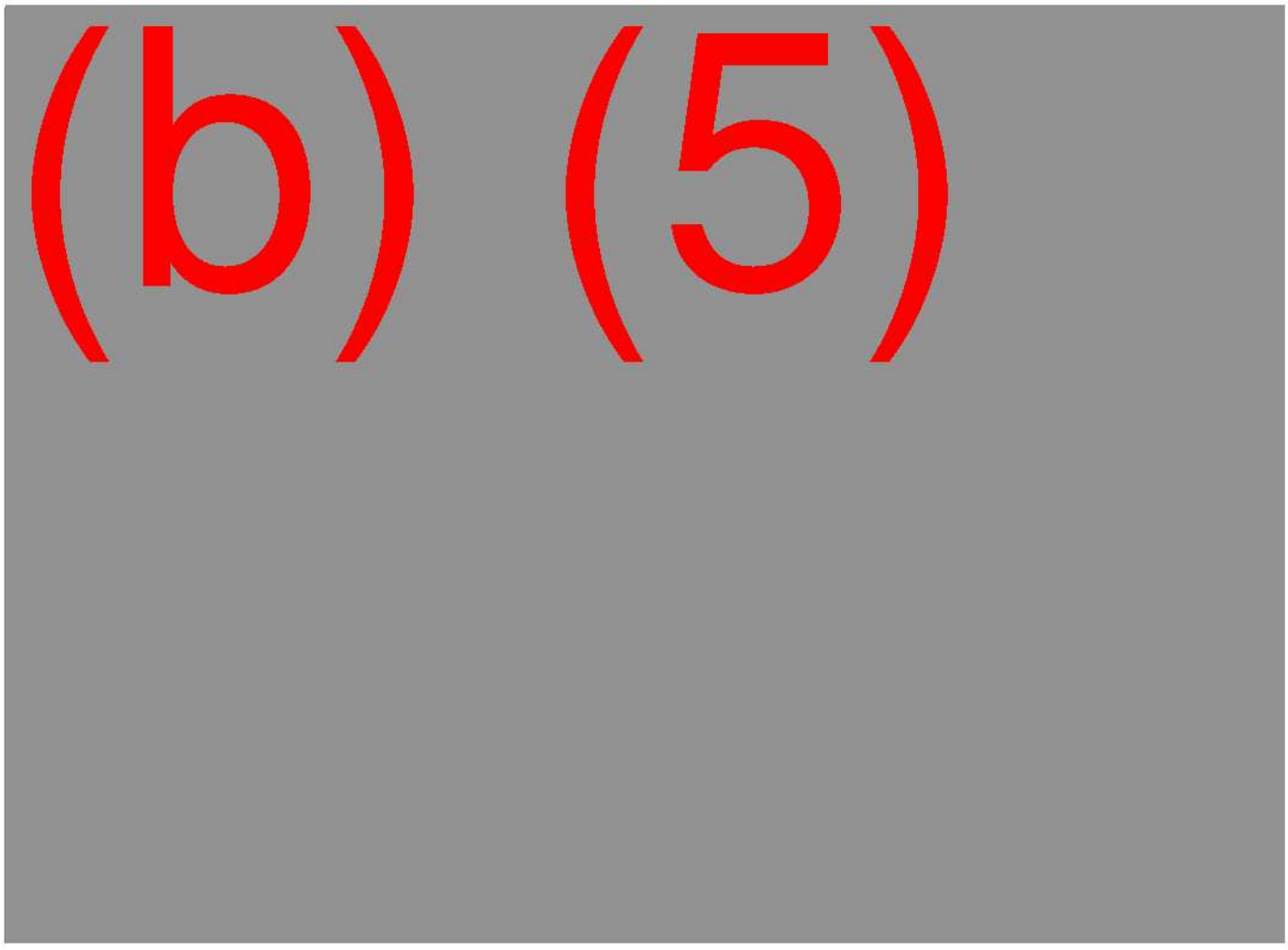
To:	VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>; VHA CO 10NC5 EXEC /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3c42d5c2321545dba9a59f4e7c6da358-VHA CO 10NC <VHACO10NC5EXEC@va.gov>
Subject:	RE: Leadership Requesting: Talking Points and Data Need for VA Mental Health Clinicians on Stellate Ganglion Block Procedure
Date:	2019/06/20 11:00:18
Priority:	Normal
Type:	Note

How's this for proposed talking points



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To: VHA 10NC5 Action <VHA10NC5Action@va.gov>
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Subject: FW: Leadership Requesting: Talking Points and Data Need for VA Mental Health Clinicians on Stellate Ganglion Block Procedure

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Tracy

Tracy L. Dudley
Health System Specialist
ADUSH for Clinical Operations (10NC)
(b6)
(iPhone)

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To: Cunningham, Kristin <(b6) va.gov>; Diamond, Sue OSI <(b6) va.gov>; Poff, Susan <(b6) va.gov>; Pedene, Paula L. <(b6) va.gov>; Burden, Rachael <(b6) va.gov>; VACO 80E1 <vaco80e1@mail.va.gov>; Greilsamer, Alan <(b6) va.gov>; Small, Stephanie T. <(b6) va.gov>; Eason, William J. <(b6) va.gov>; Ackerman, William <(b6) va.gov>; Andringa, Elizabeth D. <(b6) va.gov>; Baum, Robert <Robert.Baum@va.gov>; Bennett, Jennifer (Jenna) <Jennifer.Bennett3@va.gov>; Boyd, Teresa D. <(b6) va.gov>; Bucsko, Daniel <(b6) va.gov>; Chesney, Colin <(b6) va.gov>; Davidson, Benjamin C. (ERPi) <(b6) va.gov>; Diamond, Sue OSI <(b6) va.gov>; Goldsberry, Wilmya <(b6) va.gov>; Gore, Ohm J. (Booz Allen Hamilton) <(b6) va.gov>; Gramlick, Debbie <(b6) va.gov>; Greenstone, Clinton <(b6) va.gov>; Hayes, Terrence <(b6) va.gov>; Heard, Maureen <(b6) va.gov>; Jaastad, Derrick <(b6) va.gov>; Jenkins, Matthew A <(b6) va.gov>; Kelley, Kimberly <(b6) va.gov>; MacDonald, Jennifer E. (Physician) <(b6) va.gov>; Oshinski, Renee <(b6) va.gov>; Paige, Paula <(b6) va.gov>; Roberts, Kirsten L. (ERPI) <(b6) va.gov>; Scanlon, Aimee B. <(b6) va.gov>; Sommers, Evelyn <(b6) va.gov>; Subbu, Sankalpa <(b6) va.gov>; VHA 10D Action <VHA10DAction@va.gov>; VHA 10N Action <VHA10NAction@va.gov>; VHA 10NG Action <VHA10NGAction@va.gov>; VHA Healthcare Operations Center <VHAHOC@va.gov>; Warner, Debra L. <(b6) va.gov>; White, Crystal M. <(b6) va.gov>; Williams, Joseph A (OSI) <(b6) va.gov>; Smith, Clifford A. <(b6) va.gov>; Carroll, David (VACO)

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Kristin J. Cunningham, PMP
Executive Officer to the Deputy Under Secretary
for Health for Community Care
Office of Community Care
P – (b6)
Email: (b6) va.gov

AMERICAN OVERSIGHT

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To: Diamond, Sue OSI <(b6) va.gov>; Poff, Susan <(b6) va.gov>; Pedene, Paula L. <(b6) va.gov>; Burden, Rachael <(b6) va.gov>; VACO 80E1 <vaco80e1@mail.va.gov>; Greilsamer, Alan <(b6) va.gov>; Small, Stephanie T. <(b6) va.gov>; Eason, William J. <(b6) va.gov>; VHA MISSION Act Core Team <VHAMISSIONActCoreTeam@va.gov>
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Subject: RE: Leadership Requesting: Talking Points and Data Need for VA Mental Health Clinicians on Stellate Ganglion Block Procedure

Thank you Ms. Diamond.

From: Diamond, Sue OSI
Sent: Thursday, June 20, 2019 10:07 AM
To: RICKS, TARA <(b6) va.gov>; Poff, Susan <(b6) va.gov>; Pedene, Paula L. <(b6) va.gov>; Burden, Rachael <(b6) va.gov>; VACO 80E1 <vaco80e1@mail.va.gov>; Greilsamer, Alan <(b6) va.gov>; Small, Stephanie T. <(b6) va.gov>; Eason, William J. <(b6) va.gov>; VHA MISSION Act Core Team <VHAMISSIONActCoreTeam@va.gov>
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Subject: RE: Leadership Requesting: Talking Points and Data Need for VA Mental Health Clinicians on Stellate Ganglion Block Procedure

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Cc: Ackerman, William <(b6) va.gov>; Andringa, Elizabeth D. <(b6) va.gov>; Bagchi, Kaushiki M. (APTIVE Resources LLC) <(b6) va.gov>; Boccia, Alexis L <(b6) va.gov>; Diamond, Sue OSI <(b6) va.gov>; Galagaza, Geraldine <(b6) va.gov>; Heard, Maureen <(b6) va.gov>; Kelley, Kimberly

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<(b6) va.gov>; Parker, Ginger <(b6) va.gov>; Pedene, Paula L.
<(b6) va.gov>; Screen, Gina <(b6) va.gov>
Subject: Leadership Requesting: Talking Points and Data Need for VA Mental Health Clinicians on Stellate Ganglion Block Procedure
Importance: High

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2. • Spravato (Ketamine-like drug) LINK

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Thank you in advance.

Tara Ricks-Edger
Director of Communications
VISN 6 – U.S. Department of Veterans Affairs

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Recipient:	VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>; VHA CO 10NC5 EXEC /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3c42d5c2321545dba9a59f4e7c6da358-VHA CO 10NC <VHACO10NC5EXEC@va.gov>
Sent Date:	2019/06/20 11:00:24
Delivered Date:	2019/06/20 11:00:18
Message Flags:	Unread Unsent

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From:	Schnurr, Paula P. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC4E0F62F679499C913976FDC7B9DEFC-SCHNURR, PA <(b6) va.gov>
To:	Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>
Subject:	RE: Leadership Requesting: Talking Points and Data Need for VA Mental Health Clinicians on Stellate Ganglion Block Procedure
Date:	2019/06/20 11:23:52
Priority:	Normal
Type:	Note

Thanks, I did not have this

From: Carroll, David (VACO)
Sent: Thursday, June 20, 2019 11:20 AM
To: Schnurr, Paula P. <(b6) va.gov>; Paula P. Schnurr (b6) .edu>; Holtzheimer, Paul <(b6) va.gov>
Cc: VHA 10NC5 Action <VHA10NC5Action@va.gov>; VHA CO 10NC5 EXEC <VHACO10NC5EXEC@va.gov>
Subject: FW: Leadership Requesting: Talking Points and Data Need for VA Mental Health Clinicians on Stellate Ganglion Block Procedure

Here is our most recent iteration.

From: Carroll, David (VACO)
Sent: Thursday, June 20, 2019 11:01 AM
To: VHA 10NC5 Action <VHA10NC5Action@va.gov>; VHA CO 10NC5 EXEC <VHACO10NC5EXEC@va.gov>
Subject: RE: Leadership Requesting: Talking Points and Data Need for VA Mental Health Clinicians on Stellate Ganglion Block Procedure

How's this for proposed talking points? It combines the OCE and our response.

(b) (5)

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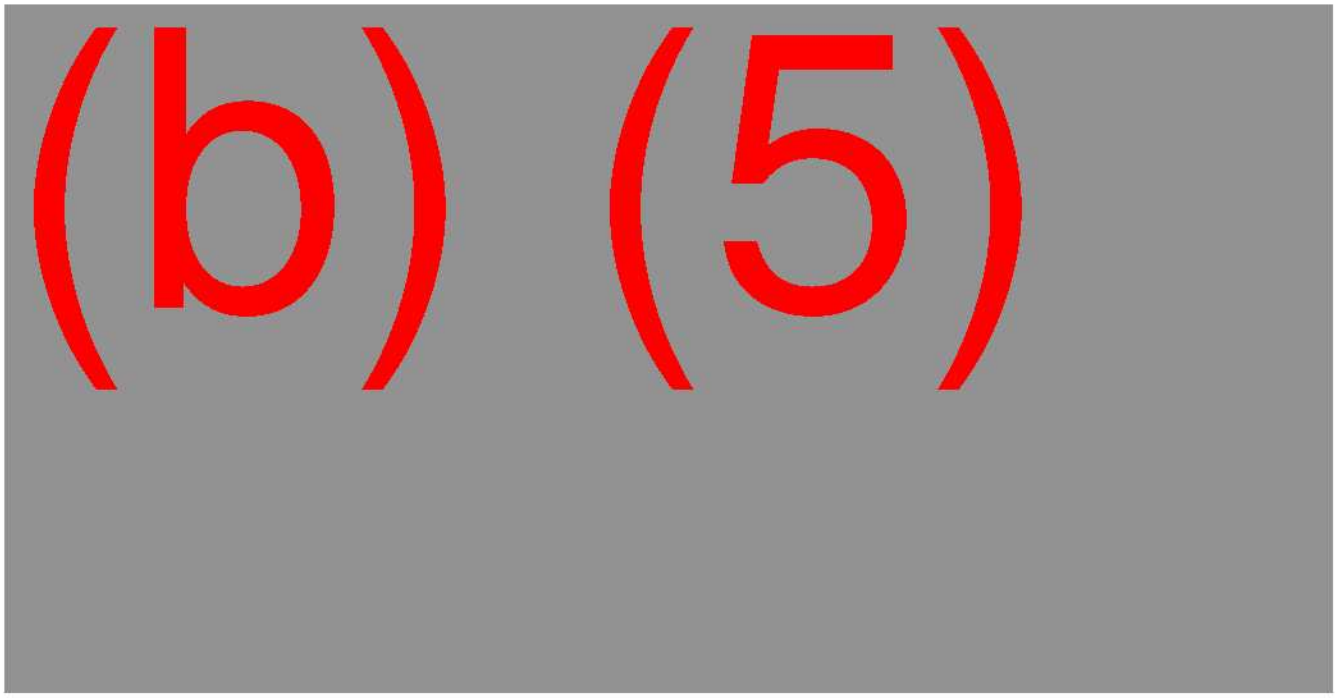

From: Dudley, Tracy
Sent: Thursday, June 20, 2019 10:34 AM
To: VHA 10NC5 Action <VHA10NC5Action@va.gov>
Cc: VHA CO 10NC Front Office HSSs <VHACO10NCFOHSSs@va.gov>
Subject: FW: Leadership Requesting: Talking Points and Data Need for VA Mental Health Clinicians on Stellate Ganglion Block Procedure

Good Morning 10NC5

Please see request below and, if your Program Office is responsive, please provide your response by **2pm today.**

Thank You!
Tracy

Tracy L. Dudley
Health System Specialist
ADUSH for Clinical Operations (10NC)
(b6)
(iPhone)

From: RICKS, TARA
Sent: Thursday, June 20, 2019 10:21 AM

AMERICAN OVERSIGHT

To: Cunningham, Kristin <(b6) va.gov>; Diamond, Sue OSI <(b6) va.gov>; Poff, Susan <(b6) va.gov>; Pedene, Paula L. <(b6) va.gov>; Burden, Rachael <(b6) va.gov>; VACO 80E1 <vaco80e1@mail.va.gov>; Greilsamer, Alan <(b6) va.gov>; Small, Stephanie T. <(b6) va.gov>; Eason, William J. <(b6) va.gov>; Ackerman, William <(b6) va.gov>; Andringa, Elizabeth D. <(b6) va.gov>; Baum, Robert <Robert.Baum@va.gov>; Bennett, Jennifer (Jenna) <Jennifer.Bennett3@va.gov>; Boyd, Teresa D. <(b6) va.gov>; Bucsko, Daniel <(b6) va.gov>; Chesney, Colin <(b6) va.gov>; Davidson, Benjamin C. (ERPi) <(b6) va.gov>; Diamond, Sue OSI <(b6) va.gov>; Goldsberry, Wilmya <(b6) va.gov>; Gore, Ohm J. (Booz Allen Hamilton) <(b6) va.gov>; Gramlick, Debbie <(b6) va.gov>; Greenstone, Clinton <(b6) va.gov>; Hayes, Terrence <(b6) va.gov>; Heard, Maureen <(b6) va.gov>; Jaastad, Derrick <(b6) va.gov>; Jenkins, Matthew A <(b6) va.gov>; Kelley, Kimberly <(b6) va.gov>; MacDonald, Jennifer E. (Physician) <(b6) va.gov>; Oshinski, Renee <(b6) va.gov>; Paige, Paula <(b6) va.gov>; Roberts, Kirsten L. (ERPI) <(b6) va.gov>; Scanlon, Aimee B. <(b6) va.gov>; Sommers, Evelyn <(b6) va.gov>; Subbu, Sankalpa <(b6) va.gov>; VHA 10D Action <VHA10DAction@va.gov>; VHA 10N Action <VHA10NAction@va.gov>; VHA 10NG Action <VHA10NGAction@va.gov>; VHA Healthcare Operations Center <VHAHOC@va.gov>; Warner, Debra L. <(b6) va.gov>; White, Crystal M. <(b6) va.gov>; Williams, Joseph A (OSI) <(b6) va.gov>; Smith, Clifford A. <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Daniels, Lindsay <(b6) va.gov>; Gavin, Stacy <(b6) va.gov>; McGuire, Marsden H. <(b6) va.gov>; Miller, Matthew (VCL Director) (b6) .gov>; Pollack, Stacey <(b6) va.gov>; Pomerantz, Andrew <(b6) va.gov>; Smith, Clifford A. <(b6) va.gov>; Strmiska, Jon G. <Jon.Strmiska@va.gov>
Cc: Ackerman, William <(b6) va.gov>; Andringa, Elizabeth D. <(b6) va.gov>; Bagchi, Kaushiki M. (APTIVE Resources LLC) <(b6) va.gov>; Boccia, Alexis L <(b6) va.gov>; Galagaza, Geraldine <(b6) va.gov>; Heard, Maureen <(b6) va.gov>; Kelley, Kimberly <(b6) va.gov>; Parker, Ginger <(b6) va.gov>; Pedene, Paula L. <(b6) va.gov>; Screen, Gina <(b6) va.gov>; Seekins, DeAnne <(b6) va.gov>; Hutchins, Anne C SAMVAMC <(b6) va.gov>; Buyck, David W SAMVAMC <(b6) va.gov>
Subject: RE: Leadership Requesting: Talking Points and Data Need for VA Mental Health Clinicians on Stellate Ganglion Block Procedure

Thank you Ms. Cunningham. We will await guidance.

Adding my ND, COS, and Mental Health Chief since the visibility of this request is moving beyond the public affairs arena.

From: Cunningham, Kristin
Sent: Thursday, June 20, 2019 10:17 AM
To: RICKS, TARA <(b6) va.gov>; Diamond, Sue OSI <(b6) va.gov>; Poff, Susan <(b6) va.gov>; Pedene, Paula L. <(b6) va.gov>; Burden, Rachael <(b6) va.gov>; VACO 80E1 <vaco80e1@mail.va.gov>; Greilsamer, Alan <(b6) va.gov>; Small, Stephanie T. <(b6) va.gov>; Eason, William J.

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<(b6) va.gov>; VHA MISSION Act Core Team <VHAMISSIONActCoreTeam@va.gov>; Smith, Clifford A. <(b6) va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>
Cc: Ackerman, William <(b6) va.gov>; Andringa, Elizabeth D. <(b6) va.gov>; Bagchi, Kaushiki M. (APTIVE Resources LLC) <(b6) va.gov>; Boccia, Alexis L <(b6) va.gov>; Galagaza, Geraldine <(b6) va.gov>; Heard, Maureen <(b6) va.gov>; Kelley, Kimberly <(b6) va.gov>; Parker, Ginger <(b6) va.gov>; Pedene, Paula L. <(b6) va.gov>; Screen, Gina <(b6) va.gov>; Cunningham, Kristin <(b6) va.gov>
Subject: RE: Leadership Requesting: Talking Points and Data Need for VA Mental Health Clinicians on Stellate Ganglion Block Procedure

Adding Dr Smith and 10NC5 action. They are working on guidance for the SGB.

Kristin J. Cunningham, PMP
Executive Officer to the Deputy Under Secretary
for Health for Community Care
Office of Community Care
P – (b6)
Email: (b6) va.gov

From: RICKS, TARA
Sent: Thursday, June 20, 2019 10:15 AM
To: Diamond, Sue OSI <(b6) va.gov>; Poff, Susan <(b6) va.gov>; Pedene, Paula L. <(b6) va.gov>; Burden, Rachael <(b6) va.gov>; VACO 80E1 <vaco80e1@mail.va.gov>; Greilsamer, Alan <(b6) va.gov>; Small, Stephanie T. <(b6) va.gov>; Eason, William J. <(b6) va.gov>; VHA MISSION Act Core Team <VHAMISSIONActCoreTeam@va.gov>
Cc: Ackerman, William <(b6) va.gov>; Andringa, Elizabeth D. <(b6) va.gov>; Bagchi, Kaushiki M. (APTIVE Resources LLC) <(b6) va.gov>; Boccia, Alexis L <(b6) va.gov>; Galagaza, Geraldine <(b6) va.gov>; Heard, Maureen <(b6) va.gov>; Kelley, Kimberly <(b6) va.gov>; Parker, Ginger <(b6) va.gov>; Pedene, Paula L. <(b6) va.gov>; Screen, Gina <(b6) va.gov>
Subject: RE: Leadership Requesting: Talking Points and Data Need for VA Mental Health Clinicians on Stellate Ganglion Block Procedure

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From: Diamond, Sue OSI
Sent: Thursday, June 20, 2019 10:07 AM
To: RICKS, TARA <(b6) va.gov>; Poff, Susan <(b6) va.gov>; Pedene, Paula L. <(b6) va.gov>; Burden, Rachael <(b6) va.gov>; VACO 80E1 <vaco80e1@mail.va.gov>; Greilsamer, Alan <(b6) va.gov>; Small, Stephanie T. (b6) a.gov>; Eason, William J. <(b6) va.gov>; VHA MISSION Act Core Team

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VISN 6 – U.S. Department of Veterans Affairs

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Recipient:	Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>
Sent Date:	2019/06/20 11:23:51
Delivered Date:	2019/06/20 11:23:52

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From:	Schnurr, Paula P. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC4E0F62F679499C913976FDC7B9DEFC-SCHNURR, PA <(b6) va.gov>
To:	Gavin, Stacy /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4017313de0a84f8e8ceade280f77d235-Gavin, Stac <(b6) va.gov>; Holtzheimer, Paul /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7a84364f6dc744019c31fcc7070ac372-Holtzheimer <(b6) va.gov>; <(b6) hitchcock.org>
CC:	Smith, Clifford A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b729882079394f37af66f66722f99400-Smith, Clif <(b6) va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Daniels, Lindsay /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ed253196fb6b4f32aa922c90dbd05f29-Daniels, Li <(b6) va.gov>
Subject:	RE: Leadership Requesting: Talking Points and Data Need for VA Mental Health Clinicians on Stellate Ganglion Block Procedure
Date:	2019/06/20 11:17:53
Priority:	Normal
Type:	Note

Stacy, Paul is working on this. He is teaching right now but will get back to you.

Dave, I believe we talked about adding to the other talking points we developed?

From: Gavin, Stacy
Sent: Thursday, June 20, 2019 10:42 AM
To: Schnurr, Paula P. <(b6) va.gov>; Holtzheimer, Paul <(b6) va.gov>
Cc: Smith, Clifford A. <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Daniels, Lindsay <(b6) va.gov>
Subject: FW: Leadership Requesting: Talking Points and Data Need for VA Mental Health Clinicians on Stellate Ganglion Block Procedure

Paula and Paul,

I believe from yesterday's call you were working on TPs for clinicians who are asked about SGB? Will you be able to send them **by 1:30p TODAY**?

Stacy

From: Dudley, Tracy
Sent: Thursday, June 20, 2019 10:34 AM
To: VHA 10NC5 Action <VHA10NC5Action@va.gov>
Cc: VHA CO 10NC Front Office HSSs <VHACO10NCFOHSSs@va.gov>

AMERICAN OVERSIGHT

Subject: FW: Leadership Requesting: Talking Points and Data Need for VA Mental Health Clinicians on Stellate Ganglion Block Procedure

Good Morning 10NC5

Please see request below and, if your Program Office is responsive, please provide your response by **2pm today.**

Thank You!
Tracy

Tracy L. Dudley
Health System Specialist
ADUSH for Clinical Operations (10NC)
(b6)
(iPhone)

From: RICKS, TARA
Sent: Thursday, June 20, 2019 10:21 AM
To: Cunningham, Kristin <(b6) va.gov>; Diamond, Sue OSI <(b6) va.gov>; Poff, Susan <(b6) va.gov>; Pedene, Paula L. <(b6) va.gov>; Burden, Rachael <(b6) va.gov>; VACO 80E1 <vaco80e1@mail.va.gov>; Greilsamer, Alan <(b6) va.gov>; Small, Stephanie T. <(b6) va.gov>; Eason, William J. <(b6) va.gov>; Ackerman, William <(b6) va.gov>; Andringa, Elizabeth D. <(b6) va.gov>; Baum, Robert <Robert.Baum@va.gov>; Bennett, Jennifer (Jenna) <Jennifer.Bennett3@va.gov>; Boyd, Teresa D. <(b6) va.gov>; Bucsko, Daniel <(b6) va.gov>; Chesney, Colin <(b6) va.gov>; Davidson, Benjamin C. (ERPi) <(b6) va.gov>; Diamond, Sue OSI <(b6) va.gov>; Goldsberry, Wilmya <(b6) va.gov>; Gore, Ohm J. (Booz Allen Hamilton) <(b6) va.gov>; Gramlick, Debbie <(b6) va.gov>; Greenstone, Clinton <(b6) va.gov>; Hayes, Terrence <(b6) va.gov>; Heard, Maureen <(b6) va.gov>; Jaastad, Derrick <(b6) va.gov>; Jenkins, Matthew A <(b6) va.gov>; Kelley, Kimberly <(b6) va.gov>; MacDonald, Jennifer E. (Physician) <(b6) va.gov>; Oshinski, Renee <(b6) va.gov>; Paige, Paula <(b6) va.gov>; Roberts, Kirsten L. (ERPI) (b6) @va.gov>; Scanlon, Aimee B. <(b6) va.gov>; Sommers, Evelyn <(b6) va.gov>; Subbu, Sankalpa <(b6) va.gov>; VHA 10D Action <VHA10DAction@va.gov>; VHA 10N Action <VHA10NAction@va.gov>; VHA 10NG Action <VHA10NGAction@va.gov>; VHA Healthcare Operations Center <VHAHOC@va.gov>; Warner, Debra L. <(b6) va.gov>; White, Crystal M. <(b6) va.gov>; Williams, Joseph A (OSI) <(b6) va.gov>; Smith, Clifford A. <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Daniels, Lindsay <(b6) va.gov>; Gavin, Stacy <(b6) va.gov>; McGuire, Marsden H. <(b6) va.gov>; Miller, Matthew (VCL Director) (b6) va.gov>; Pollack, Stacey <(b6) va.gov>; Pomerantz, Andrew <(b6) va.gov>; Smith, Clifford A. <(b6) va.gov>; Strmiska, Jon G.

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<(b6) va.gov>
Cc: Ackerman, William <(b6) va.gov>; Andringa, Elizabeth D. <(b6) va.gov>; Bagchi, Kaushiki M. (APTIVE Resources LLC) <(b6) va.gov>; Boccia, Alexis L <(b6) va.gov>; Galagaza, Geraldine <(b6) va.gov>; Heard, Maureen <(b6) va.gov>; Kelley, Kimberly <(b6) va.gov>; Parker, Ginger <(b6) va.gov>; Pedene, Paula L. <(b6) va.gov>; Screen, Gina <(b6) va.gov>; Seekins, DeAnne <(b6) va.gov>; Hutchins, Anne C SAMVAMC <(b6) va.gov>; Buyck, David W SAMVAMC <(b6) va.gov>
Subject: RE: Leadership Requesting: Talking Points and Data Need for VA Mental Health Clinicians on Stellate Ganglion Block Procedure

Thank you Ms. Cunningham. We will await guidance.

Adding my ND, COS, and Mental Health Chief since the visibility of this request is moving beyond the public affairs arena.

From: Cunningham, Kristin
Sent: Thursday, June 20, 2019 10:17 AM
To: RICKS, TARA <(b6) va.gov>; Diamond, Sue OSI <(b6) va.gov>; Poff, Susan <(b6) va.gov>; Pedene, Paula L. <(b6) va.gov>; Burden, Rachael <(b6) va.gov>; VACO 80E1 <vaco80e1@mail.va.gov>; Greilsamer, Alan <(b6) va.gov>; Small, Stephanie T. <(b6) va.gov>; Eason, William J. <(b6) va.gov>; VHA MISSION Act Core Team <VHAMISSIONActCoreTeam@va.gov>; Smith, Clifford A. <(b6) va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>
Cc: Ackerman, William <(b6) va.gov>; Andringa, Elizabeth D. <(b6) va.gov>; Bagchi, Kaushiki M. (APTIVE Resources LLC) <(b6) va.gov>; Boccia, Alexis L <(b6) va.gov>; Galagaza, Geraldine <(b6) va.gov>; Heard, Maureen <(b6) va.gov>; Kelley, Kimberly <(b6) va.gov>; Parker, Ginger <(b6) va.gov>; Pedene, Paula L. <(b6) va.gov>; Screen, Gina <(b6) va.gov>; Cunningham, Kristin <(b6) va.gov>
Subject: RE: Leadership Requesting: Talking Points and Data Need for VA Mental Health Clinicians on Stellate Ganglion Block Procedure

Adding Dr Smith and 10NC5 action. They are working on guidance for the SGB.

Kristin J. Cunningham, PMP
Executive Officer to the Deputy Under Secretary
for Health for Community Care
Office of Community Care
P – (b6)
Email: (b6) va.gov

From: RICKS, TARA
Sent: Thursday, June 20, 2019 10:15 AM

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To: Diamond, Sue OSI <(b6) va.gov>; Poff, Susan <(b6) va.gov>; Pedene, Paula L. <(b6) va.gov>; Burden, Rachael <(b6) va.gov>; VACO 80E1 <vaco80e1@mail.va.gov>; Greilsamer, Alan <(b6) va.gov>; Small, Stephanie T. <(b6) va.gov>; Eason, William J. <(b6) va.gov>; VHA MISSION Act Core Team <VHAMISSIONActCoreTeam@va.gov>
Cc: Ackerman, William <(b6) va.gov>; Andringa, Elizabeth D. <(b6) va.gov>; Bagchi, Kaushiki M. (APTIVE Resources LLC) <(b6) va.gov>; Boccia, Alexis L <(b6) va.gov>; Galagaza, Geraldine <(b6) va.gov>; Heard, Maureen <(b6) va.gov>; Kelley, Kimberly <(b6) va.gov>; Parker, Ginger <(b6) va.gov>; Pedene, Paula L. <(b6) va.gov>; Screen, Gina <(b6) va.gov>
Subject: RE: Leadership Requesting: Talking Points and Data Need for VA Mental Health Clinicians on Stellate Ganglion Block Procedure

Thank you Ms. Diamond.

From: Diamond, Sue OSI
Sent: Thursday, June 20, 2019 10:07 AM
To: RICKS, TARA <(b6) va.gov>; Poff, Susan <(b6) va.gov>; Pedene, Paula L. <(b6) va.gov>; Burden, Rachael <(b6) va.gov>; VACO 80E1 <vaco80e1@mail.va.gov>; Greilsamer, Alan <(b6) va.gov>; Small, Stephanie T. <(b6) va.gov>; Eason, William J. <(b6) va.gov>; VHA MISSION Act Core Team <VHAMISSIONActCoreTeam@va.gov>
Cc: Ackerman, William <(b6) va.gov>; Andringa, Elizabeth D. <(b6) va.gov>; Bagchi, Kaushiki M. (APTIVE Resources LLC) <(b6) va.gov>; Boccia, Alexis L <(b6) va.gov>; Galagaza, Geraldine <(b6) va.gov>; Heard, Maureen <(b6) va.gov>; Kelley, Kimberly <(b6) va.gov>; Parker, Ginger <(b6) va.gov>; Pedene, Paula L. <(b6) va.gov>; Screen, Gina <(b6) va.gov>
Subject: RE: Leadership Requesting: Talking Points and Data Need for VA Mental Health Clinicians on Stellate Ganglion Block Procedure

Adding the MISSION Act Core Team to assist with getting you a response.

From: RICKS, TARA
Sent: Thursday, June 20, 2019 10:01 AM
To: Poff, Susan <(b6) va.gov>; Pedene, Paula L. <(b6) va.gov>; Burden, Rachael <(b6) va.gov>; VACO 80E1 <vaco80e1@mail.va.gov>; Greilsamer, Alan <(b6) va.gov>; Small, Stephanie T. <(b6) va.gov>; Eason, William J. <(b6) va.gov>
Cc: Ackerman, William <(b6) va.gov>; Andringa, Elizabeth D. <(b6) va.gov>; Bagchi, Kaushiki M. (APTIVE Resources LLC) <(b6) va.gov>; Boccia, Alexis L <(b6) va.gov>; Diamond, Sue OSI <(b6) va.gov>; Galagaza, Geraldine <(b6) va.gov>; Heard, Maureen <(b6) va.gov>; Kelley, Kimberly <(b6) va.gov>; Parker, Ginger <(b6) va.gov>; Pedene, Paula L. <(b6) va.gov>; Screen, Gina <(b6) va.gov>
Subject: Leadership Requesting: Talking Points and Data Need for VA Mental Health Clinicians on

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Stellate Ganglion Block Procedure
Importance: High

Good morning everyone,

I wasn't sure who would be the best POC for this request – so I am emailing everyone.

VISN 6 is experiencing a significant up-tick in service request from Veterans regarding the stellate ganglion block procedure, to include request to use 'Mission Act resources' if the facility doesn't offer the procedure.

Our VISN COS and VISN Mental Health Chief understand that a lot of these request are being driven by the 60 minutes segment, and that this story offered our Veterans and family members hope that relief is on the way for their persisting nightmares, anger, and fear (PTSD). Veterans are now actively calling their mental health doctors wanting this procedure within our region – and our doctors don't know what to say or how to move forward with these requests. Our clinicians are wanting specific guidance **before** Veterans go out on their own and get this procedure that VA considers 'experimental.'

In addition to SGB, Leadership would also like talking points for Spravato after the results of today's national formulary meeting. The focus of these talking points would be for our mental health doctors and what they should tell patients.

Links to the story's for quick reference.

1. • The stellate ganglion block procedure LINK
2. • Spravato (Ketamine-like drug) LINK

Just to reiterate this is not a request for media talking points. This is a request for talking points for our mental health teams to communicate with patients. Leadership is concerned if we do not get ahead of this it will ulitmately turn into an access or care issue especially for the health and well-being of our Veterans receiving mental health and suicide prevention services.

Thank you in advance.

Tara Ricks-Edger
Director of Communications
VISN 6 – U.S. Department of Veterans Affairs

"It is not the critic who counts; not the man who points out how the strong man stumbles, or where the doer of deeds could have done them better. The credit belongs to the man who is actually in the arena…who strives valiantly; who errs, who comes short again and again, because there is no effort without error and shortcoming; but who does actually strive to do the deeds; who knows great enthusiasms, the great devotions; who spends himself in a worthy cause; who at the best knows in the end the triumph of high achievement, and who at the worst, if he fails, at least fails while daring greatly, so that his place shall never be with those cold and timid souls who neither know victory nor defeat." - Theodore Roosevelt

Sender:	Schnurr, Paula P. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC4E0F62F679499C913976FDC7B9DEFC-SCHNURR, PA <(b6) va.gov>
Recipient:	Gavin, Stacy /o=ExchangeLabs/ou=Exchange Administrative Group

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	(FYDIBOHF23SPDLT)/cn=Recipients/cn=4017313de0a84f8e8ceade280f77d235-Gavin, Stac (b6) @va.gov>; Holtzheimer, Paul /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7a84364f6dc744019c31fcc7070ac372-Holtzheimer <(b6) va.gov>; <(b6) hitchcock.org>; Smith, Clifford A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b729882079394f37af66f66722f99400-Smith, Clif <(b6) va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Daniels, Lindsay /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ed253196fb6b4f32aa922c90dbd05f29-Daniels, Li <(b6) va.gov>
Sent Date:	2019/06/20 11:17:52
Delivered Date:	2019/06/20 11:17:53

AMERICAN OVERSIGHT

From:	Wiechers, Ilse /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0C7B1428D9E4233A641F125C5B6FC4F-WIECHERS, I (b6) @va.gov>
To:	Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; McGuire, Marsden H. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29e9d648c29f4885828c10446fdd7379-McGuire, Ma <(b6) va.gov>; Pomerantz, Andrew /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29a9288df9a34e84bddfd00cde79f11b-Pomerantz, (b6) @va.gov>
CC:	VHA CO 10NC5 EXEC /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3c42d5c2321545dba9a59f4e7c6da358-VHA CO 10NC <VHACO10NC5EXEC@va.gov>
Subject:	RE: Ketamine/Esketamine site visit report
Date:	2019/08/22 10:48:45
Priority:	Normal
Type:	Note

Slides attached.

From: Carroll, David (VACO)
Sent: Thursday, August 22, 2019 7:47 AM
To: McGuire, Marsden H. <(b6) va.gov>; Wiechers, Ilse (b6) @va.gov>; Pomerantz, Andrew <(b6) va.gov>
Cc: VHA CO 10NC5 EXEC <VHACO10NC5EXEC@va.gov>
Subject: RE: Ketamine/Esketamine site visit report

Look forward to the update. Looks like there are slides if someone can please forward to the EXEC mail group. Thx.

From: McGuire, Marsden H.
Sent: Thursday, August 22, 2019 10:46 AM
To: Wiechers, Ilse (b6) @va.gov>; Pomerantz, Andrew <(b6) va.gov>
Cc: Carroll, David (VACO) <(b6) va.gov>; VHA CO 10NC5 EXEC <VHACO10NC5EXEC@va.gov>
Subject: RE: Ketamine/Esketamine site visit report

That would be 8 am PST/11 am EST today – thx. M

From: McGuire, Marsden H.
Sent: Thursday, August 22, 2019 10:42 AM
To: Wiechers, Ilse (b6) @va.gov>; Pomerantz, Andrew <(b6) va.gov>
Cc: Carroll, David (VACO) <(b6) va.gov>; VHA CO 10NC5 EXEC <VHACO10NC5EXEC@va.gov>
Subject: RE: Ketamine/Esketamine site visit report

VANTS: 800-767-1750, 63983#

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From: Wiechers, Ilse
Sent: Thursday, August 22, 2019 9:25 AM
To: Pomerantz, Andrew <(b6) va.gov>; McGuire, Marsden H. <(b6) va.gov>
Subject: RE: Ketamine/Esketamine site visit report

I'm free and available at 8 am PST/11 am EST today (Thursday 8/22) and tomorrow (Friday 8/23). Please clarify date/time and dial in, and I can join for discussion. Here are the summary slides on our progress from my presentation with the COS last week.

From: Pomerantz, Andrew
Sent: Thursday, August 22, 2019 5:29 AM
To: McGuire, Marsden H. <(b6) va.gov>; Wiechers, Ilse (b6) @va.gov>
Subject: RE: Ketamine/Esketamine site visit report

Enroute now. May be able to listen in on vis but not able to talk

Sent with BlackBerry Work
(www.blackberry.com)

From: McGuire, Marsden H. <(b6) va.gov>
Date: Thursday, Aug 22, 2019, 8:11 AM
To: Wiechers, Ilse <(b6) @va.gov>
Cc: Pomerantz, Andrew <(b6) va.gov>
Subject: Ketamine/Esketamine site visit report

Ilse,

Are you still available to talk with the MH Exec Leadership Team tomorrow between 11-12? If that doesn't work at this point, how about an upcoming Tue or Thu (same time)?

Adding Andy for awareness as he may be on travel during part of the day.

M

Sender:	Wiechers, Ilse /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0C7B1428D9E4233A641F125C5B6FC4F-WIECHERS, I <(b6) va.gov>
Recipient:	Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; McGuire, Marsden H. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29e9d648c29f4885828c10446fdd7379-McGuire, Ma <(b6) va.gov>; Pomerantz, Andrew /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29a9288df9a34e84bddfd00cde79f11b-Pomerantz, <(b6) z@va.gov>; VHA CO 10NC5 EXEC /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3c42d5c2321545dba9a59f4e7c6da358-VHA CO 10NC

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	<VHACO10NC5EXEC@va.gov>
Sent Date:	2019/08/22 10:48:43
Delivered Date:	2019/08/22 10:48:45

AMERICAN OVERSIGHT

From:	Mole, Larry A. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A7F4EED603A543398E4E0B0BBE52CF41-MOLE, LARRY (b6) @va.gov>
To:	Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) va.gov>
Subject:	RE: ketamine and Veterans, on CNN
Date:	2019/06/18 20:55:38
Priority:	Normal
Type:	Note

Thank you.

Sent with BlackBerry Work
(www.blackberry.com)

From: Llorente, Maria D. <(b6) va.gov>
Date: Tuesday, Jun 18, 2019, 6:01 PM
To: Mole, Larry A. (b6) @va.gov>
Subject: FW: ketamine and Veterans, on CNN

Hi Larry. Lu asked me to make you aware that a veteran received Esketamine this morning at the Boston VA for treatment resistant depression. He tolerated the procedure and was discharged with close follow up. We do not know yet if it was therapeutic. In case it comes up during your hearing

Sent with BlackBerry Work
(www.blackberry.com)

From: Beck, Lucille B. <(b6) va.gov>
Date: Tuesday, Jun 18, 2019, 4:30 PM
To: Llorente, Maria D. <(b6) va.gov>, Law, Cassandra M. <(b6) va.gov>
Subject: RE: ketamine and Veterans, on CNN

Please give Larry Mole a heads up as he is testifying about propose marijuana legislation and it May be raised.
OCLA should provide guidance on any statement.

Lucille B. Beck, Ph.D.
Deputy Under Secretary for Health
for Policy and Services (10P)
VA Central Office
Phone: (b6)

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Cell (b6)

Sent with BlackBerry Work
(www.blackberry.com).

From: Llorente, Maria D. <(b6) va.gov>
Date: Tuesday, Jun 18, 2019, 5:28 PM
To: Beck, Lucille B. <(b6) va.gov>, Law, Cassandra M. <(b6) va.gov>
Subject: RE: ketamine and Veterans, on CNN

A veteran did successfully receive a treatment today at Boston VA. Don't know outcome, but he tolerated procedure well.

Sent with BlackBerry Work
(www.blackberry.com)

From: Beck, Lucille B. <(b6) va.gov>
Date: Tuesday, Jun 18, 2019, 12:55 PM
To: Llorente, Maria D. <(b6) va.gov>, Law, Cassandra M. <(b6) va.gov>
Subject: ketamine and Veterans, on CNN

Maria,

(b6), critical piece just aired about ketamine, Veterans, and J and J.

Lucille B. Beck, Ph.D.
Deputy Under Secretary for Health
for Policy and Services (10P)
Veterans Health Administration (VHA)
Office: (b6)

Sender:	Mole, Larry A. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A7F4EED603A543398E4E0B0BBE52CF41-MOLE, LARRY (b6) @va.gov>
Recipient:	Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) va.gov>
Sent Date:	2019/06/18 20:55:37
Delivered Date:	2019/06/18 20:55:38

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From:	Dailey, Janet /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=64678944A5AA4B4B8BA1C93D93D63534-DAILEY, JAN <(b6) va.gov>
To:	Longo, Lisa (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e051d1227586439696591b30818ff996-Longo, Lisa <(b6) va.gov>; VHAPBM VISN Pharmacist Executives /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a29ff0f0291a4a708de0731733c726c0-VHAPBH VISN <VISNPharmacyExecs@va.gov>; VHAPBM Ask PBM Clinical /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=82b40b5f582040959b9edcf353b2a433-VHAPBH Ask <AskPBMClinical@va.gov>; VHAPBM MAP Committee /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51be394a33f2409a9fb44ce631b751b3-VHAPBH MAP <pbm.map@med.va.gov>; VHAPBM Pharmacy Chiefs /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b3bdd525bd2340749ff69f86d2e657f0-VHAPBH Phar <PharmacyChiefs@va.gov>; VHAPBM Clinical Pharmacy Practice Office (CPPO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c570e7181dbe4a9e8f421f03c9623fa6-VHAPBH Clin <ClinicalPharmacyPracticeOfficeCPPO@va.gov>; VHAPBM Pharmacy Informaticists /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=337358eeb0104bb8bad65ae5022c1595-VHAPBH Phar <PharmacyInformaticists@va.gov>; VHA Clinical Pharmacists /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=feeeb2640db54aeebeeb57c1e0f534ea-VHA Clinica <vha.clinical.pharmacists@va.gov>; VHA Pharmacy Residency Program Directors Only /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=97411d2945704555bd6844d97a4cf31d-VHA Pharmac <VHAPharmacyResidencyDirectorsOnly@va.gov>
CC:	Lees, Don (PBM Hines) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1b281c4c43c042808950f480ad1474e9-Lees, Don <(b6) va.gov>; Torphy, Lisa /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43ab37387c5c4ed6bae3006dcde84582-Torphy, Lis <(b6) va.gov>; Streit, Phillip P /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=acfac72743604e3b8e80a555ebba45df-Streit, Phi <(b6) va.gov>; (b6) (IHS) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d53c1d250bd340f4b4e2715b26d37dac-MatthewMill <(b6) @ihs.gov>; (b6) @ihs.gov>; (b6)
Subject:	RE: June 2019 Document Posting and Decision Announcement
Date:	2019/06/27 17:15:33
Priority:	Normal
Type:	Note

Apologize for the extra message.

Please substitute #6 with this updated schedule of educational opportunities and resources. (see below)

6. • **Educational Opportunities and Resources**

DOAC Certificate Course

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- • DOACs Certificate Course is a series of 6 free standing courses that focuses exclusively on DOAC Management and offers 35 Home Study CE hours
- • Please contact (b6) va.gov with any questions.
- • Please Note: To access course and other resources on the VA Pharmacy Online Classroom Site, an account needs to be created. Instructions on how to create an account can be found on the landing page.

PBM 2019 Monthly Webinars Schedule (to date):

a. July 16th @ 3:10 PM ET Vancomycin Dosing and Monitoring Program-
b. Registration link: Vancomycin Dosing and Monitoring for Patients with Serious Infections due to Staphylococcus aureus
c. Refer to email dated 6/20 from (b6) va.gov for details. (ACPE, ACCME, JA IPCE, ACCME-NP, ACCME accredited)
d. August 20th @ 3:10 **Title**: Targeting Vancomycin AUC Goals and Associated Risks of Nephrotoxicity-Clinical Experience
e. Please Note: New Adobe Connect Link for 2019: http://va-eerc-ees.adobeconnect.com/pbmwebinar2019/

Previous 2019 Anticoagulation Related PBM Webinars in TMS (no accreditation)

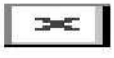
- **VA 37549** *"Periprocedural Bridging in Patients on Oral Anticoagulation - recording only"*
- **VA 37817** *"PBM Monthly Series - Periprocedural Anticoagulation Therapy: Cases (Recorded)" (companion session to VA 37549)*
- **VA 38569** *"PBM-MAP-VPE monthly Webinar Series: Direct Oral Anticoagulants – Recording"*

PBM Ez Minutes Video Updates

- • The PBM Ez Minutes Video updates are short (8-10 minutes) sound bytes on decisions made by the PBM National Formulary Committee.
- • The May 2019 Ez Minutes Video update video includes an update on the drug of choice for severe malaria AND some updates to the PCSK9 Inhibitors CFU
- • Check the PBM Education SP Site to view all videos since Sept. 2017. An option to download the ~ 10 min video to desktop is available for faster viewing if needed.

-

Janet H. Dailey PharmD
National PBM Clinical Pharmacy Program Manager-Education/Insomnia
Chair, PBM Education Advisory Committee
VHA Pharmacy Benefits Management Services (10P4P)
(b6) **va.gov** |T: (b6) (CT)
VA Pharmacy On-line Classroom (AKA Moodle site)
NEW! VA PBM Education SharePoint Site



cid:image002.jpg@01CE28E5.E9A17EE0

From: Longo, Lisa (PBM)
Sent: Thursday, June 27, 2019 1:40 PM
To: VHAPBM VISN Pharmacist Executives <VISNPharmacyExecs@va.gov>; VHAPBM Ask PBM Clinical

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<AskPBMClinical@va.gov>; VHAPBM MAP Committee <pbm.map@med.va.gov>; VHAPBM Pharmacy Chiefs <PharmacyChiefs@va.gov>; VHAPBM Clinical Pharmacy Practice Office (CPPO) <ClinicalPharmacyPracticeOfficeCPPO@va.gov>; VHAPBM Pharmacy Informaticists <PharmacyInformaticists@va.gov>; VHA Clinical Pharmacists <vha.clinical.pharmacists@va.gov>; VHA Pharmacy Residency Program Directors Only <VHAPharmacyResidencyDirectorsOnly@va.gov>
Cc: Lees, Don (PBM Hines) <(b6) va.gov>; Torphy, Lisa <(b6) va.gov>; Streit, Phillip P <(b6) va.gov>; (b6) r@ihs(b6) @ihs.gov; (b6)
Subject: June 2019 Document Posting and Decision Announcement

Dear VPEs, MAP, Chiefs of Pharmacy, VA Clinical Pharmacists and VHAPBH Pharmacy ADPACs,

This is to inform you of recent formulary decisions and of clinical documents that have been posted on the PBM INTRAnet site:

-

1. • **Drugs Added** to the VA National Formulary (and associated posted documents)
   - • Secnidazole (SOLOSEC) – PA-F, restricted to Women's Health
   - • Ceftazidime/avibactam (AVYCAZ) monograph addendum – PA-F, restricted to Infectious Diseases or facility authorized provider
   - • Amikacin liposomal inhalation solution (ARIKAYCE) PA-F Monograph and ALIS (ARIKAYCE) PA-F with CFU
   - • Tacrolimus Ointment, without prior authorization. Includes 0.03% and 0.10% strengths. (No associated documents.)
   - • Ovulation prediction kits (disposable) (no associated documents)
   - • Urine home pregnancy tests (no associated documents)
   - • Daunorubicin and Cytarabine Liposome (VYXEOS) Drug Monograph PA-F with CFU
   - • Daunorubicin and Cytarabine Liposome (VYXEOS) Criteria for Use
     Daunorubicin and Cytarabine Liposome is FDA approved for the treatment of newly diagnosed therapy-related AML (t-AML) or AML with myelodysplasia-related changes (AML-MRC). The monograph addendum highlights the investigations leading to approval.
   - • Venetoclax (VENCLEXTA) in AML - Monograph Addendum PA-F with CFU
   - • Venetoclax (VENCLEXTA) in CLL or SLL - Monograph Addendum PA-F with CFU
   - • Venetoclax (VENCLEXTA) Criteria for Use (rev. June 2019)
     Venetoclax indications have expanded to include the treatment of newly-diagnosed AML in combination with azacytidine or decitabine or low-dose cytarabine for patients ≥ 75 years or those ineligible for intensive induction chemotherapy. In addition, use in CLL/SLL has expanded to include treatment of those with or without del17p, as monotherapy, or in combination with rituximab or obinutuzumab.

2. • **Drugs Not Added** to the VA National Formulary (and associated posted documents)
   - • Cangrelor (KANGREAL) Drug Monograph
   - • Cenegermin (OXERVATE) Monograph and Cenegermin (OXERVATE) Criteria for Use
   - • Eravacycline (XERAVA) Monograph
   - • Omadacycline (NUZYRA) Monograph – *restricted to Infectious Diseases or facility authorized provider*

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- • Patisiran (Onpattro) NME Monograph
- • Inotersen (Tegsedi) NME Monograph
- • Patisiran Inotersen CFU
- • Tildrakizumab-asmn (ILUMYA) in Plaque Psoriasis Monograph
- • Bosutinib (BOSULIF) in Newly Diagnosed CML - Monograph Addendum

  Bosutinib is a 2nd generation tyrosine kinase inhibitor with recent approval in newly diagnosed chronic phase CML. The addendum highlights the investigations leading to this approval.

3. • **Drugs Removed** from the VA National Formulary
   - • Flunisolide Oral Inhaler (AEROSPAN)-product discontinued

4. • **Documents Archived**
   - none

5. • **Other** Announcements
   - Sacubitril Valsartan (ENTRESTO) Criteria for Use (Rev May 30 2019): revised ADHF criterion to monitor for minimum of 6 hours after *first* dose sacubitril/valsartan before being discharged from the hospital
   - Esketamine (SPRAVATO) – voted to be nonformulary in May 2019
     - Esketamine (SPRAVATO) Monograph and Esketamine (SPRAVATO) Criteria for Use have been posted
     - Esketamine (Spravato) has been added to the Non-Promotable List
       - • National Protocol Guidance for Intranasal Esketamine for Treatment Resistant Depression has been posted
   - • Two Plaque Psoriasis and Psoriatic Arthritis Clinical Guidances have been posted (criteria for use of interleukin inhibitors in psoriasis and psoriatic arthritis are still in process):
     - • Psoriasis and Psoriatic Arthritis Treatment Guide
     - • Anti-Tumor Necrosis Factor Biologics in Psoriasis and Psoriatic Arthritis Recommendations for Use.
   - • Tyrosine Kinase Inhibitor (TKI) Therapeutic Flow Chart for the Treatment of Chronic Phase CML (rev. June 2019)
   - • Empagliflozin (JARDIANCE) Criteria for Use (Updated June 2019) updates include use as second-line option in patients with type 2 diabetes and chronic kidney disease

6. • **Educational Opportunities and Resources**
   - • DOAC Certificate Course was released in Dec. 2018. Please refer to email from (b6) va.gov dated 12/6/18 for details. DOACs Certificate Course is a series of 6 free standing courses that focuses exclusively on DOAC Management and offers 35 Home Study CE hours. Please contact (b6) va.gov with any questions.
     a. • Please Note: To access course and other resources on the VA Pharmacy Online Classroom Site, an account needs to be created. Instructions on how to create an account can be found on the landing page.

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- • PBM 2019 Monthly Webinars Schedule (to date):
    a. • February 19th @ 3:10 PM ET: Periprocedural Anticoagulation Therapy: Cases
        1. • Taped link to January 2019 Webinar: Periprocedural Bridging in Patients on Oral Anticoagulation - recording only
    b. • May 21st @ 3:10 PM ET: PBM Updates in Anticoagulation Related Topics- Tracy Minichiello, MD and Lisa Longo, PharmD, BCPS
    c. • June 18th @ 3:10 Pm ET: Anticoagulation: Cases
    d. • Please Note: New Adobe Connect Link for 2019: http://va-eerc-ees.adobeconnect.com/pbmwebinar2019/
- • PBM Ez Minutes Video Updates
    a. • The PBM Ez Minutes Video updates are short (8-10 minutes) sound bytes on decisions made by the PBM National Formulary Committee. The January 2019 video includes an update on the Caffeine Containing Analgesics
    b. • Check the PBM Education SP Site to view all videos since Sept. 2017
- • 2019 Board Certification Study Groups
    a. • Refer to email dated January 11th, 2019 from (b6) va.gov for details and how to be added to a list serve. More details will be sent in February ONLY to the board certification list serves.

All documents can also be found under "What's New at PBM" tab at https://vaww.cmopnational.va.gov/cmop/PBM/default.aspx.
Similar changes were requested for the INTERnet site (when applicable).

Please share this information with providers and staff who may be interested in receiving this information. Direct any inquiries to AskPBMClinical@va.gov

Thank you,

Ask PBM Clinical

Sender:	Dailey, Janet /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=64678944A5AA4B4B8BA1C93D93D63534-DAILEY, JAN <(b6) va.gov>
Recipient:	Longo, Lisa (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e051d1227586439696591b30818ff996-Longo, Lisa <(b6) va.gov>; VHAPBM VISN Pharmacist Executives /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a29ff0f0291a4a708de0731733c726c0-VHAPBH VISN <VISNPharmacyExecs@va.gov>; VHAPBM Ask PBM Clinical /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=82b40b5f582040959b9edcf353b2a433-VHAPBH Ask <AskPBMClinical@va.gov>; VHAPBM MAP Committee /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51be394a33f2409a9fb44ce631b751b3-VHAPBH MAP <pbm.map@med.va.gov>; VHAPBM Pharmacy Chiefs /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b3bdd525bd2340749ff69f86d2e657f0-VHAPBH Phar

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	<PharmacyChiefs@va.gov>; VHAPBM Clinical Pharmacy Practice Office (CPPO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c570e7181dbe4a9e8f421f03c9623fa6-VHAPBH Clin <ClinicalPharmacyPracticeOfficeCPPO@va.gov>; VHAPBM Pharmacy Informaticists /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=337358eeb0104bb8bad65ae5022c1595-VHAPBH Phar <PharmacyInformaticists@va.gov>; VHA Clinical Pharmacists /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=feeeb2640db54aeebeeb57c1e0f534ea-VHA Clinica <vha.clinical.pharmacists@va.gov>; VHA Pharmacy Residency Program Directors Only /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=97411d2945704555bd6844d97a4cf31d-VHA Pharmac <VHAPharmacyResidencyDirectorsOnly@va.gov>; Lees, Don (PBM Hines) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1b281c4c43c042808950f480ad1474e9-Lees, Don <(b6) va.gov>; Torphy, Lisa /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43ab37387c5c4ed6bae3006dcde84582-Torphy, Lis <(b6) va.gov>; Streit, Phillip P /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=acfac72743604e3b8e80a555ebba45df-Streit, Phi <(b6) va.gov>; (b6) [redacted] [redacted]@ihs.gov>; (b6) [redacted]@ihs.gov>; (b6) [redacted]
Sent Date:	2019/06/27 17:15:20
Delivered Date:	2019/06/27 17:15:33
Message Flags:	Unread

AMERICAN OVERSIGHT

From:	Capehart, Bruce P. DURVAMC /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6866EFF4E9DF4A48846D056A02044C38-CAPEHART, B <(b6) va.gov>
To:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat <(b6) va.gov>; Schreiber, Matthew A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=db4d0324bf0945f183f33816c7fd1db0-Schreiber, <(b6) Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>
Subject:	RE: JAMA commentary on 'evolving issues in depression'
Date:	2019/06/26 09:50:38
Priority:	Normal
Type:	Note

(b6) [redacted]

[redacted]

From: Valentino, Michael (VACO)
Sent: Wednesday, June 26, 2019 9:44 AM
To: Capehart, Bruce P. DURVAMC <(b6) va.gov>; Fuller, Matthew A. (PBM) <(b6) va.gov>; Schreiber, Matthew A. <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: JAMA commentary on 'evolving issues in depression'

(b6) [redacted]

(b6) [redacted]. Under the ketamine section, they state "On March 5, 2019, the Food and Drug Administration approved nasal **KETAMINE** (Spravato)…."

(b6) [redacted]

From: Capehart, Bruce P. DURVAMC
Sent: Wednesday, June 26, 2019 7:47 AM

AMERICAN OVERSIGHT

To: Fuller, Matthew A. (PBM) <(b6) va.gov>; Schreiber, Matthew A. (b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>
Subject: JAMA commentary on 'evolving issues in depression'

All,

Two copies of today's JAMA commentary are attached: one as published, one with my comments. Also attached is a esketamine cost projection analysis from a while back.

The JAMA commentary claims ketamine IV infusions are expensive and nasal esketamine is a cost-effective alternative. That comment looks out of place.

According to a ketamine directory website (https://ketamineclinicsdirectory.com/ketamine-infusion-cost/), a ketamine infusion for depression should cost $400-800 each for a typical series of 6 infusions. A quick survey of the web shows several ketamine infusion centers with prices in the $400-800 range, so it's a reasonable first-pass estimate. Assuming $800 unit cost per infusion, that's $4,800 for six treatments. Earlier, I sent a spreadsheet showing projected annual esketamine cost scenarios. Initial treatment of two treatments per week for four weeks at AWP pricing for the 56mg dose is $7,080. Notice the $800 infusion cost includes facility, staffing, and supplies where the AWP for esketamine doesn't. Activity-based costing isn't simple with VA's fiscal system.

> "…while ketamine intranasal is much less expensive but requires frequent administration…[the availability of nasal esketamine] will be modulated by availability of specialty centers for administration and insurance coverage."

(b6) .

(b6) .

Regards,

Bruce

Sender:	Capehart, Bruce P. DURVAMC /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6866EFF4E9DF4A48846D056A02044C38-CAPEHART, B (b6) va.gov>
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AMERICAN OVERSIGHT

Sent Date:	2019/06/26 09:50:35
Delivered Date:	2019/06/26 09:50:38
Message Flags:	Unread

AMERICAN OVERSIGHT

To:	Capehart, Bruce P. DURVAMC /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6866eff4e9df4a48846d056a02044c38-Capehart, B (b6) va.gov>; Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat (b6) va.gov>; Schreiber, Matthew A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=db4d0324bf0945f183f33816c7fd1db0-Schreiber, (b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>
Subject:	RE: JAMA commentary on 'evolving issues in depression'
Date:	2019/06/26 09:42:28
Priority:	Normal
Type:	Note

(b6)

From: Capehart, Bruce P. DURVAMC
Sent: Wednesday, June 26, 2019 7:47 AM
To: Fuller, Matthew A. (PBM) <(b6) va.gov>; Schreiber, Matthew A. (b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>
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(b6) [redacted]

[redacted].

Regards,

Bruce

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Sent Date:	2019/06/26 09:42:31
Delivered Date:	2019/06/26 09:42:28
Message Flags:	Unread Unsent

AMERICAN OVERSIGHT

From:	Emmendorfer, Thomas (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC96BB44E7AE2C94C43B55D094-EMMENDORFER>
To:	Streit, Phillip P /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=acfac72743604e3b8e80a555ebba45df-Streit, Phi <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>
Subject:	RE: J&J updates
Date:	2019/03/12 11:30:00
Priority:	Normal
Type:	Note

Hi Phillip,

Calling you now with a few questions ☺

Tom

From: Streit, Phillip P
Sent: Tuesday, March 12, 2019 11:18 AM
To: Zacher, Jennifer L. (PBM) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: J&J updates

Tom,
The pharmacy enrollment form is attached. I also included the ordering summary. I didn't mention in the summary that the pharmacy enrollment is not operational on the website as this must be pending as they have the link on their site https://www.spravatorems.com/pharmacies. Either way, the printed form can be downloaded there as well.

Phillip

From: Zacher, Jennifer L. (PBM)
Sent: Tuesday, March 12, 2019 8:03 AM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Cc: Streit, Phillip P <(b6) va.gov>
Subject: RE: J&J updates

Yes. The said that the facilities can be registered via the online portal. The pharmacy portion is not up and running yet, but they gave me a form that can be used to register the pharmacies. I don't think they can accept patient enrollment yet because the product still isn't available.

Phillip has a draft document in the works for the REMS requirements, so including him here so that he can send to you. We will just continue to tweak as the site rolls out.

AMERICAN OVERSIGHT

Phillip, can you also attach the pharmacy enrollment form that I sent yesterday? I am technologically challenged today.
JZ

From: Emmendorfer, Thomas (PBM)
Sent: Tuesday, March 12, 2019 10:01 AM
To: Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: J&J updates

Hi Jenn,

Did J&J get back to you about the Spravato REMS website so we could work on the guidelines to the VA medical facilities that includes expectations of the authorized representative, prescribers, pharmacies, ect…?

As of this morning (about 2 hours ago), the "Register" link is still not active on the Spravato® REMS website.

Tom

Sender:	Emmendorfer, Thomas (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC96BB44E7AE2C94C43B55D094-EMMENDORFER>
Recipient:	Streit, Phillip P /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=acfac72743604e3b8e80a555ebba45df-Streit, Phi <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen (b6) @va.gov>
Sent Date:	2019/03/12 11:30:37
Delivered Date:	2019/03/12 11:30:00

AMERICAN OVERSIGHT

From:	Zacher, Jennifer L. (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9027C425646E4DE8A7D196908016331B-ZACHER, JEN <(b6) va.gov>
To:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; Streit, Phillip P /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=acfac72743604e3b8e80a555ebba45df-Streit, Phi <(b6) va.gov>
Subject:	RE: J&J updates
Date:	2019/03/12 12:12:09
Priority:	Normal
Type:	Note

Will do

From: Emmendorfer, Thomas (PBM)
Sent: Tuesday, March 12, 2019 11:11 AM
To: Streit, Phillip P <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: J&J updates

Hi Jenn,

At the next break, could you give me a call at (b6)

I have two ideas for the draft REMS document Phillip prepared and I just want to run them by you before we pick one of the options or maybe go with a different option altogether.

Tom

From: Streit, Phillip P
Sent: Tuesday, March 12, 2019 11:18 AM
To: Zacher, Jennifer L. (PBM) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: J&J updates

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AMERICAN OVERSIGHT

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Recipient:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; Streit, Phillip P /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=acfac72743604e3b8e80a555ebba45df-Streit, Phi <(b6) va.gov>
Sent Date:	2019/03/12 12:12:07
Delivered Date:	2019/03/12 12:12:09

AMERICAN OVERSIGHT

From:	Valentino, Michael (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO, <(b6) va.gov>
To:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>; Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat <(b6) va.gov>; Boyd, Teresa D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6886a7d555a43e0bee23c1e40e1c234-Boyd, Teres <(b6) va.gov>; Bernstein, Alan /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5615e4f1515c44a0bacca1342ca03634-Bernstein, (l(b6) va.gov>; Screen, Gina /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=777aa6921e794e42a45a07d8235767c5-Screen, Gin <(b6) va.gov>; Lieberman, Steven /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=25138f5d2e734afa81397f0b357cbcc1-Lieberman, (l(b6) va.gov>; Jensen, Jon M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddeb735ace76400db5c3f10603188a14-Jensen, Jon (l(b6) va.gov>; Franklin, Keita /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15ea4a5623c141d0a1d02611f7e975cd-Franklin, K (l(b6) va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) va.gov>
Subject:	RE: J&J Media Statement 5PM 6/12
Date:	2019/06/12 15:44:18
Priority:	Normal
Type:	Note

(b6) .

But in my opinion, (b6) .

(b6)

.....

Mike

AMERICAN OVERSIGHT

From: Wiechers, Ilse
Sent: Wednesday, June 12, 2019 3:31 PM
To: Carroll, David (VACO) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Fuller, Matthew A. (PBM) <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>; Bernstein, Alan (I(b6) va.gov>; Screen, Gina <(b6) va.gov>; Lieberman, Steven (I(b6) va.gov>; Jensen, Jon M. (I(b6) ov>; Franklin, Keita (I(b6) va.gov>
Subject: RE: J&J Media Statement 5PM 6/12

My concern is (b6)

Partnership with the VA

- • Throughout the partnership with the VA on this public education campaign and beyond, we have strictly complied with the laws in place that govern partnerships across industry and government related to ethics and conflicts of interest.

Ilse

From: Carroll, David (VACO)
Sent: Wednesday, June 12, 2019 12:17 PM
To: Wiechers, Ilse (b6) @va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Fuller, Matthew A. (PBM) <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>; Wiechers, Ilse <Ilse.Wiechers@va.gov>; Bernstein, Alan <(b6) va.gov>; Screen, Gina <(b6) va.gov>; Lieberman, Steven (I(b6) va.gov>; Jensen, Jon M. (I(b6) va.gov>; Franklin, Keita (I(b6) va.gov>
Subject: J&J Media Statement 5PM 6/12
Importance: High

Dr. Franklin received the attached Media Response that J&J is making to the media today (5PM). They asked for any concerns from VA. Although there may not be anything technically wrong (e.g., VA does have a MOA with J&J), the MOA has nothing to do directly with Spravato or it development or use. (b6) Adding Dr. Wiechers and other leaders involved in our implementation of Spravato for their guidance on a response.

From: Wiechers, Ilse
Sent: Wednesday, June 12, 2019 2:24 AM
To: Carroll, David (VACO) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Fuller, Matthew A. (PBM) <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>
Subject: Esketamine Community of Practice call tomorrow @ 2 pm ET

AMERICAN OVERSIGHT

Hi everyone –

A quick reminder of the call in information for those able to join tomorrow. Please use the MODERATOR code listed below, as I anticipate we may need to mute the audience due to large number of participants.

Matthew – I will turn it over to you for slides 18-19 on updates re PBM policies. Please feel free to edit those slides if you like and send me revised slides tomorrow by 1 pm ET.

Join Skype Meeting (Trouble Joining? Try Skype Web App)
Join audio by VANTS at 1-800-767-1750, moderator 13331#

Thanks,
Ilse

***

Ilse R. Wiechers, MD, MPP, MHS
National Director, Psychotropic Drug Safety Initiative (PDSI)
Associate Director, Northeast Program Evaluation Center
Office of Mental Health and Suicide Prevention (10NC5), Department of Veterans Affairs
Assistant Clinical Professor of Psychiatry, Yale University School of Medicine
cell (b6)
(b6) va.gov | (b6) yale.edu

Sender:	Valentino, Michael (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO, <(b6) va.gov>
Recipient:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>; Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat <(b6) va.gov>; Boyd, Teresa D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6886a7d555a43e0bee23c1e40e1c234-Boyd, Teres <(b6) va.gov>; Bernstein, Alan /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5615e4f1515c44a0bacca1342ca03634-Bernstein, (b6) va.gov>; Screen, Gina /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=777aa6921e794e42a45a07d8235767c5-Screen, Gin <(b6) va.gov>; Lieberman, Steven /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=25138f5d2e734afa81397f0b357cbcc1-Lieberman, (b6) va.gov>; Jensen, Jon M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddeb735ace76400db5c3f10603188a14-Jensen, Jon

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	(b6) va.gov>; Franklin, Keita /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15ea4a5623c141d0a1d02611f7e975cd-Franklin, K (b6) va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) va.gov>
Sent Date:	2019/06/12 15:44:17
Delivered Date:	2019/06/12 15:44:18
From:	Franklin, Keita /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=15EA4A5623C141D0A1D02611F7E975CD-FRANKLIN, K (b6) va.gov>
To:	(b6) @its.jnj.com>
CC:	(b6) l@its.jnj.com>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>
Subject:	RE: REVIEW REQUESTED: Media Response
Date:	2019/06/12 14:44:34
Importance:	High
Priority:	Urgent
Type:	Note

(b6)

Thanks for the note..From my perspective this looks accurate. I would add the following if you all think is helpful:

- • * We have an MOU that details out our collaboration – it is built on a 3 pronged approach – 1) outreach 2) precision medicine 3) research/data analytics. This work does not involve any exchange of funds…

I have also cc'd my supervisor – Dr. Carroll who leads our entire MH portfolio - in case he or other program offices should look at this for accuracy beyond my program office.

Keita

From: (b6) @its.jnj.com>
Sent: Wednesday, June 12, 2019 2:36 PM
To: Franklin, Keita (b6) va.gov>
Cc: (b6) @its.jnj.com>; (b6) @its.jnj.com>
Subject: [EXTERNAL] REVIEW REQUESTED: Media Response

AMERICAN OVERSIGHT

Dr. Franklin: We received a media inquiry from Center for Public Integrity. Attached is how we plan to respond. As it includes information related to our partnership with the VA, we wanted to provide you an opportunity to review to ensure the information shared is accurate.

Apologies for the tight turnaround but we need to respond to the reporter by close of business today, so kindly share any input by 5PM today. Thanks so much and feel free to call (b6) or I with any questions.

Regards,

(b6)
Business Communications Leader
Janssen
Cell: (b6)

Sender:	Franklin, Keita /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=15EA4A5623C141D0A1D02611F7E975CD-FRANKLIN, K <(b6) va.gov>
Recipient:	(b6) @its.jnj.com>; (b6) son@its.jnj.com>; (b6) its.jnj.com>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>
Sent Date:	2019/06/12 14:44:33
Delivered Date:	2019/06/12 14:44:34

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To:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>; Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat <(b6) va.gov>; Boyd, Teresa D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6886a7d555a43e0bee23c1e40e1c234-Boyd, Teres <(b6) va.gov>; Bernstein, Alan /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5615e4f1515c44a0bacca1342ca03634-Bernstein, <(b6) va.gov>; Screen, Gina /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=777aa6921e794e42a45a07d8235767c5-Screen, Gin <(b6) va.gov>; Lieberman, Steven /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=25138f5d2e734afa81397f0b357cbcc1-Lieberman, (b6) va.gov>; Jensen, Jon M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddeb735ace76400db5c3f10603188a14-Jensen, Jon (b6) va.gov>; Franklin, Keita /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15ea4a5623c141d0a1d02611f7e975cd-Franklin, K (b6) va.gov>
Subject:	RE: J&J Media Statement 5PM 6/12
Date:	2019/06/12 15:39:46
Priority:	Normal
Type:	Note

Since we don't know what questions Janssen is responding to, (b6)

From: Wiechers, Ilse
Sent: Wednesday, June 12, 2019 3:31 PM
To: Carroll, David (VACO) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Fuller, Matthew A. (PBM) <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>; Bernstein, Alan <(b6) va.gov>; Screen, Gina <(b6) va.gov>; Lieberman, Steven <(b6) va.gov>; Jensen, Jon M. <(b6) va.gov>; Franklin, Keita <(b6) va.gov>
Subject: RE: J&J Media Statement 5PM 6/12

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(b6) b6)

Partnership with the VA

- • Throughout the partnership with the VA on this public education campaign and beyond, we have strictly complied with the laws in place that govern partnerships across industry and government related to ethics and conflicts of interest.

Ilse

From: Carroll, David (VACO)
Sent: Wednesday, June 12, 2019 12:17 PM
To: Wiechers, Ilse (b6) @va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Fuller, Matthew A. (PBM) <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>; Wiechers, Ilse <Ilse.Wiechers@va.gov>; Bernstein, Alan <(b6) va.gov>; Screen, Gina <(b6) va.gov>; Lieberman, Steven <(b6) va.gov>; Jensen, Jon M. <(b6) va.gov>; Franklin, Keita <(b6) va.gov>
Subject: J&J Media Statement 5PM 6/12
Importance: High

Dr. Franklin received the attached Media Response that J&J is making to the media today (5PM). They asked for any concerns from VA. Although there may not be anything technically wrong (e.g., VA does have a MOA with J&J), (b6) . Adding Dr. Wiechers and other leaders involved in our implementation of Spravato for their guidance on a response.

From: Wiechers, Ilse
Sent: Wednesday, June 12, 2019 2:24 AM
To: Carroll, David (VACO) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Fuller, Matthew A. (PBM) <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>
Subject: Esketamine Community of Practice call tomorrow @ 2 pm ET

Hi everyone –

A quick reminder of the call in information for those able to join tomorrow. Please use the MODERATOR code listed below, as I anticipate we may need to mute the audience due to large number of participants.

Matthew – I will turn it over to you for slides 18-19 on updates re PBM policies. Please feel free to edit those slides if you like and send me revised slides tomorrow by 1 pm ET.

Join Skype Meeting (Trouble Joining? Try Skype Web App)

AMERICAN OVERSIGHT

Join audio by VANTS at 1-800-767-1750, moderator 13331#

Thanks,
Ilse

***

Ilse R. Wiechers, MD, MPP, MHS
National Director, Psychotropic Drug Safety Initiative (PDSI)
Associate Director, Northeast Program Evaluation Center
Office of Mental Health and Suicide Prevention (10NC5), Department of Veterans Affairs
Assistant Clinical Professor of Psychiatry, Yale University School of Medicine
cell (b6)
(b6) @va.gov | (b6) yale.edu

Recipient:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>; Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat <(b6) va.gov>; Boyd, Teresa D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6886a7d555a43e0bee23c1e40e1c234-Boyd, Teres <(b6) va.gov>; Bernstein, Alan /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5615e4f1515c44a0bacca1342ca03634-Bernstein, <(b6) va.gov>; Screen, Gina /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=777aa6921e794e42a45a07d8235767c5-Screen, Gin <(b6) va.gov>; Lieberman, Steven /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=25138f5d2e734afa81397f0b357cbcc1-Lieberman, <(b6) va.gov>; Jensen, Jon M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddeb735ace76400db5c3f10603188a14-Jensen, Jon <(b6) va.gov>; Franklin, Keita /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15ea4a5623c141d0a1d02611f7e975cd-Franklin, K <(b6) va.gov>
Sent Date:	2019/06/12 15:39:50
Delivered Date:	2019/06/12 15:39:46
Message Flags:	Unread Unsent

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From:	Capehart, Bruce P. DURVAMC /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6866EFF4E9DF4A48846D056A02044C38-CAPEHART, B <(b6) va.gov>
To:	Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat <(b6) va.gov>; Durkee, Melissa DURVAMC /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f2f14f08cdca46b2a8db4c77a09a93d9-Durkee, Mel <(b6) va.gov>
Subject:	RE: is this document the most recent esketamine CFU?
Date:	2019/06/24 16:07:51
Priority:	Normal
Type:	Note

Terrific. Thank you.

From: Fuller, Matthew A. (PBM)
Sent: Monday, June 24, 2019 3:41 PM
To: Capehart, Bruce P. DURVAMC <(b6) va.gov>; Durkee, Melissa DURVAMC <(b6) va.gov>
Subject: RE: is this document the most recent esketamine CFU?

Hi Bruce,

The CFU is posted. It can be accessed via this link. Esketamine (SPRAVATO) CFU.
Word document also attached.

Thanks.

Matthew

From: Capehart, Bruce P. DURVAMC
Sent: Monday, June 24, 2019 3:34 PM
To: Fuller, Matthew A. (PBM) <(b6) va.gov>; Durkee, Melissa DURVAMC <(b6) va.gov>
Subject: is this document the most recent esketamine CFU?

Matthew,

Is the attached document the final approved version? I lost track of all the changes we made on your laptop and in the final discussion.

Missy Durkee, copied above, is trying to move ahead with a local nasal esketamine protocol.

Regards,

AMERICAN OVERSIGHT

Bruce

From: Durkee, Melissa DURVAMC
Sent: Monday, June 24, 2019 1:08 PM
To: Capehart, Bruce P. DURVAMC <(b6) va.gov>
Subject: RE: news story on esketamine and VA

They're actually on the web site now dated May 2019. Think they'll change?

From: Capehart, Bruce P. DURVAMC
Sent: Monday, June 24, 2019 12:46 PM
To: Durkee, Melissa DURVAMC <(b6) va.gov>; Bryan, William E DURVAMC (b6) @va.gov>; Hashem, Mohamed G DURVAMC <(b6) @va.gov>; Harris, Robert A, DVAHCS (b6) @va.gov>; Britnell, Sara, DURVAMC (b6) @va.gov>
Subject: RE: news story on esketamine and VA

PBM will issue final documents on Wednesday. While it's helpful to start a dialogue now, important details will follow later in the week. One of those docs will be the CFU with several specific in/exclusion criteria. You may want to defer the CFU vs generic PADR until after reading PBM's final CFU document.

From: Durkee, Melissa DURVAMC
Sent: Monday, June 24, 2019 12:34 PM
To: Capehart, Bruce P. DURVAMC <(b6) va.gov>; Bryan, William E DURVAMC <(b6) @va.gov>; Hashem, Mohamed G DURVAMC <(b6) @va.gov>; Harris, Robert A, DVAHCS (b6) 3) @va.gov>; Britnell, Sara, DURVAMC (b6) @va.gov>
Subject: RE: news story on esketamine and VA

We'll need to think about the PADR process and how to document Dr. Leinbach/Mankad's approval and build that into our SOP. I'll send an email to Dr. L and get the ball rolling to see if we're going to go CFU based or general padr.

From: Capehart, Bruce P. DURVAMC
Sent: Monday, June 24, 2019 10:37 AM
To: Durkee, Melissa DURVAMC <(b6) va.gov>; Bryan, William E DURVAMC (b6) @va.gov>; Hashem, Mohamed G DURVAMC (b6) @va.gov>; Harris, Robert A, DVAHCS (b6) @va.gov>; Britnell, Sara, DURVAMC (b6) @va.gov>
Subject: news story on esketamine and VA

All,

You might be interested in this link regarding the MAP decision last week to keep nasal esketamine non-formulary:

https://www.statnews.com/2019/06/21/va-declines-broad-coverage-for-new-jj-depression-drug-touted-by-trump/

Important details are forthcoming from PBM.

AMERICAN OVERSIGHT

Regards,

Bruce

Sender:	Capehart, Bruce P. DURVAMC /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6866EFF4E9DF4A48846D056A02044C38-CAPEHART, B <(b6) va.gov>
Recipient:	Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat <(b6) va.gov>; Durkee, Melissa DURVAMC /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f2f14f08cdca46b2a8db4c77a09a93d9-Durkee, Mel <(b6) va.gov>
Sent Date:	2019/06/24 16:07:50
Delivered Date:	2019/06/24 16:07:51
Message Flags:	Unread

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From:	Wiechers, Ilse /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0C7B1428D9E4233A641F125C5B6FC4F-WIECHERS, I (b6) @va.gov>
To:	Torrise, Virginia (VHACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=519204df507344ac8fa3045b2b4fc762-Torrise, Vi (b6) @va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>
Subject:	RE: Intranasal esketamine draft guidelines
Date:	2019/03/07 10:13:42
Priority:	Normal
Type:	Note

Thanks, Ginny!

Jennifer – looks like we got connected on another esketamine thread this AM as well. Look forward to working with you and PBM on sorting things out on how best to move forward. Let me know how I can be of most help.

Thanks,
Ilse

From: Torrise, Virginia (VHACO)
Sent: Thursday, March 07, 2019 4:10 AM
To: Wiechers, Ilse (b6) @va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: Intranasal esketamine draft guidelines

Connecting you to Jennifer. She oversees our formulary committee reviews and the Clinical Pharmacy team that provides the reviews.

From: Wiechers, Ilse
Sent: Wednesday, March 06, 2019 3:30 PM
To: Torrise, Virginia (VHACO) (b6) @va.gov>
Subject: FW: Intranasal esketamine draft guidelines

Hi Ginny –

Hope all is well, and sorry to have missed you at the AD F2F in Orlando.

I'm sure you've heard the news about intranasal esketamine FDA approval. Wondering how I can help us start the process to get VHA policy sorted out for this. I worked closely with Todd and Fran on developing the IV ketamine guidance and would welcome the opportunity to work with PBM on this again now.

Thanks,
Ilse

AMERICAN OVERSIGHT

From: Wiechers, Ilse
Sent: Wednesday, March 06, 2019 12:25 PM
To: Mankad, Mehul V. DURVAMC (b6) @va.gov>
Cc: Leinbach, Jonathan E DURVAMC (b6) @va.gov>; Kahlon, Christie H. (b6) @va.gov>
Subject: RE: Intranasal esketamine draft guidelines

Mehul –

I was following the intranasal esketamine approval closely as well, and you are right, questions will start coming from patients and others soon. Currently we do not have anything drafted re intranasal, but I will start working with PBM and OMHSP to address this.

As for APA, I will indeed be there! Hope to be able to make it to the NC party.

Best,
Ilse

From: Mankad, Mehul V. DURVAMC
Sent: Wednesday, March 06, 2019 11:13 AM
To: Wiechers, Ilse (b6) @va.gov>
Cc: Leinbach, Jonathan E DURVAMC (b6) @va.gov>; Kahlon, Christie H. <(b6) @va.gov>
Subject: Intranasal esketamine draft guidelines

Hi Ilse,

We were wondering if VACO has any draft guidelines for the use of intranasal esketamine. It's a matter of time before the requests start coming in from patients and providers for this newly FDA-approved agent. We have seen the draft guidelines on intravenous ketamine for psychiatric disorders and had an opportunity to comment on those when they were being developed.

I'm including our ACOS/MH and psych clinical pharmacy specialist on this email.

Also, I imagine you will be going to APA in May given its proximity to your home. We will be hosting our second North Carolina party on Sunday night of APA. Anyone who has an NC connection is welcome to attend. I can send you details.

Regards,

Mehul Mankad, MD
Chief of Psychiatry
Chief of Acute Care Division
Durham VA HCS

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Sender:	Wiechers, Ilse /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0C7B1428D9E4233A641F125C5B6FC4F-WIECHERS, I (b6) va.gov>
Recipient:	Torrise, Virginia (VHACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=519204df507344ac8fa3045b2b4fc762-Torrise, Vi (b6) @va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>
Sent Date:	2019/03/07 10:13:41
Delivered Date:	2019/03/07 10:13:42

AMERICAN OVERSIGHT

To:	Eickhoff, Christine J. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e498b29c368442887ee6f2b7d34b51b-Eickhoff, C (b6) a.gov>
CC:	Bernstein, Alan /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5615e4f1515c44a0bacca1342ca03634-Bernstein, <(b6) va.gov>; VHA 10P10 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=274ac0217e274f43b75aee2290319945-VHA 10P10 A <VHA10P10Actions@va.gov>; Weistreich, Tracy L. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e04e4d71142c4848947404ce65bea6d1-Weistreich, (b6) @va.gov>; Law, Cassandra M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f888d507d6c54eb5a92fc44199eb5838-Law, Cassan <(b6) va.gov>; VHA 10P4 Communication Group /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4ba2ff9b4604547be7834a71415253c-VHA 10P4 Co <vha10p4comm@va.gov>; VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>
Subject:	RE: Inquires about SGB at VA Medical Centers
Date:	2019/06/24 21:02:23
Priority:	Normal
Type:	Note

Here are the talking points that have been cleared by our leadership.

From: Eickhoff, Christine J.
Sent: Monday, June 24, 2019 4:58 PM
To: Carroll, David (VACO) <(b6) va.gov>
Cc: Bernstein, Alan <(b6) va.gov>; VHA 10P10 Actions <VHA10P10Actions@va.gov>; Weistreich, Tracy L. (b6) @va.gov>; Law, Cassandra M. <(b6) va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>
Subject: Inquires about SGB at VA Medical Centers
Importance: High

Good Afternoon Dr. Carroll,

We are still receiving inquiries about the availability of SGB at various VA facilities and within specific geographic regions. We have done our best to send prompt replies with general information about how patients can follow up with their VA providers for more information about PTSD treatments and to answer specific questions about CCI's collaboration with the providers at the Long Beach VA Healthcare System. The talking points your office is developing will be very helpful, so thank you in advance for sharing those details.

Who in 10N should I refer inquires to in cases where questions are related to services provided at VA medical centers? Some of the inquiries we are receiving do not fall under the purview of our office.

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Thank you,

Christine Eickhoff
Health System Specialist
10P10 Office of Community Engagement (OCE)
Washington, DC 20420
(b6)

Recipient:	Eickhoff, Christine J. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e498b29c368442887ee6f2b7d34b51b-Eickhoff, C <(b6) @va.gov>; Bernstein, Alan /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5615e4f1515c44a0bacca1342ca03634-Bernstein, <(b6) va.gov>; VHA 10P10 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=274ac0217e274f43b75aee2290319945-VHA 10P10 A <VHA10P10Actions@va.gov>; Weistreich, Tracy L. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e04e4d71142c4848947404ce65bea6d1-Weistreich, (b6) @va.gov>; Law, Cassandra M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f888d507d6c54eb5a92fc44199eb5838-Law, Cassan <(b6) va.gov>; VHA 10P4 Communication Group /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4ba2ff9b4604547be7834a71415253c-VHA 10P4 Co <vha10p4comm@va.gov>; VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>
Sent Date:	2019/06/24 21:02:28
Delivered Date:	2019/06/24 21:02:23
Message Flags:	Unread Unsent
From:	Dudley, Tracy /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2bef1c88d64447bc9087572c951d0cb1-Dudley, Tra (b6) @va.gov>
To:	Cunningham, Kristin /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=751e0c41ec7842bf9f125e521c2210d0-Cunningham, <(b6) va.gov>; RICKS, TARA /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=78f7ce01f841454d809345d1c1d98483-RICKS, TARA <(b6) va.gov>
CC:	Diamond, Sue OSI /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dbe74b578de4d2b83334f00cc6bed3c-Diamond, Su <(b6) va.gov>; Pedene, Paula L. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0915253a9464acd9130816941bc7f5b-Pedene, Pau <(b6) va.gov>; Greilsamer, Alan /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fc02807af08443fbb5c68c590d58fa4b-Greilsamer, <(b6) va.gov>; MISSION ACT Action Items /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f18bef245b8744b9a8d49d03a22c192d-MISSION ACT <MISSIONACTActionItems@va.gov>; VHA 10NC Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aeebc70340b3476a87b15fbe600f1888-VHA 10NC Ac <vha10ncaction@va.gov>; VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group

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	(FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>; VHA MISSION Act Core Team /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3edfe913aa924e36a5c97be6976f7304-VHA MISSION <VHAMISSIONActCoreTeam@va.gov>
Subject:	FW: Leadership Requesting: Talking Points and Data Need for VA Mental Health Clinicians on Stellate Ganglion Block Procedure
Date:	2019/06/20 15:21:33
Priority:	Normal
Type:	Note

Good Afternoon

On behalf of 10NC, Dr Sherrie Schuldheis clears the response from 10NC5.

Thank You!
Tracy

Tracy L. Dudley
Health System Specialist
ADUSH for Clinical Operations (10NC)
(b6)
(b6) (iPhone)

From: Schuldheis, Sherrie L, Ph.D
Sent: Thursday, June 20, 2019 3:16 PM
To: Dudley, Tracy (b6) @va.gov>; VHA 10NC Clearance <VHA10NCClearance2@va.gov>
Subject: RE: Leadership Requesting: Talking Points and Data Need for VA Mental Health Clinicians on Stellate Ganglion Block Procedure

10NC clears

Sherrie Schuldheis, PhD, RN, CENP
Special Assistant, ADUSH Clinical Operations
VHA 10NC
810 Vermont NW
Washington, DC 20420
(b6)
(b6) va.gov

From: Gavin, Stacy
Sent: Thursday, June 20, 2019 2:57 PM
To: VHA CO 10NC Front Office HSSs <VHACO10NCFOHSSs@va.gov>

AMERICAN OVERSIGHT

Cc: VHA 10NC5 Action <VHA10NC5Action@va.gov>; Schnurr, Paula P. <(b6) va.gov>; Holtzheimer, Paul <(b6) va.gov>
Subject: FW: Leadership Requesting: Talking Points and Data Need for VA Mental Health Clinicians on Stellate Ganglion Block Procedure

Good afternoon,

With apologies for the delay, please see the talking points below:

10NC5 Response:

- (b) (5)

AMERICAN OVERSIGHT

- [redacted]

[redacted].

From: RICKS, TARA
Sent: Thursday, June 20, 2019 10:21 AM
To: Cunningham, Kristin <[redacted]>; Diamond, Sue OSI <[redacted]>; Poff, Susan <[redacted]>; Pedene, Paula L. <[redacted]>; Burden, Rachael <[redacted]>; VACO 80E1 <vaco80e1@mail.va.gov>; Greilsamer, Alan <[redacted]>; Small, Stephanie T. <[redacted]>; Eason, William J. <[redacted]>; Ackerman, William <[redacted]>; Andringa, Elizabeth D. <[redacted]>; Baum, Robert <Robert.Baum@va.gov>; Bennett, Jennifer (Jenna) <[redacted]>; Boyd, Teresa D. <[redacted]>; Bucsko, Daniel <[redacted]>; Chesney, Colin <[redacted]>; Davidson, Benjamin C. (ERPi) <[redacted]>; Diamond, Sue OSI <[redacted]>; Goldsberry, Wilmya <[redacted]>; Gore, Ohm J. (Booz Allen Hamilton) <[redacted]>; Gramlick, Debbie <[redacted]>; Greenstone, Clinton <[redacted]>; Hayes, Terrence <[redacted]>; Heard, Maureen <[redacted]>; Jaastad, Derrick <[redacted]>; Jenkins, Matthew A <[redacted]>; Kelley, Kimberly <[redacted]>; MacDonald, Jennifer E. (Physician) <[redacted]>; Oshinski, Renee <[redacted]>; Paige, Paula <[redacted]>; Roberts, Kirsten L. (ERPI) <[redacted]>; Scanlon, Aimee B. <[redacted]>; Sommers, Evelyn <[redacted]>; Subbu, Sankalpa <[redacted]>; VHA 10D Action <VHA10DAction@va.gov>; VHA 10N Action <VHA10NAction@va.gov>; VHA 10NG Action <VHA10NGAction@va.gov>; VHA Healthcare Operations Center <VHAHOC@va.gov>; Warner, Debra L. <[redacted]>; White, Crystal M. <[redacted]>; Williams, Joseph A (OSI) <[redacted]>; Smith, Clifford A. <[redacted]>; Carroll, David (VACO) <[redacted]>; Daniels, Lindsay <[redacted]>; Gavin, Stacy <[redacted]>; McGuire, Marsden H. <[redacted]>; Miller, Matthew (VCL Director) <[redacted]>; Pollack, Stacey <[redacted]>; Pomerantz, Andrew <[redacted]>; Smith, Clifford A. <[redacted]>; Strmiska, Jon G. <[redacted]>
Cc: Ackerman, William <[redacted]>; Andringa, Elizabeth D. <[redacted]>; Bagchi, Kaushiki M. (APTIVE Resources LLC) <[redacted]>; Boccia, Alexis L <[redacted]>; Galagaza, Geraldine <[redacted]>; Heard, Maureen <[redacted]>; Kelley, Kimberly <[redacted]>; Parker, Ginger <[redacted]>; Pedene, Paula L. <[redacted]>; Screen, Gina <[redacted]>; Seekins, DeAnne <[redacted]>; Hutchins, Anne C SAMVAMC <[redacted]>; Buyck, David W SAMVAMC <[redacted]>

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Subject: RE: Leadership Requesting: Talking Points and Data Need for VA Mental Health Clinicians on Stellate Ganglion Block Procedure

Thank you Ms. Cunningham. We will await guidance.

Adding my ND, COS, and Mental Health Chief since the visibility of this request is moving beyond the public affairs arena.

From: Cunningham, Kristin
Sent: Thursday, June 20, 2019 10:17 AM
To: RICKS, TARA <(b6) va.gov>; Diamond, Sue OSI <(b6) va.gov>; Poff, Susan <(b6) va.gov>; Pedene, Paula L. <(b6) va.gov>; Burden, Rachael <(b6) va.gov>; VACO 80E1 <vaco80e1@mail.va.gov>; Greilsamer, Alan <(b6) va.gov>; Small, Stephanie T. <(b6) va.gov>; Eason, William J. <(b6) va.gov>; VHA MISSION Act Core Team <VHAMISSIONActCoreTeam@va.gov>; Smith, Clifford A. <(b6) va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>
Cc: Ackerman, William <(b6) va.gov>; Andringa, Elizabeth D. <(b6) va.gov>; Bagchi, Kaushiki M. (APTIVE Resources LLC) <(b6) va.gov>; Boccia, Alexis L <(b6) va.gov>; Galagaza, Geraldine <(b6) va.gov>; Heard, Maureen <(b6) va.gov>; Kelley, Kimberly <(b6) va.gov>; Parker, Ginger <(b6) va.gov>; Pedene, Paula L. <(b6) va.gov>; Screen, Gina <(b6) va.gov>; Cunningham, Kristin <(b6) va.gov>
Subject: RE: Leadership Requesting: Talking Points and Data Need for VA Mental Health Clinicians on Stellate Ganglion Block Procedure

Adding Dr Smith and 10NC5 action. They are working on guidance for the SGB.

Kristin J. Cunningham, PMP
Executive Officer to the Deputy Under Secretary
for Health for Community Care
Office of Community Care
P – (b6)
Email: (b6) va.gov

From: RICKS, TARA
Sent: Thursday, June 20, 2019 10:15 AM
To: Diamond, Sue OSI <(b6) va.gov>; Poff, Susan <(b6) va.gov>; Pedene, Paula L. <(b6) va.gov>; Burden, Rachael <(b6) va.gov>; VACO 80E1 <vaco80e1@mail.va.gov>; Greilsamer, Alan <(b6) va.gov>; Small, Stephanie T. <(b6) va.gov>; Eason, William J. <(b6) va.gov>; VHA MISSION Act Core Team <VHAMISSIONActCoreTeam@va.gov>
Cc: Ackerman, William <(b6) va.gov>; Andringa, Elizabeth D. <(b6) va.gov>; Bagchi, Kaushiki M. (APTIVE Resources LLC) <(b6) va.gov>; Boccia, Alexis L <(b6) va.gov>; Galagaza, Geraldine <(b6) va.gov>; Heard,

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Maureen <(b6) va.gov>; Kelley, Kimberly <(b6) va.gov>; Parker, Ginger <(b6) va.gov>; Pedene, Paula L. <(b6) va.gov>; Screen, Gina <(b6) va.gov>
Subject: RE: Leadership Requesting: Talking Points and Data Need for VA Mental Health Clinicians on Stellate Ganglion Block Procedure

Thank you Ms. Diamond.

From: Diamond, Sue OSI
Sent: Thursday, June 20, 2019 10:07 AM
To: RICKS, TARA <(b6) va.gov>; Poff, Susan <(b6) va.gov>; Pedene, Paula L. <(b6) va.gov>; Burden, Rachael <(b6) va.gov>; VACO 80E1 <vaco80e1@mail.va.gov>; Greilsamer, Alan <(b6) va.gov>; Small, Stephanie T. <(b6) va.gov>; Eason, William J. <(b6) va.gov>; VHA MISSION Act Core Team <VHAMISSIONActCoreTeam@va.gov>
Cc: Ackerman, William <(b6) va.gov>; Andringa, Elizabeth D. <(b6) va.gov>; Bagchi, Kaushiki M. (APTIVE Resources LLC) <(b6) va.gov>; Boccia, Alexis L <(b6) va.gov>; Galagaza, Geraldine <(b6) va.gov>; Heard, Maureen <(b6) va.gov>; Kelley, Kimberly <(b6) va.gov>; Parker, Ginger <(b6) va.gov>; Pedene, Paula L. <(b6) va.gov>; Screen, Gina <(b6) va.gov>
Subject: RE: Leadership Requesting: Talking Points and Data Need for VA Mental Health Clinicians on Stellate Ganglion Block Procedure

Adding the MISSION Act Core Team to assist with getting you a response.

From: RICKS, TARA
Sent: Thursday, June 20, 2019 10:01 AM
To: Poff, Susan <(b6) va.gov>; Pedene, Paula L. <(b6) va.gov>; Burden, Rachael <(b6) va.gov>; VACO 80E1 <vaco80e1@mail.va.gov>; Greilsamer, Alan <(b6) va.gov>; Small, Stephanie T. <(b6) va.gov>; Eason, William J. <(b6) va.gov>
Cc: Ackerman, William <(b6) va.gov>; Andringa, Elizabeth D. <(b6) va.gov>; Bagchi, Kaushiki M. (APTIVE Resources LLC) <(b6) va.gov>; Boccia, Alexis L <(b6) va.gov>; Diamond, Sue OSI <(b6) va.gov>; Galagaza, Geraldine <(b6) va.gov>; Heard, Maureen <(b6) va.gov>; Kelley, Kimberly <(b6) va.gov>; Parker, Ginger <(b6) va.gov>; Pedene, Paula L. <(b6) va.gov>; Screen, Gina <(b6) va.gov>
Subject: Leadership Requesting: Talking Points and Data Need for VA Mental Health Clinicians on Stellate Ganglion Block Procedure
Importance: High

Good morning everyone,

I wasn't sure who would be the best POC for this request – so I am emailing everyone.

AMERICAN OVERSIGHT

VISN 6 is experiencing a significant up-tick in service request from Veterans regarding the stellate ganglion block procedure, to include request to use 'Mission Act resources' if the facility doesn't offer the procedure.

Our VISN COS and VISN Mental Health Chief understand that a lot of these request are being driven by the 60 minutes segment, and that this story offered our Veterans and family members hope that relief is on the way for their persisting nightmares, anger, and fear (PTSD). Veterans are now actively calling their mental health doctors wanting this procedure within our region – and our doctors don't know what to say or how to move forward with these requests. Our clinicians are wanting specific guidance **before** Veterans go out on their own and get this procedure that VA considers 'experimental.'

In addition to SGB, Leadership would also like talking points for Spravato after the results of today's national formulary meeting. The focus of these talking points would be for our mental health doctors and what they should tell patients.

Links to the story's for quick reference.

1. • 1. The stellate ganglion block procedure LINK
2. • 2. Spravato (Ketamine-like drug) LINK

Just to reiterate this is not a request for media talking points. This is a request for talking points for our mental health teams to communicate with patients. Leadership is concerned if we do not get ahead of this it will ulitmately turn into an access or care issue especially for the health and well-being of our Veterans receiving mental health and suicide prevention services.

Thank you in advance.

Tara Ricks-Edger
Director of Communications
VISN 6 – U.S. Department of Veterans Affairs

"It is not the critic who counts; not the man who points out how the strong man stumbles, or where the doer of deeds could have done them better. The credit belongs to the man who is actually in the arena…who strives valiantly; who errs, who comes short again and again, because there is no effort without error and shortcoming; but who does actually strive to do the deeds; who knows great enthusiasms, the great devotions; who spends himself in a worthy cause; who at the best knows in the end the triumph of high achievement, and who at the worst, if he fails, at least fails while daring greatly, so that his place shall never be with those cold and timid souls who neither know victory nor defeat." - Theodore Roosevelt

Sender:	Dudley, Tracy /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2bef1c88d64447bc9087572c951d0cb1-Dudley, Tra <(b6) a.gov>
Recipient:	Cunningham, Kristin /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=751e0c41ec7842bf9f125e521c2210d0-Cunningham, <(b6) @va.gov>; RICKS, TARA /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=78f7ce01f841454d809345d1c1d98483-RICKS, TARA <(b6) va.gov>; Diamond, Sue OSI /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dbe74b578de4d2b83334f00cc6bed3c-Diamond, Su <(b6) va.gov>; Pedene, Paula L. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0915253a9464acd9130816941bc7f5b-Pedene, Pau <(b6) va.gov>;

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	Greilsamer, Alan /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fc02807af08443fbb5c68c590d58fa4b-Greilsamer, <(b6) va.gov>; MISSION ACT Action Items /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f18bef245b8744b9a8d49d03a22c192d-MISSION ACT <MISSIONACTActionItems@va.gov>; VHA 10NC Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aeebc70340b3476a87b15fbe600f1888-VHA 10NC Ac <vha10ncaction@va.gov>; VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>; VHA MISSION Act Core Team /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3edfe913aa924e36a5c97be6976f7304-VHA MISSION <VHAMISSIONActCoreTeam@va.gov>
Sent Date:	2019/06/20 15:21:30
Delivered Date:	2019/06/20 15:21:33

AMERICAN OVERSIGHT

From:	Valentino, Michael (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO, <(b6) va.gov>
To:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; McGuire, Marsden H. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29e9d648c29f4885828c10446fdd7379-McGuire, Ma <(b6) va.gov>; Katz, Ira R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=65f4e28aa7574641932c29fed7c0b4b8-Katz, Ira R <(b6) va.gov>; Drexler, Karen MD (Atlanta) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c456a9bf391415bb4bdb9b6f88bdf45-Drexler, Ka <(b6) va.gov>; Pomerantz, Andrew /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29a9288df9a34e84bddfd00cde79f11b-Pomerantz, <(b6) @va.gov>; Smith, Clifford A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b729882079394f37af66f66722f99400-Smith, Clif <(b6) va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat <(b6) va.gov>; Cunningham, Fran /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=613f0d8e535d46af95fed310f100dcbc-Cunningham, <(b6) va.gov>; Boyd, Teresa D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6886a7d555a43e0bee23c1e40e1c234-Boyd, Teres <(b6) va.gov>
Subject:	RE: Initial press re PBM esketamine decisions
Date:	2019/06/21 17:19:35
Priority:	Normal
Type:	Note

Thanks for sending Ilse...

Sent with BlackBerry Work
(www.blackberry.com)

From: Wiechers, Ilse <(b6) va.gov>
Date: Friday, Jun 21, 2019, 4:50 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>, Llorente, Maria D. <(b6) va.gov>, Carroll, David (VACO)

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<(b6) @va.gov>, McGuire, Marsden H. <(b6) va.gov>, Katz, Ira R.
<(b6) va.gov>, Drexler, Karen MD (Atlanta) <(b6) va.gov>, Pomerantz, Andrew
<(b6) va.gov>, Smith, Clifford A. <(b6) va.gov>, Emmendorfer, Thomas (PBM)
<(b6) va.gov>, Fuller, Matthew A. (PBM) <(b6) va.gov>, Cunningham, Fran
<(b6) va.gov>, Boyd, Teresa D. <(b6) va.gov>
Subject: Initial press re PBM esketamine decisions

Just found this and wanted to share.

https://www.statnews.com/2019/06/21/va-declines-broad-coverage-for-new-jj-depression-drug-touted-by-trump/

Sender:	Valentino, Michael (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO, <(b6) va.gov>
Recipient:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; McGuire, Marsden H. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29e9d648c29f4885828c10446fdd7379-McGuire, Ma <(b6) va.gov>; Katz, Ira R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=65f4e28aa7574641932c29fed7c0b4b8-Katz, Ira R <(b6) va.gov>; Drexler, Karen MD (Atlanta) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c456a9bf391415bb4bdb9b6f88bdf45-Drexler, Ka <(b6) va.gov>; Pomerantz, Andrew /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29a9288df9a34e84bddfd00cde79f11b-Pomerantz, <(b6) @va.gov>; Smith, Clifford A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b729882079394f37af66f66722f99400-Smith, Clif <(b6) va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat <(b6) va.gov>; Cunningham, Fran /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=613f0d8e535d46af95fed310f100dcbc-Cunningham, <(b6) va.gov>; Boyd, Teresa D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6886a7d555a43e0bee23c1e40e1c234-Boyd, Teres <(b6) va.gov>
Sent Date:	2019/06/21 17:19:33
Delivered Date:	2019/06/21 17:19:35

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From:	Llorente, Maria D. </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F5C91F577D894BD9A0F09305DB34DD4F-LLORENTE, M>
To:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>
Subject:	RE: Initial press re PBM esketamine decisions
Date:	2019/06/21 17:20:00
Priority:	Normal
Type:	Note

As an FYI, there was an additional inquiry this afternoon from SVAC Majority inquiry: "Committee staff are under the assumption that this drug was rejected. Any previously cleared language would be much appreciated. We'd like to share something with them today, if possible."
Explained drug was not rejected, and then same info for NYT sent forward.

-----Original Message-----
From: Wiechers, Ilse
Sent: Friday, June 21, 2019 4:50 PM
To: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; McGuire, Marsden H. <(b6) va.gov>; Katz, Ira R. <(b6) va.gov>; Drexler, Karen MD (Atlanta) <(b6) va.gov>; Pomerantz, Andrew <(b6) va.gov>; Smith, Clifford A. <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Fuller, Matthew A. (PBM) <(b6) va.gov>; Cunningham, Fran <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>
Subject: Initial press re PBM esketamine decisions

Just found this and wanted to share.

https://www.statnews.com/2019/06/21/va-declines-broad-coverage-for-new-jj-depression-drug-touted-by-trump/

Sender:	Llorente, Maria D. </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F5C91F577D894BD9A0F09305DB34DD4F-LLORENTE, M>
Recipient:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>
Sent Date:	2019/06/21 17:20:49
Delivered Date:	2019/06/21 17:20:00

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From:	Llorente, Maria D. </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F5C91F577D894BD9A0F09305DB34DD4F-LLORENTE, M>
To:	Sharpe, Virginia A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=082e348b444d4565aa069f3c7b50a090-Sharpe, Vir <(b6) va.gov>; Tompkins, Paul A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54deee370ede4ccebf82d26d8f7f62ed-Tompkins, P (b6) va.gov>
Subject:	RE: iMedConsent - intranasal esketamine
Date:	2019/03/08 14:27:00
Priority:	Normal
Type:	Note

Fantastic! Thank you.

From: Sharpe, Virginia A.
Sent: Friday, March 8, 2019 2:28 PM
To: Llorente, Maria D. <(b6) va.gov>; Tompkins, Paul A. (b6) va.gov>
Subject: RE: iMedConsent - intranasal esketamine

Thank you, I've received the email from Ilse and will cc you on the reply.
Ashby

From: Llorente, Maria D.
Sent: Friday, March 08, 2019 2:26 PM
To: Sharpe, Virginia A. <(b6) va.gov>; Tompkins, Paul A. <(b6) va.gov>
Subject: RE: iMedConsent - intranasal esketamine

Thank you very much. Tom Emmendorfer reached out to mental health program office re the ketamine informed consent and Ilse Wiechers was going to be reaching out to you. I will forward this to the group to assure communication. Thank you again for raising this question this morning.
Maria Llorente

From: Sharpe, Virginia A.
Sent: Friday, March 8, 2019 2:17 PM
To: Llorente, Maria D. <(b6) va.gov>; Tompkins, Paul A. <(b6) va.gov>
Subject: iMedConsent - intranasal esketamine

Hi Maria – Great to meet you this morning. I wanted you to have my contact info and also provide you with information about the process to develop a consent form for intranasal esketamine. I'm adding Paul Tompkins from my office in case he has more to add.
Paul Dr. Llorente is here on detail to PCS from the DCVA.
Ashby

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Here's the information about the risk threshold for treatments and procedures requiring signature informed consent:

VHA Handbook 1004.01, Informed Consent for Clinical Treatments and Procedures, dated August 14, 2009 (Revised May 22, 2017).

(2) **Treatments and Procedures That Require Signature Consent.** Prior to undertaking certain treatments and procedures, the practitioner must document the informed consent process in detail (as specified in subpars. 13c(2)(a) and 13c(2)(b)) and obtain the patient's signature on a VA authorized consent form.
(a) The patient's signature consent must be obtained for treatments and procedures that:
1. Can be reasonably expected to produce significant pain or discomfort to the patient;
2. Can be reasonably expected to produce pain or discomfort to the patient that is substantial enough to require sedation, anesthesia, or narcotic analgesia;
3. Can be reasonably considered to have a significant risk of complication or morbidity;
4. Require injections of any substance into a joint space or body cavity (excluding the intravascular space); or
5. Are listed in Appendix A.

Here's the info. about the process for consent form development. 10NC and PCS have process in place to manage SME input.

VHA Handbook 1004.05, iMedConsent™, dated December 10, 2014.

10. CONTACTS:
b. **Clinical Content Concerns and Requests.**
(1) Concerns related to the clinical content in the iMedConsent™ program and requests for new content need to be reviewed and approved by the relevant Specialty Chief and submitted to the vendor using email (content@dialogmedical.com). Submission must include the name of the document (or proposed name if new content is being requested), the specialty (or proposed specialty), and a description of the concern or new content request.

(2) The vendor, Dialog Medical, evaluates content requests on a 90-day timeframe (estimated) to determine whether content modification or new content is needed. Dialog Medical provides a summary of actions taken in response to any field request to Patient Care Services for review.

(3) Patient Care Services, in conjunction with designated operational policy offices under the Deputy Under Secretary for Health for Operations and Management, is responsible for ensuring that consent form content is consistent with VHA policy and practice.

++++++++++++++++
Virginia Ashby Sharpe, Ph.D.
Acting Executive Director
National Center for Ethics in Health Care
Veterans Health Administration 10E1E
810 Vermont Ave. NW, Washington, DC 20420 (mail)
811 Vermont Ave. NW, Washington, DC 20420 #624 (physical)
office landline: 202-(b6)

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mobile: (b6)
fax: 202-632-8456
virginia.sharpe@va.gov
intranet: http://vaww.ethics.va.gov/
internet: http://www.ethics.va.gov/

Sender:	Llorente, Maria D. </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F5C91F577D894BD9A0F09305DB34DD4F-LLORENTE, M>
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Sent Date:	2019/03/08 14:27:59
Delivered Date:	2019/03/08 14:27:00

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From:	Fuller, Matthew A. (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=62D9CBB23B184CACB98895776E36A471-FULLER, MAT>
To:	Furmaga, Elaine /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d52c630409904d52ba09e4b755d2da99-Furmaga, El <(b6) @va.gov>
Subject:	RE: ICER Issues Final Report and Policy Recommendations on Esketamine for Treatment-Resistant Depression
Date:	2019/06/28 13:24:00
Priority:	Normal
Type:	Note

Yep. Have it. Thanks.

From: Furmaga, Elaine
Sent: Friday, June 28, 2019 1:23 PM
To: Fuller, Matthew A. (PBM) <(b6) va.gov>
Subject: FW: ICER Issues Final Report and Policy Recommendations on Esketamine for Treatment-Resistant Depression

Hi Matthew,

You have likely already seen this but I said I would forward to you (from Cliff Goodman who works with Lewin on the VA/DoD guidelines).

Thanks - Elaine

From: (b6) @Lewin.com>
Sent: Friday, June 21, 2019 11:10 AM
To: Furmaga, Elaine (b6) @va.gov>
Subject: [EXTERNAL] FW: ICER Issues Final Report and Policy Recommendations on Esketamine for Treatment-Resistant Depression

Hi Elaine – FYI. Pretty interesting from clinical and economic standpoints. -- (b6)

From: Institute for Clinical and Economic Review [mailto:info@icer-review.org]
Sent: Thursday, June 20, 2019 4:07 PM
To: (b6) @Lewin.com>
Subject: ICER Issues Final Report and Policy Recommendations on Esketamine for Treatment-Resistant Depression

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Institute for Clinical and Economic Review Issues Final Report and Policy Recommendations on Esketamine for Treatment-Resistant Depression

-- Independent appraisal committee votes that evidence is adequate to demonstrate clinical benefits of esketamine versus placebo, but concerns remain about the study criteria used to define treatment-resistant depression and the lack of longer-term data on esketamine's safety and effectiveness --

-- Esketamine's list price would require a 25-52% discount to reach a fair value-based price benchmark, and the potential short-term budget impact associated with treating the eligible patient population leads ICER to issue an Access and Affordability Alert --

BOSTON, June 20, 2019 - The Institute for Clinical and Economic Review (ICER) today released a Final Evidence Report and Report-at-a-Glance assessing the comparative clinical effectiveness and value of esketamine (Spravato™, Janssen), a nasal spray approved by the FDA in March as a therapy for treatment-resistant depression (TRD). Esketamine is one of the two mirror-image molecules (enantiomers) that make up ketamine, an anesthetic that is commonly used off-label to treat TRD.

ICER's report was reviewed at the May 2019 public meeting of the Midwest Comparative Effectiveness Public Advisory Council (Midwest CEPAC), one of ICER's three independent evidence appraisal committees. During the meeting, the CEPAC found that the evidence demonstrated esketamine plus background antidepressant to be clinically superior to background antidepressant alone. The CEPAC members found the evidence to be insufficient to demonstrate a difference in net health benefit between esketamine and ketamine, transcranial magnetic stimulation, electroconvulsive therapy, or augmentation with olanzapine.

During their deliberation, panel members weighed the therapies' other benefits and contextual considerations. They acknowledged that esketamine is intended to care for patients with a condition of high severity and a high lifetime burden of illness, and that esketamine offers a novel mechanism of action compared to other approved treatments for TRD, which may allow

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VA-19-1109-B-000213

successful treatment of many patients for who other available treatments have failed. Nevertheless, a majority of the panel felt that there is uncertainty about the long-term benefits and risks of esketamine, citing the lack of long-term trial evidence.

ICER's evaluation of long-term cost-effectiveness found that the fair value-based price benchmark for esketamine is between $17,700 and $25,200 per year, a range that would require a 25-52% discount from the announced list price of $32,400. Consistent with ICER's value-assessment framework, esketamine is deemed to deliver a "low value for money" because the treatment's incremental cost-effectiveness ratio, using the current list price, exceeds $175,000 per quality-adjusted life year (QALY) gained.

"Treatment-resistant forms of major depression are common and have large negative effects on patient quality of life, so new therapies are badly needed," said David Rind, MD, ICER's Chief Medical Officer. "It is hard to understand how a price exceeding usual cost-effectiveness thresholds is appropriate for a treatment that could be very widely used, particularly when that price is an order of magnitude higher than that of intravenous generic ketamine, a closely related therapy."

Affordability &Access Alert

Given that the clinical goal for uptake would exceed the potential budget impact threshold at the national level, ICER is issuing an Affordability and Access Alert as part of its final report on esketamine. Clinical experts queried at the public meeting suggested that esketamine would not be viewed as an appropriate treatment for all patients with TRD, but that roughly half of eligible patients may be offered the option during consultation with their physician. However, at esketamine's current list price, only 16% of eligible Americans with TRD could receive the treatment before crossing ICER's potential budget threshold of $819 million per year. Even if esketamine's price was lowered to ICER's value-based price benchmark range for long-term cost-effectiveness, only 20-30% of all eligible patients with TRD could be treated with esketamine before exceeding the potential budget impact threshold.

The purpose of an ICER Affordability and Access Alert is to signal to stakeholders and policy makers that the amount of added health care costs associated with a new service may be difficult for the health system to absorb over the short term without displacing other needed services or contributing to rapid growth in health care insurance costs that threaten sustainable access to high-value care for all patients.

Key Policy Recommendations

Following the voting session, a policy roundtable of experts - including clinicians, patient advocates, and payer representatives - convened to discuss the implications of the evidence for policy and practice. Key recommendations stemming from the roundtable discussion include:

- • Manufacturers and researchers should conduct studies directly comparing esketamine and other treatment options using standardized research protocols and outcomes that reflect what matters most to patients; this would allow real-world, long-term assessment of comparative effectiveness.

- • Given the considerable uncertainty that remains regarding the longer-term benefits

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and risks of esketamine, it is reasonable for insurers and other payers to develop prior authorization criteria to ensure that patients are carefully selected and managed by clinicians with the necessary expertise to ensure appropriate care.

- • Payers should develop mechanisms to adequately compensate clinicians for the expenses associated with monitoring and delivering esketamine within the specification of the REMS program.

ICER's detailed set of policy recommendations, including considerations for establishing prior authorization criteria, is available in the Final Evidence Report.

About ICER

The Institute for Clinical and Economic Review (ICER) is an independent non-profit research institute that produces reports analyzing the evidence on the effectiveness and value of drugs and other medical services. ICER's reports include evidence-based calculations of prices for new drugs that accurately reflect the degree of improvement expected in long-term patient outcomes, while also highlighting price levels that might contribute to unaffordable short-term cost growth for the overall health care system.

ICER's reports incorporate extensive input from all stakeholders and are the subject of public hearings through three core programs: the California Technology Assessment Forum (CTAF), the Midwest Comparative Effectiveness Public Advisory Council (Midwest CEPAC), and the New England Comparative Effectiveness Public Advisory Council (New England CEPAC). These independent panels review ICER's reports at public meetings to deliberate on the evidence and develop recommendations for how patients, clinicians, insurers, and policymakers can improve the quality and value of health care. For more information about ICER, please visit ICER's website.

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Recipient:	Furmaga, Elaine /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d52c630409904d52ba09e4b755d2da99-Furmaga, El (b6) @va.gov>
Sent Date:	2019/06/28 13:24:59
Delivered Date:	2019/06/28 13:24:00

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From:	Valentino, Michael (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO, <(b6) va.gov>
To:	Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat <(b6) va.gov>
Subject:	RE: Hi Matthew, would you mind sending me the esketamine slides you used at the MAp meeting as well as the revised CFU....
Date:	2019/06/28 10:46:12
Priority:	Normal
Type:	Note

Thanks! Perfect....

From: Fuller, Matthew A. (PBM)
Sent: Friday, June 28, 2019 10:11 AM
To: Valentino, Michael (VACO) <(b6) va.gov>
Subject: RE: Hi Matthew, would you mind sending me the esketamine slides you used at the MAp meeting as well as the revised CFU....

Sure. I have attached the slides from the MAP call in May as well as the approved CFU as requested. I also added the national protocol guidance, monograph, and slides from the F2F meeting in Chicago for reference. Please let me know if you need anything else.

Matthew

From: Valentino, Michael (VACO)
Sent: Friday, June 28, 2019 9:55 AM
To: Fuller, Matthew A. (PBM) <(b6) va.gov>
Subject: Hi Matthew, would you mind sending me the esketamine slides you used at the MAp meeting as well as the revised CFU....

I'm meeting with Congress on Monday and want to review prior to that.

Thanks in advance.

Mike

Michael A. Valentino, R.Ph., MHSA
Chief Consultant, Pharmact Benefits Management Services
Department of Veterans Affairs
(b6)
810 Vermont Avenue NW
Washington DC

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(b)(6)

Sender:	Valentino, Michael (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO, <(b6) va.gov>
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Sent Date:	2019/06/28 10:46:11
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From:	Ledesma, Mark P. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=ACBC9290CFEC4FFF8651002B5B0330C5-LEDESMA, MA {t(b6) va.gov>
To:	Copeland, Brittany R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0f1ebffbc694bb09b048ce0f296763e-Copeland, B {b6) @va.gov>
CC:	VHA 10B /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e8da02703bf40af822fcc49b8463979-VHA 10B <vha10b@va.gov>; VHA CO 10B2B Media /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12e0caca48054b8da1e793651a89d81c-VHA CO 10B2 <VHACO10B2BMedia@va.gov>; Ledesma, Mark P. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=acbc9290cfec4fff8651002b5b0330c5-Ledesma, Ma {t(b6) va.gov>
Subject:	RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED
Date:	2019/03/15 11:18:39
Priority:	Normal
Type:	Note

Thanks, Brittany. Will do.

Regards,
Mark

From: Copeland, Brittany R.
Sent: Friday, March 15, 2019 11:16 AM
To: Ledesma, Mark P. <{b6) va.gov>
Cc: VHA 10B <vha10b@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Good morning Mark,

On behalf of Krystal Toles, 10B clears the attached with edits. Please ensure PBM follows its normal distribution process for the FAQ document.

Thanks!

Brittany R. Copeland, MHA
Health System Specialist
Office of the VHA Chief of Staff (10B)
810 Vermont Ave NW | Washington, DC 20420
o:

From: Ledesma, Mark P.
Sent: Thursday, March 14, 2019 4:32 PM
To: Toles, Krystal M.{t(b6) va.gov>; Yang, Robert B.{t(b6) va.gov>

AMERICAN OVERSIGHT

Cc: VHA 10B <vha10b@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>; Ledesma, Mark (b6)(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Hi Krystal,

I was told that the message to the field will be ready for internal distribution tomorrow morning.

Regards,
Mark

From: Toles, Krystal M.
Sent: Thursday, March 14, 2019 3:36 PM
To: Ledesma, Mark P.(b6) va.gov>; Yang, Robert B.(b6) va.gov>
Cc: VHA 10B <vha10b@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Mark,

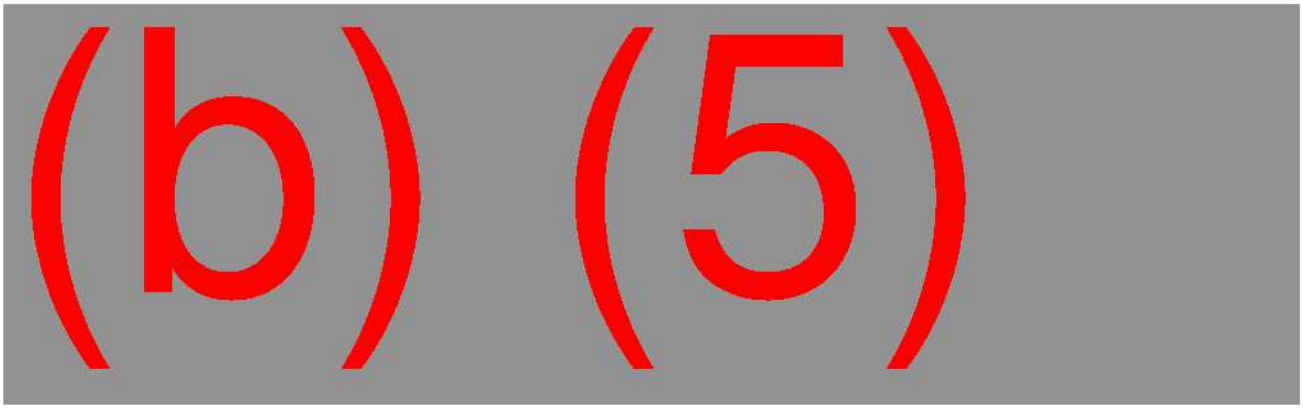
Is an internal message to the field also pending?

From: Ledesma, Mark P.
Sent: Thursday, March 14, 2019 1:22 PM
To: Yang, Robert B.(b6) va.gov>
Cc: VHA 10B <vha10b@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>; Toles, Krystal M. (b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Hi Robert,

I'm resubmitting the nasal spray news release on behalf of 10P for review/conncurence.

I have also attached the internal communication Frequently Asked Question (FAQ) document for Spravato® for review/concurrence.



AMERICAN OVERSIGHT

Please let me know if you have questions. Thanks.

Regards,
Mark

From: Yang, Robert B.
Sent: Wednesday, March 13, 2019 4:38 PM
To: Ledesma, Mark P. <(b6) va.gov>
Cc: VHA 10B <vha10b@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>; Toles, Krystal M. <(b6) va.gov>
Subject: FW: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Hello Mark,

The press release is unable to be cleared at this time. Please see highlighted below for feedback.

Thanks,

Robert B Yang
Health System Specialist
Office of the VHA Chief of the Staff (10B)
810 Vermont Ave NW
Washington DC 20420
Office: (b6)
Cell: (b6)
Robert.Yang2@va.gov

From: Toles, Krystal M.
Sent: Wednesday, March 13, 2019 4:14 PM
To: Yang, Robert B. <(b6) va.gov>
Cc: VHA 10B <vha10b@va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Thanks for your review, Robert.

We are unable to clear the press release without having an internal communication ready for review and in place. (b) (5) ?

From: Ledesma, Mark P.
Sent: Wednesday, March 13, 2019 1:22 PM
To: VHA 10B <vha10b@va.gov>
Cc: VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>; Ledesma, Mark P. <(b6) va.gov>
Subject: FW: HHS bought a nasal spray for depression - DRAFT News Release - REVISED
Importance: High

Good afternoon, 10B.

AMERICAN OVERSIGHT

We have an **urgent request for review/concurrence** of the attached news release. 10P wants to get this out ASAP – since FDA released last week and there is WH interest.

Please let me know if you have questions. Thank you.

Regards,
Mark

From: Smith, Monica (VACO)
Sent: Tuesday, March 12, 2019 4:16 PM
To: Screen, Gina <(b6) va.gov>; Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) @va.gov>
Cc: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Gina, Mark, Alan – please see the revised draft version of the press release. FAQs are being worked and will be sent asap. Pharmacy and Mental Health SMEs are on the email in case there are questions.

From: Smith, Monica (VACO)
Sent: Tuesday, March 12, 2019 12:10 PM
To: Screen, Gina <(b6) va.gov>; Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. (b6) @va.gov>
Cc: Outlaw, William N.(b6) 2@va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

Agreed. I had a lot of questions when Tom and I were reviewing the draft. We will get with Pharmacy and Mental Health to develop.

From: Screen, Gina
Sent: Tuesday, March 12, 2019 10:24 AM
To: Smith, Monica (VACO) <(b6) va.gov>; Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

I think we also need a few faq's about this… I'm sure a lot of people will have questions…

From: Smith, Monica (VACO)
Sent: Tuesday, March 12, 2019 10:22 AM
To: Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>; Screen, Gina <(b6) va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; Llorente, Maria D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; VHA 10P4

AMERICAN OVERSIGHT

Communication Group <vha10p4comm@va.gov>; Law, Cassandra M. <(b6) va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; Beck, Lucille B. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

(b) (5)

(b) (5)

Sender:	Ledesma, Mark P. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=ACBC9290CFEC4FFF8651002B5B0330C5-LEDESMA, MA <(b6) va.gov>
Recipient:	Copeland, Brittany R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0f1ebffbc694bb09b048ce0f296763e-Copeland, B (b6) @va.gov>; VHA 10B /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e8da02703bf40af822fcc49b8463979-VHA 10B <vha10b@va.gov>; VHA CO 10B2B Media /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12e0caca48054b8da1e793651a89d81c-VHA CO 10B2 <VHACO10B2BMedia@va.gov>; Ledesma, Mark P. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=acbc9290cfec4fff8651002b5b0330c5-Ledesma, Ma <(b6) va.gov>
Sent Date:	2019/03/15 11:18:36
Delivered Date:	2019/03/15 11:18:39
Message Flags:	Unread

AMERICAN OVERSIGHT

From:	Toles, Krystal M. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1156B622F1BA464FA61884615342FF18-TOLES, KRYS <(b6) va.gov>
To:	Yang, Robert B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02220930808e48bba30257972618d0cf-Yang, Rober <(b6) va.gov>; VHA 10B /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e8da02703bf40af822fcc49b8463979-VHA 10B <vha10b@va.gov>
Subject:	RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED
Date:	2019/03/15 10:05:17
Priority:	Normal
Type:	Note

The attached documents are cleared with edits. Please ensure that PBM follows its normal distribution process for the FAQ document. Thank you!

From: Yang, Robert B.
Sent: Thursday, March 14, 2019 2:26 PM
To: Toles, Krystal M. <(b6) va.gov>
Cc: VHA 10B <vha10b@va.gov>
Subject: FW: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Hello Krystal,

For clearance: the news release, internal comms FAQ document, and comms plan below for Spravato.

Thanks,

Robert B Yang
Health System Specialist
Office of the VHA Chief of the Staff (10B)
810 Vermont Ave NW
Washington DC 20420
Office: (b6)
Cell: (b6)
(b6) @va.gov

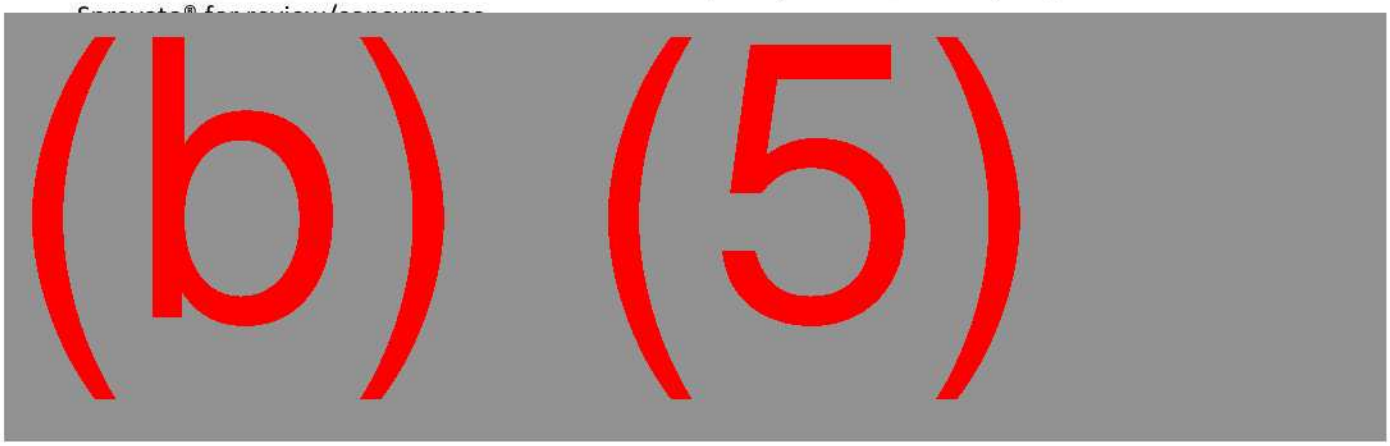
From: Ledesma, Mark P.
Sent: Thursday, March 14, 2019 1:22 PM
To: Yang, Robert B. <(b6) va.gov>
Cc: VHA 10B <vha10b@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>; Toles, Krystal M. <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Hi Robert,

AMERICAN OVERSIGHT

I'm resubmitting the nasal spray news release on behalf of 10P for review/conncurence.

I have also attached the internal communication Frequently Asked Question (FAQ) document for Saxenda® for review/concurrence.



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Thanks,

Robert B Yang
Health System Specialist
Office of the VHA Chief of the Staff (10B)
810 Vermont Ave NW
Washington DC 20420
Office: (b6)
Cell: (b6)
(b6) va.gov

From: Toles, Krystal M.
Sent: Wednesday, March 13, 2019 4:14 PM

AMERICAN OVERSIGHT

To: Yang, Robert B. <(b6) va.gov>
Cc: VHA 10B <vha10b@va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

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Cc: VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>; Ledesma, Mark P. <(b6) va.gov>
Subject: FW: HHS bought a nasal spray for depression - DRAFT News Release - REVISED
Importance: High

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Cc: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Gina, Mark, Alan – please see the revised draft version of the press release. FAQs are being worked and will be sent asap. Pharmacy and Mental Health SMEs are on the email in case there are questions.

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Cc: Outlaw, William N. <(b6) @va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

AMERICAN OVERSIGHT

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Sent: Tuesday, March 12, 2019 10:24 AM
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Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

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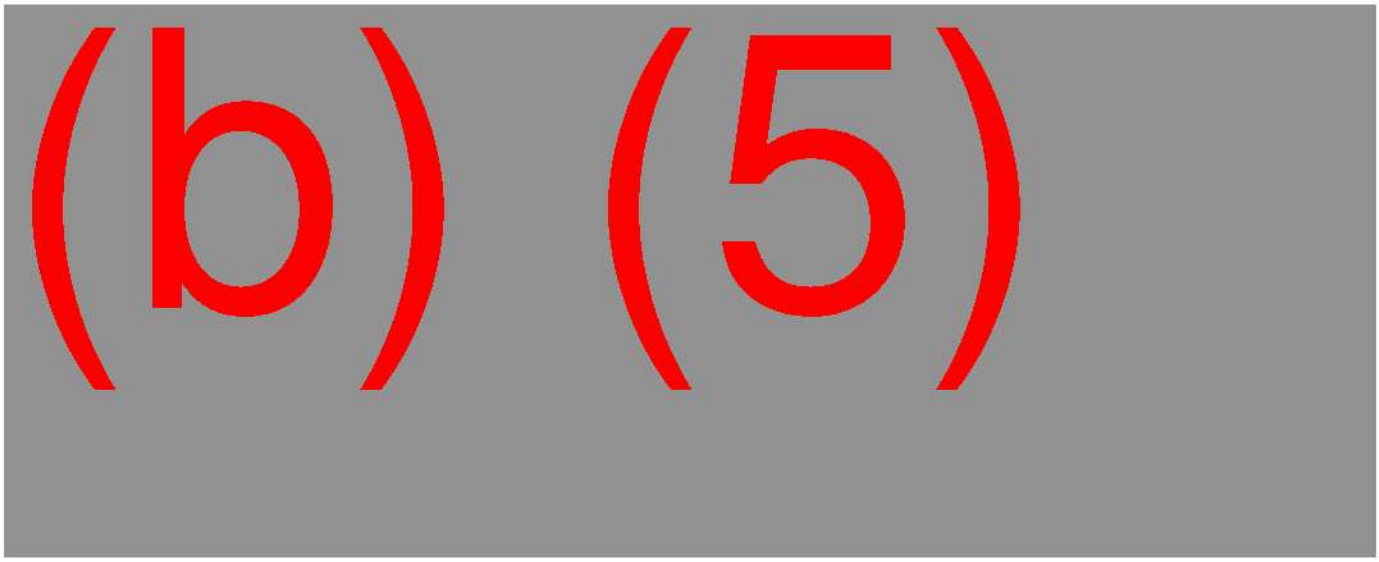
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; Llorente, Maria D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>; Law, Cassandra M. <(b6) va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; Beck, Lucille B. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release



Sender:	Toles, Krystal M. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1156B622F1BA464FA61884615342FF18-TOLES, KRYS <(b6) va.gov>
Recipient:	Yang, Robert B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02220930808e48bba30257972618d0cf-Yang, Rober <(b6) va.gov>; VHA 10B /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e8da02703bf40af822fcc49b8463979-VHA 10B <vha10b@va.gov>
Sent Date:	2019/03/15 10:05:16
Delivered Date:	2019/03/15 10:05:17

AMERICAN OVERSIGHT

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From:	Toles, Krystal M. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1156B622F1BA464FA61884615342FF18-TOLES, KRYS <(b6) va.gov>
To:	Yang, Robert B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02220930808e48bba30257972618d0cf-Yang, Rober <(b6) va.gov>
CC:	VHA 10B /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e8da02703bf40af822fcc49b8463979-VHA 10B <vha10b@va.gov>
Subject:	RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED
Date:	2019/03/13 16:14:30
Priority:	Normal
Type:	Note

Thanks for your review, Robert.

We are unable to clear the press release without having an internal communication ready for review and in place. (b) (5) ?

From: Yang, Robert B.
Sent: Wednesday, March 13, 2019 1:58 PM
To: Toles, Krystal M. <(b6) va.gov>
Cc: VHA 10B <vha10b@va.gov>
Subject: FW: HHS bought a nasal spray for depression - DRAFT News Release - REVISED
Importance: High

Hello Krystal,

For clearance: attached news release on the nasal spray Spravato.

10B2 is requesting "urgent" clearance.

Thanks,

Robert B Yang
Health System Specialist
Office of the VHA Chief of the Staff (10B)
810 Vermont Ave NW
Washington DC 20420
Office: (b6)
Cell: (b6)
(b6) @va.gov

From: Ledesma, Mark P.
Sent: Wednesday, March 13, 2019 1:22 PM
To: VHA 10B <vha10b@va.gov>
Cc: VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>; Ledesma, Mark P. <(b6) va.gov>

AMERICAN OVERSIGHT

Subject: FW: HHS bought a nasal spray for depression - DRAFT News Release - REVISED
Importance: High

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Regards,
Mark

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Sent: Tuesday, March 12, 2019 4:16 PM
To: Screen, Gina <(b6) va.gov>; Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>
Cc: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Gina, Mark, Alan – please see the revised draft version of the press release. FAQs are being worked and will be sent asap. Pharmacy and Mental Health SMEs are on the email in case there are questions.

From: Smith, Monica (VACO)
Sent: Tuesday, March 12, 2019 12:10 PM
To: Screen, Gina <(b6) va.gov>; Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>
Cc: Outlaw, William N. (b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

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From: Screen, Gina
Sent: Tuesday, March 12, 2019 10:24 AM
To: Smith, Monica (VACO) <(b6) va.gov>; Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

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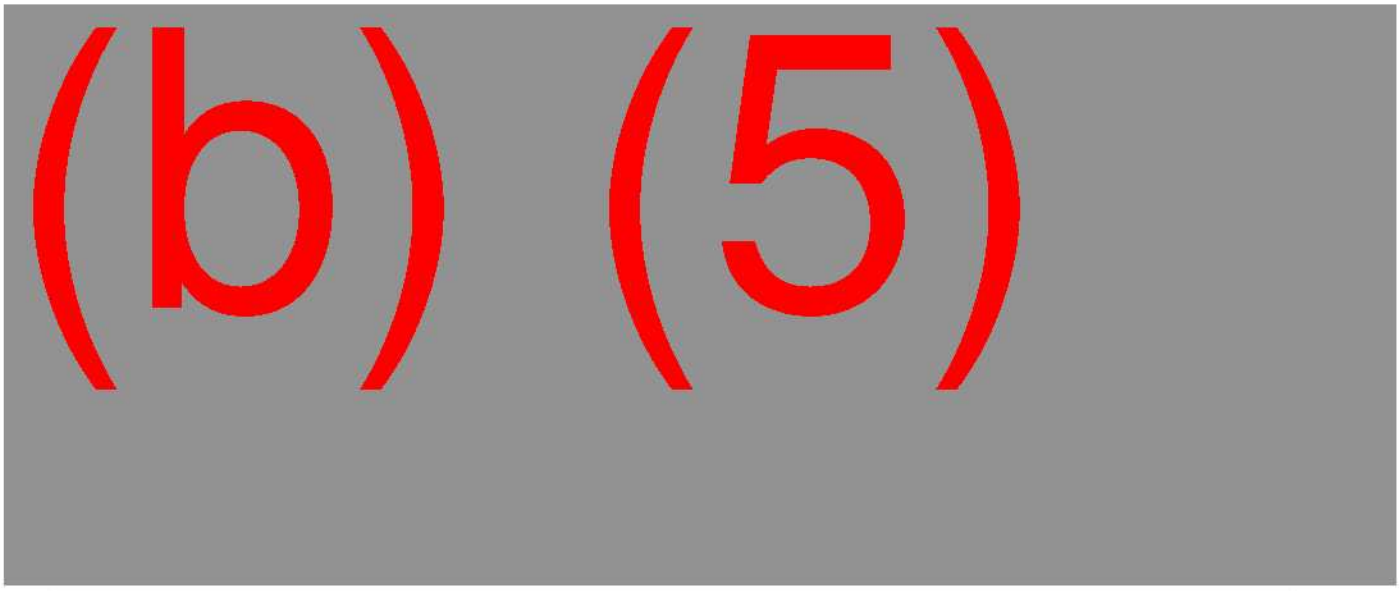
From: Smith, Monica (VACO)
Sent: Tuesday, March 12, 2019 10:22 AM
To: Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>; Screen,

AMERICAN OVERSIGHT

Gina <(b6) va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; Llorente, Maria D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>; Law, Cassandra M. <(b6) va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; Beck, Lucille B. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release



Sender:	Toles, Krystal M. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1156B622F1BA464FA61884615342FF18-TOLES, KRYS <(b6) va.gov>
Recipient:	Yang, Robert B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02220930808e48bba30257972618d0cf-Yang, Rober <(b6) va.gov>; VHA 10B /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e8da02703bf40af822fcc49b8463979-VHA 10B <vha10b@va.gov>
Sent Date:	2019/03/13 16:14:29
Delivered Date:	2019/03/13 16:14:30
Message Flags:	Unread

AMERICAN OVERSIGHT

From:	Emmendorfer, Thomas (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC96BB44E7AE2C94C43B55D094-EMMENDORFER <(b6) va.gov>
To:	Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>
CC:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Smith, Monica (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=511ea9e77a234375a91a7b34ce23719d-Smith, Moni <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>
Subject:	RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED
Date:	2019/03/13 16:06:53
Priority:	Normal
Type:	Note

Got it…I am adding that presentation and clearing to 10P4 Actions in just a few seconds….

Thank you everyone!

Tom

From: Llorente, Maria D.
Sent: Wednesday, March 13, 2019 4:06 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Wiechers, Ilse (b6) @va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Smith, Monica (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Tom, Ilse mentioned that they discussed with VISN MH Leads this past Monday.

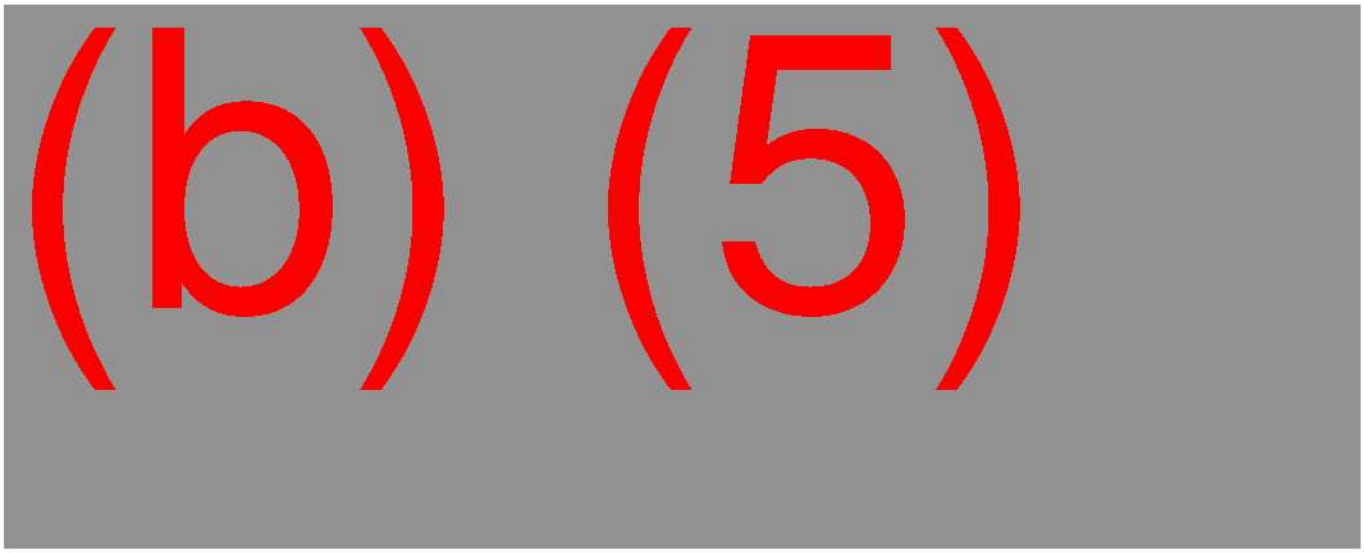
From: Emmendorfer, Thomas (PBM)
Sent: Wednesday, March 13, 2019 3:37 PM
To: Wiechers, Ilse (b6) @va.gov>
Cc: Llorente, Maria D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Smith, Monica (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: FW: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Ilse,

AMERICAN OVERSIGHT

By chance, do you know if Spravato® has been discussed on any Mental Health leadership calls yet? If so, could you please add to the list below? Also, make sure you agree with my COMMS plan that needs to be executed yet.

DRAFT message to 10P4 Actions:



From: Smith, Monica (VACO)
Sent: Wednesday, March 13, 2019 3:01 PM
To: Ledesma, Mark P. <(b6) va.gov>; Greilsamer, Alan <(b6) va.gov>; Screen, Gina <(b6) va.gov>
Cc: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Thanks. Tom and Dave – please let Mark know what the internal plans are.

From: Ledesma, Mark P.
Sent: Wednesday, March 13, 2019 3:00 PM
To: Smith, Monica (VACO) <(b6) va.gov>; Greilsamer, Alan <(b6) va.gov>; Screen, Gina <(b6) va.gov>
Cc: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; Ledesma, Mark P. (b6) @va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Thanks, Monica. I got a bit more clarity from 10B.

AMERICAN OVERSIGHT

They want to make sure that we have an internal comms plan in place to help answer questions from providers and Veterans before they clear the release.

Regards,
Mark

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Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Mark – I know Pharmacy and Mental Health are working on FAQs, but let's defer to Tom and Dave to see what plans are in place for internal communication. Let us know if you/10B want more for external, other than responses to queries/FAQs. If a statement is needed, we are happy to work on something.

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Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Hi Monica,

10B is asking where the comms plan is for this release.

Regards,
Mark

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To: Smith, Monica (VACO) <(b6) va.gov>; Screen, Gina <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>
Cc: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Monica – It is being worked. We will keep you updated on our progress. Thanks, Alan

AMERICAN OVERSIGHT

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To: Screen, Gina <(b6) va.gov>; Greilsamer, Alan (b6) @va.gov>; Ledesma, Mark P. <(b6) va.gov>
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Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Gina, Mark, Alan – please see the revised draft version of the press release. FAQs are being worked and will be sent asap. Pharmacy and Mental Health SMEs are on the email in case there are questions.

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Cc: Outlaw, William N. (b6) @va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

Agreed. I had a lot of questions when Tom and I were reviewing the draft. We will get with Pharmacy and Mental Health to develop.

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Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

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Sent: Tuesday, March 12, 2019 10:22 AM

AMERICAN OVERSIGHT

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Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; Llorente, Maria D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>; Law, Cassandra M. <(b6) va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; Beck, Lucille B. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

(b) (5)

Sender:	Emmendorfer, Thomas (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC96BB44E7AE2C94C43B55D094-EMMENDORFER <(b6) va.gov>
Recipient:	Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Smith, Monica (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=511ea9e77a234375a91a7b34ce23719d-Smith, Moni <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>
Sent Date:	2019/03/13 16:06:52
Delivered Date:	2019/03/13 16:06:53

AMERICAN OVERSIGHT

From:	Emmendorfer, Thomas (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC96BB44E7AE2C94C43B55D094-EMMENDORFER <(b6) va.gov>
To:	Smith, Monica (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=511ea9e77a234375a91a7b34ce23719d-Smith, Moni <(b6) va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>
CC:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen (b6) @va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b6) s@va.gov>; Law, Cassandra M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f888d507d6c54eb5a92fc44199eb5838-Law, Cassan <(b6) va.gov>
Subject:	RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED
Date:	2019/03/15 09:16:34
Priority:	Normal
Type:	Note

Good Morning Dave,

Monica is in my office. Mark LeDesma and Krystal Toles responded last night saying we need a message from Dr. Stone to accompany the FAQs. Monica is going to contact Krystal Toles to get clarification on what is needed (i.e. Does Dr. Stone want a couple of sentences and the FAQ to go out referencing that a memo will be coming out of 10N to the Network Directors in the next couple of days).

NOTE: Whatever is decided—some of the FAQ responses state further information will be provided on 3/18/2019…so if the FAQ does not go out today…then the FAQ document will need to be revised for the question.

Tom

From: Emmendorfer, Thomas (PBM)
Sent: Thursday, March 14, 2019 4:36 PM
To: Wiechers, Ilse <Ilse.Wiechers@va.gov>
Cc: Valentino, Michael (VACO) ((b6) va.gov) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>
Subject: FW: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Hi Ilse,

AMERICAN OVERSIGHT

The Esketamine FAQ document is ready. We will send the document out to the Pharmacy Community tomorrow am if you could have someone send it out to the Mental Health listservs. The header shows this is a joint document between our offices.

Thank you for everything you have done on this Ilse. I have been watching all the e-mails on imed consent, memos, and other documents. You are making a ton of progress in a short period of time!

Let me know if you need anything else.

Tom

From: Lahl, Dennis
Sent: Thursday, March 14, 2019 4:30 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Thanks and have a great day.

Dennis

Dennis Lahl FAC-P/PM
Office of the Assistant Deputy Under Secretary for Health for Patient Care Services (10P4)
VACO PCS IT/BCAG/ISO Liaison
TMS OPCS DM
ph: (b6)
Dennis Lahl

From: Emmendorfer, Thomas (PBM)
Sent: Thursday, March 14, 2019 4:19 PM
To: Lahl, Dennis <(b6) @va.gov>
Subject: FW: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Convert to PDF

From: Emmendorfer, Thomas (PBM)
Sent: Thursday, March 14, 2019 3:53 PM
To: Zacher, Jennifer L. (PBM) <(b6) va.gov>
Cc: Valentino, Michael (VACO) (b6) va.gov) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Hi Jenn,

AMERICAN OVERSIGHT

This is all set for final review. Could you take a look at it? Some of the responses to the FAQ are we will provide an update on 3/18/2019.

If this looks good to you, I will get it converted to a PDF and share with Maria and Ilse and then it is ready to be distributed through normal channels.

Check one more item of the list to complete!

Thank you for everything!

Tom

From: Szudarski, Lucy (PBM)
Sent: Thursday, March 14, 2019 3:42 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Tom, use this version

From: Szudarski, Lucy (PBM)
Sent: Thursday, March 14, 2019 2:38 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Here you go Tom, sorry it took so long, I had an appt at lunch and then my computer was acting up.

Hopefully this is how you wanted it, I followed pretty much the way the other document was.

Lucy

From: Emmendorfer, Thomas (PBM)
Sent: Thursday, March 14, 2019 9:19 AM
To: Szudarski, Lucy (PBM) <Lucy.Szudarski@va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Hi Lucy,

Thank you for doing this! Could you use this version of the Esketamine Frequently Asked Question document?

Could you use the headers/footers/page numbers style that was used for the Ketamine Infusion for…docx?

For the 1st page Header Page…

(b) (5)

AMERICAN OVERSIGHT

(b) (5)
[redacted]

Tom

From: Szudarski, Lucy (PBM)
Sent: Thursday, March 14, 2019 9:13 AM
To: Emmendorfer, Thomas (PBM) <(b6) [redacted] va.gov>
Subject: FW: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Hi Tom,
Here it is on our PBM letterhead, I was able to fit it on two pages. I hope this is what you wanted, let me know if this is ok.
Thanks,
Lucy

From: Emmendorfer, Thomas (PBM)
Sent: Wednesday, March 13, 2019 5:58 PM
To: Zacher, Jennifer L. (PBM) <(b6) [redacted] va.gov>; Valentino, Michael (VACO) <(b6) [redacted] va.gov>; Wiechers, Ilse (b6) [redacted] @va.gov>
Subject: FW: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

FYI...

Jenn,

Please have Lucy use this version to build the header ect...

There were two minor edits made.

Thank you,

Tom

Sent with BlackBerry Work
(www.blackberry.com)

From: Smith, Monica (VACO) <(b6) [redacted] va.gov>

AMERICAN OVERSIGHT

Date: Wednesday, Mar 13, 2019, 5:20 PM
To: Ledesma, Mark P. <(b6) va.gov>, Greilsamer, Alan <(b6) va.gov>, Screen, Gina <(b6) va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: FW: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

See attached cleared by 10P4 Acting ADUSH.

From: Llorente, Maria D. <(b6) va.gov>
Date: Wednesday, Mar 13, 2019, 5:09 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Cc: Wiechers, Ilse (b6) @va.gov>, Valentino, Michael (VACO) <(b6) va.gov>, Smith, Monica (VACO) <(b6) va.gov>
Subject: FW: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

A very minor edit. Otherwise, looks good.
Maria

From: Emmendorfer, Thomas (PBM)
Sent: Wednesday, March 13, 2019 3:37 PM
To: Wiechers, Ilse (b6) @va.gov>
Cc: Llorente, Maria D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Smith, Monica (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: FW: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Ilse,
(b) (5)
.

DRAFT message to 10P4 Actions:

(b) (5)

AMERICAN OVERSIGHT

(b) (5)

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Regards,
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Monica – It is being worked. We will keep you updated on our progress. Thanks, Alan

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AMERICAN OVERSIGHT

<VHA10P4Actions@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

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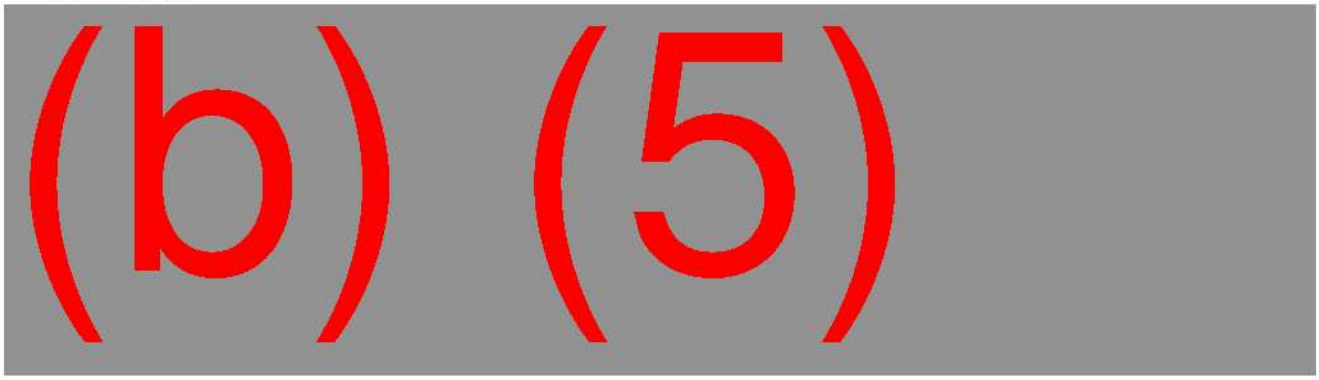
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

VHA Comms:



AMERICAN OVERSIGHT

(b) (5)

Sender:	Emmendorfer, Thomas (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC96BB44E7AE2C94C43B55D094-EMMENDORFER <(b6) va.gov>
Recipient:	Smith, Monica (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=511ea9e77a234375a91a7b34ce23719d-Smith, Moni <(b6) va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>; Law, Cassandra M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f888d507d6c54eb5a92fc44199eb5838-Law, Cassan <(b6) va.gov>
Sent Date:	2019/03/15 09:16:31
Delivered Date:	2019/03/15 09:16:34

AMERICAN OVERSIGHT

From:	Wiechers, Ilse /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0C7B1428D9E4233A641F125C5B6FC4F-WIECHERS, I (b6) @va.gov>
To:	McGuire, Marsden H. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29e9d648c29f4885828c10446fdd7379-McGuire, Ma <(b6) @va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>
Subject:	RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED
Date:	2019/03/13 15:34:12
Priority:	Normal
Type:	Note

Agreed. I spoke on the VISN MH leads call this past Monday as a heads up. I will unfortunately be out on AL (doing Advocacy Day in Sacramento at the state house with Cal Psych Association, so really need to be off-tour all day), but happy to join future calls with them as needed.

From: McGuire, Marsden H.
Sent: Wednesday, March 13, 2019 11:59 AM
To: Carroll, David (VACO) <(b6) va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>; Wiechers, Ilse (b6)(b6) @va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

At very least, we should share directly with the National Psychiatry Chiefs and VISN MH Leads. M

From: Carroll, David (VACO)
Sent: Wednesday, March 13, 2019 2:46 PM
To: VHA 10NC5 Action <VHA10NC5Action@va.gov>; Wiechers, Ilse (b6) @va.gov>
Subject: FW: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

What needs do we have for additional internal comms? If we share the press release when it is done and the FAQ and send a 10N memo with "here's what you have to do", is that enough? Thx

Sent with BlackBerry Work
(www.blackberry.com)

From: Smith, Monica (VACO) <(b6) va.gov>
Date: Wednesday, Mar 13, 2019, 2:37 PM
To: Ledesma, Mark P. <(b6) va.gov>, Greilsamer, Alan <(b6) va.gov>, Screen, Gina (b6) va.gov>
Cc: Emmendorfer, Thomas (PBM) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Valentino, Michael (VACO) <(b6) va.gov>, VHA 10P4 Actions <VHA10P4Actions@va.gov>, VHA 10P Actions <VHA10PActions@va.gov>

AMERICAN OVERSIGHT

Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Mark – I know Pharmacy and Mental Health are working on FAQs, but let's defer to Tom and Dave to see what plans are in place for internal communication. Let us know if you/10B want more for external, other than responses to queries/FAQs. If a statement is needed, we are happy to work on something.

From: Ledesma, Mark P.
Sent: Wednesday, March 13, 2019 2:11 PM
To: Greilsamer, Alan <(b6) va.gov>; Smith, Monica (VACO) <(b6) va.gov>; Screen, Gina <(b6) va.gov>
Cc: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; Ledesma, Mark P. (b6) @va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Hi Monica,

10B is asking where the comms plan is for this release.

Regards,
Mark

From: Greilsamer, Alan
Sent: Wednesday, March 13, 2019 1:16 PM
To: Smith, Monica (VACO) <(b6) va.gov>; Screen, Gina <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>
Cc: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Monica – It is being worked. We will keep you updated on our progress. Thanks, Alan

---

From: Smith, Monica (VACO)
Sent: Wednesday, March 13, 2019 12:50 PM
To: Screen, Gina <(b6) va.gov>; Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. (b6) @va.gov>
Cc: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Hi there – checking in on status. VHA wants to get this out ASAP. Since FDA released last week and there is WH interest, can you expedite review?

AMERICAN OVERSIGHT

From: Smith, Monica (VACO)
Sent: Tuesday, March 12, 2019 4:16 PM
To: Screen, Gina <(b6) va.gov>; Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>
Cc: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Gina, Mark, Alan – please see the revised draft version of the press release. FAQs are being worked and will be sent asap. Pharmacy and Mental Health SMEs are on the email in case there are questions.

From: Smith, Monica (VACO)
Sent: Tuesday, March 12, 2019 12:10 PM
To: Screen, Gina <(b6) va.gov>; Greilsamer, Alan (b6) @va.gov>; Ledesma, Mark P. <(b6) va.gov>
Cc: Outlaw, William N. (b6) @va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

Agreed. I had a lot of questions when Tom and I were reviewing the draft. We will get with Pharmacy and Mental Health to develop.

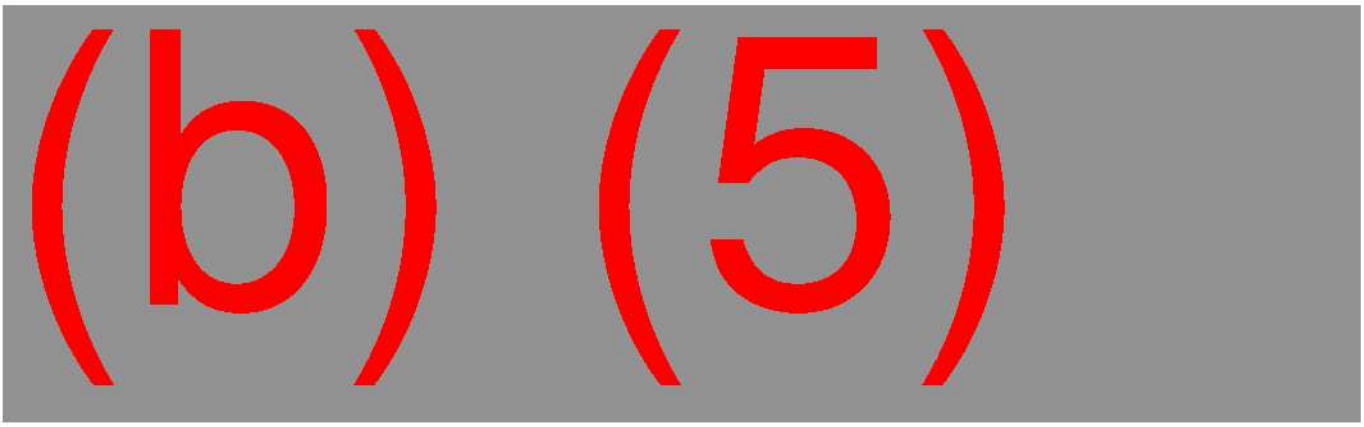
From: Screen, Gina
Sent: Tuesday, March 12, 2019 10:24 AM
To: Smith, Monica (VACO) <(b6) va.gov>; Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

I think we also need a few faq's about this… I'm sure a lot of people will have questions…

From: Smith, Monica (VACO)
Sent: Tuesday, March 12, 2019 10:22 AM
To: Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>; Screen, Gina <(b6) va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; Llorente, Maria D. <(b6) va.gov>; Valentino, Michael (VACO) (b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>; Law, Cassandra M. <(b6) va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; Beck, Lucille B. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

(b) (5)

AMERICAN OVERSIGHT



Sender:	Wiechers, Ilse /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0C7B1428D9E4233A641F125C5B6FC4F-WIECHERS, I (b6) @va.gov>
Recipient:	McGuire, Marsden H. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29e9d648c29f4885828c10446fdd7379-McGuire, Ma <(b6) @va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>
Sent Date:	2019/03/13 15:34:11
Delivered Date:	2019/03/13 15:34:12

AMERICAN OVERSIGHT

From:	Carroll, David (VACO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=95E14EBD3B6745C8952A823B04DABFF5-CARROLL, DA>
To:	Smith, Monica (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=511ea9e77a234375a91a7b34ce23719d-Smith, Moni <(b6) va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>
Subject:	RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED
Date:	2019/03/15 13:43:00
Priority:	Normal
Type:	Note

Agree

From: Smith, Monica (VACO)
Sent: Friday, March 15, 2019 1:29 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Fine by me.

From: Emmendorfer, Thomas (PBM)
Sent: Friday, March 15, 2019 1:22 PM
To: Smith, Monica (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Hi Monica,

If Dave and you agree…how about this very minor edit…in red below. (b) (5)

Tom

From: Smith, Monica (VACO)
Sent: Friday, March 15, 2019 1:13 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

What are your thoughts? Should we strike this sentence?

(b) (5)

AMERICAN OVERSIGHT

(b) (5)

From: Ledesma, Mark P.
Sent: Friday, March 15, 2019 12:31 PM
To: Smith, Monica (VACO) <{b6} va.gov>; Emmendorfer, Thomas (PBM) <{b6} va.gov>
Cc: Ledesma, Mark P. <{b6} va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

I also just noticed that 10B had a comment that needs to be addressed on the press release.

From: Ledesma, Mark P.
Sent: Friday, March 15, 2019 12:30 PM
To: Smith, Monica (VACO) <{b6} va.gov>; Emmendorfer, Thomas (PBM) <{b6} va.gov>
Cc: Ledesma, Mark P. <{b6} va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Monday is going to be tough. I'll do my best to push.

Regards,
Mark

From: Smith, Monica (VACO)
Sent: Friday, March 15, 2019 12:28 PM
To: Ledesma, Mark P. <{b6} va.gov>; Emmendorfer, Thomas (PBM) <{b6} va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

ASAP – could we shoot for Monday? The announcement to the field has started.

From: Ledesma, Mark P.
Sent: Friday, March 15, 2019 11:23 AM
To: Smith, Monica (VACO) <{b6} va.gov>; Emmendorfer, Thomas (PBM) <{b6} va.gov>
Cc: Ledesma, Mark P. <{b6} va.gov>
Subject: FW: HHS bought a nasal spray for depression - DRAFT News Release - REVISED
Importance: High

Good morning, Monica, Tom,

AMERICAN OVERSIGHT

10B cleared the two documents. I'm going to move forward with OPIA on the news release. Do we have a release date for OPIA?

Also, please note highlight from 10B.

Regards,
Mark

From: Copeland, Brittany R.
Sent: Friday, March 15, 2019 11:16 AM
To: Ledesma, Mark P. <(b6) va.gov>
Cc: VHA 10B <vha10b@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Good morning Mark,

On behalf of Krystal Toles, 10B clears the attached with edits. Please ensure PBM follows its normal distribution process for the FAQ document.

Thanks!

Brittany R. Copeland, MHA
Health System Specialist
Office of the VHA Chief of Staff (10B)
810 Vermont Ave NW | Washington, DC 20420
o: (b6)

From: Ledesma, Mark P.
Sent: Thursday, March 14, 2019 4:32 PM
To: Toles, Krystal M. <(b6) va.gov>; Yang, Robert B. <(b6) va.gov>
Cc: VHA 10B <vha10b@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>; Ledesma, Mark P. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Hi Krystal,

I was told that the message to the field will be ready for internal distribution tomorrow morning.

Regards,
Mark

From: Toles, Krystal M.
Sent: Thursday, March 14, 2019 3:36 PM

AMERICAN OVERSIGHT

To: Ledesma, Mark P. <(b6) va.gov>; Yang, Robert B. <(b6) va.gov>
Cc: VHA 10B <vha10b@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Mark,

Is an internal message to the field also pending?

From: Ledesma, Mark P.
Sent: Thursday, March 14, 2019 1:22 PM
To: Yang, Robert B. <(b6) va.gov>
Cc: VHA 10B <vha10b@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>; Toles, Krystal M. <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Hi Robert,

I'm resubmitting the nasal spray news release on behalf of 10P for review/conncurence.

I have also attached the internal communication Frequently Asked Question (FAQ) document for Spravato® for review/concurrence.



Please let me know if you have questions. Thanks.

Regards,
Mark

From: Yang, Robert B.
Sent: Wednesday, March 13, 2019 4:38 PM
To: Ledesma, Mark P. <(b6) va.gov>
Cc: VHA 10B <vha10b@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>; Toles, Krystal M. <(b6) va.gov>
Subject: FW: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Hello Mark,

AMERICAN OVERSIGHT

The press release is unable to be cleared at this time. Please see highlighted below for feedback.

Thanks,

Robert B Yang
Health System Specialist
Office of the VHA Chief of the Staff (10B)
810 Vermont Ave NW
Washington DC 20420
Office: (b6)
Cell: (b6)
Robert.Yang2@va.gov

From: Toles, Krystal M.
Sent: Wednesday, March 13, 2019 4:14 PM
To: Yang, Robert B. <(b6) va.gov>
Cc: VHA 10B <vha10b@va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Thanks for your review, Robert.

We are unable to clear the press release without having an internal communication ready for review and in place. (b) (5) ?

From: Ledesma, Mark P.
Sent: Wednesday, March 13, 2019 1:22 PM
To: VHA 10B <vha10b@va.gov>
Cc: VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>; Ledesma, Mark P. <(b6) va.gov>
Subject: FW: HHS bought a nasal spray for depression - DRAFT News Release - REVISED
Importance: High

Good afternoon, 10B.

We have an **urgent request for review/concurrence** of the attached news release. 10P wants to get this out ASAP – since FDA released last week and there is WH interest.

Please let me know if you have questions. Thank you.

Regards,
Mark

From: Smith, Monica (VACO)
Sent: Tuesday, March 12, 2019 4:16 PM
To: Screen, Gina <(b6) va.gov>; Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>
Cc: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO)

AMERICAN OVERSIGHT

<(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Gina, Mark, Alan – please see the revised draft version of the press release. FAQs are being worked and will be sent asap. Pharmacy and Mental Health SMEs are on the email in case there are questions.

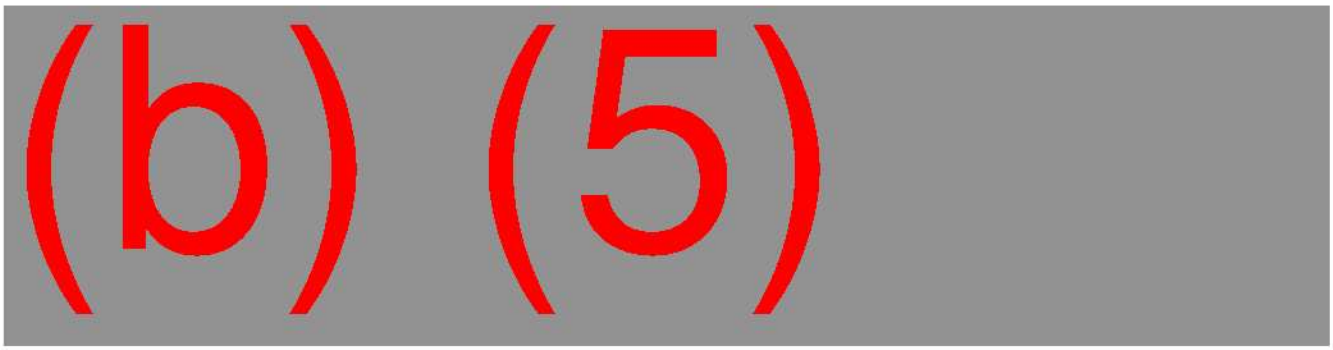
From: Smith, Monica (VACO)
Sent: Tuesday, March 12, 2019 12:10 PM
To: Screen, Gina <(b6) va.gov>; Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. (b6) @va.gov>
Cc: Outlaw, William N. <(b6) @va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

Agreed. I had a lot of questions when Tom and I were reviewing the draft. We will get with Pharmacy and Mental Health to develop.

From: Screen, Gina
Sent: Tuesday, March 12, 2019 10:24 AM
To: Smith, Monica (VACO) <(b6) va.gov>; Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

I think we also need a few faq's about this… I'm sure a lot of people will have questions…

From: Smith, Monica (VACO)
Sent: Tuesday, March 12, 2019 10:22 AM
To: Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>; Screen, Gina <(b6) va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; Llorente, Maria D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>; Law, Cassandra M. <(b6) va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; Beck, Lucille B. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release



AMERICAN OVERSIGHT

(b) (5)

Sender:	Carroll, David (VACO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=95E14EBD3B6745C8952A823B04DABFF5-CARROLL, DA>
Recipient:	Smith, Monica (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=511ea9e77a234375a91a7b34ce23719d-Smith, Moni <(b6) va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>
Sent Date:	2019/03/15 13:43:08
Delivered Date:	2019/03/15 13:43:00

AMERICAN OVERSIGHT

From:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>
To:	Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>
CC:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b6) va.gov>
Subject:	RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED
Date:	2019/03/15 09:09:02
Priority:	Normal
Type:	Note

Hi Jenn,
Please hold off on distributing the FAQ document thru our normal channels this morning. Monica is in my office and the word is that Dr. Stone wants to send out the FAQ to ND and staff.
Tom

From: Emmendorfer, Thomas (PBM)
Sent: Thursday, March 14, 2019 4:18 PM
To: Zacher, Jennifer L. (PBM) <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED
Perfect! Thank you Jenn. Dennis is going to convert to a pdf for me. Could you have someone e-mail this out tomorrow morning to the pharmacy community and post it on our internal website?

From: Zacher, Jennifer L. (PBM)
Sent: Thursday, March 14, 2019 4:09 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED
I have no edits on this.
JZ

From: Emmendorfer, Thomas (PBM)
Sent: Thursday, March 14, 2019 2:53 PM
To: Zacher, Jennifer L. (PBM) <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED
Hi Jenn,
This is all set for final review. Could you take a look at it? Some of the responses to the FAQ are we will provide an update on 3/18/2019.
If this looks good to you, I will get it converted to a PDF and share with Maria and Ilse and then it is ready to be distributed through normal channels.
Check one more item of the list to complete!

AMERICAN OVERSIGHT

Thank you for everything!
Tom

From: Szudarski, Lucy (PBM)
Sent: Thursday, March 14, 2019 3:42 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED
Tom, use this version

From: Szudarski, Lucy (PBM)
Sent: Thursday, March 14, 2019 2:38 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED
Here you go Tom, sorry it took so long, I had an appt at lunch and then my computer was acting up.
Hopefully this is how you wanted it, I followed pretty much the way the other document was.
Lucy

From: Emmendorfer, Thomas (PBM)
Sent: Thursday, March 14, 2019 9:19 AM
To: Szudarski, Lucy (PBM) <(b6) @va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED
Hi Lucy,
Thank you for doing this! Could you use this version of the Esketamine Frequently Asked Question document?
(b) (5)

Tom

From: Szudarski, Lucy (PBM)
Sent: Thursday, March 14, 2019 9:13 AM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: FW: HHS bought a nasal spray for depression - DRAFT News Release - REVISED
Hi Tom,
Here it is on our PBM letterhead, I was able to fit it on two pages. I hope this is what you wanted, let me know if this is ok.
Thanks,
Lucy

AMERICAN OVERSIGHT

From: Emmendorfer, Thomas (PBM)
Sent: Wednesday, March 13, 2019 5:58 PM
To: Zacher, Jennifer L. (PBM) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Wiechers, Ilse <(b6) va.gov>
Subject: FW: HHS bought a nasal spray for depression - DRAFT News Release - REVISED
FYI...
Jenn,
Please have Lucy use this version to build the header ect...
There were two minor edits made.
Thank you,
Tom

Sent with BlackBerry Work
(www.blackberry.com)

From: Smith, Monica (VACO) <(b6) va.gov>
Date: Wednesday, Mar 13, 2019, 5:20 PM
To: Ledesma, Mark P. <(b6) va.gov>, Greilsamer, Alan <(b6) va.gov>, Screen, Gina <(b6) va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: FW: HHS bought a nasal spray for depression - DRAFT News Release - REVISED
See attached cleared by 10P4 Acting ADUSH.

From: Llorente, Maria D. <(b6) va.gov>
Date: Wednesday, Mar 13, 2019, 5:09 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Cc: Wiechers, Ilse <(b6) va.gov>, Valentino, Michael (VACO) <(b6) va.gov>, Smith, Monica (VACO) <(b6) va.gov>
Subject: FW: HHS bought a nasal spray for depression - DRAFT News Release - REVISED
A very minor edit. Otherwise, looks good.
Maria

From: Emmendorfer, Thomas (PBM)
Sent: Wednesday, March 13, 2019 3:37 PM
To: Wiechers, Ilse <(b6) va.gov>
Cc: Llorente, Maria D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Smith, Monica (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) &lt(b6) va.gov>
Subject: FW: HHS bought a nasal spray for depression - DRAFT News Release - REVISED
Ilse,
By chance, do you know if Spravato® has been discussed on any Mental Health leadership calls yet? If so, could you please add to the list below? Also, make sure you agree with my COMMS plan that needs to be executed yet.
DRAFT message to 10P4 Actions:
(b) (5)
.

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(b) (5)

[redacted]

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Sent: Wednesday, March 13, 2019 3:01 PM
To: Ledesma, Mark P. <(b6) va.gov>; Greilsamer, Alan <(b6) va.gov>; Screen, Gina <(b6) @va.gov>
Cc: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED
Thanks. Tom and Dave – please let Mark know what the internal plans are.

From: Ledesma, Mark P.
Sent: Wednesday, March 13, 2019 3:00 PM
To: Smith, Monica (VACO) <(b6) va.gov>; Greilsamer, Alan <(b6) va.gov>; Screen, Gina <(b6) va.gov>
Cc: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; Ledesma, Mark P. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED
Thanks, Monica. I got a bit more clarity from 10B.
They want to make sure that we have an internal comms plan in place to help answer questions from providers and Veterans before they clear the release.
Regards,
Mark

From: Smith, Monica (VACO)
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To: Ledesma, Mark P. <(b6) va.gov>; Greilsamer, Alan <(b6) va.gov>; Screen, Gina <(b6) va.gov>
Cc: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David

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(VACO) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED
Mark – I know Pharmacy and Mental Health are working on FAQs, but let’s defer to Tom and Dave to see what plans are in place for internal communication. Let us know if you/10B want more for external, other than responses to queries/FAQs. If a statement is needed, we are happy to work on something.

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Cc: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; Ledesma, Mark P. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED
Hi Monica,
10B is asking where the comms plan is for this release.
Regards,
Mark

From: Greilsamer, Alan
Sent: Wednesday, March 13, 2019 1:16 PM
To: Smith, Monica (VACO) <(b6) va.gov>; Screen, Gina <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>
Cc: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED
Monica – It is being worked. We will keep you updated on our progress. Thanks, Alan

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From: Smith, Monica (VACO)
Sent: Wednesday, March 13, 2019 12:50 PM
To: Screen, Gina <(b6) va.gov>; Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>
Cc: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED
Hi there – checking in on status. VHA wants to get this out ASAP. Since FDA released last week and there is WH interest, can you expedite review?

From: Smith, Monica (VACO)
Sent: Tuesday, March 12, 2019 4:16 PM

AMERICAN OVERSIGHT

To: Screen, Gina <(b6) va.gov>; Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. &lt(b6) va.gov>
Cc: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED
Gina, Mark, Alan – please see the revised draft version of the press release. FAQs are being worked and will be sent asap. Pharmacy and Mental Health SMEs are on the email in case there are questions.

From: Smith, Monica (VACO)
Sent: Tuesday, March 12, 2019 12:10 PM
To: Screen, Gina <(b6) va.gov>; Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>
Cc: Outlaw, William N. <(b6) @va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release
Agreed. I had a lot of questions when Tom and I were reviewing the draft. We will get with Pharmacy and Mental Health to develop.

From: Screen, Gina
Sent: Tuesday, March 12, 2019 10:24 AM
To: Smith, Monica (VACO) <(b6) va.gov>; Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release
I think we also need a few faq’s about this… I’m sure a lot of people will have questions…

From: Smith, Monica (VACO)
Sent: Tuesday, March 12, 2019 10:22 AM
To: Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>; Screen, Gina <(b6) va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; Llorente, Maria D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>; Law, Cassandra M. &lt(b6) va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; Beck, Lucille B. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release
(b) (5)

AMERICAN OVERSIGHT

(b) (5) [redacted]

Sender:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) [redacted]va.gov>
Recipient:	Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) [redacted]va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) [redacted]va.gov>
Sent Date:	2019/03/15 09:09:01
Delivered Date:	2019/03/15 09:09:02
Message Flags:	Unread

AMERICAN OVERSIGHT

From:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>
To:	Smith, Monica (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=511ea9e77a234375a91a7b34ce23719d-Smith, Moni <(b6) va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>
CC:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>; Law, Cassandra M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f888d507d6c54eb5a92fc44199eb5838-Law, Cassan <(b6) va.gov>
Subject:	RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED
Date:	2019/03/15 09:16:33
Priority:	Normal
Type:	Note

Good Morning Dave,
Monica is in my office. Mark LeDesma and Krystal Toles responded last night saying we need a message from Dr. Stone to accompany the FAQs. Monica is going to contact Krystal Toles to get clarification on what is needed (i.e. Does Dr. Stone want a couple of sentences and the FAQ to go out referencing that a memo will be coming out of 10N to the Network Directors in the next couple of days).
NOTE: (b) (5) .
Tom

From: Emmendorfer, Thomas (PBM)
Sent: Thursday, March 14, 2019 4:36 PM
To: Wiechers, Ilse <(b6) va.gov>
Cc: Valentino, Michael (VACO) (b6) va.gov) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>
Subject: FW: HHS bought a nasal spray for depression - DRAFT News Release - REVISED
Hi Ilse,
The Esketamine FAQ document is ready. We will send the document out to the Pharmacy Community tomorrow am if you could have someone send it out to the Mental Health listservs. The header shows this is a joint document between our offices.

AMERICAN OVERSIGHT

Thank you for everything you have done on this Ilse. I have been watching all the e-mails on imed consent, memos, and other documents. You are making a ton of progress in a short period of time!
Let me know if you need anything else.
Tom

From: Lahl, Dennis
Sent: Thursday, March 14, 2019 4:30 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED
Thanks and have a great day.
Dennis

Dennis Lahl FAC-P/PM
Office of the Assistant Deputy Under Secretary for Health for Patient Care Services (10P4)
VACO PCS IT/BCAG/ISO Liaison
TMS OPCS DM
ph: (b6)
fax: 202-273-5483
Dennis Lahl

From: Emmendorfer, Thomas (PBM)
Sent: Thursday, March 14, 2019 4:19 PM
To: Lahl, Dennis <(b6) @va.gov>
Subject: FW: HHS bought a nasal spray for depression - DRAFT News Release - REVISED
Convert to PDF

From: Emmendorfer, Thomas (PBM)
Sent: Thursday, March 14, 2019 3:53 PM
To: Zacher, Jennifer L. (PBM) <(b6) va.gov>
Cc: Valentino, Michael (VACO) (b6) va.gov)
<(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED
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Tom, use this version

AMERICAN OVERSIGHT

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(b) (5)
px
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AMERICAN OVERSIGHT

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Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>, Emmendorfer, Thomas (PBM) <Thomas.Emmendorfer@va.gov>
Subject: FW: HHS bought a nasal spray for depression - DRAFT News Release - REVISED
See attached cleared by 10P4 Acting ADUSH.

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By chance, do you know if Spravato® has been discussed on any Mental Health leadership calls yet? If so, could you please add to the list below? Also, make sure you agree with my COMMS plan that needs to be executed yet.
DRAFT message to 10P4 Actions:
(b) (5)

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- (b) (5) [redacted]

[redacted]

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Regards,
Mark

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Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

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Gina, Mark, Alan – please see the revised draft version of the press release. FAQs are being worked and will be sent asap. Pharmacy and Mental Health SMEs are on the email in case there are questions.

From: Smith, Monica (VACO)
Sent: Tuesday, March 12, 2019 12:10 PM
To: Screen, Gina <(b6) va.gov>; Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>
Cc: Outlaw, William N. <(b6) @va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release
Agreed. I had a lot of questions when Tom and I were reviewing the draft. We will get with Pharmacy and Mental Health to develop.

From: Screen, Gina
Sent: Tuesday, March 12, 2019 10:24 AM
To: Smith, Monica (VACO) <(b6) va.gov>; Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release
I think we also need a few faq’s about this… I’m sure a lot of people will have questions…

From: Smith, Monica (VACO)
Sent: Tuesday, March 12, 2019 10:22 AM
To: Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>; Screen, Gina <(b6) va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; Llorente, Maria D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>; Law, Cassandra M. <(b6) va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; Beck, Lucille B. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release
VHA Comms:
(b) (6), (b) (5)

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Sender:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>
Recipient:	Smith, Monica (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=511ea9e77a234375a91a7b34ce23719d-Smith, Moni <(b6) va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>; Law, Cassandra M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f888d507d6c54eb5a92fc44199eb5838-Law, Cassan <(b6) va.gov>
Sent Date:	2019/03/15 09:16:31
Delivered Date:	2019/03/15 09:16:33

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From:	Smith, Monica (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=511EA9E77A234375A91A7B34CE23719D-SMITH, MONI <(b6) va.gov>
To:	Ledesma, Mark P. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=acbc9290cfec4fff8651002b5b0330c5-Ledesma, Ma <(b6) va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>
Subject:	RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED
Date:	2019/03/15 13:48:21
Priority:	Normal
Type:	Note

Hi Mark – try this please – see edit in red:

(b) (5)

From: Ledesma, Mark P.
Sent: Friday, March 15, 2019 12:31 PM
To: Smith, Monica (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>
Cc: Ledesma, Mark P. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

I also just noticed that 10B had a comment that needs to be addressed on the press release.

From: Ledesma, Mark P.
Sent: Friday, March 15, 2019 12:30 PM
To: Smith, Monica (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>
Cc: Ledesma, Mark P. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Monday is going to be tough. I'll do my best to push.

Regards,
Mark

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From: Smith, Monica (VACO)
Sent: Friday, March 15, 2019 12:28 PM
To: Ledesma, Mark P. <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

ASAP – could we shoot for Monday? The announcement to the field has started.

From: Ledesma, Mark P.
Sent: Friday, March 15, 2019 11:23 AM
To: Smith, Monica (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>
Cc: Ledesma, Mark P. <(b6) va.gov>
Subject: FW: HHS bought a nasal spray for depression - DRAFT News Release - REVISED
Importance: High

Good morning, Monica, Tom,

10B cleared the two documents. I'm going to move forward with OPIA on the news release. Do we have a release date for OPIA?

Also, please note highlight from 10B.

Regards,
Mark

From: Copeland, Brittany R.
Sent: Friday, March 15, 2019 11:16 AM
To: Ledesma, Mark P. <(b6) va.gov>
Cc: VHA 10B <vha10b@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Good morning Mark,

On behalf of Krystal Toles, 10B clears the attached with edits. Please ensure PBM follows its normal distribution process for the FAQ document.

Thanks!

Brittany R. Copeland, MHA
Health System Specialist
Office of the VHA Chief of Staff (10B)
810 Vermont Ave NW | Washington, DC 20420
o: (b6)

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From: Ledesma, Mark P.
Sent: Thursday, March 14, 2019 4:32 PM
To: Toles, Krystal M. <(b6) @va.gov>; Yang, Robert B. <(b6) va.gov>
Cc: VHA 10B <vha10b@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>; Ledesma, Mark P. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Hi Krystal,

I was told that the message to the field will be ready for internal distribution tomorrow morning.

Regards,
Mark

From: Toles, Krystal M.
Sent: Thursday, March 14, 2019 3:36 PM
To: Ledesma, Mark P. <(b6) va.gov>; Yang, Robert B. (b6) va.gov>
Cc: VHA 10B <vha10b@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Mark,

Is an internal message to the field also pending?

From: Ledesma, Mark P.
Sent: Thursday, March 14, 2019 1:22 PM
To: Yang, Robert B. <(b6) va.gov>
Cc: VHA 10B <vha10b@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>; Toles, Krystal M. <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Hi Robert,

I'm resubmitting the nasal spray news release on behalf of 10P for review/conncurence.

I have also attached the internal communication Frequently Asked Question (FAQ) document for Spravato® for review/concurrence.

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AMERICAN OVERSIGHT

(b) (5) [redacted]

Please let me know if you have questions. Thanks.

Regards,
Mark

From: Yang, Robert B.
Sent: Wednesday, March 13, 2019 4:38 PM
To: Ledesma, Mark P. <(b6) [redacted] va.gov>
Cc: VHA 10B <vha10b@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>; Toles, Krystal M. <(b6) [redacted] va.gov>
Subject: FW: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Hello Mark,

The press release is unable to be cleared at this time. Please see highlighted below for feedback.

Thanks,

Robert B Yang
Health System Specialist
Office of the VHA Chief of the Staff (10B)
810 Vermont Ave NW
Washington DC 20420
Office: (b6) [redacted]
Cell: (b6) [redacted]
(b6) [redacted] va.gov

From: Toles, Krystal M.
Sent: Wednesday, March 13, 2019 4:14 PM
To: Yang, Robert B. <(b6) [redacted] va.gov>
Cc: VHA 10B <vha10b@va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Thanks for your review, Robert.

We are unable to clear the press release without having an internal communication ready for review and in place. (b) (5) [redacted]?

From: Ledesma, Mark P.
Sent: Wednesday, March 13, 2019 1:22 PM
To: VHA 10B <vha10b@va.gov>
Cc: VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>; Ledesma, Mark P. <(b6) [redacted] va.gov>

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Subject: FW: HHS bought a nasal spray for depression - DRAFT News Release - REVISED
Importance: High

Good afternoon, 10B.

We have an **urgent request for review/concurrence** of the attached news release. 10P wants to get this out ASAP – since FDA released last week and there is WH interest.

Please let me know if you have questions. Thank you.

Regards,
Mark

From: Smith, Monica (VACO)
Sent: Tuesday, March 12, 2019 4:16 PM
To: Screen, Gina <(b6) va.gov>; Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>
Cc: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

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Cc: Outlaw, William N. (b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

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Sent: Tuesday, March 12, 2019 10:24 AM
To: Smith, Monica (VACO) <(b6) va.gov>; Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

I think we also need a few faq's about this… I'm sure a lot of people will have questions…

From: Smith, Monica (VACO)
Sent: Tuesday, March 12, 2019 10:22 AM
To: Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>; Screen,

AMERICAN OVERSIGHT

Gina <(b6) va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; Llorente, Maria D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>; Law, Cassandra M. <(b6) va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; Beck, Lucille B. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

VHA Comms:
(b) (5)

Sender:	Smith, Monica (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=511EA9E77A234375A91A7B34CE23719D-SMITH, MONI <(b6) va.gov>
Recipient:	Ledesma, Mark P. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=acbc9290cfec4fff8651002b5b0330c5-Ledesma, Ma <(b6) va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>
Sent Date:	2019/03/15 13:48:19
Delivered Date:	2019/03/15 13:48:21

AMERICAN OVERSIGHT

From:	Emmendorfer, Thomas (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC96BB44E7AE2C94C43B55D094-EMMENDORFER <(b6) va.gov>
To:	Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>
CC:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>
Subject:	RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED
Date:	2019/03/15 09:09:02
Priority:	Normal
Type:	Note

Hi Jenn,

Please hold off on distributing the FAQ document thru our normal channels this morning. Monica is in my office and the word is that Dr. Stone wants to send out the FAQ to ND and staff.

Tom

From: Emmendorfer, Thomas (PBM)
Sent: Thursday, March 14, 2019 4:18 PM
To: Zacher, Jennifer L. (PBM) <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Perfect! Thank you Jenn. Dennis is going to convert to a pdf for me. Could you have someone e-mail this out tomorrow morning to the pharmacy community and post it on our internal website?

From: Zacher, Jennifer L. (PBM)
Sent: Thursday, March 14, 2019 4:09 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

I have no edits on this.
JZ

From: Emmendorfer, Thomas (PBM)
Sent: Thursday, March 14, 2019 2:53 PM
To: Zacher, Jennifer L. (PBM) <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

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Hi Jenn,

This is all set for final review. Could you take a look at it? Some of the responses to the FAQ are we will provide an update on 3/18/2019.

If this looks good to you, I will get it converted to a PDF and share with Maria and Ilse and then it is ready to be distributed through normal channels.

Check one more item of the list to complete!

Thank you for everything!

Tom

From: Szudarski, Lucy (PBM)
Sent: Thursday, March 14, 2019 3:42 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Tom, use this version

From: Szudarski, Lucy (PBM)
Sent: Thursday, March 14, 2019 2:38 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Here you go Tom, sorry it took so long, I had an appt at lunch and then my computer was acting up.

Hopefully this is how you wanted it, I followed pretty much the way the other document was.

Lucy

From: Emmendorfer, Thomas (PBM)
Sent: Thursday, March 14, 2019 9:19 AM
To: Szudarski, Lucy (PBM) (b6) @va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Hi Lucy,

Thank you for doing this! Could you use this version of the Esketamine Frequently Asked Question document?

Could you use the headers/footers/page numbers style that was used for the Ketamine Infusion for...docx?

For the 1st page Header Page...

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(b) (5)
[redacted]

[redacted]

Tom

From: Szudarski, Lucy (PBM)
Sent: Thursday, March 14, 2019 9:13 AM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: FW: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Hi Tom,
Here it is on our PBM letterhead, I was able to fit it on two pages. I hope this is what you wanted, let me know if this is ok.
Thanks,
Lucy

From: Emmendorfer, Thomas (PBM)
Sent: Wednesday, March 13, 2019 5:58 PM
To: Zacher, Jennifer L. (PBM) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Wiechers, Ilse (b6) @va.gov>
Subject: FW: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

FYI...

Jenn,

Please have Lucy use this version to build the header ect...

There were two minor edits made.

Thank you,

Tom

Sent with BlackBerry Work
(www.blackberry.com)

AMERICAN OVERSIGHT

From: Smith, Monica (VACO) <(b6) va.gov>
Date: Wednesday, Mar 13, 2019, 5:20 PM
To: Ledesma, Mark P. <(b6) va.gov>, Greilsamer, Alan <(b6) va.gov>, Screen, Gina (b6) va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: FW: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

See attached cleared by 10P4 Acting ADUSH.

From: Llorente, Maria D. <(b6) va.gov>
Date: Wednesday, Mar 13, 2019, 5:09 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Cc: Wiechers, Ilse (b6) @va.gov>, Valentino, Michael (VACO) <(b6) va.gov>, Smith, Monica (VACO) <(b6) va.gov>
Subject: FW: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

A very minor edit. Otherwise, looks good.
Maria

From: Emmendorfer, Thomas (PBM)
Sent: Wednesday, March 13, 2019 3:37 PM
To: Wiechers, Ilse (b6) @va.gov>
Cc: Llorente, Maria D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Smith, Monica (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: FW: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Ilse,
By chance, do you know if Spravato® has been discussed on any Mental Health leadership calls yet? If so, could you please add to the list below? Also, make sure you agree with my COMMS plan that needs to be executed yet.

DRAFT message to 10P4 Actions:

(b) (5)

[redacted]

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(b) (5)

From: Smith, Monica (VACO)
Sent: Wednesday, March 13, 2019 3:01 PM
To: Ledesma, Mark P. <(b6) va.gov>; Greilsamer, Alan <(b6) va.gov>; Screen, Gina <(b6) va.gov>
Cc: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Thanks. Tom and Dave – please let Mark know what the internal plans are.

From: Ledesma, Mark P.
Sent: Wednesday, March 13, 2019 3:00 PM
To: Smith, Monica (VACO) <(b6) va.gov>; Greilsamer, Alan <(b6) va.gov>; Screen, Gina <(b6) va.gov>
Cc: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; Ledesma, Mark P. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Thanks, Monica. I got a bit more clarity from 10B.

They want to make sure that we have an internal comms plan in place to help answer questions from providers and Veterans before they clear the release.

Regards,
Mark

From: Smith, Monica (VACO)
Sent: Wednesday, March 13, 2019 2:37 PM
To: Ledesma, Mark P. <(b6) va.gov>; Greilsamer, Alan <(b6) va.gov>; Screen, Gina <(b6) va.gov>
Cc: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Mark – I know Pharmacy and Mental Health are working on FAQs, but let's defer to Tom and Dave to see what plans are in place for internal communication. Let us know if you/10B want more for external, other than responses to queries/FAQs. If a statement is needed, we are happy to work on something.

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From: Ledesma, Mark P.
Sent: Wednesday, March 13, 2019 2:11 PM
To: Greilsamer, Alan <(b6) va.gov>; Smith, Monica (VACO) <(b6) va.gov>; Screen, Gina <(b6) va.gov>
Cc: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; Ledesma, Mark P. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Hi Monica,

10B is asking where the comms plan is for this release.

Regards,
Mark

From: Greilsamer, Alan
Sent: Wednesday, March 13, 2019 1:16 PM
To: Smith, Monica (VACO) <(b6) va.gov>; Screen, Gina <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>
Cc: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Monica – It is being worked. We will keep you updated on our progress. Thanks, Alan

---

From: Smith, Monica (VACO)
Sent: Wednesday, March 13, 2019 12:50 PM
To: Screen, Gina <(b6) va.gov>; Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>
Cc: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Hi there – checking in on status. VHA wants to get this out ASAP. Since FDA released last week and there is WH interest, can you expedite review?

From: Smith, Monica (VACO)
Sent: Tuesday, March 12, 2019 4:16 PM
To: Screen, Gina <(b6) va.gov>; Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>
Cc: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; VHA 10P4 Actions

AMERICAN OVERSIGHT

<VHA10P4Actions@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Gina, Mark, Alan – please see the revised draft version of the press release. FAQs are being worked and will be sent asap. Pharmacy and Mental Health SMEs are on the email in case there are questions.

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Sent: Tuesday, March 12, 2019 12:10 PM
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Cc: Outlaw, William N. (b6) @va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

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Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

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Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; Llorente, Maria D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>; Law, Cassandra M. <(b6) va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; Beck, Lucille B. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

VHA Comms:
(b) (5)

AMERICAN OVERSIGHT

- (b) (5) [redacted].

Sender:	Emmendorfer, Thomas (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC96BB44E7AE2C94C43B55D094-EMMENDORFER <(b6) [redacted]va.gov>
Recipient:	Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) [redacted]va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) [redacted]va.gov>
Sent Date:	2019/03/15 09:09:01
Delivered Date:	2019/03/15 09:09:02
Message Flags:	Unread

AMERICAN OVERSIGHT

From:	Cunningham, Fran /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=613F0D8E535D46AF95FED310F100DCBC-CUNNINGHAM, <(b6) va.gov>
To:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>
Subject:	RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED
Date:	2019/03/15 12:04:33
Priority:	Normal
Type:	Note

Perfect!! Going to make sure she posts to the What's new at PBM spot on the intranet.

Fran

From: Emmendorfer, Thomas (PBM)
Sent: Friday, March 15, 2019 11:04 AM
To: Cunningham, Fran <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Yes, please.

From: Cunningham, Fran
Sent: Friday, March 15, 2019 12:00 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Tom – Does Pharmacy Informatics need the FAQ as well. That's the other group on the list. I thought so but wanted to double check.

From: Emmendorfer, Thomas (PBM)
Sent: Friday, March 15, 2019 10:41 AM
To: Cunningham, Fran <(b6) va.gov>
Subject: FW: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

All systems cleared for launch ☺

We have the green light to post and e-mail the FAQ.

Once it e-mailed, could you ask Marie to forward me the e-mail? I know I am in the groups, but my Outlook has two tabs now 'Focused' and 'Other' and some e-mails randomly show-up in 'Other'.

Thank you!

Tom

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From: Ledesma, Mark P.
Sent: Friday, March 15, 2019 11:23 AM
To: Smith, Monica (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>
Cc: Ledesma, Mark P. <(b6) va.gov>
Subject: FW: HHS bought a nasal spray for depression - DRAFT News Release - REVISED
Importance: High

Good morning, Monica, Tom,

10B cleared the two documents. I'm going to move forward with OPIA on the news release. Do we have a release date for OPIA?

Also, please note highlight from 10B.

Regards,
Mark

From: Copeland, Brittany R.
Sent: Friday, March 15, 2019 11:16 AM
To: Ledesma, Mark P. <(b6) va.gov>
Cc: VHA 10B <vha10b@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Good morning Mark,

On behalf of Krystal Toles, 10B clears the attached with edits. Please ensure PBM follows its normal distribution process for the FAQ document.

Thanks!

Brittany R. Copeland, MHA
Health System Specialist
Office of the VHA Chief of Staff (10B)
810 Vermont Ave NW | Washington, DC 20420
o: (b6)

From: Ledesma, Mark P.
Sent: Thursday, March 14, 2019 4:32 PM
To: Toles, Krystal M. <(b6) va.gov>; Yang, Robert B. <(b6) va.gov>
Cc: VHA 10B <vha10b@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>; Ledesma, Mark P. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

AMERICAN OVERSIGHT

Hi Krystal,

I was told that the message to the field will be ready for internal distribution tomorrow morning.

Regards,
Mark

From: Toles, Krystal M.
Sent: Thursday, March 14, 2019 3:36 PM
To: Ledesma, Mark P. <(b6) va.gov>; Yang, Robert B. <(b6) va.gov>
Cc: VHA 10B <vha10b@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Mark,

Is an internal message to the field also pending?

From: Ledesma, Mark P.
Sent: Thursday, March 14, 2019 1:22 PM
To: Yang, Robert B. <(b6) va.gov>
Cc: VHA 10B <vha10b@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>; Toles, Krystal M. <Krystal.Toles@va.gov>; Ledesma, Mark P. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Hi Robert,

I'm resubmitting the nasal spray news release on behalf of 10P for review/conncurence.

I have also attached the internal communication Frequently Asked Question (FAQ) document for Spravato® for review/concurrence.

(b) (5)

Please let me know if you have questions. Thanks.

Regards,

AMERICAN OVERSIGHT

Mark

From: Yang, Robert B.
Sent: Wednesday, March 13, 2019 4:38 PM
To: Ledesma, Mark P. <(b6) va.gov>
Cc: VHA 10B <vha10b@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>; Toles, Krystal M. <(b6) va.gov>
Subject: FW: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Hello Mark,

The press release is unable to be cleared at this time. Please see highlighted below for feedback.

Thanks,

Robert B Yang
Health System Specialist
Office of the VHA Chief of the Staff (10B)
810 Vermont Ave NW
Washington DC 20420
Office: (b6)
Cell: (b6)
(b6) va.gov

From: Toles, Krystal M.
Sent: Wednesday, March 13, 2019 4:14 PM
To: Yang, Robert B. <(b6) va.gov>
Cc: VHA 10B <vha10b@va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Thanks for your review, Robert.

We are unable to clear the press release without having an internal communication ready for review and in place. (b) (5) ?

From: Ledesma, Mark P.
Sent: Wednesday, March 13, 2019 1:22 PM
To: VHA 10B <vha10b@va.gov>
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Subject: FW: HHS bought a nasal spray for depression - DRAFT News Release - REVISED
Importance: High

Good afternoon, 10B.

We have an **urgent request for review/concurrence** of the attached news release. 10P wants to get this out ASAP – since FDA released last week and there is WH interest.

AMERICAN OVERSIGHT

Please let me know if you have questions. Thank you.

Regards,
Mark

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Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

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Cc: Outlaw, William N. <(b6) @va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>
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AMERICAN OVERSIGHT

VHA Comms:

(b) (5)

[redacted]

7.

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Recipient:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) [redacted] va.gov>
Sent Date:	2019/03/15 12:04:32
Delivered Date:	2019/03/15 12:04:33

AMERICAN OVERSIGHT

From:	Smith, Monica (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=511EA9E77A234375A91A7B34CE23719D-SMITH, MONI <(b6) va.gov>
To:	Ledesma, Mark P. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=acbc9290cfec4fff8651002b5b0330c5-Ledesma, Ma <(b6) va.gov>
CC:	VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>; Greilsamer, Alan /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fc02807af08443fbb5c68c590d58fa4b-Greilsamer, <(b6) va.gov>; Screen, Gina /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=777aa6921e794e42a45a07d8235767c5-Screen, Gin (b6) @va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>
Subject:	RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED
Date:	2019/03/13 16:53:04
Priority:	Normal
Type:	Note

Mark - Waiting for the Acting ADUSH to clear the FAQs. Meanwhile, see below.

(b) (5) [redacted]

From: Ledesma, Mark P.
Sent: Wednesday, March 13, 2019 4:45 PM
To: Smith, Monica (VACO) <(b6) va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; Greilsamer, Alan <(b6) va.gov>; Screen, Gina <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>
Subject: FW: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Hi Monica,

Please see response from 10B.

AMERICAN OVERSIGHT

Regards,
Mark

From: Yang, Robert B.
Sent: Wednesday, March 13, 2019 4:38 PM
To: Ledesma, Mark P. <(b6) va.gov>
Cc: VHA 10B <vha10b@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>; Toles, Krystal M. <(b6) va.gov>
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Health System Specialist
Office of the VHA Chief of the Staff (10B)
810 Vermont Ave NW
Washington DC 20420
Office: (b6)
Cell: (b6)
(b6) va.gov

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Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

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VHA Comms:

(b) (5) [redacted]

Sender:	Smith, Monica (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=511EA9E77A234375A91A7B34CE23719D-SMITH, MONI <(b6) [redacted]va.gov>
Recipient:	Ledesma, Mark P. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=acbc9290cfec4fff8651002b5b0330c5-Ledesma, Ma <(b6) [redacted]va.gov>; VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>; Greilsamer, Alan /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fc02807af08443fbb5c68c590d58fa4b-Greilsamer, <(b6) [redacted]va.gov>; Screen, Gina /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=777aa6921e794e42a45a07d8235767c5-Screen, Gin <(b6) [redacted]va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) [redacted]va.gov>
Sent Date:	2019/03/13 16:53:03
Delivered Date:	2019/03/13 16:53:04

AMERICAN OVERSIGHT

From:	Szudarski, Lucy (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7D92492F1757463DA2417401F68A598E-SZUDARSKI, <(b6) i@va.gov>
To:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>
Subject:	RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED
Date:	2019/03/14 15:56:55
Priority:	Normal
Type:	Note

Prego!!

From: Emmendorfer, Thomas (PBM)
Sent: Thursday, March 14, 2019 2:53 PM
To: Szudarski, Lucy (PBM) <(b6) @va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Gratzi!!!!

From: Szudarski, Lucy (PBM)
Sent: Thursday, March 14, 2019 3:42 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Tom, use this version

From: Szudarski, Lucy (PBM)
Sent: Thursday, March 14, 2019 2:38 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Here you go Tom, sorry it took so long, I had an appt at lunch and then my computer was acting up.

Hopefully this is how you wanted it, I followed pretty much the way the other document was.

Lucy

From: Emmendorfer, Thomas (PBM)
Sent: Thursday, March 14, 2019 9:19 AM
To: Szudarski, Lucy (PBM) (b6) @va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Hi Lucy,

AMERICAN OVERSIGHT

Thank you for doing this! Could you use this version of the Esketamine Frequently Asked Question document?

(b) (5)

Tom

From: Szudarski, Lucy (PBM)
Sent: Thursday, March 14, 2019 9:13 AM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: FW: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Hi Tom,
Here it is on our PBM letterhead, I was able to fit it on two pages. I hope this is what you wanted, let me know if this is ok.
Thanks,
Lucy

From: Emmendorfer, Thomas (PBM)
Sent: Wednesday, March 13, 2019 5:58 PM
To: Zacher, Jennifer L. (PBM) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Wiechers, Ilse (b6) @va.gov>
Subject: FW: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

FYI...

Jenn,

Please have Lucy use this version to build the header ect...

There were two minor edits made.

AMERICAN OVERSIGHT

Thank you,

Tom

Sent with BlackBerry Work
(www.blackberry.com)

From: Smith, Monica (VACO) <(b6) va.gov>
Date: Wednesday, Mar 13, 2019, 5:20 PM
To: Ledesma, Mark P. <(b6) va.gov>, Greilsamer, Alan <(b6) va.gov>, Screen, Gina (b6) n@va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: FW: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

See attached cleared by 10P4 Acting ADUSH.

From: Llorente, Maria D. <(b6) va.gov>
Date: Wednesday, Mar 13, 2019, 5:09 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Cc: Wiechers, Ilse (b6) .@va.gov>, Valentino, Michael (VACO) <(b6) va.gov>, Smith, Monica (VACO) <(b6) va.gov>
Subject: FW: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

A very minor edit. Otherwise, looks good.
Maria

From: Emmendorfer, Thomas (PBM)
Sent: Wednesday, March 13, 2019 3:37 PM
To: Wiechers, Ilse (b6) @va.gov>
Cc: Llorente, Maria D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Smith, Monica (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: FW: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Ilse,
By chance, do you know if Spravato® has been discussed on any Mental Health leadership calls yet? If so, could you please add to the list below? Also, make sure you agree with my COMMS plan that needs to be executed yet.

DRAFT message to 10P4 Actions:

(b) (5)

AMERICAN OVERSIGHT

(b) (5)

[redacted]

From: Smith, Monica (VACO)
Sent: Wednesday, March 13, 2019 3:01 PM
To: Ledesma, Mark P. <(b6) va.gov>; Greilsamer, Alan <(b6) va.gov>; Screen, Gina <(b6) va.gov>
Cc: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Valentino, Michael (VACO) <Michael.Valentino@va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Thanks. Tom and Dave – please let Mark know what the internal plans are.

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Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Thanks, Monica. I got a bit more clarity from 10B.

They want to make sure that we have an internal comms plan in place to help answer questions from providers and Veterans before they clear the release.

Regards,
Mark

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Cc: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO)

AMERICAN OVERSIGHT

<(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
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Mark – I know Pharmacy and Mental Health are working on FAQs, but let's defer to Tom and Dave to see what plans are in place for internal communication. Let us know if you/10B want more for external, other than responses to queries/FAQs. If a statement is needed, we are happy to work on something.

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Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Hi Monica,

10B is asking where the comms plan is for this release.

Regards,
Mark

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Sent: Wednesday, March 13, 2019 1:16 PM
To: Smith, Monica (VACO) <(b6) va.gov>; Screen, Gina <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>
Cc: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Monica – It is being worked. We will keep you updated on our progress. Thanks, Alan

---

From: Smith, Monica (VACO)
Sent: Wednesday, March 13, 2019 12:50 PM
To: Screen, Gina <(b6) va.gov>; Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>
Cc: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
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Hi there – checking in on status. VHA wants to get this out ASAP. Since FDA released last week and there is WH interest, can you expedite review?

AMERICAN OVERSIGHT

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Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Gina, Mark, Alan – please see the revised draft version of the press release. FAQs are being worked and will be sent asap. Pharmacy and Mental Health SMEs are on the email in case there are questions.

From: Smith, Monica (VACO)
Sent: Tuesday, March 12, 2019 12:10 PM
To: Screen, Gina <(b6) va.gov>; Greilsamer, Alan <(b6) @va.gov>; Ledesma, Mark P. <(b6) va.gov>
Cc: Outlaw, William N. (t(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

Agreed. I had a lot of questions when Tom and I were reviewing the draft. We will get with Pharmacy and Mental Health to develop.

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Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; Llorente, Maria D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>; Law, Cassandra M. <(b6) va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; Beck, Lucille B. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

VHA Comms:
(b) (5)

AMERICAN OVERSIGHT

(b) (5)

Sender:	Szudarski, Lucy (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7D92492F1757463DA2417401F68A598E-SZUDARSKI, <(b6) @va.gov>
Recipient:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>
Sent Date:	2019/03/14 15:56:54
Delivered Date:	2019/03/14 15:56:55

AMERICAN OVERSIGHT

From:	Ledesma, Mark P. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=ACBC9290CFEC4FFF8651002B5B0330C5-LEDESMA, MA <(b6) va.gov>
To:	Smith, Monica (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=511ea9e77a234375a91a7b34ce23719d-Smith, Moni <(b6) va.gov>; Greilsamer, Alan /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fc02807af08443fbb5c68c590d58fa4b-Greilsamer, <(b6) va.gov>; Screen, Gina /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=777aa6921e794e42a45a07d8235767c5-Screen, Gin <(b6) va.gov>
CC:	VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; Ledesma, Mark P. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=acbc9290cfec4fff8651002b5b0330c5-Ledesma, Ma <(b6) va.gov>
Subject:	RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED
Date:	2019/03/14 09:24:42
Priority:	Normal
Type:	Note

Thanks, Monica. I'll submit the attached along with the list of internal actions to 10B.

Regards,
Mark

From: Smith, Monica (VACO)
Sent: Wednesday, March 13, 2019 5:21 PM
To: Ledesma, Mark P. <(b6) va.gov>; Greilsamer, Alan <(b6) va.gov>; Screen, Gina <(b6) va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: FW: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

See attached cleared by 10P4 Acting ADUSH.

From: Llorente, Maria D. <(b6) va.gov>
Date: Wednesday, Mar 13, 2019, 5:09 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Cc: Wiechers, Ilse (b6) @va.gov>, Valentino, Michael (VACO) <(b6) va.gov>, Smith, Monica (VACO) <(b6) va.gov>

AMERICAN OVERSIGHT

Subject: FW: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

A very minor edit. Otherwise, looks good.
Maria

From: Emmendorfer, Thomas (PBM)
Sent: Wednesday, March 13, 2019 3:37 PM
To: Wiechers, Ilse (b6) @va.gov>
Cc: Llorente, Maria D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Smith, Monica (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>
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AMERICAN OVERSIGHT

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Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

AMERICAN OVERSIGHT

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Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

VHA Comms:
As you may have seen in the news last week, there is a new drug coming on the market to treat depression. VA will offer this to Veterans. Please see attached draft press release for your expedited review. Our Pharmacy SMEs (Tom Emmendorfer and Mike Valentino) are on the cc: line to address any questions. I also understand there is internal communication in draft for communication to the field.

(b) (5)

Sender:	Ledesma, Mark P. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=ACBC9290CFEC4FFF8651002B5B0330C5-LEDESMA, MA <(b6) va.gov>
Recipient:	Smith, Monica (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=511ea9e77a234375a91a7b34ce23719d-Smith, Moni <(b6) va.gov>; Greilsamer, Alan /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fc02807af08443fbb5c68c590d58fa4b-Greilsamer, <(b6) va.gov>; Screen, Gina /o=ExchangeLabs/ou=Exchange Administrative Group

AMERICAN OVERSIGHT

	(FYDIBOHF23SPDLT)/cn=Recipients/cn=777aa6921e794e42a45a07d8235767c5-Screen, Gin <(b6) va.gov>; VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; Ledesma, Mark P. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=acbc9290cfec4fff8651002b5b0330c5-Ledesma, Ma <(b6) va.gov>
Sent Date:	2019/03/14 09:24:40
Delivered Date:	2019/03/14 09:24:42

AMERICAN OVERSIGHT

From:	Smith, Monica (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=511EA9E77A234375A91A7B34CE23719D-SMITH, MONI <(b6) va.gov>
To:	Ledesma, Mark P. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=acbc9290cfec4fff8651002b5b0330c5-Ledesma, Ma <(b6) va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>
Subject:	RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED
Date:	2019/03/14 12:22:19
Priority:	Normal
Type:	Note

Thanks much.

From: Ledesma, Mark P.
Sent: Thursday, March 14, 2019 12:21 PM
To: Smith, Monica (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>
Cc: Ledesma, Mark P. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Got it. I'll send the attachment and bullet points and let you know if 10B wants more.

Regards,
Mark

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To: Ledesma, Mark P. <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Mark – can you submit the bullets as evidence that there is a **plan to communicate** and that communication has been/being done. I also sent along the FAQs for 10B's clearance. If you/10B expect something different, please advise. Thanks much!

From: Ledesma, Mark P.
Sent: Thursday, March 14, 2019 11:38 AM
To: Smith, Monica (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>
Cc: Ledesma, Mark P. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Hi Monica,

AMERICAN OVERSIGHT

I just want to make sure I'm not missing anything. Per 10B:

"We are unable to clear the press release without having an internal communication ready for review and in place. (b) (5) ?"

Are we providing the bullet points to show what we're internally communicating?

Regards,
Mark

From: Smith, Monica (VACO)
Sent: Thursday, March 14, 2019 11:32 AM
To: Ledesma, Mark P. <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Hi Mark:

Are you looking for something other than bullet points below on the Comms effort?

From: Ledesma, Mark P. <(b6) va.gov>
Date: Thursday, Mar 14, 2019, 10:35 AM
To: Smith, Monica (VACO) <(b6) va.gov>, Greilsamer, Alan <(b6) va.gov>, Screen, Gina <(b6) va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>, Ledesma, Mark P. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Good morning, Tom, Monica,

Are we sharing the comms plan with 10B? I didn't received it.

Regards,
Mark

From: Emmendorfer, Thomas (PBM)
Sent: Wednesday, March 13, 2019 3:37 PM
To: Wiechers, Ilse (b6) @va.gov>
Cc: Llorente, Maria D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Smith, Monica (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: FW: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

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DRAFT message to 10P4 Actions:

(b) (5)

[redacted]

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Cc: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; Ledesma, Mark P. (b6) @va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

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AMERICAN OVERSIGHT

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Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

VHA Comms:
As you may have seen in the news last week, there is a new drug coming on the market to treat depression. VA will offer this to Veterans. Please see attached draft press release for your expedited review. Our Pharmacy SMEs (Tom Emmendorfer and Mike Valentino) are on the cc: line to address any questions. I also understand there is internal communication in draft for communication to the field.

(b) (5)

Sender:	Smith, Monica (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=511EA9E77A234375A91A7B34CE23719D-SMITH, MONI <(b6) va.gov>
Recipient:	Ledesma, Mark P. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=acbc9290cfec4fff8651002b5b0330c5-Ledesma, Ma <(b6) va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>
Sent Date:	2019/03/14 12:22:17
Delivered Date:	2019/03/14 12:22:19

AMERICAN OVERSIGHT

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Subject:	RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED
Date:	2019/03/13 16:26:00
Priority:	Normal
Type:	Note

Thank you Jenn!

From: Zacher, Jennifer L. (PBM)
Sent: Wednesday, March 13, 2019 4:26 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>
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I asked Lucy to work on this in the am

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AMERICAN OVERSIGHT

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(b) (5)

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Sent Date:	2019/03/13 16:26:39
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Subject:	RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED
Date:	2019/03/13 15:52:00
Priority:	Normal
Type:	Note

Will do! We will work on that tomorrow am. I got everything prepped for Maria to review and clear…

Ilse,

If you wouldn't mind, could you check out that e-mail next? I want to try and get out of here at a reasonable hour today and as soon as we got that wrapped up…I am out of here ☺

Thank you so much!

Tom

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AMERICAN OVERSIGHT

Agreed. I had a lot of questions when Tom and I were reviewing the draft. We will get with Pharmacy and Mental Health to develop.

From: Screen, Gina
Sent: Tuesday, March 12, 2019 10:24 AM
To: Smith, Monica (VACO) <(b6) va.gov>; Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

I think we also need a few faq's about this… I'm sure a lot of people will have questions…

From: Smith, Monica (VACO)
Sent: Tuesday, March 12, 2019 10:22 AM
To: Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>; Screen, Gina <(b6) va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; Llorente, Maria D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>; Law, Cassandra M. <(b6) va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; Beck, Lucille B. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

VHA Comms:
(b) (5)

Sender:	Emmendorfer, Thomas (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC96BB44E7AE2C94C43B55D094-EMMENDORFER>
Recipient:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>
Sent Date:	2019/03/13 15:52:48
Delivered Date:	2019/03/13 15:52:00

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From:	Emmendorfer, Thomas (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC96BB44E7AE2C94C43B55D094-EMMENDORFER>
To:	Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>
Subject:	RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED
Date:	2019/03/13 15:42:00
Priority:	Normal
Type:	Note

Nope, it can wait until tomorrow.

From: Zacher, Jennifer L. (PBM)
Sent: Wednesday, March 13, 2019 3:41 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Do you need this today? Lucy is gone, and Lisa is here…….

From: Emmendorfer, Thomas (PBM)
Sent: Wednesday, March 13, 2019 2:40 PM
To: Zacher, Jennifer L. (PBM) <(b6) va.gov>
Cc: Wiechers, Ilse (b6) @va.gov>
Subject: FW: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Hi Jenn,

Can you have someone add our professional header/footer to the document and make it look nice and convert into a PDF?

Isle,

Do you what the header to read "Office of Mental Health and Suicide Prevention (OMHSP)" show it reflects a joint effort between our two Program Offices?

Tom

From: Emmendorfer, Thomas (PBM)
Sent: Wednesday, March 13, 2019 3:37 PM
To: Wiechers, Ilse <(b6) @va.gov>
Cc: Llorente, Maria D. <(b6) va.gov>; Valentino, Michael (VACO) (b6) va.gov) <(b6) va.gov>; Smith, Monica (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) (b6) va.gov>
Subject: FW: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

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Ilse,
By chance, do you know if Spravato® has been discussed on any Mental Health leadership calls yet? If so, could you please add to the list below? Also, make sure you agree with my COMMS plan that needs to be executed yet.

DRAFT message to 10P4 Actions:

(b) (5)

[redacted]

From: Smith, Monica (VACO)
Sent: Wednesday, March 13, 2019 3:01 PM
To: Ledesma, Mark P. <(b6) va.gov>; Greilsamer, Alan <(b6) va.gov>; Screen, Gina <(b6) va.gov>
Cc: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Thanks. Tom and Dave – please let Mark know what the internal plans are.

From: Ledesma, Mark P.
Sent: Wednesday, March 13, 2019 3:00 PM
To: Smith, Monica (VACO) <(b6) va.gov>; Greilsamer, Alan <(b6) va.gov>; Screen, Gina <(b6) va.gov>
Cc: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; Ledesma, Mark P. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Thanks, Monica. I got a bit more clarity from 10B.

AMERICAN OVERSIGHT

They want to make sure that we have an internal comms plan in place to help answer questions from providers and Veterans before they clear the release.

Regards,
Mark

From: Smith, Monica (VACO)
Sent: Wednesday, March 13, 2019 2:37 PM
To: Ledesma, Mark P. <(b6) va.gov>; Greilsamer, Alan <(b6) va.gov>; Screen, Gina <(b6) va.gov>
Cc: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Mark – I know Pharmacy and Mental Health are working on FAQs, but let's defer to Tom and Dave to see what plans are in place for internal communication. Let us know if you/10B want more for external, other than responses to queries/FAQs. If a statement is needed, we are happy to work on something.

From: Ledesma, Mark P.
Sent: Wednesday, March 13, 2019 2:11 PM
To: Greilsamer, Alan <(b6) va.gov>; Smith, Monica (VACO) <(b6) va.gov>; Screen, Gina <(b6) va.gov>
Cc: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; Ledesma, Mark P. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Hi Monica,

10B is asking where the comms plan is for this release.

Regards,
Mark

From: Greilsamer, Alan
Sent: Wednesday, March 13, 2019 1:16 PM
To: Smith, Monica (VACO) <(b6) va.gov>; Screen, Gina <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>
Cc: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Monica – It is being worked. We will keep you updated on our progress. Thanks, Alan

AMERICAN OVERSIGHT

From: Smith, Monica (VACO)
Sent: Wednesday, March 13, 2019 12:50 PM
To: Screen, Gina <(b6) va.gov>; Greilsamer, Alan (b6) @va.gov>; Ledesma, Mark P. <(b6) va.gov>
Cc: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Hi there – checking in on status. VHA wants to get this out ASAP. Since FDA released last week and there is WH interest, can you expedite review?

From: Smith, Monica (VACO)
Sent: Tuesday, March 12, 2019 4:16 PM
To: Screen, Gina <(b6) va.gov>; Greilsamer, Alan (b6) @va.gov>; Ledesma, Mark P. <(b6) va.gov>
Cc: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Gina, Mark, Alan – please see the revised draft version of the press release. FAQs are being worked and will be sent asap. Pharmacy and Mental Health SMEs are on the email in case there are questions.

From: Smith, Monica (VACO)
Sent: Tuesday, March 12, 2019 12:10 PM
To: Screen, Gina <(b6) va.gov>; Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>
Cc: Outlaw, William N. (b6) @va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

Agreed. I had a lot of questions when Tom and I were reviewing the draft. We will get with Pharmacy and Mental Health to develop.

From: Screen, Gina
Sent: Tuesday, March 12, 2019 10:24 AM
To: Smith, Monica (VACO) <(b6) va.gov>; Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

I think we also need a few faq's about this… I'm sure a lot of people will have questions…

From: Smith, Monica (VACO)
Sent: Tuesday, March 12, 2019 10:22 AM

AMERICAN OVERSIGHT

To: Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>; Screen, Gina <(b6) va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; Llorente, Maria D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>; Law, Cassandra M. <(b6) va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; Beck, Lucille B. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

VHA Comms:
(b) (5)

Sender:	Emmendorfer, Thomas (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC96BB44E7AE2C94C43B55D094-EMMENDORFER>
Recipient:	Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>
Sent Date:	2019/03/13 15:42:05
Delivered Date:	2019/03/13 15:42:00

AMERICAN OVERSIGHT

From:	Cunningham, Fran /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=613F0D8E535D46AF95FED310F100DCBC-CUNNINGHAM, <(b6) va.gov>
To:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>
Subject:	RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED
Date:	2019/03/15 11:44:15
Priority:	Normal
Type:	Note

Thanks Tom Will do!!

From: Emmendorfer, Thomas (PBM)
Sent: Friday, March 15, 2019 10:41 AM
To: Cunningham, Fran <(b6) va.gov>
Subject: FW: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

All systems cleared for launch ☺

We have the green light to post and e-mail the FAQ.

Once it e-mailed, could you ask Marie to forward me the e-mail? I know I am in the groups, but my Outlook has two tabs now 'Focused' and 'Other' and some e-mails randomly show-up in 'Other'.

Thank you!

Tom

From: Ledesma, Mark P.
Sent: Friday, March 15, 2019 11:23 AM
To: Smith, Monica (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>
Cc: Ledesma, Mark P. <(b6) va.gov>
Subject: FW: HHS bought a nasal spray for depression - DRAFT News Release - REVISED
Importance: High

Good morning, Monica, Tom,

10B cleared the two documents. I'm going to move forward with OPIA on the news release. Do we have a release date for OPIA?

Also, please note highlight from 10B.

Regards,

AMERICAN OVERSIGHT

Mark

From: Copeland, Brittany R.
Sent: Friday, March 15, 2019 11:16 AM
To: Ledesma, Mark P. <{b6} va.gov>
Cc: VHA 10B <vha10b@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Good morning Mark,

On behalf of Krystal Toles, 10B clears the attached with edits. Please ensure PBM follows its normal distribution process for the FAQ document.

Thanks!

Brittany R. Copeland, MHA
Health System Specialist
Office of the VHA Chief of Staff (10B)
810 Vermont Ave NW | Washington, DC 20420
o: [redacted]

From: Ledesma, Mark P.
Sent: Thursday, March 14, 2019 4:32 PM
To: Toles, Krystal M. <{b6} va.gov>; Yang, Robert B. <{b6} va.gov>
Cc: VHA 10B <vha10b@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>; Ledesma, Mark P. <{b6} va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Hi Krystal,

I was told that the message to the field will be ready for internal distribution tomorrow morning.

Regards,
Mark

From: Toles, Krystal M.
Sent: Thursday, March 14, 2019 3:36 PM
To: Ledesma, Mark P. <{b6} va.gov>; Yang, Robert B. <{b6} va.gov>
Cc: VHA 10B <vha10b@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Mark,

Is an internal message to the field also pending?

AMERICAN OVERSIGHT

From: Ledesma, Mark P.
Sent: Thursday, March 14, 2019 1:22 PM
To: Yang, Robert B. <(b6) va.gov>
Cc: VHA 10B <vha10b@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>; Toles, Krystal M. <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Hi Robert,

I'm resubmitting the nasal spray news release on behalf of 10P for review/conncurence.

I have also attached the internal communication Frequently Asked Question (FAQ) document for Spravato® for review/concurrence.

(b) (5)

Please let me know if you have questions. Thanks.

Regards,
Mark

From: Yang, Robert B.
Sent: Wednesday, March 13, 2019 4:38 PM
To: Ledesma, Mark P. <(b6) va.gov>
Cc: VHA 10B <vha10b@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>; Toles, Krystal M. <(b6) va.gov>
Subject: FW: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Hello Mark,

The press release is unable to be cleared at this time. Please see highlighted below for feedback.

Thanks,

Robert B Yang
Health System Specialist

AMERICAN OVERSIGHT

Office of the VHA Chief of the Staff (10B)
810 Vermont Ave NW
Washington DC 20420
Office: (b6)
Cell: (b6)
R(b6) @va.gov

From: Toles, Krystal M.
Sent: Wednesday, March 13, 2019 4:14 PM
To: Yang, Robert B. <(b6) va.gov>
Cc: VHA 10B <vha10b@va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Thanks for your review, Robert.

We are unable to clear the press release without having an internal communication ready for review and in place. (b) (5) ?

From: Ledesma, Mark P.
Sent: Wednesday, March 13, 2019 1:22 PM
To: VHA 10B <vha10b@va.gov>
Cc: VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>; Ledesma, Mark P. <(b6) va.gov>
Subject: FW: HHS bought a nasal spray for depression - DRAFT News Release - REVISED
Importance: High

Good afternoon, 10B.

We have an **urgent request for review/concurrence** of the attached news release. 10P wants to get this out ASAP – since FDA released last week and there is WH interest.

Please let me know if you have questions. Thank you.

Regards,
Mark

From: Smith, Monica (VACO)
Sent: Tuesday, March 12, 2019 4:16 PM
To: Screen, Gina <(b6) va.gov>; Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. (b6) @va.gov>
Cc: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

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AMERICAN OVERSIGHT

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Sent: Tuesday, March 12, 2019 12:10 PM
To: Screen, Gina <(b6) va.gov>; Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>
Cc: Outlaw, William N. <(b6) @va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

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Sent: Tuesday, March 12, 2019 10:24 AM
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Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

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Sent: Tuesday, March 12, 2019 10:22 AM
To: Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>; Screen, Gina <(b6) va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; Llorente, Maria D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) @va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>; Law, Cassandra M. <(b6) va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; Beck, Lucille B. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

VHA Comms:
(b) (5)

Sender: Cunningham, Fran /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

AMERICAN OVERSIGHT

	(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=613F0D8E535D46AF95FED310F100DCBC-CUNNINGHAM, <(b6) va.gov>
Recipient:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>
Sent Date:	2019/03/15 11:44:14
Delivered Date:	2019/03/15 11:44:15

AMERICAN OVERSIGHT

From:	Toles, Krystal M. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1156B622F1BA464FA61884615342FF18-TOLES, KRYS <(b6) va.gov>
To:	Ledesma, Mark P. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=acbc9290cfec4fff8651002b5b0330c5-Ledesma, Ma <(b6) va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; Smith, Monica (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=511ea9e77a234375a91a7b34ce23719d-Smith, Moni <(b6) va.gov>; Sullivan, Kathleen /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fa96d167d71b40a894e5a4972b71eb36-Sullivan, K (b6) @va.gov>; Poff, Susan /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=519dcdd750084898b69e224e24ebeecc-Poff, Susan <(b6) va.gov>
CC:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b6) @va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>; Greilsamer, Alan /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fc02807af08443fbb5c68c590d58fa4b-Greilsamer, <(b6) va.gov>; Ledesma, Mark P. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=acbc9290cfec4fff8651002b5b0330c5-Ledesma, Ma <(b6) va.gov>
Subject:	RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED
Date:	2019/03/14 17:22:27
Priority:	Normal
Type:	Note

Thanks Mark
We don't want to add work and we can use the same language that goes out to the NDs. Essentially we would want to give the field awareness this is coming and explain additional details will be forthcoming and send the press release immediately afterwards.

Sent with BlackBerry Work
(www.blackberry.com)

From: Ledesma, Mark P. <(b6) va.gov>
Date: Thursday, Mar 14, 2019, 5:11 PM

AMERICAN OVERSIGHT

To: Carroll, David (VACO) <{b6} va.gov>, Emmendorfer, Thomas (PBM) <{b6} va.gov>, Smith, Monica (VACO) <{b6} va.gov>, Toles, Krystal M. <{b6} va.gov>, Sullivan, Kathleen {b6} @va.gov>, Poff, Susan <{b6} va.gov>
Cc: Valentino, Michael (VACO) <{b6} va.gov>, Zacher, Jennifer L. (PBM) <{b6} va.gov>, Llorente, Maria D. <{b6} va.gov>, Wiechers, Ilse <Ilse.Wiechers@va.gov>, Greilsamer, Alan <{b6} va.gov>, Ledesma, Mark P. <{b6} va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Dr. Carroll et al.

I got word from 10B that Dr. Stone wants the message to also come from his level. Can 10P craft a message for Dr. Stone to use to send to the field along with the FAQ?

Adding Krystal, Kathleen and Susan to help coordinate in this effort.

Regards,
Mark

From: Carroll, David (VACO)
Sent: Thursday, March 14, 2019 4:39 PM
To: Emmendorfer, Thomas (PBM) <{b6} va.gov>; Smith, Monica (VACO) <{b6} va.gov>; Ledesma, Mark P. <{b6} va.gov>
Cc: Valentino, Michael (VACO) <{b6} va.gov>; Zacher, Jennifer L. (PBM) <{b6} va.gov>; Llorente, Maria D. <{b6} va.gov>; Wiechers, Ilse <Ilse.Wiechers@va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Regret being late to the discussion. As you know, we are working on a 10N memo which will give direction to facilities about what they need to do to prepare for providing Spravato. It will be a fairly operational (how to) type of communication, but it would be vehicle on which to include a FAQ document. Typically after the communication is sent to the Network Directors, we recirculate it to all relevant email groups which would help spread all of the relevant information.

From: Emmendorfer, Thomas (PBM)
Sent: Thursday, March 14, 2019 4:23 PM
To: Smith, Monica (VACO) <{b6} va.gov>; Ledesma, Mark P. <{b6} va.gov>; Carroll, David (VACO) <{b6} va.gov>
Cc: Valentino, Michael (VACO) <{b6} va.gov>; Zacher, Jennifer L. (PBM) <{b6} va.gov>; Llorente, Maria D. <{b6} va.gov>; Wiechers, Ilse {b6} @va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Hi Mark,

I hope all is going well. The internal Frequently Asked Questions (FAQ) document that was sent to you the other day has been finalized and it will be ready for internal distribution for tomorrow morning.

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Tom

From: Smith, Monica (VACO)
Sent: Thursday, March 14, 2019 3:46 PM
To: Ledesma, Mark P. <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Looping in Dave Carroll as well.

From: Ledesma, Mark P.
Sent: Thursday, March 14, 2019 3:44 PM
To: Smith, Monica (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>
Cc: Ledesma, Mark P. <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>
Subject: FW: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Monica, Tom,

Could you please help answer Krystal's question?

Regards,
Mark

From: Toles, Krystal M.
Sent: Thursday, March 14, 2019 3:36 PM
To: Ledesma, Mark P. <(b6) va.gov>; Yang, Robert B. <(b6) va.gov>
Cc: VHA 10B <vha10b@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Mark,

Is an internal message to the field also pending?

From: Ledesma, Mark P.
Sent: Thursday, March 14, 2019 1:22 PM
To: Yang, Robert B. <(b6) va.gov>
Cc: VHA 10B <vha10b@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>; Toles, Krystal M. <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Hi Robert,

I'm resubmitting the nasal spray news release on behalf of 10P for review/conncurence.

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I have also attached the internal communication Frequently Asked Question (FAQ) document for Spravato® for review/concurrence.

(b) (5)

Please let me know if you have questions. Thanks.

Regards,
Mark

From: Yang, Robert B.
Sent: Wednesday, March 13, 2019 4:38 PM
To: Ledesma, Mark P. <(b6) va.gov>
Cc: VHA 10B <vha10b@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>; Toles, Krystal M. <(b6) va.gov>
Subject: FW: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Hello Mark,

The press release is unable to be cleared at this time. Please see highlighted below for feedback.

Thanks,

Robert B Yang
Health System Specialist
Office of the VHA Chief of the Staff (10B)
810 Vermont Ave NW
Washington DC 20420
Office: (b6)
Cell: (b6)
(b6) va.gov

From: Toles, Krystal M.
Sent: Wednesday, March 13, 2019 4:14 PM
To: Yang, Robert B. <(b6) va.gov>
Cc: VHA 10B <vha10b@va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

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Thanks for your review, Robert.

We are unable to clear the press release without having an internal communication ready for review and in place. (b) (5) ?

From: Ledesma, Mark P.
Sent: Wednesday, March 13, 2019 1:22 PM
To: VHA 10B <vha10b@va.gov>
Cc: VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>; Ledesma, Mark P. <(b6) @va.gov>
Subject: FW: HHS bought a nasal spray for depression - DRAFT News Release - REVISED
Importance: High

Good afternoon, 10B.

We have an **urgent request for review/concurrence** of the attached news release. 10P wants to get this out ASAP – since FDA released last week and there is WH interest.

Please let me know if you have questions. Thank you.

Regards,
Mark

From: Smith, Monica (VACO)
Sent: Tuesday, March 12, 2019 4:16 PM
To: Screen, Gina <(b6) va.gov>; Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>
Cc: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Gina, Mark, Alan – please see the revised draft version of the press release. FAQs are being worked and will be sent asap. Pharmacy and Mental Health SMEs are on the email in case there are questions.

From: Smith, Monica (VACO)
Sent: Tuesday, March 12, 2019 12:10 PM
To: Screen, Gina <(b6) va.gov>; Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. (b6) @va.gov>
Cc: Outlaw, William N. <(b6) @va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

Agreed. I had a lot of questions when Tom and I were reviewing the draft. We will get with Pharmacy and Mental Health to develop.

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From: Screen, Gina
Sent: Tuesday, March 12, 2019 10:24 AM
To: Smith, Monica (VACO) <(b6) va.gov>; Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

I think we also need a few faq's about this… I'm sure a lot of people will have questions…

From: Smith, Monica (VACO)
Sent: Tuesday, March 12, 2019 10:22 AM
To: Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>; Screen, Gina <(b6) va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; Llorente, Maria D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>; Law, Cassandra M. <(b6) va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; Beck, Lucille B. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

VHA Comms:
(b) (5)

Sender:	Toles, Krystal M. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1156B622F1BA464FA61884615342FF18-TOLES, KRYS <(b6) va.gov>
Recipient:	Ledesma, Mark P. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=acbc9290cfec4fff8651002b5b0330c5-Ledesma, Ma <(b6) va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; Smith, Monica (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=511ea9e77a234375a91a7b34ce23719d-Smith, Moni <(b6) va.gov>;

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	Sullivan, Kathleen /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fa96d167d71b40a894e5a4972b71eb36-Sullivan, K <(b6) @va.gov>; Poff, Susan /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=519dcdd750084898b69e224e24ebeecc-Poff, Susan <(b6) va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>; Greilsamer, Alan /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fc02807af08443fbb5c68c590d58fa4b-Greilsamer, <(b6) va.gov>; Ledesma, Mark P. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=acbc9290cfec4fff8651002b5b0330c5-Ledesma, Ma <(b6) va.gov>
Sent Date:	2019/03/14 17:22:25
Delivered Date:	2019/03/14 17:22:27

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From:	Boyd, Teresa D. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F6886A7D555A43E0BEE23C1E40E1C234-BOYD, TERES <(b6) va.gov>
To:	Schuldheis, Sherrie L, Ph.D /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aecbe9a1f74d4a94a2206db8e404a63d-Schuldheis, <(b6) @va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Saslo, Christopher M (VHABIL) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=23f487d85a3e47bdb0b1d4d6274bf2da-Saslo, Mark <(b6) va.gov>; O'Toole, Thomas P.(b6) va.gov </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c5a34d8a4b294e9986ef6e1aa8009b3f-O'Toole, Th>
CC:	VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>
Subject:	RE: HHS bought a nasal spray for depression - DRAFT News Release
Date:	2019/03/12 11:39:44
Priority:	Normal
Type:	Note

According to our discussions, the Veteran has to come to the certified site, self/administer intranasal drug and then be monitored for 2 hours by the prescriber at the site. The Veteran cannot get the intranasal med mailed to him/her for self-administration outside a certified site.

Sent with BlackBerry Work
(www.blackberry.com)

From: Schuldheis, Sherrie L, Ph.D <(b6) va.gov>
Date: Tuesday, Mar 12, 2019, 10:36 AM
To: Boyd, Teresa D. <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Saslo, Christopher M (VHABIL) <(b6) va.gov>, O'Toole, Thomas P. <(b6) va.gov>
Cc: VHA 10NC5 Action <VHA10NC5Action@va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

No, this is not a self-administered medication. It must be administered by a provider and patient has to be observed after.

Sherrie Schuldheis, PhD, RN, CENP
Special Assistant, ADUSH Clinical Operations
VHA 10NC
810 Vermont NW
Washington, DC 20420
(b6) (cell)
(b6) va.gov

From: Boyd, Teresa D.
Sent: Tuesday, March 12, 2019 8:35 AM

AMERICAN OVERSIGHT

To: Carroll, David (VACO) <(b6) va.gov>; Saslo, Christopher M (VHABIL) <(b6) va.gov>; O'Toole, Thomas P. <(b6) va.gov>; Schuldheis, Sherrie L, Ph.D <(b6) va.gov>
Cc: VHA 10NC5 Action <VHA10NC5Action@va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

And a clarification / this is a self-administered drug and not administered by the provider.

Sent with BlackBerry Work
(www.blackberry.com)

From: Carroll, David (VACO) <(b6) va.gov>
Date: Tuesday, Mar 12, 2019, 9:56 AM
To: Boyd, Teresa D. <(b6) va.gov>, Saslo, Christopher M (VHABIL) <(b6) va.gov>, O'Toole, Thomas P. <(b6) va.gov>, Schuldheis, Sherrie L, Ph.D <(b6) va.gov>
Cc: VHA 10NC5 Action <VHA10NC5Action@va.gov>
Subject: FW: HHS bought a nasal spray for depression - DRAFT News Release

FYI. I don't see 10NC/10N on this message. Our office has been working with Pharmacy on this matter. 10P has moved a press release forward to VHA Comms.

From: Smith, Monica (VACO)
Sent: Tuesday, March 12, 2019 10:22 AM
To: Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>; Screen, Gina <(b6) va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; Llorente, Maria D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>; Law, Cassandra M. <(b6) va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; Beck, Lucille B. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

VHA Comms:
(b) (5)

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- (b) (5) [redacted]

From: Law, Cassandra M.
Sent: Monday, March 11, 2019 3:53 PM
To: VHA 10P4 Communication Group <vha10p4comm@va.gov>; Smith, Monica (VACO) <(b6) va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; Llorente, Maria D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Good afternoon Monica and team. Do you format draft press releases prior to clearing to 10B2B media team? Given the high level attention and involvement, would like to clear this forward, but am unsure about format.

Please make any necessary changes and forward for VHA comms review and VHA 10B as there's a potential quote included to attribute to either Dr. Stone or SECVA.

Thank you, Cassie

From: Emmendorfer, Thomas (PBM)
Sent: Monday, March 11, 2019 3:21 PM
To: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Cc: Llorente, Maria D. <(b6) va.gov>; Outlaw, William N. <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Wiechers, Ilse (b6) @va.gov>
Subject: FW: HHS bought a nasal spray for depression

The attached external press release has been developed in coordination with 10P4P and 10NC5. We left a place holder in for a potential quote from Dr. Stone.

Request clearance to 10P for review.

From: Thomas Emmendorfer <(b6) va.gov>
Date: Thursday, March 7, 2019 at 7:45 AM
To: Jon Jensen <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Beck, Lucille B." <(b6) va.gov>, "Howard, Kristi" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

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Will do.

From: Jon Jensen <(b6) va.gov>
Date: Thursday, March 7, 2019 at 7:41 AM
To: Thomas Emmendorfer <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Beck, Lucille B." <(b6) va.gov>, "Howard, Kristi" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Tom, can you come to Morning Report today to discuss? Starts at 9:30.

From: Emmendorfer, Thomas (PBM)
Sent: Wednesday, March 06, 2019 10:15 PM
To: Jensen, Jon M. (b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Howard, Kristi <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Hi Jon,

I hope all is going well. Below is the information that Jenn, Mike, and I pulled together for you. Let us know if you need anything else.

Tom

(b) (5)

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- (b) (5) [redacted]



From: Jensen, Jon M.
Sent: Wednesday, March 06, 2019 7:50 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Howard, Kristi <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Thanks Tom!

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:49 PM
To: Jensen, Jon M. <(b6) va.gov>, Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Hi Jon,

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We will work on it and get a response back.

Tom

Sent with BlackBerry Work
(www.blackberry.com)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:34 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Adding Jennifer

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:27 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Just spoke to Dr Stone. We need to get something a little earlier than 10. As soon as you can would be fantastic.
Secva has asked for an update.

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 5:40 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi (b6) .gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: HHS bought a nasal spray for depression

Good evening, need some information on a nasal spray used for depression? POTUS heard HHS recently purchased and he felt it would be great for us. That's all I got. Can you pull info on what it

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would be, if we purchase currently, if we are looking into it etc. would sure appreciate anything you could provide by 10am.

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

Sender:	Boyd, Teresa D. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F6886A7D555A43E0BEE23C1E40E1C234-BOYD, TERES <(b6) va.gov>
Recipient:	Schuldheis, Sherrie L, Ph.D /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aecbe9a1f74d4a94a2206db8e404a63d-Schuldheis, <(b6) va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Saslo, Christopher M (VHABIL) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=23f487d85a3e47bdb0b1d4d6274bf2da-Saslo, Mark <(b6) va.gov>; O'Toole, Thomas P.(b6) va.gov </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c5a34d8a4b294e9986ef6e1aa8009b3f-O'Toole, Th>; VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>
Sent Date:	2019/03/12 11:39:42
Delivered Date:	2019/03/12 11:39:44

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From:	Smith, Monica (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=511EA9E77A234375A91A7B34CE23719D-SMITH, MONI <(b6) va.gov>
To:	Screen, Gina /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=777aa6921e794e42a45a07d8235767c5-Screen, Gin <(b6) va.gov>; Greilsamer, Alan /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fc02807af08443fbb5c68c590d58fa4b-Greilsamer, <(b6) va.gov>; Ledesma, Mark P. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=acbc9290cfec4fff8651002b5b0330c5-Ledesma, Ma <(b6) va.gov>
CC:	Outlaw, William N. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3e1067978634fbf96a382bdcd5c1115-Outlaw, Wil <(b6) @va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>
Subject:	RE: HHS bought a nasal spray for depression - DRAFT News Release
Date:	2019/03/12 12:10:05
Priority:	Normal
Type:	Note

Agreed. I had a lot of questions when Tom and I were reviewing the draft. We will get with Pharmacy and Mental Health to develop.

From: Screen, Gina
Sent: Tuesday, March 12, 2019 10:24 AM
To: Smith, Monica (VACO) <(b6) va.gov>; Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

I think we also need a few faq's about this… I'm sure a lot of people will have questions…

From: Smith, Monica (VACO)
Sent: Tuesday, March 12, 2019 10:22 AM
To: Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>; Screen, Gina <(b6) va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; Llorente, Maria D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>; Law, Cassandra M. <(b6) va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; Beck, Lucille B. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

VHA Comms:
As you may have seen in the news last week, there is a new drug coming on the market to treat depression. VA will offer this to Veterans. Please see attached draft press release for your expedited

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review. Our Pharmacy SMEs (Tom Emmendorfer and Mike Valentino) are on the cc: line to address any questions. I also understand there is internal communication in draft for communication to the field.

(b) (5)

[redacted]

From: Law, Cassandra M.
Sent: Monday, March 11, 2019 3:53 PM
To: VHA 10P4 Communication Group <vha10p4comm@va.gov>; Smith, Monica (VACO) <(b6) va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; Llorente, Maria D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Good afternoon Monica and team. Do you format draft press releases prior to clearing to 10B2B media team? Given the high level attention and involvement, would like to clear this forward, but am unsure about format.

Please make any necessary changes and forward for VHA comms review and VHA 10B as there's a potential quote included to attribute to either Dr. Stone or SECVA.

Thank you, Cassie

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Sent: Monday, March 11, 2019 3:21 PM
To: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Cc: Llorente, Maria D. <(b6) va.gov>; Outlaw, William N. (b6) @va.gov>; Carroll, David (VACO) <(b6) va.gov>; Wiechers, Ilse (b6) @va.gov>
Subject: FW: HHS bought a nasal spray for depression

The attached external press release has been developed in coordination with 10P4P and 10NC5. We left a place holder in for a potential quote from Dr. Stone.

Request clearance to 10P for review.

AMERICAN OVERSIGHT

From: Thomas Emmendorfer <(b6) va.gov>
Date: Thursday, March 7, 2019 at 7:45 AM
To: Jon Jensen <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Beck, Lucille B." <(b6) va.gov>, "Howard, Kristi" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Will do.

From: Jon Jensen <(b6) va.gov>
Date: Thursday, March 7, 2019 at 7:41 AM
To: Thomas Emmendorfer <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Beck, Lucille B." <(b6) va.gov>, "Howard, Kristi" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Tom, can you come to Morning Report today to discuss? Starts at 9:30.

From: Emmendorfer, Thomas (PBM)
Sent: Wednesday, March 06, 2019 10:15 PM
To: Jensen, Jon M. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Howard, Kristi <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Hi Jon,

I hope all is going well. Below is the information that Jenn, Mike, and I pulled together for you. Let us know if you need anything else.

Tom

(b) (5)

AMERICAN OVERSIGHT



From: Jensen, Jon M.
Sent: Wednesday, March 06, 2019 7:50 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Howard, Kristi <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Thanks Tom!

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

AMERICAN OVERSIGHT

From: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:49 PM
To: Jensen, Jon M. <(b6) va.gov>, Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Hi Jon,

We will work on it and get a response back.

Tom

Sent with BlackBerry Work
(www.blackberry.com)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:34 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Adding Jennifer

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:27 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Just spoke to Dr Stone. We need to get something a little earlier than 10. As soon as you can would be fantastic.
Secva has asked for an update.

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

AMERICAN OVERSIGHT

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 5:40 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: HHS bought a nasal spray for depression

Good evening, need some information on a nasal spray used for depression? POTUS heard HHS recently purchased and he felt it would be great for us. That's all I got. Can you pull info on what it would be, if we purchase currently, if we are looking into it etc. would sure appreciate anything you could provide by 10am.

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

Sender:	Smith, Monica (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=511EA9E77A234375A91A7B34CE23719D-SMITH, MONI <(b6) va.gov>
Recipient:	Screen, Gina /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=777aa6921e794e42a45a07d8235767c5-Screen, Gin <(b6) va.gov>; Greilsamer, Alan /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fc02807af08443fbb5c68c590d58fa4b-Greilsamer, <(b6) va.gov>; Ledesma, Mark P. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=acbc9290cfec4fff8651002b5b0330c5-Ledesma, Ma <(b6) va.gov>; Outlaw, William N. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3e1067978634fbf96a382bdcd5c1115-Outlaw, Wil (b6) @va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>
Sent Date:	2019/03/12 12:10:03
Delivered Date:	2019/03/12 12:10:05

AMERICAN OVERSIGHT

From:	Saslo, Christopher M (VHABIL) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=23F487D85A3E47BDB0B1D4D6274BF2DA-SASLO, MARK <(b6) va.gov>
To:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>
Subject:	RE: HHS bought a nasal spray for depression - DRAFT News Release
Date:	2019/03/12 13:32:58
Priority:	Normal
Type:	Note

No worries.

Chris

Dr. M. Christopher Saslo DNS, ARNP-BC, FAANP
Acting Deputy ADUSH for Clinical Operations (10NC)
810 Vermont Ave. NW
Washington, D.C. 20420
(b6)

"One of the deep secrets of life is that all that is really worth doing is what we do for others"....Lewis Carroll

---

From: Valentino, Michael (VACO)
Sent: Tuesday, March 12, 2019 1:21 PM
To: Saslo, Christopher M (VHABIL) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

Sorry for the confusion....looks like a version control problem. Good catch!

Sent with BlackBerry Work
(www.blackberry.com)

From: Saslo, Christopher M (VHABIL) <(b6) va.gov>
Date: Tuesday, Mar 12, 2019, 11:59 AM
To: Valentino, Michael (VACO) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

Thanks sir, appreciate response.

Chris

Dr. M. Christopher Saslo DNS, ARNP-BC, FAANP
Acting Deputy ADUSH for Clinical Operations (10NC)

AMERICAN OVERSIGHT

810 Vermont Ave. NW
Washington, D.C. 20420
(b6)

"One of the deep secrets of life is that all that is really worth doing is what we do for others"....Lewis Carroll

---

From: Valentino, Michael (VACO)
Sent: Tuesday, March 12, 2019 12:54 PM
To: Saslo, Christopher M (VHABIL) <(b6) va.gov>; Schuldheis, Sherrie L, Ph.D <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Smith, Monica (VACO) <(b6) va.gov>; Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>; Screen, Gina <(b6) va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; Llorente, Maria D. <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>; Law, Cassandra M. <(b6) va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; Beck, Lucille B. <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>; O'Toole, Thomas P. <(b6) va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>; Wiechers, Ilse <(b6) @va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

This may be the wrong version. (b) (5)

Sent with BlackBerry Work
(www.blackberry.com)

From: Saslo, Christopher M (VHABIL) <(b6) va.gov>
Date: Tuesday, Mar 12, 2019, 11:41 AM
To: Schuldheis, Sherrie L, Ph.D <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Smith, Monica (VACO) <(b6) va.gov>, Greilsamer, Alan <(b6) va.gov>, Ledesma, Mark P. <(b6) va.gov>, Screen, Gina <(b6) va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>, Llorente, Maria D. <(b6) va.gov>, Valentino, Michael (VACO) <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>, VHA 10P4 Communication Group <vha10p4comm@va.gov>, Law, Cassandra M. <(b6) va.gov>, VHA 10P Actions <VHA10PActions@va.gov>, Beck, Lucille B. <(b6) va.gov>, Boyd, Teresa D. <(b6) va.gov>, O'Toole, Thomas P. <(b6) va.gov>, VHA 10NC5 Action <VHA10NC5Action@va.gov>, Wiechers, Ilse <(b6) @va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

I thought Dr. Boyd had a conversation with Dr. Valentino already. Can we clarify if this has taken place?

Chris

Dr. M. Christopher Saslo DNS, ARNP-BC, FAANP
Acting Deputy ADUSH for Clinical Operations (10NC)

AMERICAN OVERSIGHT

810 Vermont Ave. NW
Washington, D.C. 20420
(b6)

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From: Schuldheis, Sherrie L, Ph.D
Sent: Tuesday, March 12, 2019 12:39 PM
To: Carroll, David (VACO) <(b6) va.gov>; Smith, Monica (VACO) <(b6) va.gov>; Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>; Screen, Gina <(b6) va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; Llorente, Maria D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>; Law, Cassandra M. <(b6) va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; Beck, Lucille B. <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>; Saslo, Christopher M (VHABIL) <(b6) va.gov>; O'Toole, Thomas P. <(b6) va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>; Wiechers, Ilse (b6) @va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

Agree Dave. Do you want to call Pharmacy, or do you want 10NC to call for clarification?

Sherrie Schuldheis, PhD, RN, CENP
Special Assistant, ADUSH Clinical Operations
VHA 10NC
810 Vermont NW
Washington, DC 20420
(b6) (cell)
(b6) va.gov

From: Carroll, David (VACO)
Sent: Tuesday, March 12, 2019 9:37 AM
To: Smith, Monica (VACO) <(b6) va.gov>; Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>; Screen, Gina <(b6) va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; Llorente, Maria D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>; Law, Cassandra M. <(b6) va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; Beck, Lucille B. <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>; Saslo, Christopher M (VHABIL) <(b6) va.gov>; O'Toole, Thomas P. <(b6) va.gov>; Schuldheis, Sherrie L, Ph.D <(b6) va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>; Wiechers, Ilse (b6) @va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

I shared this with our leadership team in 10NC who identified an apparent discrepancy in the communication. Perhaps not intended, it seems to be saying two different things – (b) (5)

AMERICAN OVERSIGHT

(b) (5)
Recommend clarity in advance of release. Thanks.

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VHA Comms:
(b) (5)

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AMERICAN OVERSIGHT

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Thank you, Cassie

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Subject: FW: HHS bought a nasal spray for depression

The attached external press release has been developed in coordination with 10P4P and 10NC5. We left a place holder in for a potential quote from Dr. Stone.

Request clearance to 10P for review.

From: Thomas Emmendorfer <(b6) va.gov>
Date: Thursday, March 7, 2019 at 7:45 AM
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Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Beck, Lucille B." <(b6) va.gov>, "Howard, Kristi" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Will do.

From: Jon Jensen <(b6) va.gov>
Date: Thursday, March 7, 2019 at 7:41 AM
To: Thomas Emmendorfer <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Beck, Lucille B." <(b6) va.gov>, "Howard, Kristi" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
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AMERICAN OVERSIGHT

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Subject: RE: HHS bought a nasal spray for depression

Hi Jon,

I hope all is going well. Below is the information that Jenn, Mike, and I pulled together for you. Let us know if you need anything else.

Tom

(b) (5)

AMERICAN OVERSIGHT

- (b) (5)

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Subject: RE: HHS bought a nasal spray for depression

Thanks Tom!

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VHA Acting Deputy Chief of Staff
(b6)
(b6)

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Subject: RE: HHS bought a nasal spray for depression

Adding Jennifer

Jon Jensen

AMERICAN OVERSIGHT

VHA Acting Deputy Chief of Staff
(b6)
(b6)

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Date: Wednesday, Mar 06, 2019, 7:27 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

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Jon Jensen
VHA Acting Deputy Chief of Staff
W:(b6)
(b6)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 5:40 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: HHS bought a nasal spray for depression

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Jon Jensen
VHA Acting Deputy Chief of Staff
W(b6)
(b6)

Sender:	Saslo, Christopher M (VHABIL) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=23F487D85A3E47BDB0B1D4D6274BF2DA-SASLO, MARK <(b6) va.gov>
Recipient:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>
Sent Date:	2019/03/12 13:32:57
Delivered Date:	2019/03/12 13:32:58

AMERICAN OVERSIGHT

From:	Saslo, Christopher M (VHABIL) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=23f487d85a3e47bdb0b1d4d6274bf2da-Saslo, Mark <(b6) va.gov>
To:	Schuldheis, Sherrie L, Ph.D /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aecbe9a1f74d4a94a2206db8e404a63d-Schuldheis, <(b6) va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Smith, Monica (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=511ea9e77a234375a91a7b34ce23719d-Smith, Moni <(b6) va.gov>; Greilsamer, Alan /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fc02807af08443fbb5c68c590d58fa4b-Greilsamer, <(b6) va.gov>; Ledesma, Mark P. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=acbc9290cfec4fff8651002b5b0330c5-Ledesma, Ma <(b6) va.gov>; Screen, Gina /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=777aa6921e794e42a45a07d8235767c5-Screen, Gin <(b6) va.gov>
CC:	VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; VHA 10P4 Communication Group /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4ba2ff9b4604547be7834a71415253c-VHA 10P4 Co <vha10p4comm@va.gov>; Law, Cassandra M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f888d507d6c54eb5a92fc44199eb5838-Law, Cassan <(b6) va.gov>; VHA 10P Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5098b521b1f34f8a97f74be24709d62f-VHA 10P Act <VHA10PActions@va.gov>; Beck, Lucille B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=845480228a8b43e7a5fef5716ded04c2-Beck, Lucil <(b6) va.gov>; Boyd, Teresa D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6886a7d555a43e0bee23c1e40e1c234-Boyd, Teres <(b6) va.gov>; O'Toole, Thomas P.(b6) va.gov </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c5a34d8a4b294e9986ef6e1aa8009b3f-O'Toole, Th>; VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>
Subject:	RE: HHS bought a nasal spray for depression - DRAFT News Release
Date:	2019/03/12 12:41:31
Priority:	Normal
Type:	Note

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I thought Dr. Boyd had a conversation with Dr. Valentino already. Can we clarify if this has taken place?

Chris

Dr. M. Christopher Saslo DNS, ARNP-BC, FAANP
Acting Deputy ADUSH for Clinical Operations (10NC)
810 Vermont Ave. NW
Washington, D.C. 20420
(b6)

"One of the deep secrets of life is that all that is really worth doing is what we do for others"….Lewis Carroll

---

From: Schuldheis, Sherrie L, Ph.D
Sent: Tuesday, March 12, 2019 12:39 PM
To: Carroll, David (VACO) <(b6) va.gov>; Smith, Monica (VACO) <(b6) va.gov>; Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. &lt(b6) va.gov>; Screen, Gina <(b6) va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; Llorente, Maria D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>; Law, Cassandra M. &lt(b6) va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; Beck, Lucille B. <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>; Saslo, Christopher M (VHABIL) <(b6) va.gov>; O'Toole, Thomas P. <(b6) va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>; Wiechers, Ilse <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

Agree Dave. Do you want to call Pharmacy, or do you want 10NC to call for clarification?

Sherrie Schuldheis, PhD, RN, CENP
Special Assistant, ADUSH Clinical Operations
VHA 10NC
810 Vermont NW
Washington, DC 20420
(b6) (cell)
(b6) va.gov

From: Carroll, David (VACO)
Sent: Tuesday, March 12, 2019 9:37 AM
To: Smith, Monica (VACO) <(b6) va.gov>; Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>; Screen, Gina <(b6) va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; Llorente, Maria D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM)

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<(b6) va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>; Law, Cassandra M. <(b6) va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; Beck, Lucille B. <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>; Saslo, Christopher M (VHABIL) <(b6) va.gov>; O'Toole, Thomas P. <(b6) va.gov>; Schuldheis, Sherrie L, Ph.D <(b6) va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>; Wiechers, Ilse <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

I shared this with our leadership team in 10NC who identified an apparent discrepancy in the communication. Perhaps not intended, it seems to be saying two different things – (b) (5)

Recommend clarity in advance of release. Thanks.

From: Smith, Monica (VACO)
Sent: Tuesday, March 12, 2019 10:22 AM
To: Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>; Screen, Gina <(b6) va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; Llorente, Maria D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>; Law, Cassandra M. <(b6) va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; Beck, Lucille B. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

VHA Comms:

(b) (5)

AMERICAN OVERSIGHT

From: Law, Cassandra M.
Sent: Monday, March 11, 2019 3:53 PM
To: VHA 10P4 Communication Group <vha10p4comm@va.gov>; Smith, Monica (VACO) <(b6) va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; Llorente, Maria D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Good afternoon Monica and team. Do you format draft press releases prior to clearing to 10B2B media team? Given the high level attention and involvement, would like to clear this forward, but am unsure about format.
Please make any necessary changes and forward for VHA comms review and VHA 10B as there's a potential quote included to attribute to either Dr. Stone or SECVA.
Thank you, Cassie

From: Emmendorfer, Thomas (PBM)
Sent: Monday, March 11, 2019 3:21 PM
To: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Cc: Llorente, Maria D. <(b6) va.gov>; Outlaw, William N. <(b6) va.gov>; Carroll, David (VACO) <(b6) @va.gov>; Wiechers, Ilse <(b6) va.gov>
Subject: FW: HHS bought a nasal spray for depression

The attached external press release has been developed in coordination with 10P4P and 10NC5. We left a place holder in for a potential quote from Dr. Stone.
Request clearance to 10P for review.

From: Thomas Emmendorfer <(b6) va.gov>
Date: Thursday, March 7, 2019 at 7:45 AM
To: Jon Jensen <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Beck, Lucille B." <(b6) va.gov>, "Howard, Kristi" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Will do.

From: Jon Jensen <(b6) va.gov>
Date: Thursday, March 7, 2019 at 7:41 AM
To: Thomas Emmendorfer <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Beck, Lucille B." <(b6) va.gov>, "Howard, Kristi" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M."

AMERICAN OVERSIGHT

<(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Tom, can you come to Morning Report today to discuss? Starts at 9:30.

From: Emmendorfer, Thomas (PBM)
Sent: Wednesday, March 06, 2019 10:15 PM
To: Jensen, Jon M. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Howard, Kristi <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Hi Jon,
I hope all is going well. Below is the information that Jenn, Mike, and I pulled together for you. Let us know if you need anything else.
Tom
(b) (5)

AMERICAN OVERSIGHT

- (b) (5)

From: Jensen, Jon M.
Sent: Wednesday, March 06, 2019 7:50 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Howard, Kristi <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Thanks Tom!

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:49 PM
To: Jensen, Jon M. &lt(b6) va.gov>, Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Hi Jon,
We will work on it and get a response back.
Tom

Sent with BlackBerry Work
(www.blackberry.com)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:34 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Adding Jennifer

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Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Jensen, Jon M. &lt(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:27 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Just spoke to Dr Stone. We need to get something a little earlier than 10. As soon as you can would be fantastic.
Secva has asked for an update.

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 5:40 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: HHS bought a nasal spray for depression

Good evening, need some information on a nasal spray used for depression? POTUS heard HHS recently purchased and he felt it would be great for us. That's all I got. Can you pull info on what it would be, if we purchase currently, if we are looking into it etc. would sure appreciate anything you could provide by 10am.

Jon Jensen
VHA Acting Deputy Chief of Staff
W(b6)
(b6)

Sender:	Saslo, Christopher M (VHABIL) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=23f487d85a3e47bdb0b1d4d6274bf2da-Saslo, Mark <(b6) va.gov>
Recipient:	Schuldheis, Sherrie L, Ph.D /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aecbe9a1f74d4a94a2206db8e404a63d-Schuldheis, <(b6) va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Smith, Monica (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=511ea9e77a234375a91a7b34ce23719d-Smith, Moni <(b6) va.gov>; Greilsamer, Alan /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fc02807af08443fbb5c68c590d58fa4b-Greilsamer,

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	<(b6) va.gov>; Ledesma, Mark P. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=acbc9290cfec4fff8651002b5b0330c5-Ledesma, Ma <(b6) va.gov>; Screen, Gina /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=777aa6921e794e42a45a07d8235767c5-Screen, Gin <(b6) va.gov>; VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; VHA 10P4 Communication Group /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4ba2ff9b4604547be7834a71415253c-VHA 10P4 Co <vha10p4comm@va.gov>; Law, Cassandra M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f888d507d6c54eb5a92fc44199eb5838-Law, Cassan <(b6) va.gov>; VHA 10P Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5098b521b1f34f8a97f74be24709d62f-VHA 10P Act <VHA10PActions@va.gov>; Beck, Lucille B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=845480228a8b43e7a5fef5716ded04c2-Beck, Lucil <(b6) va.gov>; Boyd, Teresa D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6886a7d555a43e0bee23c1e40e1c234-Boyd, Teres <(b6) va.gov>; O'Toole, Thomas P.(b6) va.gov </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c5a34d8a4b294e9986ef6e1aa8009b3f-O'Toole, Th>; VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>
Sent Date:	2019/03/12 12:41:28
Delivered Date:	2019/03/12 12:41:31

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From:	Smith, Monica (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=511ea9e77a234375a91a7b34ce23719d-Smith, Moni <(b6) va.gov>
To:	Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Greilsamer, Alan /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fc02807af08443fbb5c68c590d58fa4b-Greilsamer, <(b6) va.gov>; Ledesma, Mark P. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=acbc9290cfec4fff8651002b5b0330c5-Ledesma, Ma <(b6) va.gov>; Screen, Gina /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=777aa6921e794e42a45a07d8235767c5-Screen, Gin <(b6) va.gov>
CC:	VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; VHA 10P4 Communication Group /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4ba2ff9b4604547be7834a71415253c-VHA 10P4 Co <vha10p4comm@va.gov>; Law, Cassandra M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f888d507d6c54eb5a92fc44199eb5838-Law, Cassan <(b6) va.gov>; VHA 10P Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5098b521b1f34f8a97f74be24709d62f-VHA 10P Act <VHA10PActions@va.gov>; Beck, Lucille B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=845480228a8b43e7a5fef5716ded04c2-Beck, Lucil <(b6) va.gov>; Boyd, Teresa D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6886a7d555a43e0bee23c1e40e1c234-Boyd, Teres <(b6) va.gov>; Saslo, Christopher M (VHABIL) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=23f487d85a3e47bdb0b1d4d6274bf2da-Saslo, Mark <(b6) va.gov>; O'Toole, Thomas P.(b6) va.gov </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c5a34d8a4b294e9986ef6e1aa8009b3f-O'Toole, Th>; Schuldheis, Sherrie L, Ph.D /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aecbe9a1f74d4a94a2206db8e404a63d-Schuldheis, <(b6) va.gov>; VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>
Subject:	RE: HHS bought a nasal spray for depression - DRAFT News Release
Date:	2019/03/12 12:48:47
Priority:	Normal
Type:	Note

AMERICAN OVERSIGHT

Thanks Dr. Carroll for calling. Tom and I just talked with Dr. Carroll and the news release is correct. Patients will administer the drug under the provider's direct supervision. The text provided below under BLUF was submitted as context/background in the email thread.

From: Carroll, David (VACO)
Sent: Tuesday, March 12, 2019 12:37 PM
To: Smith, Monica (VACO) <(b6) va.gov>; Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>; Screen, Gina <(b6) va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; Llorente, Maria D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>; Law, Cassandra M. &lt(b6) va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; Beck, Lucille B. <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>; Saslo, Christopher M (VHABIL) <(b6) va.gov>; O'Toole, Thomas P. <(b6) va.gov>; Schuldheis, Sherrie L, Ph.D <(b6) va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>; Wiechers, Ilse <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

I shared this with our leadership team in 10NC who identified an apparent discrepancy in the communication. Perhaps not intended, it seems to be saying two different things – does the Veteran administer or does the provider. In the BLUF below in the email it states "Spravato® will be available to VA providers to administer to Veterans based on their clinical assessment…" However, in the news release it says "Veterans will self-administer Spravato® nasal spray under the direct observation…" Recommend clarity in advance of release. Thanks.

From: Smith, Monica (VACO)
Sent: Tuesday, March 12, 2019 10:22 AM
To: Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>; Screen, Gina <(b6) va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; Llorente, Maria D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>; Law, Cassandra M. &lt(b6) va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; Beck, Lucille B. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

VHA Comms:
(b) (5)

AMERICAN OVERSIGHT

(b) (5)

[redacted]

From: Law, Cassandra M.
Sent: Monday, March 11, 2019 3:53 PM
To: VHA 10P4 Communication Group <vha10p4comm@va.gov>; Smith, Monica (VACO) <(b6) va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; Llorente, Maria D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <Thomas.Emmendorfer@va.gov>; Carroll, David (VACO) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Good afternoon Monica and team. Do you format draft press releases prior to clearing to 10B2B media team? Given the high level attention and involvement, would like to clear this forward, but am unsure about format.
Please make any necessary changes and forward for VHA comms review and VHA 10B as there's a potential quote included to attribute to either Dr. Stone or SECVA.
Thank you, Cassie

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Sent: Monday, March 11, 2019 3:21 PM
To: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Cc: Llorente, Maria D. <(b6) va.gov>; Outlaw, William N. <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Wiechers, Ilse <(b6) va.gov>
Subject: FW: HHS bought a nasal spray for depression
The attached external press release has been developed in coordination with 10P4P and 10NC5. We left a place holder in for a potential quote from Dr. Stone.
Request clearance to 10P for review.

From: Thomas Emmendorfer &(b6) @va.gov>
Date: Thursday, March 7, 2019 at 7:45 AM
To: Jon Jensen <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Beck, Lucille B." <(b6) va.gov>, "Howard, Kristi" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D."

AMERICAN OVERSIGHT

<(b6) va.gov>, "Law, Cassandra M."
<(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression
Will do.

From: Jon Jensen <(b6) va.gov>
Date: Thursday, March 7, 2019 at 7:41 AM
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Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Beck, Lucille B." <(b6) va.gov>, "Howard, Kristi" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
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Tom, can you come to Morning Report today to discuss? Starts at 9:30.

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Sent: Wednesday, March 06, 2019 10:15 PM
To: Jensen, Jon M. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Howard, Kristi <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Hi Jon,
I hope all is going well. Below is the information that Jenn, Mike, and I pulled together for you. Let us know if you need anything else.
Tom
(b) (5)



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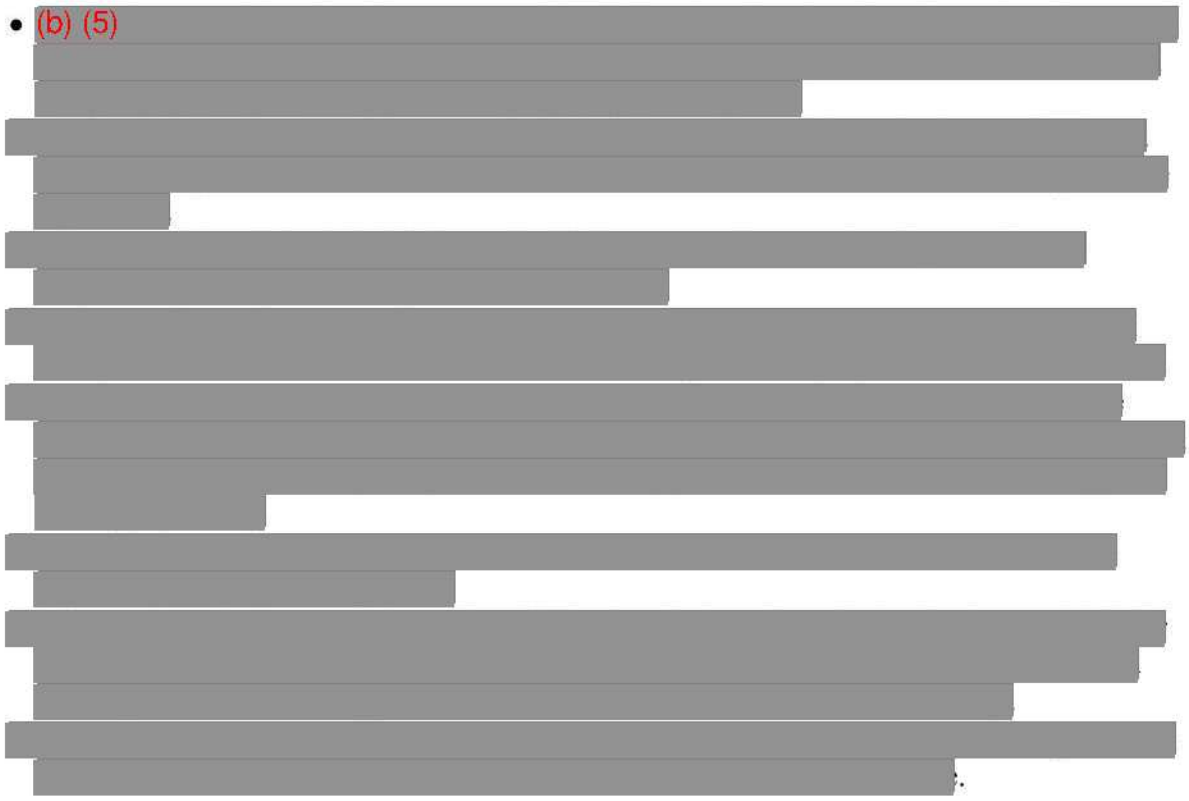
- (b) (5)



From: Jensen, Jon M.
Sent: Wednesday, March 06, 2019 7:50 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Howard, Kristi <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Thanks Tom!

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

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Date: Wednesday, Mar 06, 2019, 7:49 PM
To: Jensen, Jon M. <(b6) va.gov>, Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Hi Jon,
We will work on it and get a response back.

AMERICAN OVERSIGHT

Tom

Sent with BlackBerry Work
(www.blackberry.com)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:34 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Adding Jennifer

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:27 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) @va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Just spoke to Dr Stone. We need to get something a little earlier than 10. As soon as you can would be fantastic.
Secva has asked for an update.

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6(b6)
(b6)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 5:40 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: HHS bought a nasal spray for depression
Good evening, need some information on a nasal spray used for depression? POTUS heard HHS recently purchased and he felt it would be great for us. That's all I got. Can you pull info on what it would be, if we purchase currently, if we are looking into it etc. would sure appreciate anything you could provide by 10am.

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Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

Sender:	Smith, Monica (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=511ea9e77a234375a91a7b34ce23719d-Smith, Moni <(b6) va.gov>
Recipient:	Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Greilsamer, Alan /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fc02807af08443fbb5c68c590d58fa4b-Greilsamer, <(b6) va.gov>; Ledesma, Mark P. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=acbc9290cfec4fff8651002b5b0330c5-Ledesma, Ma <(b6) va.gov>; Screen, Gina /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=777aa6921e794e42a45a07d8235767c5-Screen, Gin <(b6) va.gov>; VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; VHA 10P4 Communication Group /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4ba2ff9b4604547be7834a71415253c-VHA 10P4 Co <vha10p4comm@va.gov>; Law, Cassandra M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f888d507d6c54eb5a92fc44199eb5838-Law, Cassan <(b6) va.gov>; VHA 10P Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5098b521b1f34f8a97f74be24709d62f-VHA 10P Act <VHA10PActions@va.gov>; Beck, Lucille B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=845480228a8b43e7a5fef5716ded04c2-Beck, Lucil <(b6) va.gov>; Boyd, Teresa D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6886a7d555a43e0bee23c1e40e1c234-Boyd, Teres <(b6) va.gov>; Saslo, Christopher M (VHABIL) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=23f487d85a3e47bdb0b1d4d6274bf2da-Saslo, Mark <(b6) va.gov>; O'Toole, Thomas P.(b6) va.gov </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c5a34d8a4b294e9986ef6e1aa8009b3f-O'Toole, Th>; Schuldheis, Sherrie L, Ph.D /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aecbe9a1f74d4a94a2206db8e404a63d-Schuldheis, <(b6) va.gov>; VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>
Sent Date:	2019/03/12 12:48:45
Delivered Date:	2019/03/12 12:48:47

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Message Flags:	Unread

AMERICAN OVERSIGHT

From:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>
To:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>
CC:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>
Subject:	RE: HHS bought a nasal spray for depression - DRAFT News Release
Date:	2019/03/12 12:57:03
Priority:	Normal
Type:	Note

The last version of the press release I saw starts with the following sentence, which I think may be leading to the confusion:

(b) (5)

Thoughts?
Ilse

From: Valentino, Michael (VACO)
Sent: Tuesday, March 12, 2019 9:54 AM
To: Saslo, Christopher M (VHABIL) <(b6) va.gov>; Schuldheis, Sherrie L, Ph.D &(b6) @va.gov>; Carroll, David (VACO) &l(b6) l@va.gov>; Smith, Monica (VACO) <(b6) va.gov>; Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>; Screen, Gina <(b6) va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; Llorente, Maria D. <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>; Law, Cassandra M. &lt(b6) va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; Beck, Lucille B. <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>; O'Toole, Thomas P. <(b6) va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>; Wiechers, Ilse <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release
This may be the wrong version. It should specify that the patient self administers under provider observation

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Sent with BlackBerry Work
(www.blackberry.com)

From: Saslo, Christopher M (VHABIL) <(b6) va.gov>
Date: Tuesday, Mar 12, 2019, 11:41 AM
To: Schuldheis, Sherrie L, Ph.D <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Smith, Monica (VACO) <(b6) va.gov>, Greilsamer, Alan <(b6) va.gov>, Ledesma, Mark P. &lt(b6) va.gov>, Screen, Gina <(b6) va.gov>
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Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

I thought Dr. Boyd had a conversation with Dr. Valentino already. Can we clarify if this has taken place?

Chris

Dr. M. Christopher Saslo DNS, ARNP-BC, FAANP
Acting Deputy ADUSH for Clinical Operations (10NC)
810 Vermont Ave. NW
Washington, D.C. 20420
(b6)

deep secrets of life is that all that is really worth doing is what we do for others”….Lewis Carroll

---

From: Schuldheis, Sherrie L, Ph.D
Sent: Tuesday, March 12, 2019 12:39 PM
To: Carroll, David (VACO) <(b6) va.gov>; Smith, Monica (VACO) <(b6) va.gov>; Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>; Screen, Gina <(b6) va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; Llorente, Maria D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>; Law, Cassandra M. <(b6) va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; Beck, Lucille B. <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>; Saslo, Christopher M (VHABIL) <(b6) va.gov>; O'Toole, Thomas P. <(b6) va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>; Wiechers, Ilse <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

Agree Dave. Do you want to call Pharmacy, or do you want 10NC to call for clarification?
Sherrie Schuldheis, PhD, RN, CENP
Special Assistant, ADUSH Clinical Operations

AMERICAN OVERSIGHT

VHA 10NC
810 Vermont NW
Washington, DC 20420
(b6) (cell)
(b6) va.gov

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To: Smith, Monica (VACO) <(b6) va.gov>; Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>; Screen, Gina <(b6) va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; Llorente, Maria D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>; Law, Cassandra M. <(b6) va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; Beck, Lucille B. <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>; Saslo, Christopher M (VHABIL) <(b6) va.gov>; O'Toole, Thomas P. <(b6) va.gov>; Schuldheis, Sherrie L, Ph.D <(b6) va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>; Wiechers, Ilse <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release
I shared this with our leadership team in 10NC who identified an apparent discrepancy in the communication. Perhaps not intended, it seems to be saying two different things – (b) (5)

Recommend clarity in advance of release. Thanks.

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Sent: Tuesday, March 12, 2019 10:22 AM
To: Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>; Screen, Gina <(b6) va.gov>
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Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release
VHA Comms:
As you may have seen in the news last week, there is a new drug coming on the market to treat depression. VA will offer this to Veterans. Please see attached draft press release for your expedited review. Our Pharmacy SMEs (Tom Emmendorfer and Mike Valentino) are on the cc: line to address any questions. I also understand there is internal communication in draft for communication to the field.

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(b) (5)

[redacted]

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Sent: Monday, March 11, 2019 3:53 PM
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Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; Llorente, Maria D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

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Please make any necessary changes and forward for VHA comms review and VHA 10B as there’s a potential quote included to attribute to either Dr. Stone or SECVA.

Thank you, Cassie

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Cc: Llorente, Maria D. <(b6) va.gov>; Outlaw, William N. <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Wiechers, Ilse <(b6) va.gov>
Subject: FW: HHS bought a nasal spray for depression

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Request clearance to 10P for review.

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Date: Thursday, March 7, 2019 at 7:45 AM
To: Jon Jensen <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Beck, Lucille B." <(b6) va.gov>, "Howard, Kristi" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D."

AMERICAN OVERSIGHT

<(b6) va.gov>, "Law, Cassandra M."
<(b6) va.gov>
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Date: Thursday, March 7, 2019 at 7:41 AM
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Subject: RE: HHS bought a nasal spray for depression
Tom, can you come to Morning Report today to discuss? Starts at 9:30.

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Cc: Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Howard, Kristi <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Hi Jon,
I hope all is going well. Below is the information that Jenn, Mike, and I pulled together for you. Let us know if you need anything else.
Tom
(b) (5)

AMERICAN OVERSIGHT

- (b) (5)

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To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Howard, Kristi <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Thanks Tom!

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:49 PM
To: Jensen, Jon M. <(b6) va.gov>, Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) &lt(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Hi Jon,
We will work on it and get a response back.

AMERICAN OVERSIGHT

Tom

Sent with BlackBerry Work
(www.blackberry.com)

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Date: Wednesday, Mar 06, 2019, 7:34 PM
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Subject: RE: HHS bought a nasal spray for depression
Adding Jennifer

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:27 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi &(b6) @va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Just spoke to Dr Stone. We need to get something a little earlier than 10. As soon as you can would be fantastic.
Secva has asked for an update.

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 5:40 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: HHS bought a nasal spray for depression
Good evening, need some information on a nasal spray used for depression? POTUS heard HHS recently purchased and he felt it would be great for us. That’s all I got. Can you pull info on what it would be, if we purchase currently, if we are looking into it etc. would sure appreciate anything you could provide by 10am.

AMERICAN OVERSIGHT

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

Sender:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>
Recipient:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>
Sent Date:	2019/03/12 12:57:02
Delivered Date:	2019/03/12 12:57:03

AMERICAN OVERSIGHT

From:	Saslo, Christopher M (VHABIL) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=23f487d85a3e47bdb0b1d4d6274bf2da-Saslo, Mark <(b6) va.gov>
To:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>
Subject:	RE: HHS bought a nasal spray for depression - DRAFT News Release
Date:	2019/03/12 13:32:58
Priority:	Normal
Type:	Note

No worries.

Chris

Dr. M. Christopher Saslo DNS, ARNP-BC, FAANP
Acting Deputy ADUSH for Clinical Operations (10NC)
810 Vermont Ave. NW
Washington, D.C. 20420
(b6)

“One of the deep secrets of life is that all that is really worth doing is what we do for others”….Lewis Carroll

---

From: Valentino, Michael (VACO)
Sent: Tuesday, March 12, 2019 1:21 PM
To: Saslo, Christopher M (VHABIL) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release
Sorry for the confusion....looks like a version control problem. Good catch!

Sent with BlackBerry Work
(www.blackberry.com)

From: Saslo, Christopher M (VHABIL) <(b6) va.gov>
Date: Tuesday, Mar 12, 2019, 11:59 AM
To: Valentino, Michael (VACO) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release
Thanks sir, appreciate response.

Chris

Dr. M. Christopher Saslo DNS, ARNP-BC, FAANP
Acting Deputy ADUSH for Clinical Operations (10NC)
810 Vermont Ave. NW
Washington, D.C. 20420
(b6)

“One of the deep secrets of life is that all that is really worth doing is what we do for others”….Lewis Carroll

AMERICAN OVERSIGHT

From: Valentino, Michael (VACO)
Sent: Tuesday, March 12, 2019 12:54 PM
To: Saslo, Christopher M (VHABIL) <(b6) va.gov>; Schuldheis, Sherrie L, Ph.D <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Smith, Monica (VACO) <(b6) va.gov>; Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>; Screen, Gina <(b6) va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; Llorente, Maria D. <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>; Law, Cassandra M. <(b6) va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; Beck, Lucille B. <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>; O'Toole, Thomas P. <(b6) va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>; Wiechers, Ilse <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release
This may be the wrong version. It should specify that the patient self administers under provider observation

Sent with BlackBerry Work
(www.blackberry.com)

From: Saslo, Christopher M (VHABIL) <(b6) va.gov>
Date: Tuesday, Mar 12, 2019, 11:41 AM
To: Schuldheis, Sherrie L, Ph.D <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Smith, Monica (VACO) <(b6) va.gov>, Greilsamer, Alan <(b6) va.gov>, Ledesma, Mark P. <(b6) va.gov>, Screen, Gina <(b6) va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>, Llorente, Maria D. <(b6) va.gov>, Valentino, Michael (VACO) <(b6) @va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>, VHA 10P4 Communication Group <vha10p4comm@va.gov>, Law, Cassandra M. <(b6) va.gov>, VHA 10P Actions <VHA10PActions@va.gov>, Beck, Lucille B. <(b6) va.gov>, Boyd, Teresa D. <(b6) va.gov>, O'Toole, Thomas P. <(b6) va.gov>, VHA 10NC5 Action <VHA10NC5Action@va.gov>, Wiechers, Ilse <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release
I thought Dr. Boyd had a conversation with Dr. Valentino already. Can we clarify if this has taken place?

Chris

Dr. M. Christopher Saslo DNS, ARNP-BC, FAANP
Acting Deputy ADUSH for Clinical Operations (10NC)
810 Vermont Ave. NW
Washington, D.C. 20420
(b6)

“One of the deep secrets of life is that all that is really worth doing is what we do for others”….Lewis Carroll

AMERICAN OVERSIGHT

From: Schuldheis, Sherrie L, Ph.D
Sent: Tuesday, March 12, 2019 12:39 PM
To: Carroll, David (VACO) <(b6) va.gov>; Smith, Monica (VACO) <(b6) va.gov>; Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>; Screen, Gina <(b6) va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; Llorente, Maria D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>; Law, Cassandra M. <(b6) va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; Beck, Lucille B. <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>; Saslo, Christopher M (VHABIL) <(b6) va.gov>; O'Toole, Thomas P. <(b6) va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>; Wiechers, Ilse <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

Agree Dave. Do you want to call Pharmacy, or do you want 10NC to call for clarification?

Sherrie Schuldheis, PhD, RN, CENP
Special Assistant, ADUSH Clinical Operations
VHA 10NC
810 Vermont NW
Washington, DC 20420
(b6) (cell)
(b6) va.gov

From: Carroll, David (VACO)
Sent: Tuesday, March 12, 2019 9:37 AM
To: Smith, Monica (VACO) <(b6) va.gov>; Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>; Screen, Gina <(b6) va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; Llorente, Maria D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>; Law, Cassandra M. <(b6) va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; Beck, Lucille B. <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>; Saslo, Christopher M (VHABIL) <(b6) va.gov>; O'Toole, Thomas P. <(b6) va.gov>; Schuldheis, Sherrie L, Ph.D <(b6) va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>; Wiechers, Ilse <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

I shared this with our leadership team in 10NC who identified an apparent discrepancy in the communication. Perhaps not intended, it seems to be saying two different things – (b) (5)

AMERICAN OVERSIGHT

(b) (5) Recommend clarity in advance of release. Thanks.

From: Smith, Monica (VACO)
Sent: Tuesday, March 12, 2019 10:22 AM
To: Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>; Screen, Gina <(b6) va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; Llorente, Maria D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>; Law, Cassandra M. <(b6) va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; Beck, Lucille B. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

VHA Comms:

(b) (5)

From: Law, Cassandra M.
Sent: Monday, March 11, 2019 3:53 PM
To: VHA 10P4 Communication Group <vha10p4comm@va.gov>; Smith, Monica (VACO) <(b6) va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; Llorente, Maria D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Good afternoon Monica and team. Do you format draft press releases prior to clearing to 10B2B media team? Given the high level attention and involvement, would like to clear this forward, but am unsure about format.

AMERICAN OVERSIGHT

Please make any necessary changes and forward for VHA comms review and VHA 10B as there’s a potential quote included to attribute to either Dr. Stone or SECVA. Thank you, Cassie

From: Emmendorfer, Thomas (PBM)
Sent: Monday, March 11, 2019 3:21 PM
To: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Cc: Llorente, Maria D. <(b6) va.gov>; Outlaw, William N. <(b6) @va.gov>; Carroll, David (VACO) <(b6) va.gov>; Wiechers, Ilse <(b6) va.gov>
Subject: FW: HHS bought a nasal spray for depression
The attached external press release has been developed in coordination with 10P4P and 10NC5. We left a place holder in for a potential quote from Dr. Stone.
Request clearance to 10P for review.

From: Thomas Emmendorfer <(b6) va.gov>
Date: Thursday, March 7, 2019 at 7:45 AM
To: Jon Jensen <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Beck, Lucille B." <(b6) va.gov>, "Howard, Kristi" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression
Will do.

From: Jon Jensen <(b6) va.gov>
Date: Thursday, March 7, 2019 at 7:41 AM
To: Thomas Emmendorfer <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Beck, Lucille B." <(b6) va.gov>, "Howard, Kristi" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Tom, can you come to Morning Report today to discuss? Starts at 9:30.

From: Emmendorfer, Thomas (PBM)
Sent: Wednesday, March 06, 2019 10:15 PM
To: Jensen, Jon M. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Howard, Kristi <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Hi Jon,

AMERICAN OVERSIGHT

I hope all is going well. Below is the information that Jenn, Mike, and I pulled together for you. Let us know if you need anything else.

Tom

(b) (5)

[redacted]

(b) (5)

[redacted]

From: Jensen, Jon M.
Sent: Wednesday, March 06, 2019 7:50 PM
To: Emmendorfer, Thomas (PBM) <(b6) [redacted] va.gov>; Valentino, Michael

AMERICAN OVERSIGHT

(VACO) <(b6) va.gov>; Carroll, David (VACO)
<(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Howard, Kristi
<(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Thanks Tom!

Jon Jensen
VHA Acting Deputy Chief of Staff
W(b6)
(b6)

From: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:49 PM
To: Jensen, Jon M. <(b6) va.gov>, Valentino, Michael (VACO)
<(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B.
<(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Zacher, Jennifer L. (PBM)
<(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Hi Jon,
We will work on it and get a response back.
Tom

Sent with BlackBerry Work
(www.blackberry.com)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:34 PM
To: Valentino, Michael (VACO) <(b6) @va.gov>, Carroll, David (VACO)
<(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi
<(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>,
Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Adding Jennifer

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:27 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO)
<(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi
<(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

AMERICAN OVERSIGHT

Just spoke to Dr Stone. We need to get something a little earlier than 10. As soon as you can would be fantastic.
Secva has asked for an update.

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 5:40 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: HHS bought a nasal spray for depression

Good evening, need some information on a nasal spray used for depression? POTUS heard HHS recently purchased and he felt it would be great for us. That’s all I got. Can you pull info on what it would be, if we purchase currently, if we are looking into it etc. would sure appreciate anything you could provide by 10am.

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

Sender:	Saslo, Christopher M (VHABIL) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=23f487d85a3e47bdb0b1d4d6274bf2da-Saslo, Mark <(b6) va.gov>
Recipient:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>
Sent Date:	2019/03/12 13:32:57
Delivered Date:	2019/03/12 13:32:58

AMERICAN OVERSIGHT

From:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>
To:	Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Smith, Monica (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=511ea9e77a234375a91a7b34ce23719d-Smith, Moni <(b6) va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>
CC:	Outlaw, William N. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3e1067978634fbf96a382bdcd5c1115-Outlaw, Wil <(b6) va.gov>
Subject:	RE: HHS bought a nasal spray for depression - DRAFT News Release
Date:	2019/03/12 14:05:23
Priority:	Normal
Type:	Note

Agree, looks good. Thanks.

From: Carroll, David (VACO)
Sent: Tuesday, March 12, 2019 10:51 AM
To: Smith, Monica (VACO) <(b6) va.gov>; Wiechers, Ilse <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>
Cc: Outlaw, William N. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release
Looks good – appreciate the edits.

From: Smith, Monica (VACO)
Sent: Tuesday, March 12, 2019 1:45 PM
To: Carroll, David (VACO) <(b6) va.gov>; Wiechers, Ilse <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>
Cc: Outlaw, William N. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release
Team – Sending to this small group of leaders only. Please review once more and approve before we re-send this to VHA Comms. Changes were made to the headline, the lead sentence and first two paragraphs.

From: Smith, Monica (VACO)
Sent: Tuesday, March 12, 2019 1:27 PM

AMERICAN OVERSIGHT

To: Carroll, David (VACO) <(b6) va.gov>; Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>; Screen, Gina <(b6) va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; Llorente, Maria D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>; Law, Cassandra M. <(b6) va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; Beck, Lucille B. <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>; Saslo, Christopher M (VHABIL) <(b6) va.gov>; O'Toole, Thomas P. <(b6) va.gov>; Schuldheis, Sherrie L, Ph.D <(b6) va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>; Wiechers, Ilse <(b6) @va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

Thanks Dr. Carroll for calling. Tom and I just talked with Dr. Carroll. We will review the release once again and send any updates shortly. The text provided below under BLUF was submitted as context/background only in the email thread.

From: Carroll, David (VACO)
Sent: Tuesday, March 12, 2019 12:37 PM
To: Smith, Monica (VACO) <(b6) va.gov>; Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>; Screen, Gina <(b6) va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; Llorente, Maria D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>; Law, Cassandra M. <(b6) va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; Beck, Lucille B. <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>; Saslo, Christopher M (VHABIL) <(b6) va.gov>; O'Toole, Thomas P. <(b6) va.gov>; Schuldheis, Sherrie L, Ph.D <(b6) va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>; Wiechers, Ilse <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

I shared this with our leadership team in 10NC who identified an apparent discrepancy in the communication. Perhaps not intended, it seems to be saying two different things – (b) (5)

Recommend clarity in advance of release. Thanks.

From: Smith, Monica (VACO)
Sent: Tuesday, March 12, 2019 10:22 AM
To: Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>; Screen, Gina <(b6) va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; Llorente, Maria D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM)

AMERICAN OVERSIGHT

<(b6) va.gov>; Carroll, David (VACO)
<(b6) va.gov>; VHA 10P4 Communication Group
<vha10p4comm@va.gov>; Law, Cassandra M. <(b6) va.gov>; VHA
10P Actions <VHA10PActions@va.gov>; Beck, Lucille B. &lt(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release
VHA Comms:
(b) (5)

From: Law, Cassandra M.
Sent: Monday, March 11, 2019 3:53 PM
To: VHA 10P4 Communication Group <vha10p4comm@va.gov>; Smith, Monica
(VACO) <(b6) va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; Llorente, Maria D.
<(b6) va.gov>; Valentino, Michael (VACO)
<(b6) va.gov>; Emmendorfer, Thomas (PBM)
<(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Good afternoon Monica and team. Do you format draft press releases prior to clearing to 10B2B media team? Given the high level attention and involvement, would like to clear this forward, but am unsure about format.
Please make any necessary changes and forward for VHA comms review and VHA 10B as there's a potential quote included to attribute to either Dr. Stone or SECVA.
Thank you, Cassie

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To: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Cc: Llorente, Maria D. <(b6) va.gov>; Outlaw, William N.
<(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>;
Wiechers, Ilse <(b6) va.gov>
Subject: FW: HHS bought a nasal spray for depression

AMERICAN OVERSIGHT

The attached external press release has been developed in coordination with 10P4P and 10NC5.
We left a place holder in for a potential quote from Dr. Stone.
Request clearance to 10P for review.

From: Thomas Emmendorfer <(b6) va.gov>
Date: Thursday, March 7, 2019 at 7:45 AM
To: Jon Jensen <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Beck, Lucille B." <(b6) va.gov>, "Howard, Kristi" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression
Will do.

From: Jon Jensen <(b6) va.gov>
Date: Thursday, March 7, 2019 at 7:41 AM
To: Thomas Emmendorfer <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Beck, Lucille B." <(b6) va.gov>, "Howard, Kristi" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Tom, can you come to Morning Report today to discuss? Starts at 9:30.

From: Emmendorfer, Thomas (PBM)
Sent: Wednesday, March 06, 2019 10:15 PM
To: Jensen, Jon M. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Howard, Kristi <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Hi Jon,
I hope all is going well. Below is the information that Jenn, Mike, and I pulled together for you. Let us know if you need anything else.
Tom
(b) (5)

AMERICAN OVERSIGHT



From: Jensen, Jon M.
Sent: Wednesday, March 06, 2019 7:50 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Howard, Kristi <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Thanks Tom!

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Emmendorfer, Thomas (PBM) <(b6) va.gov>

AMERICAN OVERSIGHT

Date: Wednesday, Mar 06, 2019, 7:49 PM
To: Jensen, Jon M. <(b6) va.gov>, Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Hi Jon,
We will work on it and get a response back.
Tom

Sent with BlackBerry Work
(www.blackberry.com)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:34 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Adding Jennifer

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:27 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Just spoke to Dr Stone. We need to get something a little earlier than 10. As soon as you can would be fantastic.
Secva has asked for an update.

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 5:40 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>

AMERICAN OVERSIGHT

Subject: HHS bought a nasal spray for depression

Good evening, need some information on a nasal spray used for depression? POTUS heard HHS recently purchased and he felt it would be great for us. That's all I got. Can you pull info on what it would be, if we purchase currently, if we are looking into it etc. would sure appreciate anything you could provide by 10am.

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

Sender:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>
Recipient:	Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Smith, Monica (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=511ea9e77a234375a91a7b34ce23719d-Smith, Moni <(b6) va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; Outlaw, William N. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3e1067978634fbf96a382bdcd5c1115-Outlaw, Wil (b6) @va.gov>
Sent Date:	2019/03/12 14:05:21
Delivered Date:	2019/03/12 14:05:23
Message Flags:	Unread

AMERICAN OVERSIGHT

From:	Wiechers, Ilse /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0C7B1428D9E4233A641F125C5B6FC4F-WIECHERS, I <(b6) va.gov>
To:	Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Smith, Monica (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=511ea9e77a234375a91a7b34ce23719d-Smith, Moni <(b6) va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>
CC:	Outlaw, William N. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3e1067978634fbf96a382bdcd5c1115-Outlaw, Wil <(b6) va.gov>
Subject:	RE: HHS bought a nasal spray for depression - DRAFT News Release
Date:	2019/03/12 14:05:23
Priority:	Normal
Type:	Note

Agree, looks good. Thanks.

From: Carroll, David (VACO)
Sent: Tuesday, March 12, 2019 10:51 AM
To: Smith, Monica (VACO) <(b6) va.gov>; Wiechers, Ilse (b6) @va.gov>; Llorente, Maria D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>
Cc: Outlaw, William N. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

Looks good – appreciate the edits.

From: Smith, Monica (VACO)
Sent: Tuesday, March 12, 2019 1:45 PM
To: Carroll, David (VACO) <(b6) va.gov>; Wiechers, Ilse (b6) @va.gov>; Llorente, Maria D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>
Cc: Outlaw, William N. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

Team – Sending to this small group of leaders only. Please review once more and approve before we re-send this to VHA Comms. Changes were made to the headline, the lead sentence and first two paragraphs.

AMERICAN OVERSIGHT

From: Smith, Monica (VACO)
Sent: Tuesday, March 12, 2019 1:27 PM
To: Carroll, David (VACO) <(b6) va.gov>; Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>; Screen, Gina <(b6) va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; Llorente, Maria D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>; Law, Cassandra M. <(b6) va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; Beck, Lucille B. <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>; Saslo, Christopher M (VHABIL) <(b6) va.gov>; O'Toole, Thomas P. <(b6) va.gov>; Schuldheis, Sherrie L, Ph.D <(b6) va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>; Wiechers, Ilse <Ilse.Wiechers@va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

Thanks Dr. Carroll for calling. Tom and I just talked with Dr. Carroll. We will review the release once again and send any updates shortly. The text provided below under BLUF was submitted as context/background only in the email thread.

From: Carroll, David (VACO)
Sent: Tuesday, March 12, 2019 12:37 PM
To: Smith, Monica (VACO) <(b6) va.gov>; Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>; Screen, Gina <(b6) va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; Llorente, Maria D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>; Law, Cassandra M. <(b6) va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; Beck, Lucille B. <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>; Saslo, Christopher M (VHABIL) <(b6) va.gov>; O'Toole, Thomas P. <(b6) va.gov>; Schuldheis, Sherrie L, Ph.D <(b6) va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>; Wiechers, Ilse (b6) @va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

I shared this with our leadership team in 10NC who identified an apparent discrepancy in the communication. Perhaps not intended, it seems to be saying two different things – (b) (5) [redacted] Recommend clarity in advance of release. Thanks.

From: Smith, Monica (VACO)
Sent: Tuesday, March 12, 2019 10:22 AM
To: Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>; Screen, Gina <(b6) va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; Llorente, Maria D. <(b6) va.gov>;

AMERICAN OVERSIGHT

Valentino, Michael (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>; Law, Cassandra M. <(b6) va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; Beck, Lucille B. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

VHA Comms:
(b) (5)

From: Law, Cassandra M.
Sent: Monday, March 11, 2019 3:53 PM
To: VHA 10P4 Communication Group <vha10p4comm@va.gov>; Smith, Monica (VACO) <(b6) va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; Llorente, Maria D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Good afternoon Monica and team. Do you format draft press releases prior to clearing to 10B2B media team? Given the high level attention and involvement, would like to clear this forward, but am unsure about format.

Please make any necessary changes and forward for VHA comms review and VHA 10B as there's a potential quote included to attribute to either Dr. Stone or SECVA.

Thank you, Cassie

From: Emmendorfer, Thomas (PBM)
Sent: Monday, March 11, 2019 3:21 PM
To: VHA 10P4 Actions <VHA10P4Actions@va.gov>

AMERICAN OVERSIGHT

Cc: Llorente, Maria D. <(b6) va.gov>; Outlaw, William N. (b6) @va.gov>; Carroll, David (VACO) <(b6) va.gov>; Wiechers, Ilse (b6) @va.gov>
Subject: FW: HHS bought a nasal spray for depression

The attached external press release has been developed in coordination with 10P4P and 10NC5. We left a place holder in for a potential quote from Dr. Stone.

Request clearance to 10P for review.

From: Thomas Emmendorfer <(b6) va.gov>
Date: Thursday, March 7, 2019 at 7:45 AM
To: Jon Jensen <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Beck, Lucille B." <(b6) va.gov>, "Howard, Kristi" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Will do.

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Date: Thursday, March 7, 2019 at 7:41 AM
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Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Beck, Lucille B." <(b6) va.gov>, "Howard, Kristi" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Tom, can you come to Morning Report today to discuss? Starts at 9:30.

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Sent: Wednesday, March 06, 2019 10:15 PM
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Cc: Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Howard, Kristi <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

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AMERICAN OVERSIGHT

Tom

(b) (5) [redacted]

[redacted] Jensen, Jon M.
Sent: Wednesday, March 06, 2019 7:50 PM
To: Emmendorfer, Thomas (PBM) <(b6) [redacted]va.gov>; Valentino, Michael (VACO) <(b6) [redacted]va.gov>; Carroll, David (VACO) <(b6) [redacted]va.gov>; Beck, Lucille B. <(b6) [redacted]va.gov>; Howard, Kristi <(b6) [redacted]va.gov>; Zacher, Jennifer L. (PBM) <(b6) [redacted]va.gov>
Subject: RE: HHS bought a nasal spray for depression

AMERICAN OVERSIGHT

Thanks Tom!

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:49 PM
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Subject: RE: HHS bought a nasal spray for depression

Hi Jon,

We will work on it and get a response back.

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Sent with BlackBerry Work
(www.blackberry.com)

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Date: Wednesday, Mar 06, 2019, 7:34 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Adding Jennifer

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

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Date: Wednesday, Mar 06, 2019, 7:27 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

AMERICAN OVERSIGHT

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Jon Jensen
VHA Acting Deputy Chief of Staff
W:(b6)
(b6)

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VHA Acting Deputy Chief of Staff
(b6)
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Recipient:	Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Smith, Monica (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=511ea9e77a234375a91a7b34ce23719d-Smith, Moni <(b6) va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; Outlaw, William N. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3e1067978634fbf96a382bdcd5c1115-Outlaw, Wil (b6) va.gov>
Sent Date:	2019/03/12 14:05:21
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AMERICAN OVERSIGHT

From:	Smith, Monica (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=511EA9E77A234375A91A7B34CE23719D-SMITH, MONI <(b6) va.gov>
To:	Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>
CC:	Outlaw, William N. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3e1067978634fbf96a382bdcd5c1115-Outlaw, Wil <(b6) va.gov>
Subject:	RE: HHS bought a nasal spray for depression - DRAFT News Release
Date:	2019/03/12 16:08:15
Priority:	Normal
Type:	Note

Ok, thank you all. I will send this new version to VHA and also let them know our offices are working on the FAQs to follow.

From: Llorente, Maria D.
Sent: Tuesday, March 12, 2019 4:04 PM
To: Smith, Monica (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Wiechers, Ilse (b6) @va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>
Cc: Outlaw, William N. <William.Outlaw2@va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

Looks good. Thanks to everyone.

From: Smith, Monica (VACO)
Sent: Tuesday, March 12, 2019 1:45 PM
To: Carroll, David (VACO) <(b6) va.gov>; Wiechers, Ilse <(b6) a.gov>; Llorente, Maria D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>
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From: Smith, Monica (VACO)
Sent: Tuesday, March 12, 2019 1:27 PM
To: Carroll, David (VACO) <(b6) va.gov>; Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>; Screen, Gina <(b6) va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; Llorente, Maria D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>; Law, Cassandra M. <(b6) va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; Beck, Lucille B. <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>; Saslo, Christopher M (VHABIL) <(b6) va.gov>; O'Toole, Thomas P. <(b6) va.gov>; Schuldheis, Sherrie L, Ph.D <(b6) va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>; Wiechers, Ilse <Ilse.Wiechers@va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

Thanks Dr. Carroll for calling. Tom and I just talked with Dr. Carroll. We will review the release once again and send any updates shortly. The text provided below under BLUF was submitted as context/background only in the email thread.

From: Carroll, David (VACO)
Sent: Tuesday, March 12, 2019 12:37 PM
To: Smith, Monica (VACO) <(b6) va.gov>; Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>; Screen, Gina <(b6) va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; Llorente, Maria D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>; Law, Cassandra M. <(b6) va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; Beck, Lucille B. <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>; Saslo, Christopher M (VHABIL) <(b6) va.gov>; O'Toole, Thomas P. <(b6) va.gov>; Schuldheis, Sherrie L, Ph.D <(b6) va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>; Wiechers, Ilse (b6) @va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

I shared this with our leadership team in 10NC who identified an apparent discrepancy in the communication. Perhaps not intended, it seems to be saying two different things – (b) (5) [redacted] Recommend clarity in advance of release. Thanks.

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Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; Llorente, Maria D. <(b6) va.gov>;

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Valentino, Michael (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>; Law, Cassandra M. <(b6) va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; Beck, Lucille B. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

VHA Comms:
(b) (5)

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To: VHA 10P4 Communication Group <vha10p4comm@va.gov>; Smith, Monica (VACO) <(b6) va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; Llorente, Maria D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Good afternoon Monica and team. Do you format draft press releases prior to clearing to 10B2B media team? Given the high level attention and involvement, would like to clear this forward, but am unsure about format.

Please make any necessary changes and forward for VHA comms review and VHA 10B as there's a potential quote included to attribute to either Dr. Stone or SECVA.

Thank you, Cassie

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Sent: Monday, March 11, 2019 3:21 PM
To: VHA 10P4 Actions <VHA10P4Actions@va.gov>

AMERICAN OVERSIGHT

Cc: Llorente, Maria D. <(b6) va.gov>; Outlaw, William N. (b6) @va.gov>; Carroll, David (VACO) <(b6) va.gov>; Wiechers, Ilse (b6) @va.gov>
Subject: FW: HHS bought a nasal spray for depression

The attached external press release has been developed in coordination with 10P4P and 10NC5. We left a place holder in for a potential quote from Dr. Stone.

Request clearance to 10P for review.

From: Thomas Emmendorfer <(b6) va.gov>
Date: Thursday, March 7, 2019 at 7:45 AM
To: Jon Jensen <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Beck, Lucille B." <(b6) va.gov>, "Howard, Kristi" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Will do.

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Date: Thursday, March 7, 2019 at 7:41 AM
To: Thomas Emmendorfer <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Beck, Lucille B." <(b6) va.gov>, "Howard, Kristi" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Tom, can you come to Morning Report today to discuss? Starts at 9:30.

From: Emmendorfer, Thomas (PBM)
Sent: Wednesday, March 06, 2019 10:15 PM
To: Jensen, Jon M. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Howard, Kristi <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Hi Jon,

I hope all is going well. Below is the information that Jenn, Mike, and I pulled together for you. Let us know if you need anything else.

AMERICAN OVERSIGHT

Tom

(b) (5) [redacted]

[redacted] Jensen, Jon M.
Sent: Wednesday, March 06, 2019 7:50 PM
To: Emmendorfer, Thomas (PBM) <(b6) [redacted]va.gov>; Valentino, Michael (VACO) <(b6) [redacted]va.gov>; Carroll, David (VACO) <(b6) [redacted]va.gov>; Beck, Lucille B. <(b6) [redacted]va.gov>; Howard, Kristi <(b6) [redacted]va.gov>; Zacher, Jennifer L. (PBM) <(b6) [redacted]va.gov>
Subject: RE: HHS bought a nasal spray for depression

AMERICAN OVERSIGHT

Thanks Tom!

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:49 PM
To: Jensen, Jon M. <(b6) va.gov>, Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Hi Jon,

We will work on it and get a response back.

Tom

Sent with BlackBerry Work
(www.blackberry.com)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:34 PM
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Subject: RE: HHS bought a nasal spray for depression

Adding Jennifer

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

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Date: Wednesday, Mar 06, 2019, 7:27 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

AMERICAN OVERSIGHT

Just spoke to Dr Stone. We need to get something a little earlier than 10. As soon as you can would be fantastic.
Secva has asked for an update.

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 5:40 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: HHS bought a nasal spray for depression

Good evening, need some information on a nasal spray used for depression? POTUS heard HHS recently purchased and he felt it would be great for us. That's all I got. Can you pull info on what it would be, if we purchase currently, if we are looking into it etc. would sure appreciate anything you could provide by 10am.

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

Sender:	Smith, Monica (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=511EA9E77A234375A91A7B34CE23719D-SMITH, MONI <(b6) va.gov>
Recipient:	Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; Outlaw, William N. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3e1067978634fbf96a382bdcd5c1115-Outlaw, Wil (b6) @va.gov>
Sent Date:	2019/03/12 16:08:12
Delivered Date:	2019/03/12 16:08:15

AMERICAN OVERSIGHT

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To:	Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Greilsamer, Alan /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fc02807af08443fbb5c68c590d58fa4b-Greilsamer, <(b6) va.gov>; Ledesma, Mark P. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=acbc9290cfec4fff8651002b5b0330c5-Ledesma, Ma <(b6) va.gov>; Screen, Gina /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=777aa6921e794e42a45a07d8235767c5-Screen, Gin <(b6) va.gov>
CC:	VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; VHA 10P4 Communication Group /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4ba2ff9b4604547be7834a71415253c-VHA 10P4 Co <vha10p4comm@va.gov>; Law, Cassandra M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f888d507d6c54eb5a92fc44199eb5838-Law, Cassan <(b6) va.gov>; VHA 10P Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5098b521b1f34f8a97f74be24709d62f-VHA 10P Act <VHA10PActions@va.gov>; Beck, Lucille B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=845480228a8b43e7a5fef5716ded04c2-Beck, Lucil <(b6) va.gov>; Boyd, Teresa D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6886a7d555a43e0bee23c1e40e1c234-Boyd, Teres <(b6) va.gov>; Saslo, Christopher M (VHABIL) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=23f487d85a3e47bdb0b1d4d6274bf2da-Saslo, Mark <(b6) va.gov>; O'Toole, Thomas P.(b6) va.gov </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c5a34d8a4b294e9986ef6e1aa8009b3f-O'Toole, Th>; Schuldheis, Sherrie L, Ph.D /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aecbe9a1f74d4a94a2206db8e404a63d-Schuldheis, <(b6) va.gov>; VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>
Subject:	RE: HHS bought a nasal spray for depression - DRAFT News Release
Date:	2019/03/12 12:48:47
Priority:	Normal
Type:	Note

AMERICAN OVERSIGHT

Thanks Dr. Carroll for calling. Tom and I just talked with Dr. Carroll and the news release is correct. Patients will administer the drug under the provider's direct supervision. The text provided below under BLUF was submitted as context/background in the email thread.

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Sent: Tuesday, March 12, 2019 12:37 PM
To: Smith, Monica (VACO) <(b6) va.gov>; Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>; Screen, Gina <(b6) va.gov>
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Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

VHA Comms:
As you may have seen in the news last week, there is a new drug coming on the market to treat depression. VA will offer this to Veterans. Please see attached draft press release for your expedited review. Our Pharmacy SMEs (Tom Emmendorfer and Mike Valentino) are on the cc: line to address any questions. I also understand there is internal communication in draft for communication to the field.

AMERICAN OVERSIGHT

(b) (5)

[redacted]

From: Law, Cassandra M.
Sent: Monday, March 11, 2019 3:53 PM
To: VHA 10P4 Communication Group <vha10p4comm@va.gov>; Smith, Monica (VACO) <(b6) va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; Llorente, Maria D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>
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AMERICAN OVERSIGHT

Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Beck, Lucille B." <(b6) va.gov>, "Howard, Kristi" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

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Cc: Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Howard, Kristi <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
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Tom

(b) (5)

AMERICAN OVERSIGHT

- (b) (5) [redacted]

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Subject: RE: HHS bought a nasal spray for depression

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Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

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Date: Wednesday, Mar 06, 2019, 7:49 PM

AMERICAN OVERSIGHT

To: Jensen, Jon M. <(b6) va.gov>, Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

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We will work on it and get a response back.

Tom

Sent with BlackBerry Work
(www.blackberry.com)

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Date: Wednesday, Mar 06, 2019, 7:34 PM
To: Valentino, Michael (VACO) (b6) gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Adding Jennifer

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

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Date: Wednesday, Mar 06, 2019, 7:27 PM
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VHA Acting Deputy Chief of Staff
(b6)
(b6)

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Date: Wednesday, Mar 06, 2019, 5:40 PM

AMERICAN OVERSIGHT

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(b6)
(b6)

Sender:	Smith, Monica (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=511EA9E77A234375A91A7B34CE23719D-SMITH, MONI <(b6) va.gov>
Recipient:	Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Greilsamer, Alan /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fc02807af08443fbb5c68c590d58fa4b-Greilsamer, <(b6) va.gov>; Ledesma, Mark P. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=acbc9290cfec4fff8651002b5b0330c5-Ledesma, Ma <(b6) va.gov>; Screen, Gina /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=777aa6921e794e42a45a07d8235767c5-Screen, Gin <(b6) va.gov>; VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) @va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; VHA 10P4 Communication Group /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4ba2ff9b4604547be7834a71415253c-VHA 10P4 Co <vha10p4comm@va.gov>; Law, Cassandra M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f888d507d6c54eb5a92fc44199eb5838-Law, Cassan <(b6) va.gov>; VHA 10P Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5098b521b1f34f8a97f74be24709d62f-VHA 10P Act <VHA10PActions@va.gov>; Beck, Lucille B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=845480228a8b43e7a5fef5716ded04c2-Beck, Lucil <(b6) va.gov>; Boyd, Teresa D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6886a7d555a43e0bee23c1e40e1c234-Boyd, Teres <(b6) va.gov>; Saslo, Christopher M (VHABIL) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=23f487d85a3e47bdb0b1d4d6274bf2da-Saslo, Mark

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	<(b6) va.gov>; O'Toole, Thomas P.(b6) va.gov </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c5a34d8a4b294e9986ef6e1aa8009b3f-O'Toole, Th>; Schuldheis, Sherrie L, Ph.D /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aecbe9a1f74d4a94a2206db8e404a63d-Schuldheis, (b6) s@va.gov>; VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b6) @va.gov>
Sent Date:	2019/03/12 12:48:45
Delivered Date:	2019/03/12 12:48:47
Message Flags:	Unread

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From:	Wiechers, Ilse /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0C7B1428D9E4233A641F125C5B6FC4F-WIECHERS, I <(b6) @va.gov>
To:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>
CC:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>
Subject:	RE: HHS bought a nasal spray for depression - DRAFT News Release
Date:	2019/03/12 12:57:03
Priority:	Normal
Type:	Note

The last version of the press release I saw starts with the following sentence, which I think may be leading to the confusion:

(b) (5)

e.

Thoughts?
Ilse

From: Valentino, Michael (VACO)
Sent: Tuesday, March 12, 2019 9:54 AM
To: Saslo, Christopher M (VHABIL) <(b6) va.gov>; Schuldheis, Sherrie L, Ph.D <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Smith, Monica (VACO) <(b6) va.gov>; Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>; Screen, Gina <(b6) va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; Llorente, Maria D. <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>; Law, Cassandra M. <(b6) va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; Beck, Lucille B. <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>; O'Toole, Thomas P. <(b6) va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>; Wiechers, Ilse (b6) @va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

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This may be the wrong version. It should specify that the patient self administers under provider observation

Sent with BlackBerry Work
(www.blackberry.com)

From: Saslo, Christopher M (VHABIL) <(b6) va.gov>
Date: Tuesday, Mar 12, 2019, 11:41 AM
To: Schuldheis, Sherrie L, Ph.D <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Smith, Monica (VACO) <(b6) va.gov>, Greilsamer, Alan <(b6) va.gov>, Ledesma, Mark P. <(b6) va.gov>, Screen, Gina <(b6) va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>, Llorente, Maria D. <(b6) va.gov>, Valentino, Michael (VACO) <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>, VHA 10P4 Communication Group <vha10p4comm@va.gov>, Law, Cassandra M. <(b6) va.gov>, VHA 10P Actions <VHA10PActions@va.gov>, Beck, Lucille B. <(b6) va.gov>, Boyd, Teresa D. <(b6) va.gov>, O'Toole, Thomas P. <(b6) va.gov>, VHA 10NC5 Action <VHA10NC5Action@va.gov>, Wiechers, Ilse (b6) @va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

I thought Dr. Boyd had a conversation with Dr. Valentino already. Can we clarify if this has taken place?

Chris

Dr. M. Christopher Saslo DNS, ARNP-BC, FAANP
Acting Deputy ADUSH for Clinical Operations (10NC)
810 Vermont Ave. NW
Washington, D.C. 20420
(b6)

"One of the deep secrets of life is that all that is really worth doing is what we do for others"....Lewis Carroll

---

From: Schuldheis, Sherrie L, Ph.D
Sent: Tuesday, March 12, 2019 12:39 PM
To: Carroll, David (VACO) <(b6) va.gov>; Smith, Monica (VACO) <(b6) va.gov>; Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>; Screen, Gina <(b6) va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; Llorente, Maria D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>; Law, Cassandra M. <(b6) va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; Beck, Lucille B. <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>; Saslo, Christopher M (VHABIL) (b6) va.gov>; O'Toole, Thomas P. <(b6) va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>; Wiechers, (b6) @va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

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Agree Dave. Do you want to call Pharmacy, or do you want 10NC to call for clarification?

Sherrie Schuldheis, PhD, RN, CENP
Special Assistant, ADUSH Clinical Operations
VHA 10NC
810 Vermont NW
Washington, DC 20420
(b6) (cell)
(b6) va.gov

From: Carroll, David (VACO)
Sent: Tuesday, March 12, 2019 9:37 AM
To: Smith, Monica (VACO) <(b6) va.gov>; Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>; Screen, Gina <(b6) va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; Llorente, Maria D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>; Law, Cassandra M. <(b6) va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; Beck, Lucille B. <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>; Saslo, Christopher M (VHABIL) <(b6) va.gov>; O'Toole, Thomas P. <(b6) va.gov>; Schuldheis, Sherrie L, Ph.D <(b6) va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>; Wiechers, Ilse (b6) @va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

I shared this with our leadership team in 10NC who identified an apparent discrepancy in the communication. Perhaps not intended, it seems to be saying two different things – (b) (5)

Recommend clarity in advance of release. Thanks.

From: Smith, Monica (VACO)
Sent: Tuesday, March 12, 2019 10:22 AM
To: Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>; Screen, Gina <(b6) va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; Llorente, Maria D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>; Law, Cassandra M. <(b6) va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; Beck, Lucille B. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

VHA Comms:
As you may have seen in the news last week, there is a new drug coming on the market to treat depression. VA will offer this to Veterans. Please see attached draft press release for your expedited

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review. Our Pharmacy SMEs (Tom Emmendorfer and Mike Valentino) are on the cc: line to address any questions. I also understand there is internal communication in draft for communication to the field.

(b) (5)

[redacted]

From: Law, Cassandra M.
Sent: Monday, March 11, 2019 3:53 PM
To: VHA 10P4 Communication Group <vha10p4comm@va.gov>; Smith, Monica (VACO) <(b6) va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; Llorente, Maria D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Good afternoon Monica and team. Do you format draft press releases prior to clearing to 10B2B media team? Given the high level attention and involvement, would like to clear this forward, but am unsure about format.

Please make any necessary changes and forward for VHA comms review and VHA 10B as there's a potential quote included to attribute to either Dr. Stone or SECVA.

Thank you, Cassie

From: Emmendorfer, Thomas (PBM)
Sent: Monday, March 11, 2019 3:21 PM
To: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Cc: Llorente, Maria D. <(b6) va.gov>; Outlaw, William N. (b6) @va.gov>; Carroll, David (VACO) <(b6) va.gov>; Wiechers, Ilse (b6) @va.gov>
Subject: FW: HHS bought a nasal spray for depression

The attached external press release has been developed in coordination with 10P4P and 10NC5. We left a place holder in for a potential quote from Dr. Stone.

Request clearance to 10P for review.

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From: Thomas Emmendorfer <(b6) va.gov>
Date: Thursday, March 7, 2019 at 7:45 AM
To: Jon Jensen <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Beck, Lucille B." <(b6) va.gov>, "Howard, Kristi" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Will do.

From: Jon Jensen <(b6) va.gov>
Date: Thursday, March 7, 2019 at 7:41 AM
To: Thomas Emmendorfer <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Beck, Lucille B." <(b6) va.gov>, "Howard, Kristi" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Tom, can you come to Morning Report today to discuss? Starts at 9:30.

From: Emmendorfer, Thomas (PBM)
Sent: Wednesday, March 06, 2019 10:15 PM
To: Jensen, Jon M. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Howard, Kristi <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Hi Jon,

I hope all is going well. Below is the information that Jenn, Mike, and I pulled together for you. Let us know if you need anything else.

Tom

(b) (5)

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- (b) (5)



From: Jensen, Jon M.
Sent: Wednesday, March 06, 2019 7:50 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Howard, Kristi <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Thanks Tom!

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

AMERICAN OVERSIGHT

From: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:49 PM
To: Jensen, Jon M. <(b6) va.gov>, Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Hi Jon,

We will work on it and get a response back.

Tom

Sent with BlackBerry Work
(www.blackberry.com)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:34 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Adding Jennifer

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:27 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Just spoke to Dr Stone. We need to get something a little earlier than 10. As soon as you can would be fantastic.
Secva has asked for an update.

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

AMERICAN OVERSIGHT

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 5:40 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: HHS bought a nasal spray for depression

Good evening, need some information on a nasal spray used for depression? POTUS heard HHS recently purchased and he felt it would be great for us. That's all I got. Can you pull info on what it would be, if we purchase currently, if we are looking into it etc. would sure appreciate anything you could provide by 10am.

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

Sender:	Wiechers, Ilse /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0C7B1428D9E4233A641F125C5B6FC4F-WIECHERS, I <(b6) va.gov>
Recipient:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>
Sent Date:	2019/03/12 12:57:02
Delivered Date:	2019/03/12 12:57:03

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From:	Saslo, Christopher M (VHABIL) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=23F487D85A3E47BDB0B1D4D6274BF2DA-SASLO, MARK <(b6) va.gov>
To:	Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Schuldheis, Sherrie L, Ph.D /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aecbe9a1f74d4a94a2206db8e404a63d-Schuldheis, <(b6) va.gov>
Subject:	RE: HHS bought a nasal spray for depression - DRAFT News Release
Date:	2019/03/12 12:47:10
Priority:	Normal
Type:	Note

Thanks Dr. Carroll, appreciate it.

Chris

Dr. M. Christopher Saslo DNS, ARNP-BC, FAANP
Acting Deputy ADUSH for Clinical Operations (10NC)
810 Vermont Ave. NW
Washington, D.C. 20420
(b6)

"One of the deep secrets of life is that all that is really worth doing is what we do for others"....Lewis Carroll

---

From: Carroll, David (VACO)
Sent: Tuesday, March 12, 2019 12:46 PM
To: Saslo, Christopher M (VHABIL) <(b6) va.gov>; Schuldheis, Sherrie L, Ph.D <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

I just talked with Monica Smith and Tom Emmendorfer. The Press Release is correct (b) (5) .

From: Saslo, Christopher M (VHABIL)
Sent: Tuesday, March 12, 2019 12:41 PM
To: Schuldheis, Sherrie L, Ph.D <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Smith, Monica (VACO) <(b6) va.gov>; Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>; Screen, Gina <(b6) va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; Llorente, Maria D. <(b6) va.gov>;

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Valentino, Michael (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>; Law, Cassandra M. <(b6) va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; Beck, Lucille B. <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>; O'Toole, Thomas P. <(b6) va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>; Wiechers, Ilse (b6) @va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

I thought Dr. Boyd had a conversation with Dr. Valentino already. Can we clarify if this has taken place?

Chris

Dr. M. Christopher Saslo DNS, ARNP-BC, FAANP
Acting Deputy ADUSH for Clinical Operations (10NC)
810 Vermont Ave. NW
Washington, D.C. 20420
(b6)

"One of the deep secrets of life is that all that is really worth doing is what we do for others"....Lewis Carroll

---

From: Schuldheis, Sherrie L, Ph.D
Sent: Tuesday, March 12, 2019 12:39 PM
To: Carroll, David (VACO) <(b6) va.gov>; Smith, Monica (VACO) <(b6) va.gov>; Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>; Screen, Gina <(b6) va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; Llorente, Maria D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>; Law, Cassandra M. <(b6) va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; Beck, Lucille B. <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>; Saslo, Christopher M (VHABIL) <(b6) va.gov>; O'Toole, Thomas P. <(b6) va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>; Wiechers, Ilse (b6) @va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

Agree Dave. Do you want to call Pharmacy, or do you want 10NC to call for clarification?

Sherrie Schuldheis, PhD, RN, CENP
Special Assistant, ADUSH Clinical Operations
VHA 10NC
810 Vermont NW
Washington, DC 20420
(b6) (cell)
(b6) va.gov

From: Carroll, David (VACO)
Sent: Tuesday, March 12, 2019 9:37 AM

AMERICAN OVERSIGHT

To: Smith, Monica (VACO) <(b6) va.gov>; Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>; Screen, Gina <(b6) va.gov>
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(b) (5)

AMERICAN OVERSIGHT

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AMERICAN OVERSIGHT

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(www.blackberry.com)

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(b6)
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(b6)
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AMERICAN OVERSIGHT

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VHA Acting Deputy Chief of Staff
(b6)
(b6)

Sender:	Saslo, Christopher M (VHABIL) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=23F487D85A3E47BDB0B1D4D6274BF2DA-SASLO, MARK <(b6) va.gov>
Recipient:	Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Schuldheis, Sherrie L, Ph.D /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aecbe9a1f74d4a94a2206db8e404a63d-Schuldheis, <(b6) va.gov>
Sent Date:	2019/03/12 12:47:09
Delivered Date:	2019/03/12 12:47:10

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From:	Schuldheis, Sherrie L, Ph.D /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AECBE9A1F74D4A94A2206DB8E404A63D-SCHULDHEIS, <(b6) va.gov>
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Subject:	RE: HHS bought a nasal spray for depression - DRAFT News Release
Date:	2019/03/12 12:46:55
Priority:	Normal
Type:	Note

Thanks Dave!

Sherrie Schuldheis, PhD, RN, CENP
Special Assistant, ADUSH Clinical Operations
VHA 10NC
810 Vermont NW
Washington, DC 20420
(b6) (cell)
(b6) va.gov

From: Carroll, David (VACO)
Sent: Tuesday, March 12, 2019 9:46 AM
To: Saslo, Christopher M (VHABIL) <(b6) va.gov>; Schuldheis, Sherrie L, Ph.D <(b6) va.gov>
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I just talked with Monica Smith and Tom Emmendorfer. The Press Release is correct (under direct provider supervision, (b) (5)
forward.

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I thought Dr. Boyd had a conversation with Dr. Valentino already. Can we clarify if this has taken place?

Chris

Dr. M. Christopher Saslo DNS, ARNP-BC, FAANP
Acting Deputy ADUSH for Clinical Operations (10NC)
810 Vermont Ave. NW
Washington, D.C. 20420
(b6)

"One of the deep secrets of life is that all that is really worth doing is what we do for others"....Lewis Carroll

---

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Agree Dave. Do you want to call Pharmacy, or do you want 10NC to call for clarification?

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Sent Date:	2019/03/12 12:46:54
Delivered Date:	2019/03/12 12:46:55

AMERICAN OVERSIGHT

From:	Boyd, Teresa D. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F6886A7D555A43E0BEE23C1E40E1C234-BOYD, TERES <(b6) va.gov>
To:	Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Saslo, Christopher M (VHABIL) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=23f487d85a3e47bdb0b1d4d6274bf2da-Saslo, Mark <(b6) va.gov>; O'Toole, Thomas P.(b6) va.gov </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c5a34d8a4b294e9986ef6e1aa8009b3f-O'Toole, Th>; Schuldheis, Sherrie L, Ph.D /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aecbe9a1f74d4a94a2206db8e404a63d-Schuldheis, (b6) @va.gov>
CC:	VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>
Subject:	RE: HHS bought a nasal spray for depression - DRAFT News Release
Date:	2019/03/12 11:30:35
Priority:	Normal
Type:	Note

Thanks Dave.
Appreciate being looped in since indeed we have been heavily involved in this TK date
Teresa

Sent with BlackBerry Work
(www.blackberry.com)

From: Carroll, David (VACO) <(b6) va.gov>
Date: Tuesday, Mar 12, 2019, 9:56 AM
To: Boyd, Teresa D. <(b6) va.gov>, Saslo, Christopher M (VHABIL) <(b6) va.gov>, O'Toole, Thomas P. <(b6) va.gov>, Schuldheis, Sherrie L, Ph.D <(b6) va.gov>
Cc: VHA 10NC5 Action <VHA10NC5Action@va.gov>
Subject: FW: HHS bought a nasal spray for depression - DRAFT News Release

FYI. I don't see 10NC/10N on this message. Our office has been working with Pharmacy on this matter. 10P has moved a press release forward to VHA Comms.

From: Smith, Monica (VACO)
Sent: Tuesday, March 12, 2019 10:22 AM
To: Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>; Screen, Gina <(b6) va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; Llorente, Maria D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>; Law, Cassandra M. <(b6) va.gov>; VHA

AMERICAN OVERSIGHT

10P Actions <VHA10PActions@va.gov>; Beck, Lucille B. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

VHA Comms:
As you may have seen in the news last week, there is a new drug coming on the market to treat depression. VA will offer this to Veterans. Please see attached draft press release for your expedited review. Our Pharmacy SMEs (Tom Emmendorfer and Mike Valentino) are on the cc: line to address any questions. I also understand there is internal communication in draft for communication to the field.

(b) (5)

From: Law, Cassandra M.
Sent: Monday, March 11, 2019 3:53 PM
To: VHA 10P4 Communication Group <vha10p4comm@va.gov>; Smith, Monica (VACO) <(b6) va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; Llorente, Maria D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Good afternoon Monica and team. Do you format draft press releases prior to clearing to 10B2B media team? Given the high level attention and involvement, would like to clear this forward, but am unsure about format.

Please make any necessary changes and forward for VHA comms review and VHA 10B as there's a potential quote included to attribute to either Dr. Stone or SECVA.

Thank you, Cassie

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Sent: Monday, March 11, 2019 3:21 PM
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Cc: Llorente, Maria D. <(b6) va.gov>; Outlaw, William N. (b6) .gov>; Carroll, David (VACO) <(b6) va.gov>; Wiechers, Ilse (b6) @va.gov>
Subject: FW: HHS bought a nasal spray for depression

AMERICAN OVERSIGHT

The attached external press release has been developed in coordination with 10P4P and 10NC5. We left a place holder in for a potential quote from Dr. Stone.

Request clearance to 10P for review.

From: Thomas Emmendorfer <(b6) va.gov>
Date: Thursday, March 7, 2019 at 7:45 AM
To: Jon Jensen <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Beck, Lucille B." <(b6) va.gov>, "Howard, Kristi" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Will do.

From: Jon Jensen <(b6) va.gov>
Date: Thursday, March 7, 2019 at 7:41 AM
To: Thomas Emmendorfer <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Beck, Lucille B." <(b6) va.gov>, "Howard, Kristi" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Tom, can you come to Morning Report today to discuss? Starts at 9:30.

From: Emmendorfer, Thomas (PBM)
Sent: Wednesday, March 06, 2019 10:15 PM
To: Jensen, Jon M. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Howard, Kristi <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Hi Jon,

I hope all is going well. Below is the information that Jenn, Mike, and I pulled together for you. Let us know if you need anything else.

Tom

(b) (5)

AMERICAN OVERSIGHT

(b) (5)



From: Jensen, Jon M.
Sent: Wednesday, March 06, 2019 7:50 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Howard, Kristi <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Thanks Tom!

AMERICAN OVERSIGHT

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:49 PM
To: Jensen, Jon M. <(b6) va.gov>, Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Hi Jon,

We will work on it and get a response back.

Tom

Sent with BlackBerry Work
(www.blackberry.com)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:34 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Adding Jennifer

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:27 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Just spoke to Dr Stone. We need to get something a little earlier than 10. As soon as you can would be fantastic.
Secva has asked for an update.

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Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 5:40 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: HHS bought a nasal spray for depression

Good evening, need some information on a nasal spray used for depression? POTUS heard HHS recently purchased and he felt it would be great for us. That's all I got. Can you pull info on what it would be, if we purchase currently, if we are looking into it etc. would sure appreciate anything you could provide by 10am.

Jon Jensen
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(b6)

Sender:	Boyd, Teresa D. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F6886A7D555A43E0BEE23C1E40E1C234-BOYD, TERES <(b6) va.gov>
Recipient:	Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Saslo, Christopher M (VHABIL) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=23f487d85a3e47bdb0b1d4d6274bf2da-Saslo, Mark <(b6) va.gov>; O'Toole, Thomas P.(b6) va.gov </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c5a34d8a4b294e9986ef6e1aa8009b3f-O'Toole, Th>; Schuldheis, Sherrie L, Ph.D /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aecbe9a1f74d4a94a2206db8e404a63d-Schuldheis, (b6) @va.gov>; VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>
Sent Date:	2019/03/12 11:30:31
Delivered Date:	2019/03/12 11:30:35

AMERICAN OVERSIGHT

From:	Saslo, Christopher M (VHABIL) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=23F487D85A3E47BDB0B1D4D6274BF2DA-SASLO, MARK <(b6) va.gov>
To:	Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Boyd, Teresa D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6886a7d555a43e0bee23c1e40e1c234-Boyd, Teres <(b6) va.gov>; O'Toole, Thomas P.(b6) va.gov </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c5a34d8a4b294e9986ef6e1aa8009b3f-O'Toole, Th>; Schuldheis, Sherrie L, Ph.D /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aecbe9a1f74d4a94a2206db8e404a63d-Schuldheis, (b6) @va.gov>
CC:	VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>
Subject:	RE: HHS bought a nasal spray for depression - DRAFT News Release
Date:	2019/03/12 12:29:13
Priority:	Normal
Type:	Note

(b) (5)

Chris

Dr. M. Christopher Saslo DNS, ARNP-BC, FAANP
Acting Deputy ADUSH for Clinical Operations (10NC)
810 Vermont Ave. NW
Washington, D.C. 20420
(b6)

"One of the deep secrets of life is that all that is really worth doing is what we do for others"....Lewis Carroll

---

From: Carroll, David (VACO)
Sent: Tuesday, March 12, 2019 10:57 AM
To: Boyd, Teresa D. <(b6) va.gov>; Saslo, Christopher M (VHABIL) <(b6) va.gov>; O'Toole, Thomas P. <(b6) va.gov>; Schuldheis, Sherrie L, Ph.D <(b6) va.gov>
Cc: VHA 10NC5 Action <VHA10NC5Action@va.gov>
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(b) (5)

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Subject: RE: HHS bought a nasal spray for depression

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Sent: Monday, March 11, 2019 3:21 PM
To: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Cc: Llorente, Maria D. <(b6) va.gov>; Outlaw, William N. (b6) @va.gov>; Carroll, David (VACO) <(b6) va.gov>; Wiechers, Ilse (b6) @va.gov>
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Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Beck, Lucille B." <(b6) va.gov>, "Howard, Kristi" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
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Subject: RE: HHS bought a nasal spray for depression

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To: Jensen, Jon M. <(b6) va.gov>

AMERICAN OVERSIGHT

Cc: Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Howard, Kristi <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
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(b) (5)

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AMERICAN OVERSIGHT

- (b) (5) [redacted]

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VHA Acting Deputy Chief of Staff
(b6)
(b6)

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Subject: RE: HHS bought a nasal spray for depression

Adding Jennifer

Jon Jensen

AMERICAN OVERSIGHT

VHA Acting Deputy Chief of Staff
(b6)
(b6)

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Date: Wednesday, Mar 06, 2019, 7:27 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
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(b6)
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VHA Acting Deputy Chief of Staff
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	(FYDIBOHF23SPDLT)/cn=Recipients/cn=aecbe9a1f74d4a94a2206db8e404a63d-Schuldheis, <(b6) va.gov>; VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>
Sent Date:	2019/03/12 12:29:11
Delivered Date:	2019/03/12 12:29:13

AMERICAN OVERSIGHT

From:	Smith, Monica (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=511ea9e77a234375a91a7b34ce23719d-Smith, Moni <(b6) va.gov>
To:	Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>
CC:	Outlaw, William N. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3e1067978634fbf96a382bdcd5c1115-Outlaw, Wil <(b6) va.gov>
Subject:	RE: HHS bought a nasal spray for depression - DRAFT News Release
Date:	2019/03/12 16:08:15
Priority:	Normal
Type:	Note

Ok, thank you all. I will send this new version to VHA and also let them know our offices are working on the FAQs to follow.

From: Llorente, Maria D.
Sent: Tuesday, March 12, 2019 4:04 PM
To: Smith, Monica (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Wiechers, Ilse <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>
Cc: Outlaw, William N. <William.Outlaw2@va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release
Looks good. Thanks to everyone.

From: Smith, Monica (VACO)
Sent: Tuesday, March 12, 2019 1:45 PM
To: Carroll, David (VACO) <(b6) va.gov>; Wiechers, Ilse <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>
Cc: Outlaw, William N. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release
Team – Sending to this small group of leaders only. Please review once more and approve before we re-send this to VHA Comms. Changes were made to the headline, the lead sentence and first two paragraphs.

AMERICAN OVERSIGHT

From: Smith, Monica (VACO)
Sent: Tuesday, March 12, 2019 1:27 PM
To: Carroll, David (VACO) <(b6) va.gov>; Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. &lt(b6) va.gov>; Screen, Gina <(b6) va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; Llorente, Maria D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>; Law, Cassandra M. <(b6) va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; Beck, Lucille B. <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>; Saslo, Christopher M (VHABIL) <(b6) va.gov>; O'Toole, Thomas P. <(b6) va.gov>; Schuldheis, Sherrie L, Ph.D <(b6) va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>; Wiechers, Ilse <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release
Thanks Dr. Carroll for calling. Tom and I just talked with Dr. Carroll. We will review the release once again and send any updates shortly. The text provided below under BLUF was submitted as context/background only in the email thread.

From: Carroll, David (VACO)
Sent: Tuesday, March 12, 2019 12:37 PM
To: Smith, Monica (VACO) <(b6) va.gov>; Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>; Screen, Gina <(b6) va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; Llorente, Maria D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>; Law, Cassandra M. <(b6) va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; Beck, Lucille B. <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>; Saslo, Christopher M (VHABIL) <(b6) va.gov>; O'Toole, Thomas P. <(b6) va.gov>; Schuldheis, Sherrie L, Ph.D <(b6) va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>; Wiechers, Ilse <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release
I shared this with our leadership team in 10NC who identified an apparent discrepancy in the communication. Perhaps not intended, it seems to be saying two different things – (b) (5) Recommend clarity in advance of release. Thanks.

From: Smith, Monica (VACO)
Sent: Tuesday, March 12, 2019 10:22 AM
To: Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>; Screen, Gina <(b6) va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; Llorente, Maria D.

AMERICAN OVERSIGHT

<(b6) va.gov>; Valentino, Michael (VACO)
<(b6) va.gov>; Emmendorfer, Thomas (PBM)
<(b6) va.gov>; Carroll, David (VACO)
<(b6) va.gov>; VHA 10P4 Communication Group
<vha10p4comm@va.gov>; Law, Cassandra M. <(b6) va.gov>; VHA
10P Actions <VHA10PActions@va.gov>; Beck, Lucille B. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release
VHA Comms:
As you may have seen in the news last week, there is a new drug coming on the market to treat depression. VA will offer this to Veterans. Please see attached draft press release for your expedited review. Our Pharmacy SMEs (Tom Emmendorfer and Mike Valentino) are on the cc: line to address any questions. I also understand there is internal communication in draft for communication to the field.
(b) (5)

From: Law, Cassandra M.
Sent: Monday, March 11, 2019 3:53 PM
To: VHA 10P4 Communication Group <vha10p4comm@va.gov>; Smith, Monica (VACO) <(b6) va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; Llorente, Maria D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Good afternoon Monica and team. Do you format draft press releases prior to clearing to 10B2B media team? Given the high level attention and involvement, would like to clear this forward, but am unsure about format.
Please make any necessary changes and forward for VHA comms review and VHA 10B as there's a potential quote included to attribute to either Dr. Stone or SECVA.
Thank you, Cassie

From: Emmendorfer, Thomas (PBM)
Sent: Monday, March 11, 2019 3:21 PM
To: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Cc: Llorente, Maria D. <(b6) va.gov>; Outlaw, William N. <(b6) va.gov>; Carroll, David (VACO) <(b6) ov>;

AMERICAN OVERSIGHT

Wiechers, Ilse <(b6) va.gov>
Subject: FW: HHS bought a nasal spray for depression
The attached external press release has been developed in coordination with 10P4P and 10NC5. We left a place holder in for a potential quote from Dr. Stone.
Request clearance to 10P for review.

From: Thomas Emmendorfer <(b6) va.gov>
Date: Thursday, March 7, 2019 at 7:45 AM
To: Jon Jensen <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Beck, Lucille B." <(b6) va.gov>, "Howard, Kristi" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression
Will do.

From: Jon Jensen <(b6) va.gov>
Date: Thursday, March 7, 2019 at 7:41 AM
To: Thomas Emmendorfer <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Beck, Lucille B." <(b6) va.gov>, "Howard, Kristi" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Tom, can you come to Morning Report today to discuss? Starts at 9:30.

From: Emmendorfer, Thomas (PBM)
Sent: Wednesday, March 06, 2019 10:15 PM
To: Jensen, Jon M. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Howard, Kristi <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Hi Jon,
I hope all is going well. Below is the information that Jenn, Mike, and I pulled together for you. Let us know if you need anything else.
Tom
(b) (5)

AMERICAN OVERSIGHT

- (b) (5) [redacted]



From: Jensen, Jon M.
Sent: Wednesday, March 06, 2019 7:50 PM
To: Emmendorfer, Thomas (PBM) &lt(b6) [redacted] @va.gov>; Valentino, Michael (VACO) <(b6) [redacted] va.gov>; Carroll, David (VACO) &lt:(b6) [redacted] va.gov>; Beck, Lucille B. &lt:(b6) [redacted] va.gov>; Howard, Kristi &lt:(b6) [redacted] va.gov>; Zacher, Jennifer L. (PBM) &lt:(b6) [redacted] va.gov>
Subject: RE: HHS bought a nasal spray for depression
Thanks Tom!

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6) [redacted]
(b6) [redacted]

AMERICAN OVERSIGHT

From: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:49 PM
To: Jensen, Jon M. <(b6) va.gov>, Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Hi Jon,
We will work on it and get a response back.
Tom

Sent with BlackBerry Work
(www.blackberry.com)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:34 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Adding Jennifer

Jon Jensen
VHA Acting Deputy Chief of Staff
W(b6)
(b6)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:27 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Just spoke to Dr Stone. We need to get something a little earlier than 10. As soon as you can would be fantastic.
Secva has asked for an update.

Jon Jensen
VHA Acting Deputy Chief of Staff
W(b6)
(b6)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 5:40 PM

AMERICAN OVERSIGHT

To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: HHS bought a nasal spray for depression

Good evening, need some information on a nasal spray used for depression? POTUS heard HHS recently purchased and he felt it would be great for us. That's all I got. Can you pull info on what it would be, if we purchase currently, if we are looking into it etc. would sure appreciate anything you could provide by 10am.

Jon Jensen
VHA Acting Deputy Chief of Staff
W(b6)
(b6)

Sender:	Smith, Monica (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=511ea9e77a234375a91a7b34ce23719d-Smith, Moni <(b6) va.gov>
Recipient:	Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b6) a.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; Outlaw, William N. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3e1067978634fbf96a382bdcd5c1115-Outlaw, Wil <(b6) va.gov>
Sent Date:	2019/03/12 16:08:12
Delivered Date:	2019/03/12 16:08:15

AMERICAN OVERSIGHT

From:	Law, Cassandra M. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F888D507D6C54EB5A92FC44199EB5838-LAW, CASSAN <(b6) va.gov>
To:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>
CC:	Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b6) a.gov>; Beck, Lucille B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=845480228a8b43e7a5fef5716ded04c2-Beck, Lucil <(b6) va.gov>
Subject:	RE: HHS bought a nasal spray for depression
Date:	2019/03/06 20:50:53
Priority:	Normal
Type:	Note

Wonderful – thank you very much Tom and Jennifer!

Much appreciated, Cassie

From: Emmendorfer, Thomas (PBM)
Sent: Wednesday, March 06, 2019 8:48 PM
To: Law, Cassandra M. <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>
Cc: Llorente, Maria D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Hi Cassie,

Jenn and I are on the phone together and we are working on the request now. I called Jon about 30 minutes ago to make sure what we are working on…is what they are looking for….we will send the info as soon as we are done.

Thank you,

Tom

From: Law, Cassandra M.
Sent: Wednesday, March 06, 2019 8:46 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>
Cc: Llorente, Maria D. <(b6) va.gov>; Valentino, Michael (VACO)

AMERICAN OVERSIGHT

<{b6} va.gov>; Beck, Lucille B. <{b6} va.gov>
Subject: FW: HHS bought a nasal spray for depression

Good evening Tom and Jennifer. I am reaching out to you per Mike's Out of Office regarding the SECVA request for information for tomorrow morning (Jon Jensen email).

Sorry for the late outreach, but since information is requested for early tomorrow morning, trying to cover all bases to gain insight. Jennifer, the number in the Out of Office for Mike does not appear to be yours so I did not leave a voice mail message.

This may be a MH / Dave Carrol question regarding awareness and efficacy and potential VA interest, but want to be sure we weigh-in with any relevant information.

Thank you for any assistance, Cassie

From: Law, Cassandra M.
Sent: Wednesday, March 06, 2019 8:28 PM
To: Jensen, Jon M. <{b6} va.gov>; Valentino, Michael (VACO) <{b6} va.gov>; Carroll, David (VACO) <{b6} va.gov>; Beck, Lucille B. <{b6} va.gov>; Howard, Kristi <{b6} va.gov>; Emmendorfer, Thomas (PBM) <{b6} va.gov>; Zacher, Jennifer L. (PBM) <{b6} va.gov>
Subject: RE: HHS bought a nasal spray for depression

Thanks Jon. While this is not what SECVA needs for tomorrow, it may be useful. I just read an article on this yesterday in the NY Times (see link below). It's a nasal spray version of the drug ketamine called esketamine. It was developed by a branch of J&J and is to be marketed under the name Spravato.

There is a National Institute of Mental Health Chief / researcher involved so no surprise with HHS backing. I am not aware of VA pursuit, but will see if Mike/Tom and Dave C have additional more relevant insight.

https://www.nytimes.com/2019/03/05/health/depression-treatment-ketamine-fda.html?smid=nytcore-ios-share

Cassie

From: Jensen, Jon M.
Sent: Wednesday, March 06, 2019 7:48 PM
To: Valentino, Michael (VACO) <{b6} va.gov>; Carroll, David (VACO) <{b6} va.gov>; Beck, Lucille B. <{b6} va.gov>; Howard, Kristi <{b6} va.gov>; Emmendorfer, Thomas (PBM) <{b6} va.gov>; Zacher, Jennifer L. (PBM) <{b6} va.gov>; Law, Cassandra M. <{b6} va.gov>
Subject: RE: HHS bought a nasal spray for depression

And Cassie

AMERICAN OVERSIGHT

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:34 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Adding Jennifer

Jon Jensen
VHA Acting Deputy Chief of Staff
W(b6)
(b6)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:27 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Just spoke to Dr Stone. We need to get something a little earlier than 10. As soon as you can would be fantastic.
Secva has asked for an update.

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 5:40 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: HHS bought a nasal spray for depression

Good evening, need some information on a nasal spray used for depression? POTUS heard HHS recently purchased and he felt it would be great for us. That's all I got. Can you pull info on what it would be, if we purchase currently, if we are looking into it etc. would sure appreciate anything you could provide by 10am.

AMERICAN OVERSIGHT

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

Sender:	Law, Cassandra M. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F888D507D6C54EB5A92FC44199EB5838-LAW, CASSAN <(b6) va.gov>
Recipient:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Beck, Lucille B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=845480228a8b43e7a5fef5716ded04c2-Beck, Lucil <(b6) va.gov>
Sent Date:	2019/03/06 20:50:52
Delivered Date:	2019/03/06 20:50:53
Message Flags:	Unread

AMERICAN OVERSIGHT

From:	Valentino, Michael (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO, <(b6) va.gov>
To:	Jensen, Jon M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddeb735ace76400db5c3f10603188a14-Jensen, Jon <(b6) va.gov>; Beck, Lucille B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=845480228a8b43e7a5fef5716ded04c2-Beck, Lucil <(b6) va.gov>
Subject:	RE: HHS bought a nasal spray for depression
Date:	2019/03/06 21:49:02
Priority:	Normal
Type:	Note

You'll have it soon Jon

Sent with BlackBerry Work
(www.blackberry.com)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 6:34 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Adding Jennifer

Jon Jensen
VHA Acting Deputy Chief of Staff
W(b6)
(b6)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:27 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Just spoke to Dr Stone. We need to get something a little earlier than 10. As soon as you can would be fantastic.
Secva has asked for an update.

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Jon Jensen
VHA Acting Deputy Chief of Staff
W(b6)
(b6)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 5:40 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: HHS bought a nasal spray for depression

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Jon Jensen
VHA Acting Deputy Chief of Staff
W(b6)
(b6)

Sender:	Valentino, Michael (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO, <(b6) va.gov>
Recipient:	Jensen, Jon M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddeb735ace76400db5c3f10603188a14-Jensen, Jon <(b6) va.gov>; Beck, Lucille B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=845480228a8b43e7a5fef5716ded04c2-Beck, Lucil <(b6) va.gov>
Sent Date:	2019/03/06 21:49:00
Delivered Date:	2019/03/06 21:49:02

AMERICAN OVERSIGHT

From:	Llorente, Maria D. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F5C91F577D894BD9A0F09305DB34DD4F-LLORENTE, M <(b6) va.gov>
To:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>
CC:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen (b6) va.gov>; Law, Cassandra M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f888d507d6c54eb5a92fc44199eb5838-Law, Cassan <(b6) va.gov>
Subject:	RE: HHS bought a nasal spray for depression
Date:	2019/03/07 10:42:45
Priority:	Normal
Type:	Note

There were sites in Minneapolis, Boston and Houston. Unfortunately, the specific PI and site is not listed, just the city. Just as an FYI, the study participants were aged 18-64.

From: Wiechers, Ilse
Sent: Thursday, March 7, 2019 9:56 AM
To: Carroll, David (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Below are the sites reporting use in FY15 from the assessment we did of the field back in fall 2016. The 2019 assessment went to the field in Feb and we are working to gather the final data from sites now. Hope to have updated data about sites using IV ketamine for treatment of MH conditions sometime later this month.

1-(689) VA Connecticut HCS, CT
18-(501) New Mexico HCS
23-(618) Minneapolis, MN
1-(523) VA Boston HCS, MA
6-(659) Salisbury, NC
12-(607) Madison, WI
16-(580) Houston, TX

AMERICAN OVERSIGHT

21-(662) San Francisco, CA

Best,
Ilse

From: Carroll, David (VACO)
Sent: Thursday, March 07, 2019 6:39 AM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Wiechers, Ilse (b6) @va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

I do not. Ilse may have a list or can otherwise find out.

From: Emmendorfer, Thomas (PBM)
Sent: Thursday, March 7, 2019 9:25 AM
To: Carroll, David (VACO) <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Hi Dave,

The briefing went very well. By chance, do you have a list of known VA medical facilities that are using intravenous ketamine for the treatment of refractory depression?

Thank you,

Tom

From: Thomas Emmendorfer <(b6) va.gov>
Date: Thursday, March 7, 2019 at 7:45 AM
To: Jon Jensen <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Beck, Lucille B." <(b6) va.gov>, "Howard, Kristi" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Will do.

AMERICAN OVERSIGHT

From: Jon Jensen <(b6) va.gov>
Date: Thursday, March 7, 2019 at 7:41 AM
To: Thomas Emmendorfer <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Beck, Lucille B." <(b6) va.gov>, "Howard, Kristi" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Tom, can you come to Morning Report today to discuss? Starts at 9:30.

From: Emmendorfer, Thomas (PBM)
Sent: Wednesday, March 06, 2019 10:15 PM
To: Jensen, Jon M. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Howard, Kristi <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Hi Jon,

I hope all is going well. Below is the information that Jenn, Mike, and I pulled together for you. Let us know if you need anything else.

Tom

(b) (5)

AMERICAN OVERSIGHT

- (b) (5) [redacted]

From: Jensen, Jon M.
Sent: Wednesday, March 06, 2019 7:50 PM
To: Emmendorfer, Thomas (PBM) <(b6) [redacted]va.gov>; Valentino, Michael (VACO) <(b6) [redacted]va.gov>; Carroll, David (VACO) <(b6) [redacted]va.gov>; Beck, Lucille B. <(b6) [redacted]va.gov>; Howard, Kristi <(b6) [redacted]va.gov>; Zacher, Jennifer L. (PBM) <(b6) [redacted]va.gov>
Subject: RE: HHS bought a nasal spray for depression

Thanks Tom!

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6) [redacted]
(b6) [redacted]

From: Emmendorfer, Thomas (PBM) <(b6) [redacted]va.gov>
Date: Wednesday, Mar 06, 2019, 7:49 PM
To: Jensen, Jon M. <(b6) [redacted]va.gov>, Valentino, Michael (VACO) <(b6) [redacted]va.gov>, Carroll, David (VACO) <(b6) [redacted]va.gov>, Beck, Lucille B. <(b6) [redacted]va.gov>, Howard, Kristi <(b6) [redacted]va.gov>, Zacher, Jennifer L. (PBM) <(b6) [redacted]va.gov>
Subject: RE: HHS bought a nasal spray for depression

Hi Jon,

We will work on it and get a response back.

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Tom

Sent with BlackBerry Work
(www.blackberry.com)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:34 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Adding Jennifer

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:27 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Just spoke to Dr Stone. We need to get something a little earlier than 10. As soon as you can would be fantastic.
Secva has asked for an update.

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 5:40 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: HHS bought a nasal spray for depression

Good evening, need some information on a nasal spray used for depression? POTUS heard HHS recently purchased and he felt it would be great for us. That's all I got. Can you pull info on what it would be, if we purchase currently, if we are looking into it etc. would sure appreciate anything you could provide by 10am.

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Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

Sender:	Llorente, Maria D. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F5C91F577D894BD9A0F09305DB34DD4F-LLORENTE, M <(b6) va.gov>
Recipient:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>; Law, Cassandra M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f888d507d6c54eb5a92fc44199eb5838-Law, Cassan <(b6) va.gov>
Sent Date:	2019/03/07 10:42:43
Delivered Date:	2019/03/07 10:42:45

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From:	Llorente, Maria D. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F5C91F577D894BD9A0F09305DB34DD4F-LLORENTE, M <(b6) va.gov>
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Subject:	RE: HHS bought a nasal spray for depression
Date:	2019/03/07 10:37:28
Priority:	Normal
Type:	Note

That's a very good point. The list just gives the city location. There is no site listed in New Haven CT.

From: Wiechers, Ilse
Sent: Thursday, March 7, 2019 10:10 AM
To: Llorente, Maria D. <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

I am not sure about VAMC participation in the study, but I'd bet that we have some academic affiliates who were participants. Hence there may be some of our staff psychiatrists who had experience from their non-VA work. VA Connecticut/Yale is almost certainly one of those.

From: Llorente, Maria D.
Sent: Thursday, March 07, 2019 7:03 AM
To: Carroll, David (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Wiechers, Ilse (b6) @va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

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I think it would be helpful as those sites may be more likely to have early interest in administration. Also, per the FDA clinical trials site, there were more than 90 participating locations for the clinical trial. Do you know if any VA medical centers participated in the clinical trial?

From: Carroll, David (VACO)
Sent: Thursday, March 7, 2019 9:39 AM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Wiechers, Ilse (b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
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Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Hi Dave,

The briefing went very well. By chance, do you have a list of known VA medical facilities that are using intravenous ketamine for the treatment of refractory depression?

Thank you,

Tom

From: Thomas Emmendorfer <(b6) va.gov>
Date: Thursday, March 7, 2019 at 7:45 AM
To: Jon Jensen <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Beck, Lucille B." <(b6) va.gov>, "Howard, Kristi" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Will do.

From: Jon Jensen <(b6) va.gov>
Date: Thursday, March 7, 2019 at 7:41 AM

AMERICAN OVERSIGHT

To: Thomas Emmendorfer <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Beck, Lucille B." <(b6) va.gov>, "Howard, Kristi" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Tom, can you come to Morning Report today to discuss? Starts at 9:30.

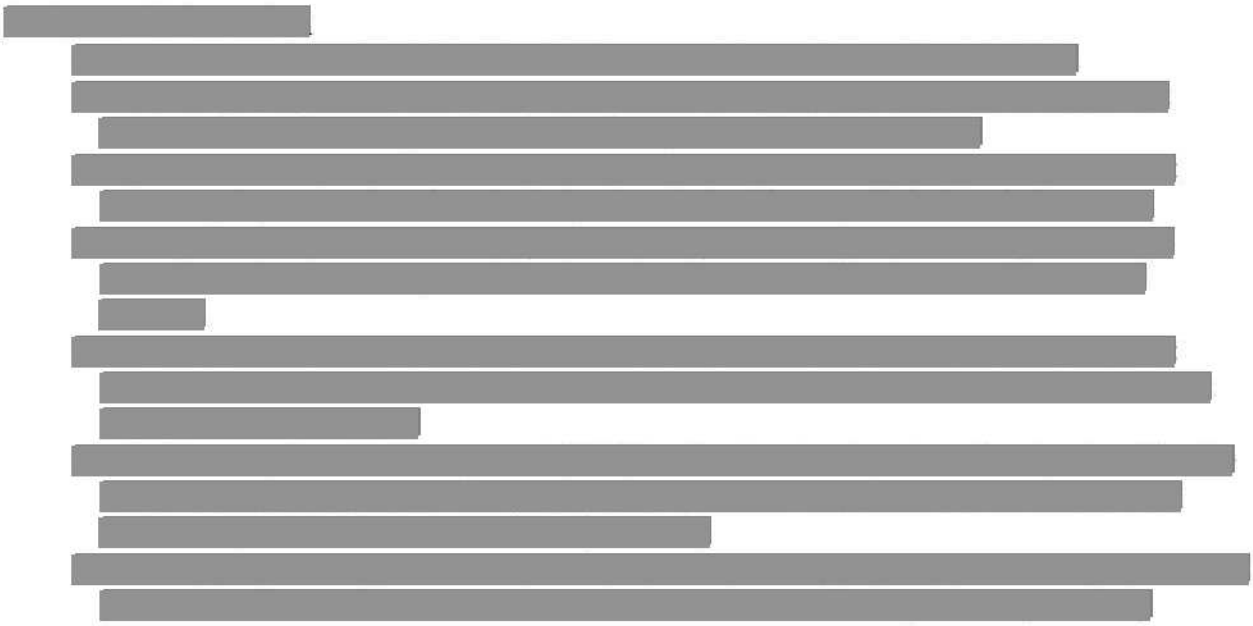
From: Emmendorfer, Thomas (PBM)
Sent: Wednesday, March 06, 2019 10:15 PM
To: Jensen, Jon M. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Howard, Kristi <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Hi Jon,

I hope all is going well. Below is the information that Jenn, Mike, and I pulled together for you. Let us know if you need anything else.

Tom

(b) (5)



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- (b) (5)
[redacted]

From: Jensen, Jon M.
Sent: Wednesday, March 06, 2019 7:50 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Howard, Kristi <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Thanks Tom!

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:49 PM
To: Jensen, Jon M. <(b6) va.gov>, Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Hi Jon,

We will work on it and get a response back.

Tom

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Sent with BlackBerry Work
(www.blackberry.com)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:34 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi (b6) @va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Adding Jennifer

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:27 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi (b6) @va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Just spoke to Dr Stone. We need to get something a little earlier than 10. As soon as you can would be fantastic.
Secva has asked for an update.

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 5:40 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi (b6) @va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: HHS bought a nasal spray for depression

Good evening, need some information on a nasal spray used for depression? POTUS heard HHS recently purchased and he felt it would be great for us. That's all I got. Can you pull info on what it would be, if we purchase currently, if we are looking into it etc. would sure appreciate anything you could provide by 10am.

Jon Jensen

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VHA Acting Deputy Chief of Staff
(b6)
(b6)

Sender:	Llorente, Maria D. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F5C91F577D894BD9A0F09305DB34DD4F-LLORENTE, M <(b6) va.gov>
Recipient:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b6) @va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen (b6) @va.gov>; Law, Cassandra M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f888d507d6c54eb5a92fc44199eb5838-Law, Cassan <(b6) va.gov>
Sent Date:	2019/03/07 10:37:27
Delivered Date:	2019/03/07 10:37:28

AMERICAN OVERSIGHT

From:	Wiechers, Ilse /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0C7B1428D9E4233A641F125C5B6FC4F-WIECHERS, I {b6} @va.gov>
To:	Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <{b6} va.gov>; McGuire, Marsden H. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29e9d648c29f4885828c10446fdd7379-McGuire, Ma <{b6} va.gov>; Pomerantz, Andrew /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29a9288df9a34e84bddfd00cde79f11b-Pomerantz, {b6} @va.gov>; Katz, Ira R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=65f4e28aa7574641932c29fed7c0b4b8-Katz, Ira R <{b6} va.gov>
CC:	VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>
Subject:	RE: HHS bought a nasal spray for depression
Date:	2019/03/06 19:15:01
Priority:	Normal
Type:	Note

I've already reached out to Ginny Torrise in PBM to see if they are starting to work on national guidance around this, like Todd Semla developed re IV ketamine. I worked with him on that process and would be willing to do the same for the intranasal.
Also, I've already received a question from the field about this today (from Chief of Mental Health at Durham VA) wanting to know what VA is going to do about this. The questions from Veterans themselves are not likely far behind.
Also, around the product itself, I talked with people involved with the drug development at J&J a while ago (at the ketamine conference I attended for VA at Cold Spring Harbor). I suspect they will have the needed support up and ready to go very quickly - they've been waiting on this for a long time.
Ilse

Sent with BlackBerry Work
(www.blackberry.com)

From: Carroll, David (VACO) {b6} @va.gov>
Date: Wednesday, Mar 06, 2019, 3:46 PM
To: Wiechers, Ilse <{b6} va.gov>, McGuire, Marsden H. <{b6} va.gov>, Pomerantz, Andrew <{b6} va.gov>, Katz, Ira R. <{b6} va.gov>
Cc: VHA 10NC5 Action <VHA10NC5Action@va.gov>
Subject: FW: HHS bought a nasal spray for depression

What do we know about this? My only info came from a New York Times article posted this morning. Although FDA approved it, I'm not sure when it will be available or the supports are in place for its use (e.g., the requirement to enter patient response information into a national database). Thanks.

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https://www.nytimes.com/2019/03/05/health/depression-treatment-ketamine-fda.html

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From: Jensen, Jon M.
Sent: Wednesday, March 6, 2019 5:41 PM
To: Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Howard, Kristi <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: HHS bought a nasal spray for depression

Good evening, need some information on a nasal spray used for depression? POTUS heard HHS recently purchased and he felt it would be great for us. That's all I got. Can you pull info on what it would be, if we purchase currently, if we are looking into it etc. would sure appreciate anything you could provide by 10am.

Jon Jensen
VHA Acting Deputy Chief of Staff
W(b6)
(b6)

Sender:	Wiechers, Ilse /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0C7B1428D9E4233A641F125C5B6FC4F-WIECHERS, I <(b6) va.gov>
Recipient:	Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; McGuire, Marsden H. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29e9d648c29f4885828c10446fdd7379-McGuire, Ma <(b6) va.gov>; Pomerantz, Andrew /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29a9288df9a34e84bddfd00cde79f11b-Pomerantz, <(b6) @va.gov>; Katz, Ira R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=65f4e28aa7574641932c29fed7c0b4b8-Katz, Ira R <(b6) va.gov>; VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>
Sent Date:	2019/03/06 19:14:59
Delivered Date:	2019/03/06 19:15:01

AMERICAN OVERSIGHT

From:	Davis, Lashelle (VHACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0C9BFFD03B3B47DAA8B6DB6F8933A7E7-DAVIS, LASH (b6) va.gov>
To:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; O'Toole, Thomas P.(b6) va.gov </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c5a34d8a4b294e9986ef6e1aa8009b3f-O'Toole, Th>
CC:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Boyd, Teresa D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6886a7d555a43e0bee23c1e40e1c234-Boyd, Teres <(b6) va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Davis, Lashelle (VHACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0c9bffd03b3b47daa8b6db6f8933a7e7-Davis, Lash (b6) va.gov>
Subject:	RE: HHS bought a nasal spray for depression
Date:	2019/03/11 09:47:37
Priority:	Normal
Type:	Note

Good morning,

Please send any materials you would like to share with the group ASAP. Below is the call information.

VHA VISN CMO/QMO Weekly Conference Call
VANTS: 1 (800) 767-1750 Access Code 32018#
Mon 3/11/2019 at 2:00pm-3:00pm ET

Thank you,

Lashelle

From: Emmendorfer, Thomas (PBM)
Sent: Friday, March 08, 2019 4:16 PM
To: O'Toole, Thomas P. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>; Davis, Lashelle (VHACO) (b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Thank you Tom!

AMERICAN OVERSIGHT

Lashelle,

Could you please send the calendar invite to Maria, Mike, and Dave as well?

Topic: Spravato® (esketamine)
Time: 15 minutes

Slides/Handouts: Work in progress.

From: "O'Toole, Thomas P." <(b6) va.gov>
Date: Friday, March 8, 2019 at 4:11 PM
To: Thomas Emmendorfer <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, "Boyd, Teresa D." <(b6) va.gov>, "Davis, Lashelle (VHACO)" (b6) @va.gov>
Subject: RE: HHS bought a nasal spray for depression

Good - we'll make it work.

Lashelle - can you please add Dr. Emmendorfer to the agenda.
Tom - if you have any slides or handouts, please forward to Lashelle Davis and she can get them out to the group.

Sent with BlackBerry Work
(www.blackberry.com)

From: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Date: Friday, Mar 08, 2019, 4:08 PM
To: O'Toole, Thomas P. <(b6) va.gov>, Llorente, Maria D. <(b6) va.gov>, Wiechers, Ilse <(b6) @va.gov>, Carroll, David (VACO) <(b6) va.gov>, Outlaw, William N. (b6) @va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>, Law, Cassandra M. <(b6) va.gov>, Boyd, Teresa D. <(b6) va.gov>, Meyer, Laurence (l(b6) va.gov>, Denietolis, Angela L. (l(b6) va.gov>, Davis, Lashelle (VHACO) (l(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Hi Tom,

This topic is pretty hot so this upcoming Monday will work.

Thank you!

Tom

AMERICAN OVERSIGHT

From: "O'Toole, Thomas P." <(b6) va.gov>
Date: Friday, March 8, 2019 at 4:01 PM
To: Thomas Emmendorfer <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Wiechers, Ilse" (b6) @va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Outlaw, William N." (b6) @va.gov>
Cc: Michael Valentino <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>, "Boyd, Teresa D." <(b6) va.gov>, "Meyer, Laurence" (l(b6) va.gov>, "Denietolis, Angela L." <(b6) va.gov>, "Davis, Lashelle (VHACO)" (l(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Hi Tom - we can definitely get you on the CMO call for this upcoming Monday at 2pm- if you think you need more prep time, let me know and we can push it back to the 18th
Ton

Sent with BlackBerry Work
(www.blackberry.com)

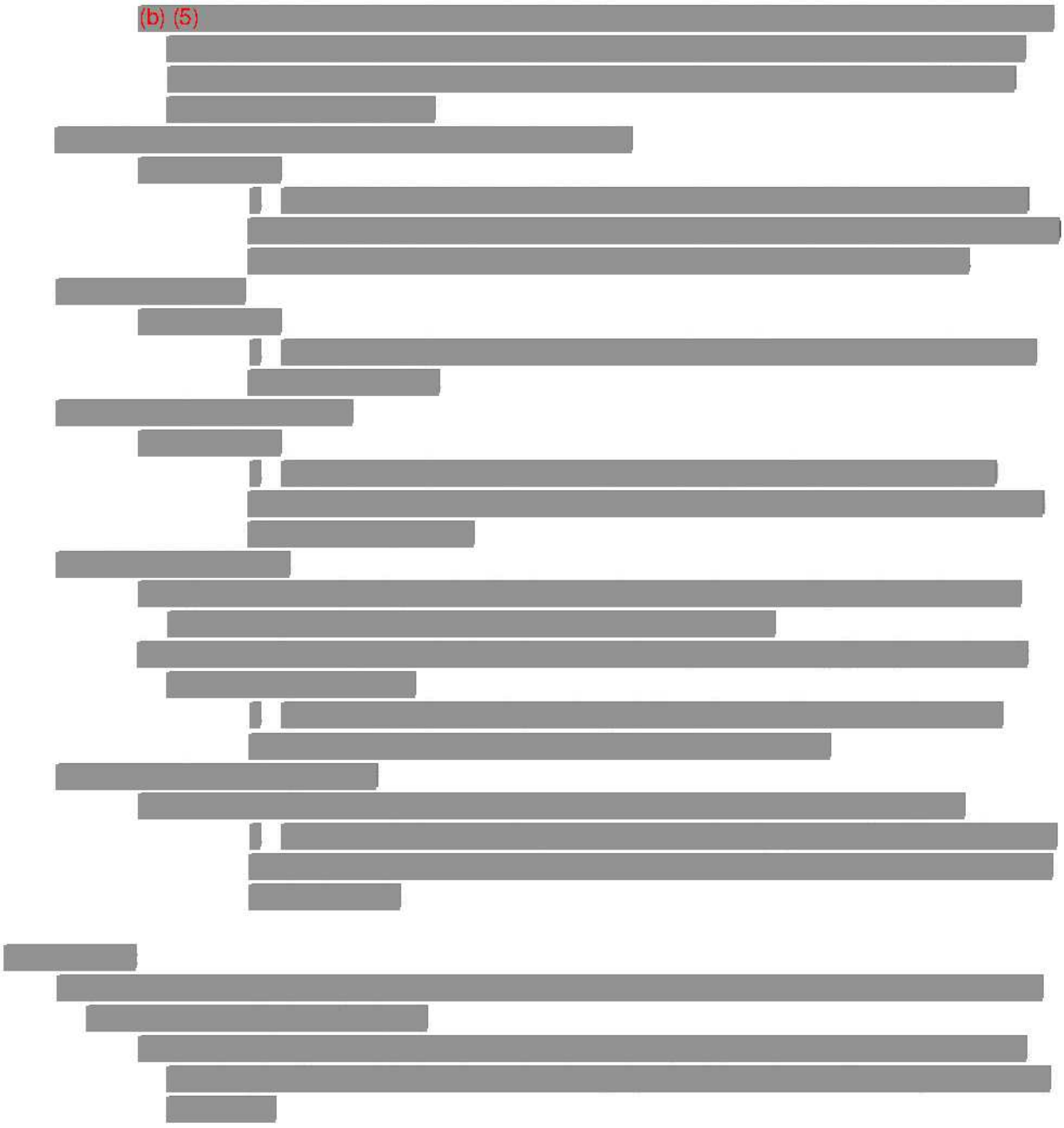
From: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Date: Friday, Mar 08, 2019, 3:57 PM
To: Llorente, Maria D. <(b6) va.gov>, Wiechers, Ilse (b6) @va.gov>, Carroll, David (VACO) <(b6) va.gov>, Outlaw, William N. (b6) @va.gov>, O'Toole, Thomas P. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>, Law, Cassandra M. <(b6) va.gov>, Boyd, Teresa D. <(b6) va.gov>, Meyer, Laurence (l(b6) va.gov>, Denietolis, Angela L. (b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Summary of Actions for Spravato® (esketamine) to date

OPEN:

(b) (5)

AMERICAN OVERSIGHT



From: "Llorente, Maria D." (b6) va.gov>
Date: Friday, March 8, 2019 at 1:47 PM
To: "Wiechers, (b6) @va.gov>, Thomas Emmendorfer <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Outlaw, William N." <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

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Very helpful. Thank you!

From: Wiechers, Ilse
Sent: Friday, March 8, 2019 1:47 PM
To: Llorente, Maria D. <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. (b6) @va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Will do.

I've spoken to several private ketamine clinics in recent years, and the only physician type missing on your list that I have heard about is ED physicians. I also know of several clinics using APRNs under the supervision of one of those physicians listed below.

From: Llorente, Maria D.
Sent: Friday, March 08, 2019 10:43 AM
To: Wiechers, Ilse (b6) @va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. (b6) @va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Yes, if you could. My understanding is that in private sector, psychiatrists, anesthesiologists, neurologists, and pain medicine providers may administer. This is in part because IV ketamine is also used for intractable pain.

From: Wiechers, Ilse
Sent: Friday, March 8, 2019 1:29 PM
To: Llorente, Maria D. <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. <(b6) @va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

We do not have information on that. I can follow up on the responses to the Somatic Treatment Field Assessment and reach out to facilities that report providing IV ketamine and ask them.

From: Llorente, Maria D.
Sent: Friday, March 08, 2019 10:23 AM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Wiechers, Ilse (b6) @va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N.

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(b6) @va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Ilse, do you know if all the current VA providers who administer IV ketamine for treatment resistant depression are psychiatrists? Do we have any anesthesiologists for example?

From: Emmendorfer, Thomas (PBM)
Sent: Friday, March 8, 2019 12:50 PM
To: Llorente, Maria D. <(b6) va.gov>; Wiechers, Ilse (b6) @va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. (b6) @va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Thank you Ilse!

I just sent the internal communications document to Jenn for review (setup as a FAQ). When she is done with her review and edits she will send it over to you.

Tom

From: "Llorente, Maria D." <(b6) va.gov>
Date: Friday, March 8, 2019 at 12:08 PM
To: "Wiechers, Ilse" (b6) @va.gov>, Thomas Emmendorfer <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Outlaw, William N." (b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Thank you all very much.

From: Wiechers, Ilse
Sent: Friday, March 8, 2019 12:04 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Tom –

AMERICAN OVERSIGHT

I'll reach out to Ethics to get things started. Happy to look at draft documents whenever you and Jenn have something ready to share.

Best,
Ilse

From: Emmendorfer, Thomas (PBM)
Sent: Friday, March 08, 2019 8:02 AM
To: Wiechers, Ilse (b6) @va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Hi Ilse,

Dave and I spoke this morning after the briefing to Dr. Stone. Action items

- (b) (5)

Bill,

I adding you to the e-mail as well as we will need your assistance with getting the external communication through the process.

Thank you!

Tom

From: "Wiechers, Ilse" (b6) @va.gov>
Date: Thursday, March 7, 2019 at 10:04 AM
To: Thomas Emmendorfer <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Yes – self reported data from the field.

Attached is a copy of the full Somatic Treatment Field Assessment – ketamine for MH is section III.

AMERICAN OVERSIGHT

From: Emmendorfer, Thomas (PBM)
Sent: Thursday, March 07, 2019 7:00 AM
To: Wiechers, Ilse (b6) @va.gov>; Carroll, David (VACO) <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Hi Ilse,

Thank you very much for the information below!

Will the updated data also include any info on number of Veterans that have received ketamine for treatment of MH conditions?

Tom

From: "Wiechers, Ilse" (b6) @va.gov>
Date: Thursday, March 7, 2019 at 9:55 AM
To: "Carroll, David (VACO)" <(b6) va.gov>, Thomas Emmendorfer <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Below are the sites reporting use in FY15 from the assessment we did of the field back in fall 2016. The 2019 assessment went to the field in Feb and we are working to gather the final data from sites now. Hope to have updated data about sites using IV ketamine for treatment of MH conditions sometime later this month.

1-(689) VA Connecticut HCS, CT
18-(501) New Mexico HCS
23-(618) Minneapolis, MN
1-(523) VA Boston HCS, MA
6-(659) Salisbury, NC
12-(607) Madison, WI
16-(580) Houston, TX
21-(662) San Francisco, CA

Best,
Ilse

AMERICAN OVERSIGHT

From: Carroll, David (VACO)
Sent: Thursday, March 07, 2019 6:39 AM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Wiechers, Ilse (b6) @va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

I do not. Ilse may have a list or can otherwise find out.

From: Emmendorfer, Thomas (PBM)
Sent: Thursday, March 7, 2019 9:25 AM
To: Carroll, David (VACO) <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Hi Dave,

The briefing went very well. By chance, do you have a list of known VA medical facilities that are using intravenous ketamine for the treatment of refractory depression?

Thank you,

Tom

From: Thomas Emmendorfer <(b6) va.gov>
Date: Thursday, March 7, 2019 at 7:45 AM
To: Jon Jensen <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Beck, Lucille B." <(b6) va.gov>, "Howard, Kristi" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Will do.

From: Jon Jensen <(b6) va.gov>
Date: Thursday, March 7, 2019 at 7:41 AM
To: Thomas Emmendorfer <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Beck, Lucille B." <(b6) va.gov>, "Howard, Kristi"

AMERICAN OVERSIGHT

<(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Tom, can you come to Morning Report today to discuss? Starts at 9:30.

From: Emmendorfer, Thomas (PBM)
Sent: Wednesday, March 06, 2019 10:15 PM
To: Jensen, Jon M. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Howard, Kristi <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Hi Jon,

I hope all is going well. Below is the information that Jenn, Mike, and I pulled together for you. Let us know if you need anything else.

Tom

(b) (5)

AMERICAN OVERSIGHT

- (b) (5)

From: Jensen, Jon M.
Sent: Wednesday, March 06, 2019 7:50 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Howard, Kristi <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Thanks Tom!

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:49 PM
To: Jensen, Jon M. <(b6) va.gov>, Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Hi Jon,

We will work on it and get a response back.

Tom

Sent with BlackBerry Work
(www.blackberry.com)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:34 PM

AMERICAN OVERSIGHT

To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Adding Jennifer

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:27 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi (b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Just spoke to Dr Stone. We need to get something a little earlier than 10. As soon as you can would be fantastic.
Secva has asked for an update.

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 5:40 PM
To: Valentino, Michael (VACO) (b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: HHS bought a nasal spray for depression

Good evening, need some information on a nasal spray used for depression? POTUS heard HHS recently purchased and he felt it would be great for us. That's all I got. Can you pull info on what it would be, if we purchase currently, if we are looking into it etc. would sure appreciate anything you could provide by 10am.

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

AMERICAN OVERSIGHT

Sender:	Davis, Lashelle (VHACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0C9BFFD03B3B47DAA8B6DB6F8933A7E7-DAVIS, LASH (b6) va.gov>
Recipient:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; O'Toole, Thomas P.(b6) va.gov </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c5a34d8a4b294e9986ef6e1aa8009b3f-O'Toole, Th>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Boyd, Teresa D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6886a7d555a43e0bee23c1e40e1c234-Boyd, Teres <(b6) va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Davis, Lashelle (VHACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0c9bffd03b3b47daa8b6db6f8933a7e7-Davis, Lash (b6) va.gov>
Sent Date:	2019/03/11 09:47:35
Delivered Date:	2019/03/11 09:47:37

AMERICAN OVERSIGHT

From:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>
To:	Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Outlaw, William N. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3e1067978634fbf96a382bdcd5c1115-Outlaw, Wil (b6) @va.gov>; O'Toole, Thomas P.(b6) va.gov </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c5a34d8a4b294e9986ef6e1aa8009b3f-O'Toole, Th>
CC:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>; Law, Cassandra M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f888d507d6c54eb5a92fc44199eb5838-Law, Cassan <(b6) va.gov>; Boyd, Teresa D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6886a7d555a43e0bee23c1e40e1c234-Boyd, Teres <(b6) va.gov>; Meyer, Laurence /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=56f0ba2c110d4e60863b66f9728f669d-Meyer, Laur <(b6) va.gov>; Denietolis, Angela L. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b51b87cff64f4354b78eb943f97b47f3-Denietolis, (b6) va.gov>
Subject:	RE: HHS bought a nasal spray for depression
Date:	2019/03/11 09:50:07
Priority:	Normal
Type:	Note

I will have PERC rerun the national numbers with and without trazodone. And I have facility reported data on ECT use and also know NEPEC has pulled data based on CPT codes in the past. I'll work on getting those as well.
Ilse

Sent with BlackBerry Work
(www.blackberry.com)

From: Llorente, Maria D. <(b6) va.gov>
Date: Monday, Mar 11, 2019, 6:30 AM
To: Wiechers, Ilse <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Outlaw, William N. <(b6) 2@va.gov>, O'Toole, Thomas P. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>, Law, Cassandra M. <(b6) va.gov>, Boyd, Teresa D.

AMERICAN OVERSIGHT

<(b6) va.gov>, Meyer, Laurence <(b6) va.gov>, Denietolis, Angela L. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

I agree. (b) (5)
.

From: Wiechers, Ilse
Sent: Monday, March 11, 2019 9:28 AM
To: Llorente, Maria D. &lt(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. <(b6) @va.gov>; O'Toole, Thomas P. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>; Boyd, Teresa D. &lt(b6) va.gov>; Meyer, Laurence &lt((b6) va.gov>; Denietolis, Angela L. &lt:(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
(b) (5)

Sent with BlackBerry Work
(www.blackberry.com)

From: Llorente, Maria D. &lt:(b6) va.gov>
Date: Monday, Mar 11, 2019, 5:02 AM
To: Wiechers, Ilse &lt:(b6) va.gov>, Emmendorfer, Thomas (PBM) &lt:(b6) va.gov>, Carroll, David (VACO) &lt:(b6) va.gov>, Outlaw, William N. &lt(b6) va.gov>, O'Toole, Thomas P. &lt:(b6) va.gov>
Cc: Valentino, Michael (VACO) &lt:(b6) va.gov>, Zacher, Jennifer L. (PBM) &lt:(b6) va.gov>, Law, Cassandra M. &lt:(b6) va.gov>, Boyd, Teresa D. &lt:(b6) va.gov>, Meyer, Laurence &lt((b6) va.gov>, Denietolis, Angela L. &lt((b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Thank you very much. (b) (5)
.

From: Wiechers, Ilse
Sent: Sunday, March 10, 2019 10:06 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Llorente, Maria D. &lt:(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. &lt(b6) va.gov>; O'Toole, Thomas P. <Thomas.O'Toole@va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L.

AMERICAN OVERSIGHT

(PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>; Meyer, Laurence <(b6) va.gov>; Denietolis, Angela L. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Hello everyone –

(b) (5)

Ilse

From: Emmendorfer, Thomas (PBM)
Sent: Friday, March 08, 2019 12:57 PM
To: Llorente, Maria D. <(b6) va.gov>; Wiechers, Ilse <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. <(b6) @va.gov>; O'Toole, Thomas P. <Thomas.O'Toole@va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>; Meyer, Laurence

AMERICAN OVERSIGHT

<(b6) va.gov>; Denietolis, Angela L. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression
Summary of Actions for Spravato® (esketamine) to date
OPEN:

1. • CMO Call:
    a. • ACTIONS: **Tom O'Toole**—Could you add Spravato® (esketamine) to the agenda for the next call? (Estimated Time: 15 minutes)
        i. PCS Calendar invite for Maria, Mike V., and me
        ii. Dave-who do you want to be on the call from Mental Health?
2. • Database:
    a. • ACTIONS:

(b) (5)

?

3. • Privileging
    a. (b) (5)

5. • iMed Consent
    a. • ACTIONS:
        i. (b) (5)

.

6. • External Communication
    a. • ACTIONS:

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i. (b) (5) [redacted]

8. • National Formulary Review

a. • ([redacted]

[redacted].

From: "Llorente, Maria D." <(b6) [redacted]va.gov>
Date: Friday, March 8, 2019 at 1:47 PM
To: "Wiechers, Ilse" <(b6) [redacted]va.gov>, Thomas Emmendorfer <(b6) [redacted]va.gov>, "Carroll, David (VACO)" <(b6) [redacted]va.gov>, "Outlaw, William N." <(b6) [redacted]va.gov>
Cc: Michael Valentino <(b6) [redacted]va.gov>, Jennifer Zacher <(b6) [redacted]va.gov>, "Law, Cassandra M." <(b6) [redacted]va.gov>
Subject: RE: HHS bought a nasal spray for depression
Very helpful. Thank you!

From: Wiechers, Ilse
Sent: Friday, March 8, 2019 1:47 PM
To: Llorente, Maria D. <(b6) [redacted]va.gov>; Emmendorfer, Thomas (PBM) <(b6) [redacted]va.gov>; Carroll, David (VACO) <(b6) [redacted]va.gov>; Outlaw, William N. <(b6) [redacted]@va.gov>
Cc: Valentino, Michael (VACO) <(b6) [redacted]va.gov>; Zacher, Jennifer L.

AMERICAN OVERSIGHT

(PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Will do.

I've spoken to several private ketamine clinics in recent years, and the only physician type missing on your list that I have heard about is ED physicians. I also know of several clinics using APRNs under the supervision of one of those physicians listed below.

From: Llorente, Maria D.
Sent: Friday, March 08, 2019 10:43 AM
To: Wiechers, Ilse <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Yes, if you could. My understanding is that in private sector, psychiatrists, anesthesiologists, neurologists, and pain medicine providers may administer. This is in part because IV ketamine is also used for intractable pain.

From: Wiechers, Ilse
Sent: Friday, March 8, 2019 1:29 PM
To: Llorente, Maria D. <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
We do not have information on that. I can follow up on the responses to the Somatic Treatment Field Assessment and reach out to facilities that report providing IV ketamine and ask them.

From: Llorente, Maria D.
Sent: Friday, March 08, 2019 10:23 AM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Wiechers, Ilse <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Ilse, do you know if all the current VA providers who administer IV ketamine for treatment resistant depression are psychiatrists? Do we have any anesthesiologists for example?

From: Emmendorfer, Thomas (PBM)
Sent: Friday, March 8, 2019 12:50 PM
To: Llorente, Maria D. <(b6) va.gov>; Wiechers, Ilse <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. <(b6) @va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L.

AMERICAN OVERSIGHT

(PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression
Thank you Ilse!
I just sent the internal communications document to Jenn for review (setup as a FAQ). When she is done with her review and edits she will send it over to you.
Tom

From: "Llorente, Maria D." <(b6) va.gov>
Date: Friday, March 8, 2019 at 12:08 PM
To: "Wiechers, Ilse" <(b6) va.gov>, Thomas Emmendorfer <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Outlaw, William N." <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Thank you all very much.

From: Wiechers, Ilse
Sent: Friday, March 8, 2019 12:04 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Tom –
I'll reach out to Ethics to get things started. Happy to look at draft documents whenever you and Jenn have something ready to share.
Best,
Ilse

From: Emmendorfer, Thomas (PBM)
Sent: Friday, March 08, 2019 8:02 AM
To: Wiechers, Ilse <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression
Hi Ilse,
Dave and I spoke this morning after the briefing to Dr. Stone. Action items

- • (b) (5)

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AMERICAN OVERSIGHT

- (b) (5) [redacted]

Bill,
I adding you to the e-mail as well as we will need your assistance with getting the external communication through the process.
Thank you!

Tom

From: "Wiechers, Ilse" <(b6) [redacted] va.gov>
Date: Thursday, March 7, 2019 at 10:04 AM
To: Thomas Emmendorfer <(b6) [redacted] va.gov>, "Carroll, David (VACO)" <(b6) [redacted] va.gov>
Cc: Michael Valentino <(b6) [redacted] va.gov>, Jennifer Zacher <(b6) [redacted] va.gov>, "Llorente, Maria D." <(b6) [redacted] va.gov>, "Law, Cassandra M." <(b6) [redacted] va.gov>
Subject: RE: HHS bought a nasal spray for depression
Yes – self reported data from the field.
Attached is a copy of the full Somatic Treatment Field Assessment – ketamine for MH is section III.

From: Emmendorfer, Thomas (PBM)
Sent: Thursday, March 07, 2019 7:00 AM
To: Wiechers, Ilse <(b6) [redacted] va.gov>; Carroll, David (VACO) <(b6) [redacted] va.gov>
Cc: Valentino, Michael (VACO) <(b6) [redacted] va.gov>; Zacher, Jennifer L. (PBM) <(b6) [redacted] va.gov>; Llorente, Maria D. <(b6) [redacted] va.gov>; Law, Cassandra M. <(b6) [redacted] va.gov>
Subject: Re: HHS bought a nasal spray for depression
Hi Ilse,
Thank you very much for the information below!
Will the updated data also include any info on number of Veterans that have received ketamine for treatment of MH conditions?
Tom

From: "Wiechers, Ilse" <(b6) [redacted] va.gov>
Date: Thursday, March 7, 2019 at 9:55 AM
To: "Carroll, David (VACO)" <(b6) [redacted] va.gov>, Thomas Emmendorfer <(b6) [redacted] va.gov>
Cc: Michael Valentino <(b6) [redacted] va.gov>, Jennifer Zacher <(b6) [redacted] va.gov>, "Llorente, Maria D." <(b6) [redacted] va.gov>, "Law, Cassandra M." <(b6) [redacted] va.gov>
Subject: RE: HHS bought a nasal spray for depression

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Below are the sites reporting use in FY15 from the assessment we did of the field back in fall 2016. The 2019 assessment went to the field in Feb and we are working to gather the final data from sites now. Hope to have updated data about sites using IV ketamine for treatment of MH conditions sometime later this month.
1-(689) VA Connecticut HCS, CT
18-(501) New Mexico HCS
23-(618) Minneapolis, MN
1-(523) VA Boston HCS, MA
6-(659) Salisbury, NC
12-(607) Madison, WI
16-(580) Houston, TX
21-(662) San Francisco, CA
Best,
Ilse

From: Carroll, David (VACO)
Sent: Thursday, March 07, 2019 6:39 AM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Wiechers, Ilse <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
I do not. Ilse may have a list or can otherwise find out.

From: Emmendorfer, Thomas (PBM)
Sent: Thursday, March 7, 2019 9:25 AM
To: Carroll, David (VACO) <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression
Hi Dave,
The briefing went very well. By chance, do you have a list of known VA medical facilities that are using intravenous ketamine for the treatment of refractory depression?
Thank you,
Tom

From: Thomas Emmendorfer <(b6) va.gov>
Date: Thursday, March 7, 2019 at 7:45 AM
To: Jon Jensen <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Beck, Lucille B." <(b6) va.gov>, "Howard, Kristi" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression
Will do.

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From: Jon Jensen <(b6) va.gov>
Date: Thursday, March 7, 2019 at 7:41 AM
To: Thomas Emmendorfer <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Beck, Lucille B." <(b6) va.gov>, "Howard, Kristi" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Tom, can you come to Morning Report today to discuss? Starts at 9:30.

From: Emmendorfer, Thomas (PBM)
Sent: Wednesday, March 06, 2019 10:15 PM
To: Jensen, Jon M. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Howard, Kristi <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Hi Jon,

I hope all is going well. Below is the information that Jenn, Mike, and I pulled together for you. Let us know if you need anything else.

Tom

(b) (5)

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- (b) (5) [redacted]



From: Jensen, Jon M.
Sent: Wednesday, March 06, 2019 7:50 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Howard, Kristi <(b6) va.gov>; Zacher, Jennifer L. (PBM) &lt(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Thanks Tom!

Jon Jensen
VHA Acting Deputy Chief of Staff
W:(b6)
(b6)

From: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:49 PM
To: Jensen, Jon M. <(b6) va.gov>, Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Hi Jon,
We will work on it and get a response back.
Tom

Sent with BlackBerry Work
(www.blackberry.com)

From: Jensen, Jon M. &lt(b6) va.gov>

AMERICAN OVERSIGHT

Date: Wednesday, Mar 06, 2019, 7:34 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Adding Jennifer

Jon Jensen
VHA Acting Deputy Chief of Staff
W(b6)
(b6)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:27 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Just spoke to Dr Stone. We need to get something a little earlier than 10. As soon as you can would be fantastic.
Secva has asked for an update.

Jon Jensen
VHA Acting Deputy Chief of Staff
W(b6)
(b6)

From: Jensen, Jon M. &lt(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 5:40 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: HHS bought a nasal spray for depression

Good evening, need some information on a nasal spray used for depression? POTUS heard HHS recently purchased and he felt it would be great for us. That's all I got. Can you pull info on what it would be, if we purchase currently, if we are looking into it etc. would sure appreciate anything you could provide by 10am.

Jon Jensen
VHA Acting Deputy Chief of Staff
W(b6)
(b6)

Sender:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I

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	<(b6) va.gov>
Recipient:	Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Outlaw, William N. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3e1067978634fbf96a382bdcd5c1115-Outlaw, Wil <(b6) va.gov>; O'Toole, Thomas P.(b6) va.gov </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c5a34d8a4b294e9986ef6e1aa8009b3f-O'Toole, Th>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b6) @va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>; Law, Cassandra M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f888d507d6c54eb5a92fc44199eb5838-Law, Cassan <(b6) va.gov>; Boyd, Teresa D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6886a7d555a43e0bee23c1e40e1c234-Boyd, Teres <(b6) va.gov>; Meyer, Laurence /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=56f0ba2c110d4e60863b66f9728f669d-Meyer, Laur (b6) va.gov>; Denietolis, Angela L. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b51b87cff64f4354b78eb943f97b47f3-Denietolis, <(b6) va.gov>
Sent Date:	2019/03/11 09:50:06
Delivered Date:	2019/03/11 09:50:07

AMERICAN OVERSIGHT

From:	Davis, Lashelle (VHACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0c9bffd03b3b47daa8b6db6f8933a7e7-Davis, Lash <(b6) va.gov>
To:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; O'Toole, Thomas P.(b6) va.gov </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c5a34d8a4b294e9986ef6e1aa8009b3f-O'Toole, Th>
CC:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Boyd, Teresa D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6886a7d555a43e0bee23c1e40e1c234-Boyd, Teres <(b6) va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Davis, Lashelle (VHACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0c9bffd03b3b47daa8b6db6f8933a7e7-Davis, Lash (b6) va.gov>
Subject:	RE: HHS bought a nasal spray for depression
Date:	2019/03/11 09:47:37
Priority:	Normal
Type:	Note

Good morning,
Please send any materials you would like to share with the group ASAP. Below is the call information.
VHA VISN CMO/QMO Weekly Conference Call
VANTS: 1 (800) 767-1750 Access Code 32018#
Mon 3/11/2019 at 2:00pm-3:00pm ET
Thank you,
Lashelle

From: Emmendorfer, Thomas (PBM)
Sent: Friday, March 08, 2019 4:16 PM
To: O'Toole, Thomas P. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>; Davis, Lashelle (VHACO) <(b6) @va.gov>; Llorente, Maria D. <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression
Thank you Tom!
Lashelle,
Could you please send the calendar invite to Maria, Mike, and Dave as well?
Topic: Spravato® (esketamine)
Time: 15 minutes
Slides/Handouts: Work in progress.

AMERICAN OVERSIGHT

From: "O'Toole, Thomas P." <(b6) va.gov>
Date: Friday, March 8, 2019 at 4:11 PM
To: Thomas Emmendorfer <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, "Boyd, Teresa D." <(b6) va.gov>, "Davis, Lashelle (VHACO)" <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Good - we'll make it work.
Lashelle - can you please add Dr. Emmendorfer to the agenda.
Tom - if you have any slides or handouts, please forward to Lashelle Davis and she can get them out to the group.

Sent with BlackBerry Work
(www.blackberry.com)

From: Emmendorfer, Thomas (PBM) <(b6) @va.gov>
Date: Friday, Mar 08, 2019, 4:08 PM
To: O'Toole, Thomas P. <(b6) va.gov>, Llorente, Maria D. <(b6) va.gov>, Wiechers, Ilse <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Outlaw, William N. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>, Law, Cassandra M. <(b6) va.gov>, Boyd, Teresa D. <(b6) va.gov>, Meyer, Laurence <(b6) va.gov>, Denietolis, Angela L. <(b6) va.gov>, Davis, Lashelle (VHACO) <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression
Hi Tom,
This topic is pretty hot so this upcoming Monday will work.
Thank you!
Tom

From: "O'Toole, Thomas P." <(b6) va.gov>
Date: Friday, March 8, 2019 at 4:01 PM
To: Thomas Emmendorfer <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Wiechers, Ilse" <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Outlaw, William N." <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>, "Boyd, Teresa D." <(b6) va.gov>, "Meyer, Laurence" <(b6) va.gov>, "Denietolis, Angela L." <(b6) va.gov>, "Davis, Lashelle (VHACO)" &lt(b6) @va.gov>
Subject: RE: HHS bought a nasal spray for depression
Hi Tom - we can definitely get you on the CMO call for this upcoming Monday at 2pm- if you think you need more prep time, let me know and we can push it back to the 18th

AMERICAN OVERSIGHT

Ton

Sent with BlackBerry Work
(www.blackberry.com)

From: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Date: Friday, Mar 08, 2019, 3:57 PM
To: Llorente, Maria D. <(b6) va.gov>, Wiechers, Ilse <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Outlaw, William N. <(b6) va.gov>, O'Toole, Thomas P. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>, Law, Cassandra M. <(b6) va.gov>, Boyd, Teresa D. <(b6) va.gov>, Meyer, Laurence <(b6) va.gov>, Denietolis, Angela L. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Summary of Actions for Spravato® (esketamine) to date
OPEN:

1. • CMO Call:

    a. • (b) (5)

AMERICAN OVERSIGHT

i. (b) (5) [redacted]

a. • PBM worked with the National Acquisition Center and the drug company today and the drug has been added to the Federal Supply Schedule with an effective price starting tomorrow.

From: "Llorente, Maria D." <(b6) [redacted] va.gov>
Date: Friday, March 8, 2019 at 1:47 PM

AMERICAN OVERSIGHT

To: "Wiechers, Ilse" <(b6) va.gov>, Thomas Emmendorfer <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Outlaw, William N." <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Very helpful. Thank you!

From: Wiechers, Ilse
Sent: Friday, March 8, 2019 1:47 PM
To: Llorente, Maria D. <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. <(b6) @va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Will do.

I've spoken to several private ketamine clinics in recent years, and the only physician type missing on your list that I have heard about is ED physicians. I also know of several clinics using APRNs under the supervision of one of those physicians listed below.

From: Llorente, Maria D.
Sent: Friday, March 08, 2019 10:43 AM
To: Wiechers, Ilse <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Yes, if you could. My understanding is that in private sector, psychiatrists, anesthesiologists, neurologists, and pain medicine providers may administer. This is in part because IV ketamine is also used for intractable pain.

From: Wiechers, Ilse
Sent: Friday, March 8, 2019 1:29 PM
To: Llorente, Maria D. <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. &lt(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
We do not have information on that. I can follow up on the responses to the Somatic Treatment Field Assessment and reach out to facilities that report providing IV ketamine and ask them.

From: Llorente, Maria D.
Sent: Friday, March 08, 2019 10:23 AM

AMERICAN OVERSIGHT

To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Wiechers, Ilse <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Ilse, do you know if all the current VA providers who administer IV ketamine for treatment resistant depression are psychiatrists? Do we have any anesthesiologists for example?

From: Emmendorfer, Thomas (PBM)
Sent: Friday, March 8, 2019 12:50 PM
To: Llorente, Maria D. <(b6) va.gov>; Wiechers, Ilse <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. <(b6) @va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression
Thank you Ilse!
I just sent the internal communications document to Jenn for review (setup as a FAQ). When she is done with her review and edits she will send it over to you.
Tom

From: "Llorente, Maria D." <(b6) va.gov>
Date: Friday, March 8, 2019 at 12:08 PM
To: "Wiechers, Ilse" <(b6) va.gov>, Thomas Emmendorfer <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Outlaw, William N." <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Thank you all very much.

From: Wiechers, Ilse
Sent: Friday, March 8, 2019 12:04 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. <(b6) @va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Tom –
I'll reach out to Ethics to get things started. Happy to look at draft documents whenever you and Jenn have something ready to share.
Best,
Ilse

AMERICAN OVERSIGHT

From: Emmendorfer, Thomas (PBM)
Sent: Friday, March 08, 2019 8:02 AM
To: Wiechers, Ilse <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. &l(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Hi Ilse,

Dave and I spoke this morning after the briefing to Dr. Stone. Action items

- • Mental Health and PBM to start working together with the Comms team to develop internal/external communication.
    - • NEXT STEPS: Jenn Z. and I can work with you on the communication. Jenn and I will send you over a draft document to review.
- • iMed Consent: At morning report-Ethics asked if Spravato will need an iMed Consent.
    - • NEXT STEPS: Could you contact Ethics and work with them to determine and develop an imed consent (if needed) for Spravato?

Bill,

I adding you to the e-mail as well as we will need your assistance with getting the external communication through the process.

Thank you!

Tom

From: "Wiechers, Ilse" <(b6) va.gov>
Date: Thursday, March 7, 2019 at 10:04 AM
To: Thomas Emmendorfer <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Yes – self reported data from the field.

Attached is a copy of the full Somatic Treatment Field Assessment – ketamine for MH is section III.

From: Emmendorfer, Thomas (PBM)
Sent: Thursday, March 07, 2019 7:00 AM
To: Wiechers, Ilse <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>;

AMERICAN OVERSIGHT

Law, Cassandra M. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression
Hi Ilse,
Thank you very much for the information below!
Will the updated data also include any info on number of Veterans that have received ketamine for treatment of MH conditions?
Tom

From: "Wiechers, Ilse" <(b6) va.gov>
Date: Thursday, March 7, 2019 at 9:55 AM
To: "Carroll, David (VACO)" <(b6) va.gov>, Thomas Emmendorfer <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Below are the sites reporting use in FY15 from the assessment we did of the field back in fall 2016. The 2019 assessment went to the field in Feb and we are working to gather the final data from sites now. Hope to have updated data about sites using IV ketamine for treatment of MH conditions sometime later this month.

1-(689) VA Connecticut HCS, CT

18-(501) New Mexico HCS

23-(618) Minneapolis, MN

1-(523) VA Boston HCS, MA

6-(659) Salisbury, NC

12-(607) Madison, WI

16-(580) Houston, TX

21-(662) San Francisco, CA
Best,
Ilse

From: Carroll, David (VACO)
Sent: Thursday, March 07, 2019 6:39 AM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Wiechers, Ilse <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
I do not. Ilse may have a list or can otherwise find out.

From: Emmendorfer, Thomas (PBM)
Sent: Thursday, March 7, 2019 9:25 AM
To: Carroll, David (VACO) <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression
Hi Dave,
The briefing went very well. By chance, do you have a list of known VA medical facilities that are using intravenous ketamine for the treatment of refractory depression?
Thank you,
Tom

From: Thomas Emmendorfer <(b6) va.gov>
Date: Thursday, March 7, 2019 at 7:45 AM
To: Jon Jensen <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Beck, Lucille B." <(b6) va.gov>, "Howard, Kristi" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression
Will do.

From: Jon Jensen <(b6) va.gov>
Date: Thursday, March 7, 2019 at 7:41 AM
To: Thomas Emmendorfer <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Beck, Lucille B." <(b6) va.gov>, "Howard, Kristi" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Tom, can you come to Morning Report today to discuss? Starts at 9:30.

From: Emmendorfer, Thomas (PBM)
Sent: Wednesday, March 06, 2019 10:15 PM
To: Jensen, Jon M. &lt(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Howard, Kristi <(b6) va.gov>; Zacher, Jennifer L. (PBM) &lt(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Hi Jon,

AMERICAN OVERSIGHT

I hope all is going well. Below is the information that Jenn, Mike, and I pulled together for you. Let us know if you need anything else.

Tom

(b) (5)



From: Jensen, Jon M.
Sent: Wednesday, March 06, 2019 7:50 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Howard, Kristi

AMERICAN OVERSIGHT

<(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Thanks Tom!

Jon Jensen
VHA Acting Deputy Chief of Staff
W:(b6)
(b6)

From: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:49 PM
To: Jensen, Jon M. <(b6) va.gov>, Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Hi Jon,
We will work on it and get a response back.
Tom

Sent with BlackBerry Work
(www.blackberry.com)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:34 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Adding Jennifer

Jon Jensen
VHA Acting Deputy Chief of Staff
W(b6)
(b6)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:27 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Just spoke to Dr Stone. We need to get something a little earlier than 10. As soon as you can would be fantastic.

AMERICAN OVERSIGHT

Secva has asked for an update.

Jon Jensen
VHA Acting Deputy Chief of Staff
W:(b6)
(b6)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 5:40 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: HHS bought a nasal spray for depression

Good evening, need some information on a nasal spray used for depression? POTUS heard HHS recently purchased and he felt it would be great for us. That's all I got. Can you pull info on what it would be, if we purchase currently, if we are looking into it etc. would sure appreciate anything you could provide by 10am.

Jon Jensen
VHA Acting Deputy Chief of Staff
W(b6)
(b6)

Sender:	Davis, Lashelle (VHACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0c9bffd03b3b47daa8b6db6f8933a7e7-Davis, Lash <(b6) va.gov>
Recipient:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; O'Toole, Thomas P.(b6) va.gov </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c5a34d8a4b294e9986ef6e1aa8009b3f-O'Toole, Th>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Boyd, Teresa D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6886a7d555a43e0bee23c1e40e1c234-Boyd, Teres <(b6) va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Davis, Lashelle (VHACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0c9bffd03b3b47daa8b6db6f8933a7e7-Davis, Lash <(b6) va.gov>
Sent Date:	2019/03/11 09:47:35
Delivered Date:	2019/03/11 09:47:37

AMERICAN OVERSIGHT

From:	Valentino, Michael (VACO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO,>
To:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>
Subject:	RE: HHS bought a nasal spray for depression
Date:	2019/03/08 07:51:11
Priority:	Normal
Type:	Note

Just keep in folder and thanks for the bullets!

Sent with BlackBerry Work
(www.blackberry.com)

From: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Date: Friday, Mar 08, 2019, 6:45 AM
To: Valentino, Michael (VACO) <(b6) va.gov>, Zacher, Jennifer L. (PBM) (b6) va.gov>
Subject: FW: HHS bought a nasal spray for depression

Hi Mike,

On the way in this morning, I thought it may be good to send you a few bullet points on Spravato (just in case Dr Stone has any questions). Also, If you want me to hand out any of the materials that were hyperlinked in slides, just let me know I will have the materials with me at the meeting…otherwise, I will just keep the documents in my folder.

I printed 5 copies of your slides to bring down to the briefing as well.

Quick summary of points for Spravato:

- (b) (5)

From: Wiechers, Ilse
Sent: Thursday, March 07, 2019 10:04 AM

AMERICAN OVERSIGHT

To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Yes – self reported data from the field.

Attached is a copy of the full Somatic Treatment Field Assessment – ketamine for MH is section III.

From: Emmendorfer, Thomas (PBM)
Sent: Thursday, March 07, 2019 7:00 AM
To: Wiechers, Ilse (b6) @va.gov>; Carroll, David (VACO) <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Hi Ilse,

Thank you very much for the information below!

Will the updated data also include any info on number of Veterans that have received ketamine for treatment of MH conditions?

Tom

From: "Wiechers, Ilse" (b6) @va.gov>
Date: Thursday, March 7, 2019 at 9:55 AM
To: "Carroll, David (VACO)" <(b6) va.gov>, Thomas Emmendorfer <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Below are the sites reporting use in FY15 from the assessment we did of the field back in fall 2016. The 2019 assessment went to the field in Feb and we are working to gather the final data from sites now. Hope to have updated data about sites using IV ketamine for treatment of MH conditions sometime later this month.

1-(689) VA Connecticut HCS, CT
18-(501) New Mexico HCS
23-(618) Minneapolis, MN
1-(523) VA Boston HCS, MA

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6-(659) Salisbury, NC
12-(607) Madison, WI
16-(580) Houston, TX
21-(662) San Francisco, CA

Best,
Ilse

From: Carroll, David (VACO)
Sent: Thursday, March 07, 2019 6:39 AM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Wiechers, Ilse (b6) @va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

I do not. Ilse may have a list or can otherwise find out.

From: Emmendorfer, Thomas (PBM)
Sent: Thursday, March 7, 2019 9:25 AM
To: Carroll, David (VACO) <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Hi Dave,

The briefing went very well. By chance, do you have a list of known VA medical facilities that are using intravenous ketamine for the treatment of refractory depression?

Thank you,

Tom

From: Thomas Emmendorfer <(b6) va.gov>
Date: Thursday, March 7, 2019 at 7:45 AM
To: Jon Jensen <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Beck, Lucille B." <(b6) va.gov>, "Howard, Kristi" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

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Will do.

From: Jon Jensen <(b6) va.gov>
Date: Thursday, March 7, 2019 at 7:41 AM
To: Thomas Emmendorfer <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Beck, Lucille B." <(b6) va.gov>, "Howard, Kristi" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Tom, can you come to Morning Report today to discuss? Starts at 9:30.

From: Emmendorfer, Thomas (PBM)
Sent: Wednesday, March 06, 2019 10:15 PM
To: Jensen, Jon M. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Howard, Kristi <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Hi Jon,

I hope all is going well. Below is the information that Jenn, Mike, and I pulled together for you. Let us know if you need anything else.

Tom

(b) (5)

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- (b) (5) [redacted]

From: Jensen, Jon M.
Sent: Wednesday, March 06, 2019 7:50 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Howard, Kristi (b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Thanks Tom!

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:49 PM
To: Jensen, Jon M. <(b6) va.gov>, Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi (b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Hi Jon,

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We will work on it and get a response back.

Tom

Sent with BlackBerry Work
(www.blackberry.com)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:34 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Adding Jennifer

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:27 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Just spoke to Dr Stone. We need to get something a little earlier than 10. As soon as you can would be fantastic.
Secva has asked for an update.

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 5:40 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi (b6) .gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: HHS bought a nasal spray for depression

Good evening, need some information on a nasal spray used for depression? POTUS heard HHS recently purchased and he felt it would be great for us. That's all I got. Can you pull info on what it

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would be, if we purchase currently, if we are looking into it etc. would sure appreciate anything you could provide by 10am.

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

Sender:	Valentino, Michael (VACO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO,>
Recipient:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>
Sent Date:	2019/03/08 07:51:10
Delivered Date:	2019/03/08 07:51:11

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From:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>
To:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; Boyd, Teresa D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6886a7d555a43e0bee23c1e40e1c234-Boyd, Teres <(b6) va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Outlaw, William N. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3e1067978634fbf96a382bdcd5c1115-Outlaw, Wil <(b6) va.gov>; O'Toole, Thomas P.(b6) va.gov </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c5a34d8a4b294e9986ef6e1aa8009b3f-O'Toole, Th>
CC:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>; Law, Cassandra M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f888d507d6c54eb5a92fc44199eb5838-Law, Cassan <(b6) va.gov>; Meyer, Laurence /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=56f0ba2c110d4e60863b66f9728f669d-Meyer, Laur (b6) va.gov>; Denietolis, Angela L. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b51b87cff64f4354b78eb943f97b47f3-Denietolis, (b6) va.gov>
Subject:	RE: HHS bought a nasal spray for depression
Date:	2019/03/11 09:30:43
Priority:	Normal
Type:	Note

Tom,
We don't really have a good way to pull the data on IV ketamine use. That is in part why we conducted the somatic treatment field assessment back in 2016 and now again this past month. I'll have data on reported number of patients treated with IV ketamine from the recent survey sometime soon. But the number reportedly treated in FY15 was 43 Veterans.
Ilse

Sent with BlackBerry Work
(www.blackberry.com)

From: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Date: Monday, Mar 11, 2019, 4:56 AM

AMERICAN OVERSIGHT

To: Boyd, Teresa D. <(b6) va.gov>, Wiechers, Ilse <(b6) va.gov>, Llorente, Maria D. <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Outlaw, William N. &lt(b6) va.gov>, O'Toole, Thomas P. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>, Law, Cassandra M. <(b6) va.gov>, Meyer, Laurence &lt((b6) va.gov>, Denietolis, Angela L. &lt((b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Ilse,
This is great work. Could the PERC run a query for IV Ketamine users for treatment refractory depression?
We are getting requests for these data as well.
Thank you,
Tom

From: "Boyd, Teresa D." <(b6) va.gov>
Date: Monday, March 11, 2019 at 5:16 AM
To: "Wiechers, Ilse" <(b6) va.gov>, Thomas Emmendorfer <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Outlaw, William N." <(b6) va.gov>, "O'Toole, Thomas P." <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>, "Meyer, Laurence" <(b6) va.gov>, "Denietolis, Angela L." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Great work, Ilse! Gives the agency the overall potential demand (and costing), and suspect sites will want to know their potential local demand. Really appreciate the great work by PBM to coordinate this work and Dr. Llorente.
Teresa

Sent with BlackBerry Work
(www.blackberry.com)

From: Wiechers, Ilse <(b6) va.gov>
Date: Sunday, Mar 10, 2019, 10:05 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>, Llorente, Maria D. <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Outlaw, William N. <(b6) va.gov>, O'Toole, Thomas P. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>, Law, Cassandra M. &lt(b6) va.gov>, Boyd, Teresa D. <(b6) va.gov>, Meyer, Laurence &lt((b6) .gov>, Denietolis, Angela L. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Hello everyone –

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Here is what I've been able to pull together with PERC to answer the request "define the universe of patients that may meet the criteria for prescribing of Spravato®."

(b) (5)



Ilse

From: Emmendorfer, Thomas (PBM)
Sent: Friday, March 08, 2019 12:57 PM
To: Llorente, Maria D. &lt(b6) va.gov>; Wiechers, Ilse <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. <(b6) va.gov>; O'Toole, Thomas P. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>; Boyd, Teresa D. &lt(b6) va.gov>; Meyer, Laurence &lt((b6) va.gov>; Denietolis, Angela L. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression
Summary of Actions for Spravato® (esketamine) to date
OPEN:

1. • CMO Call:

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a. • ACTIONS: **Tom O'Toole**—(b) (5)
agenda for (b) (5)

i. [redacted]

ii. [redacted]?

2. • Database:

a. • ACTIONS:

i. (b) (5) [redacted]

3. • Privileging

[redacted]

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a. • ((b) (5) [redacted]

[redacted]

[redacted]

[

missing on your list that I have heard about is ED physicians. I also know of several clinics using APRNs under the supervision of one of those physicians listed below.

From: Llorente, Maria D.
Sent: Friday, March 08, 2019 10:43 AM
To: Wiechers, Ilse <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. <(b6) @va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Yes, if you could. My understanding is that in private sector, psychiatrists, anesthesiologists, neurologists, and pain medicine providers may administer. This is in part because IV ketamine is also used for intractable pain.

From: Wiechers, Ilse
Sent: Friday, March 8, 2019 1:29 PM
To: Llorente, Maria D. <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
We do not have information on that. I can follow up on the responses to the Somatic Treatment Field Assessment and reach out to facilities that report providing IV ketamine and ask them.

From: Llorente, Maria D.
Sent: Friday, March 08, 2019 10:23 AM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Wiechers, Ilse <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Ilse, do you know if all the current VA providers who administer IV ketamine for treatment resistant depression are psychiatrists? Do we have any anesthesiologists for example?

From: Emmendorfer, Thomas (PBM)
Sent: Friday, March 8, 2019 12:50 PM
To: Llorente, Maria D. <(b6) va.gov>; Wiechers, Ilse <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression
Thank you Ilse!
I just sent the internal communications document to Jenn for review (setup as a FAQ). When she is done with her review and edits she will send it over to you.
Tom

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From: "Llorente, Maria D." <(b6) va.gov>
Date: Friday, March 8, 2019 at 12:08 PM
To: "Wiechers, Ilse" <(b6) va.gov>, Thomas Emmendorfer <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Outlaw, William N." <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Thank you all very much.

From: Wiechers, Ilse
Sent: Friday, March 8, 2019 12:04 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Tom –
I'll reach out to Ethics to get things started. Happy to look at draft documents whenever you and Jenn have something ready to share.
Best,
Ilse

From: Emmendorfer, Thomas (PBM)
Sent: Friday, March 08, 2019 8:02 AM
To: Wiechers, Ilse <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. &lt(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression
Hi Ilse,
Dave and I spoke this morning after the briefing to Dr. Stone. Action items

- • (b) (5)

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Bill,
I adding you to the e-mail as well as we will need your assistance with getting the external communication through the process.
Thank you!

Tom

From: "Wiechers, Ilse" <(b6) va.gov>
Date: Thursday, March 7, 2019 at 10:04 AM
To: Thomas Emmendorfer <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Yes – self reported data from the field.
Attached is a copy of the full Somatic Treatment Field Assessment – ketamine for MH is section III.

From: Emmendorfer, Thomas (PBM)
Sent: Thursday, March 07, 2019 7:00 AM
To: Wiechers, Ilse <(b6) va.gov>; Carroll, David (VACO) &lt(b6) @va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression
Hi Ilse,
Thank you very much for the information below!
Will the updated data also include any info on number of Veterans that have received ketamine for treatment of MH conditions?
Tom

From: "Wiechers, Ilse" <(b6) va.gov>
Date: Thursday, March 7, 2019 at 9:55 AM
To: "Carroll, David (VACO)" <(b6) va.gov>, Thomas Emmendorfer <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Below are the sites reporting use in FY15 from the assessment we did of the field back in fall 2016. The 2019 assessment went to the field in Feb and we are working to gather the final data from sites now. Hope to have updated data about sites using IV ketamine for treatment of MH conditions sometime later this month.
1-(689) VA Connecticut HCS, CT
18-(501) New Mexico HCS

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23-(618) Minneapolis, MN
1-(523) VA Boston HCS, MA
6-(659) Salisbury, NC
12-(607) Madison, WI
16-(580) Houston, TX
21-(662) San Francisco, CA
Best,
Ilse

From: Carroll, David (VACO)
Sent: Thursday, March 07, 2019 6:39 AM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Wiechers, Ilse <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
I do not. Ilse may have a list or can otherwise find out.

From: Emmendorfer, Thomas (PBM)
Sent: Thursday, March 7, 2019 9:25 AM
To: Carroll, David (VACO) <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression
Hi Dave,
The briefing went very well. By chance, do you have a list of known VA medical facilities that are using intravenous ketamine for the treatment of refractory depression?
Thank you,
Tom

From: Thomas Emmendorfer <(b6) va.gov>
Date: Thursday, March 7, 2019 at 7:45 AM
To: Jon Jensen <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Beck, Lucille B." <(b6) va.gov>, "Howard, Kristi" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression
Will do.

From: Jon Jensen <(b6) va.gov>
Date: Thursday, March 7, 2019 at 7:41 AM
To: Thomas Emmendorfer <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Beck, Lucille B."

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<(b6) va.gov>, "Howard, Kristi" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Tom, can you come to Morning Report today to discuss? Starts at 9:30.

From: Emmendorfer, Thomas (PBM)
Sent: Wednesday, March 06, 2019 10:15 PM
To: Jensen, Jon M. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Howard, Kristi <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Hi Jon,

I hope all is going well. Below is the information that Jenn, Mike, and I pulled together for you. Let us know if you need anything else.

Tom

(b) (5)



AMERICAN OVERSIGHT

- (b) (5)

From: Jensen, Jon M.
Sent: Wednesday, March 06, 2019 7:50 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Howard, Kristi <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Thanks Tom!

Jon Jensen
VHA Acting Deputy Chief of Staff
W:(b6)
(b6)

From: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:49 PM
To: Jensen, Jon M. <(b6) va.gov>, Valentino, Michael (VACO) <(b6) @va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Hi Jon,
We will work on it and get a response back.
Tom

Sent with BlackBerry Work
(www.blackberry.com)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:34 PM
To: Valentino, Michael (VACO) <(b6) @va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>

AMERICAN OVERSIGHT

Subject: RE: HHS bought a nasal spray for depression
Adding Jennifer

Jon Jensen
VHA Acting Deputy Chief of Staff
W[(b6)
(b6)

From: Jensen, Jon M. <[(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:27 PM
To: Valentino, Michael (VACO) <[(b6) va.gov>, Carroll, David (VACO) <[(b6) va.gov>, Beck, Lucille B. <[(b6) va.gov>, Howard, Kristi <[(b6) va.gov>, Emmendorfer, Thomas (PBM) <[(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Just spoke to Dr Stone. We need to get something a little earlier than 10. As soon as you can would be fantastic.
Secva has asked for an update.

Jon Jensen
VHA Acting Deputy Chief of Staff
W[(b6)
(b6)

From: Jensen, Jon M. <[(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 5:40 PM
To: Valentino, Michael (VACO) <[(b6) va.gov>, Carroll, David (VACO) <[(b6) va.gov>, Beck, Lucille B. <[(b6) va.gov>, Howard, Kristi <[(b6) va.gov>, Emmendorfer, Thomas (PBM) <[(b6) va.gov>
Subject: HHS bought a nasal spray for depression
Good evening, need some information on a nasal spray used for depression? POTUS heard HHS recently purchased and he felt it would be great for us. That's all I got. Can you pull info on what it would be, if we purchase currently, if we are looking into it etc. would sure appreciate anything you could provide by 10am.

Jon Jensen
VHA Acting Deputy Chief of Staff
W:[(b6)
(b6)

Sender:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I [(b6) @va.gov>
Recipient:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <[(b6) va.gov>; Boyd, Teresa D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6886a7d555a43e0bee23c1e40e1c234-Boyd, Teres

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	<(b6) va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Outlaw, William N. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3e1067978634fbf96a382bdcd5c1115-Outlaw, Wil <(b6) va.gov>; O'Toole, Thomas P.(b6) va.gov </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c5a34d8a4b294e9986ef6e1aa8009b3f-O'Toole, Th>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>; Law, Cassandra M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f888d507d6c54eb5a92fc44199eb5838-Law, Cassan <(b6) va.gov>; Meyer, Laurence /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=56f0ba2c110d4e60863b66f9728f669d-Meyer, Laur (b6) va.gov>; Denietolis, Angela L. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b51b87cff64f4354b78eb943f97b47f3-Denietolis, (b6) va.gov>
Sent Date:	2019/03/11 09:30:41
Delivered Date:	2019/03/11 09:30:43

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From:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>
To:	Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Outlaw, William N. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3e1067978634fbf96a382bdcd5c1115-Outlaw, Wil (b6) @va.gov>; O'Toole, Thomas P.(b6) va.gov </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c5a34d8a4b294e9986ef6e1aa8009b3f-O'Toole, Th>
CC:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>; Law, Cassandra M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f888d507d6c54eb5a92fc44199eb5838-Law, Cassan <(b6) va.gov>; Boyd, Teresa D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6886a7d555a43e0bee23c1e40e1c234-Boyd, Teres <(b6) va.gov>; Meyer, Laurence /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=56f0ba2c110d4e60863b66f9728f669d-Meyer, Laur (b6) va.gov>; Denietolis, Angela L. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b51b87cff64f4354b78eb943f97b47f3-Denietolis, (b6) va.gov>
Subject:	RE: HHS bought a nasal spray for depression
Date:	2019/03/11 09:28:08
Priority:	Normal
Type:	Note

(b) (5)

Sent with BlackBerry Work
(www.blackberry.com)

From: Llorente, Maria D. <(b6) va.gov>
Date: Monday, Mar 11, 2019, 5:02 AM
To: Wiechers, Ilse <(b6) @va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Outlaw, William N. <(b6) va.gov>, O'Toole, Thomas P. <(b6) va.gov>

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Cc: Valentino, Michael (VACO) <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>, Law, Cassandra M. <(b6) va.gov>, Boyd, Teresa D. <(b6) va.gov>, Meyer, Laurence <(b6) va.gov>, Denietolis, Angela L. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Thank you very much. Could some of these be individuals for whom a sedating antidepressant was added for sleep (trazadone added to SSRIs, for example?). Those prescriptions would be treating a side effect, rather than a reflection of a treatment resistance.

From: Wiechers, Ilse
Sent: Sunday, March 10, 2019 10:06 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. <(b6) va.gov>; O'Toole, Thomas P. &(b6) @va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>; Meyer, Laurence <(b6) va.gov>; Denietolis, Angela L. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Hello everyone –
Here is what I've been able to pull together with PERC to answer the request "define the universe of patients that may meet the criteria for prescribing of Spravato®."
(b) (5)

AMERICAN OVERSIGHT

(b) (5)
.

Ilse

From: Emmendorfer, Thomas (PBM)
Sent: Friday, March 08, 2019 12:57 PM
To: Llorente, Maria D. <(b6) va.gov>; Wiechers, Ilse <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. &(b6) @va.gov>; O'Toole, Thomas P. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>; Meyer, Laurence <(b6) va.gov>; Denietolis, Angela L. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Summary of Actions for Spravato® (esketamine) to date

OPEN:

1. • CMO Call:
    a. • (b) (5)

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a. • ACTIONS:

i. (b) (5) [redacted]

[redacted]

From: "Llorente, Maria D." <(b6) [redacted] va.gov>
Date: Friday, March 8, 2019 at 1:47 PM
To: "Wiechers, Ilse" <(b6) [redacted] va.gov>, Thomas Emmendorfer <(b6) [redacted] va.gov>, "Carroll, David (VACO)" &lt(b6) [redacted] @va.gov>, "Outlaw, William N." <(b6) [redacted] va.gov>
Cc: Michael Valentino <(b6) [redacted] va.gov>, Jennifer Zacher <(b6) [redacted] va.gov>, "Law, Cassandra M." <(b6) [redacted] va.gov>
Subject: RE: HHS bought a nasal spray for depression
Very helpful. Thank you!

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From: Wiechers, Ilse
Sent: Friday, March 8, 2019 1:47 PM
To: Llorente, Maria D. <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Will do.

I've spoken to several private ketamine clinics in recent years, and the only physician type missing on your list that I have heard about is ED physicians. I also know of several clinics using APRNs under the supervision of one of those physicians listed below.

From: Llorente, Maria D.
Sent: Friday, March 08, 2019 10:43 AM
To: Wiechers, Ilse <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Yes, if you could. My understanding is that in private sector, psychiatrists, anesthesiologists, neurologists, and pain medicine providers may administer. This is in part because IV ketamine is also used for intractable pain.

From: Wiechers, Ilse
Sent: Friday, March 8, 2019 1:29 PM
To: Llorente, Maria D. <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
We do not have information on that. I can follow up on the responses to the Somatic Treatment Field Assessment and reach out to facilities that report providing IV ketamine and ask them.

From: Llorente, Maria D.
Sent: Friday, March 08, 2019 10:23 AM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Wiechers, Ilse <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. <(b6) @va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Ilse, do you know if all the current VA providers who administer IV ketamine for treatment resistant depression are psychiatrists? Do we have any anesthesiologists for example?

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From: Emmendorfer, Thomas (PBM)
Sent: Friday, March 8, 2019 12:50 PM
To: Llorente, Maria D. <(b6) va.gov>; Wiechers, Ilse <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. &lt(b6) 2@va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression
Thank you Ilse!
I just sent the internal communications document to Jenn for review (setup as a FAQ). When she is done with her review and edits she will send it over to you.
Tom

From: "Llorente, Maria D." <(b6) va.gov>
Date: Friday, March 8, 2019 at 12:08 PM
To: "Wiechers, Ilse" <(b6) va.gov>, Thomas Emmendorfer <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Outlaw, William N." <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Thank you all very much.

From: Wiechers, Ilse
Sent: Friday, March 8, 2019 12:04 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Tom –
I'll reach out to Ethics to get things started. Happy to look at draft documents whenever you and Jenn have something ready to share.
Best,
Ilse

From: Emmendorfer, Thomas (PBM)
Sent: Friday, March 08, 2019 8:02 AM
To: Wiechers, Ilse <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

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Hi Ilse,
Dave and I spoke this morning after the briefing to Dr. Stone. Action items

- • Mental Health and PBM to start working together with the Comms team to develop internal/external communication.
  - • NEXT STEPS: Jenn Z. and I can work with you on the communication. Jenn and I will send you over a draft document to review.
- • iMed Consent: At morning report-Ethics asked if Spravato will need an iMed Consent.
  - • NEXT STEPS: Could you contact Ethics and work with them to determine and develop an imed consent (if needed) for Spravato?

Bill,
I adding you to the e-mail as well as we will need your assistance with getting the external communication through the process.
Thank you!

Tom

From: "Wiechers, Ilse" <(b6) va.gov>
Date: Thursday, March 7, 2019 at 10:04 AM
To: Thomas Emmendorfer <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Yes – self reported data from the field.
Attached is a copy of the full Somatic Treatment Field Assessment – ketamine for MH is section III.

From: Emmendorfer, Thomas (PBM)
Sent: Thursday, March 07, 2019 7:00 AM
To: Wiechers, Ilse <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression
Hi Ilse,
Thank you very much for the information below!
Will the updated data also include any info on number of Veterans that have received ketamine for treatment of MH conditions?
Tom

From: "Wiechers, Ilse" <(b6) va.gov>
Date: Thursday, March 7, 2019 at 9:55 AM
To: "Carroll, David (VACO)" <(b6) va.gov>, Thomas Emmendorfer <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, Jennifer Zacher

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<(b6) va.gov>, "Llorente, Maria D."
<(b6) va.gov>, "Law, Cassandra M."
<(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Below are the sites reporting use in FY15 from the assessment we did of the field back in fall 2016. The 2019 assessment went to the field in Feb and we are working to gather the final data from sites now. Hope to have updated data about sites using IV ketamine for treatment of MH conditions sometime later this month.
1-(689) VA Connecticut HCS, CT
18-(501) New Mexico HCS
23-(618) Minneapolis, MN
1-(523) VA Boston HCS, MA
6-(659) Salisbury, NC
12-(607) Madison, WI
16-(580) Houston, TX
21-(662) San Francisco, CA
Best,
Ilse

From: Carroll, David (VACO)
Sent: Thursday, March 07, 2019 6:39 AM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Wiechers, Ilse <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
I do not. Ilse may have a list or can otherwise find out.

From: Emmendorfer, Thomas (PBM)
Sent: Thursday, March 7, 2019 9:25 AM
To: Carroll, David (VACO) <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression
Hi Dave,
The briefing went very well. By chance, do you have a list of known VA medical facilities that are using intravenous ketamine for the treatment of refractory depression?
Thank you,
Tom

From: Thomas Emmendorfer <(b6) va.gov>
Date: Thursday, March 7, 2019 at 7:45 AM
To: Jon Jensen <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) a.gov>, "Beck, Lucille B." <(b6) va.gov>, "Howard, Kristi" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D."

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<(b6) va.gov>, "Law, Cassandra M."
<(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression
Will do.

From: Jon Jensen <(b6) va.gov>
Date: Thursday, March 7, 2019 at 7:41 AM
To: Thomas Emmendorfer <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Beck, Lucille B." <(b6) va.gov>, "Howard, Kristi" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Tom, can you come to Morning Report today to discuss? Starts at 9:30.

From: Emmendorfer, Thomas (PBM)
Sent: Wednesday, March 06, 2019 10:15 PM
To: Jensen, Jon M. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Howard, Kristi <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Hi Jon,
I hope all is going well. Below is the information that Jenn, Mike, and I pulled together for you. Let us know if you need anything else.
Tom
(b) (5)



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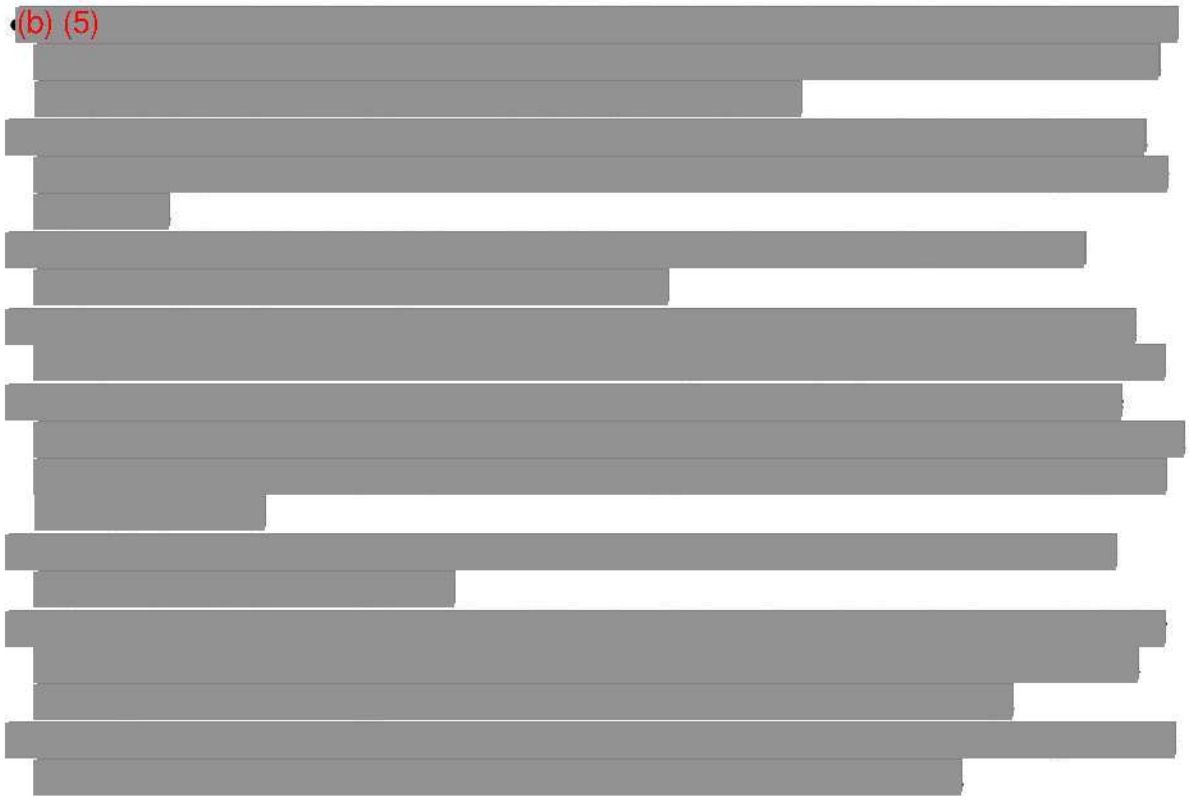

From: Jensen, Jon M.
Sent: Wednesday, March 06, 2019 7:50 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Howard, Kristi <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Thanks Tom!

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:49 PM
To: Jensen, Jon M. <(b6) va.gov>, Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Hi Jon,
We will work on it and get a response back.

AMERICAN OVERSIGHT

Tom

Sent with BlackBerry Work
(www.blackberry.com)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:34 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Adding Jennifer

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:27 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) @va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Just spoke to Dr Stone. We need to get something a little earlier than 10. As soon as you can would be fantastic.
Secva has asked for an update.

Jon Jensen
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W(b6)
(b6)

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AMERICAN OVERSIGHT

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VHA Acting Deputy Chief of Staff
W(b6)
(b6)

Sender:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>
Recipient:	Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Outlaw, William N. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3e1067978634fbf96a382bdcd5c1115-Outlaw, Wil <(b6) va.gov>; O'Toole, Thomas P.(b6) va.gov </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c5a34d8a4b294e9986ef6e1aa8009b3f-O'Toole, Th>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b6) @va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>; Law, Cassandra M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f888d507d6c54eb5a92fc44199eb5838-Law, Cassan <(b6) va.gov>; Boyd, Teresa D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6886a7d555a43e0bee23c1e40e1c234-Boyd, Teres <(b6) va.gov>; Meyer, Laurence /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=56f0ba2c110d4e60863b66f9728f669d-Meyer, Laur (b6) a.gov>; Denietolis, Angela L. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b51b87cff64f4354b78eb943f97b47f3-Denietolis, (b6) va.gov>
Sent Date:	2019/03/11 09:28:06
Delivered Date:	2019/03/11 09:28:08

AMERICAN OVERSIGHT

From:	Emmendorfer, Thomas (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC96BB44E7AE2C94C43B55D094-EMMENDORFER <(b6) va.gov>
To:	Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>
CC:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>
Subject:	RE: HHS bought a nasal spray for depression
Date:	2019/03/10 15:42:07
Priority:	Normal
Type:	Note

Thank you Jenn!

From: Zacher, Jennifer L. (PBM)
Sent: Saturday, March 09, 2019 7:32 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Sorry…here's the purchase data you asked for. I didn't see this email in the midst of all the other ones on this topic.
JZ

From: Emmendorfer, Thomas (PBM)
Sent: Thursday, March 07, 2019 6:48 AM
To: Zacher, Jennifer L. (PBM) <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>
Subject: FW: HHS bought a nasal spray for depression

Hi Jenn,

Could you have someone pull the ketamine PPV purchases for the last Fisal Year? I know we cannot tie that back to what is being used as part of protocol….but I just want to have it.

Also, could you call the J&J Federal Account Manager and found out if any health care system is able to buy this yet and the answers to the other questions you asked him last night?

Thank you!

Tom

From: Thomas Emmendorfer <(b6) va.gov>
Date: Thursday, March 7, 2019 at 7:45 AM

AMERICAN OVERSIGHT

To: Jon Jensen <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Beck, Lucille B." <(b6) va.gov>, "Howard, Kristi" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Will do.

From: Jon Jensen <(b6) va.gov>
Date: Thursday, March 7, 2019 at 7:41 AM
To: Thomas Emmendorfer <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Beck, Lucille B." <(b6) va.gov>, "Howard, Kristi" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
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(b) (5)

AMERICAN OVERSIGHT

- (b) (5) [redacted]

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Thanks Tom!

Jon Jensen
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(b6)
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Subject: RE: HHS bought a nasal spray for depression

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Sent Date:	2019/03/10 15:42:05
Delivered Date:	2019/03/10 15:42:07

AMERICAN OVERSIGHT

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Subject:	Re: HHS bought a nasal spray for depression
Date:	2019/03/07 08:06:32
Priority:	Normal
Type:	Note

Thank you Lu.

From: "Beck, Lucille B." <(b6) va.gov>
Date: Thursday, March 7, 2019 at 8:05 AM
To: Jon Jensen <(b6) va.gov>, Thomas Emmendorfer <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Howard, Kristi" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Questions being asked?

So, will it be available in VA?

Is it now?

AMERICAN OVERSIGHT

What training is needed to implement?

Lucille B. Beck, Ph.D.
Deputy Under Secretary for Health
for Policy and Services (10P)
VA Central Office
Phone: (b6)

Sent with BlackBerry Work
(www.blackberry.com).

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AMERICAN OVERSIGHT

- • (b) (5) [redacted]



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VHA Acting Deputy Chief of Staff
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Sent Date:	2019/03/07 08:06:31
Delivered Date:	2019/03/07 08:06:32

AMERICAN OVERSIGHT

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Subject:	Re: HHS bought a nasal spray for depression
Date:	2019/03/07 07:54:43
Priority:	Normal
Type:	Note

Hi Jenn,

One other item that we talked about last night that may come up this am. National Formulary review process. I can describe that process. If we need to move this review up—how long do you think it would take for the Formulary Committee to review Spravato?

I will send everyone the materials I am going to bring down to morning report with me. I can take about 6 copies and check with Maria when she gets in to see if she wants to join me.

Tom

From: Thomas Emmendorfer <(b6) va.gov>
Date: Thursday, March 7, 2019 at 7:47 AM
To: Jennifer Zacher <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>
Subject: FW: HHS bought a nasal spray for depression

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AMERICAN OVERSIGHT

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From: Jensen, Jon M.
Sent: Wednesday, March 06, 2019 7:50 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Howard, Kristi <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Thanks Tom!

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

AMERICAN OVERSIGHT

From: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:49 PM
To: Jensen, Jon M. <(b6) va.gov>, Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Hi Jon,

We will work on it and get a response back.

Tom

Sent with BlackBerry Work
(www.blackberry.com)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:34 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Adding Jennifer

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:27 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Just spoke to Dr Stone. We need to get something a little earlier than 10. As soon as you can would be fantastic.

AMERICAN OVERSIGHT

Secva has asked for an update.

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 5:40 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: HHS bought a nasal spray for depression

Good evening, need some information on a nasal spray used for depression? POTUS heard HHS recently purchased and he felt it would be great for us. That's all I got. Can you pull info on what it would be, if we purchase currently, if we are looking into it etc. would sure appreciate anything you could provide by 10am.

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

Sender:	Emmendorfer, Thomas (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC96BB44E7AE2C94C43B55D094-EMMENDORFER <(b6) va.gov>
Recipient:	Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>
Sent Date:	2019/03/07 07:54:42
Delivered Date:	2019/03/07 07:54:43

AMERICAN OVERSIGHT

From:	Jensen, Jon M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddeb735ace76400db5c3f10603188a14-Jensen, Jon <(b6) va.gov>
To:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>
CC:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>
Subject:	RE: HHS bought a nasal spray for depression
Date:	2019/03/11 15:51:40
Priority:	Normal
Type:	Note

Many thanks. Great job by PBM!

Jon Jensen
VHA Acting Deputy Chief of Staff
W:(b6)
(b6)

From: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Date: Monday, Mar 11, 2019, 3:22 PM
To: Jensen, Jon M. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>
Subject: FW: HHS bought a nasal spray for depression

Hi Jon,
This is just a heads up that the draft External Communication for Spravato® is going through the review process now.
Tom

From: Thomas Emmendorfer <(b6) va.gov>
Date: Monday, March 11, 2019 at 3:20 PM
To: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Cc: "Llorente, Maria D." <(b6) va.gov>, "Outlaw, William N." <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Wiechers, Ilse" <(b6) va.gov>
Subject: FW: HHS bought a nasal spray for depression
The attached external press release has been developed in coordination with 10P4P and 10NC5. We left a place holder in for a potential quote from Dr. Stone.
Request clearance to 10P for review.

From: Thomas Emmendorfer <(b6) va.gov>
Date: Thursday, March 7, 2019 at 7:45 AM
To: Jon Jensen <(b6) va.gov>

AMERICAN OVERSIGHT

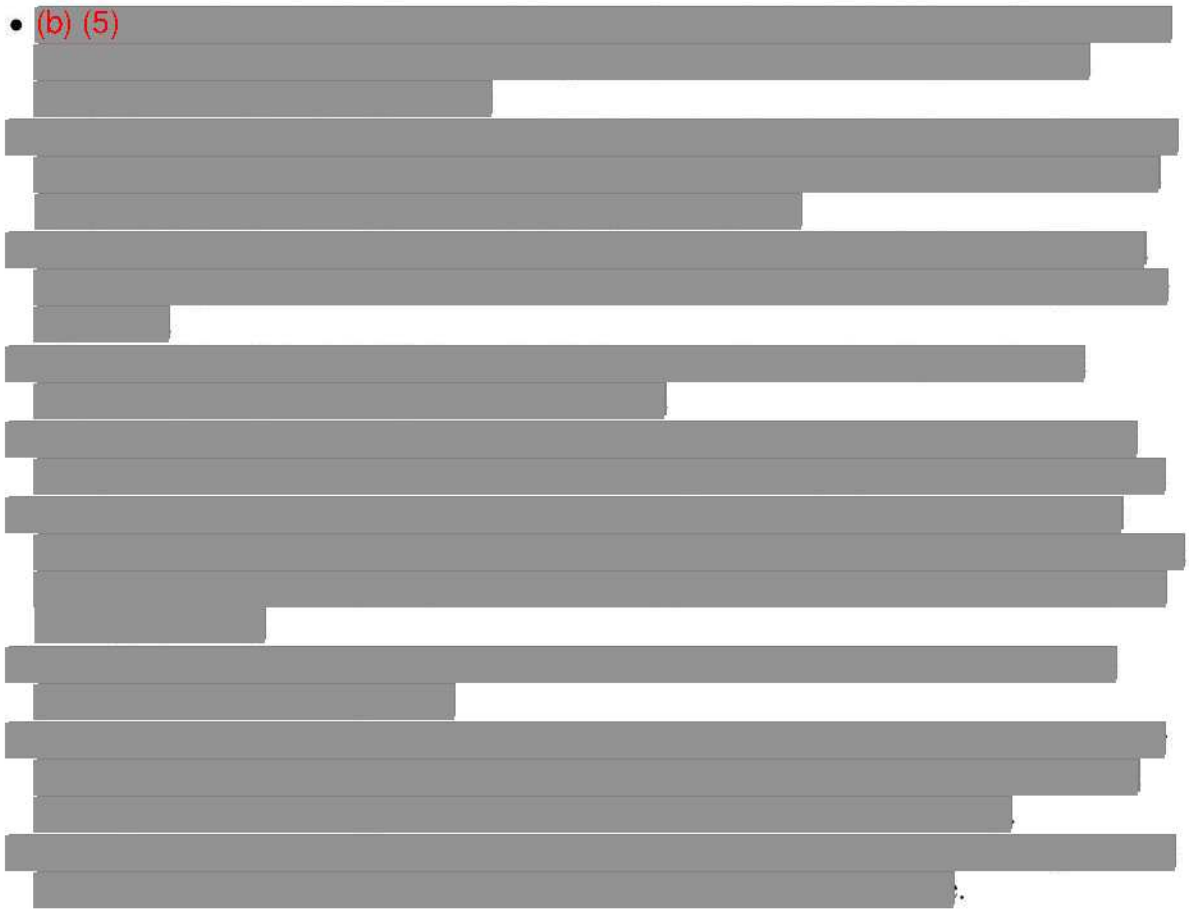
Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Beck, Lucille B." <(b6) va.gov>, "Howard, Kristi" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression
Will do.

From: Jon Jensen <(b6) va.gov>
Date: Thursday, March 7, 2019 at 7:41 AM
To: Thomas Emmendorfer <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Beck, Lucille B." <(b6) va.gov>, "Howard, Kristi" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Tom, can you come to Morning Report today to discuss? Starts at 9:30.

From: Emmendorfer, Thomas (PBM)
Sent: Wednesday, March 06, 2019 10:15 PM
To: Jensen, Jon M. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Howard, Kristi <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Hi Jon,
I hope all is going well. Below is the information that Jenn, Mike, and I pulled together for you. Let us know if you need anything else.
Tom
(b) (5)

AMERICAN OVERSIGHT

- (b) (5)



From: Jensen, Jon M.
Sent: Wednesday, March 06, 2019 7:50 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Beck, Lucille B. &lt(b6) va.gov>; Howard, Kristi <(b6) va.gov>; Zacher, Jennifer L. (PBM) &lt(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Thanks Tom!

Jon Jensen
VHA Acting Deputy Chief of Staff
W(b6)
(b6)

From: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:49 PM
To: Jensen, Jon M. &lt(b6) va.gov>, Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

AMERICAN OVERSIGHT

Hi Jon,
We will work on it and get a response back.
Tom

Sent with BlackBerry Work
(www.blackberry.com)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:34 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Adding Jennifer

Jon Jensen
VHA Acting Deputy Chief of Staff
W:(b6)
(b6)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:27 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Just spoke to Dr Stone. We need to get something a little earlier than 10. As soon as you can would be fantastic.
Secva has asked for an update.

Jon Jensen
VHA Acting Deputy Chief of Staff
W(b6)
(b6)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 5:40 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: HHS bought a nasal spray for depression
Good evening, need some information on a nasal spray used for depression? POTUS heard HHS recently purchased and he felt it would be great for us. That's all I got. Can you pull info on what it would be, if we purchase currently, if we are looking into it etc. would sure appreciate anything you could provide by 10am.

AMERICAN OVERSIGHT

Jon Jensen
VHA Acting Deputy Chief of Staff
W(b6)
(b6)

Sender:	Jensen, Jon M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddeb735ace76400db5c3f10603188a14-Jensen, Jon <(b6) va.gov>
Recipient:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>
Sent Date:	2019/03/11 15:51:39
Delivered Date:	2019/03/11 15:51:40

AMERICAN OVERSIGHT

From:	Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) va.gov>
To:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Outlaw, William N. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3e1067978634fbf96a382bdcd5c1115-Outlaw, Wil (b6) @va.gov>; O'Toole, Thomas P.(b6) va.gov </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c5a34d8a4b294e9986ef6e1aa8009b3f-O'Toole, Th>
CC:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>; Law, Cassandra M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f888d507d6c54eb5a92fc44199eb5838-Law, Cassan <(b6) va.gov>; Boyd, Teresa D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6886a7d555a43e0bee23c1e40e1c234-Boyd, Teres <(b6) va.gov>; Meyer, Laurence /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=56f0ba2c110d4e60863b66f9728f669d-Meyer, Laur <(b6) va.gov>; Denietolis, Angela L. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b51b87cff64f4354b78eb943f97b47f3-Denietolis, <(b6) va.gov>
Subject:	RE: HHS bought a nasal spray for depression
Date:	2019/03/11 20:25:47
Priority:	Normal
Type:	Note

Thank you. OMHSP has been extremely responsive!

From: Wiechers, Ilse
Sent: Monday, March 11, 2019 7:30 PM
To: Llorente, Maria D. &lt(b6) va.gov>; Emmendorfer, Thomas (PBM) <Thomas.Emmendorfer@va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. <(b6) va.gov>; O'Toole, Thomas P. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>; Boyd, Teresa D. &lt(b6) va.gov>; Meyer, Laurence <(b6) va.gov>; Denietolis, Angela L. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Updates on data:

AMERICAN OVERSIGHT

(b) (5) [redacted]

Please let me know if you have any questions.
Ilse

From: Llorente, Maria D.
Sent: Monday, March 11, 2019 9:13 AM
To: Wiechers, Ilse <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. <(b6) @va.gov>; O'Toole, Thomas P. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>; Meyer, Laurence <(b6) va.gov>; Denietolis, Angela L. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
HI, this is extremely helpful. Thank you.

From: Wiechers, Ilse
Sent: Monday, March 11, 2019 12:01 PM
To: Llorente, Maria D. <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. <(b6) va.gov>; O'Toole, Thomas P. &lt(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>; Meyer, Laurence <(b6) va.gov>; Denietolis, Angela L. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
ECT data is below. This on captures ECT provided at VA facilities. There are likely some number of patients who need ECT and receive care at the 85 facilities that do not provide service on site, who subsequently get referred to care in the community for their ECT.
FY15
# of facilities providing on site ECT = 55 out of 140
# of unique Veterans receiving ECT = 849
FY17 (most recent year we have data)
# of facilities providing on site ECT = unknown
# of unique Veterans receiving ECT = 852

AMERICAN OVERSIGHT

I asked NEPEC to re-run the # of uniques for FY18 and I’ll have # of facilities later this month once we have the completed Somatic Treatment Field Assessment.
Ilse

From: Llorente, Maria D.
Sent: Monday, March 11, 2019 6:57 AM
To: Wiechers, Ilse <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) @va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. <(b6) va.gov>; O'Toole, Thomas P. &lt(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>; Meyer, Laurence <(b6) va.gov>; Denietolis, Angela L. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Great, thank you!!

From: Wiechers, Ilse
Sent: Monday, March 11, 2019 9:50 AM
To: Llorente, Maria D. <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. &lt(b6) va.gov>; O'Toole, Thomas P. <Thomas.O'Toole@va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. &lt(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>; Meyer, Laurence <(b6) va.gov>; Denietolis, Angela L. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
I will have PERC rerun the national numbers with and without trazodone. And I have facility reported data on ECT use and also know NEPEC has pulled data based on CPT codes in the past. I’ll work on getting those as well.
Ilse

Sent with BlackBerry Work
(www.blackberry.com)

From: Llorente, Maria D. <(b6) va.gov>
Date: Monday, Mar 11, 2019, 6:30 AM
To: Wiechers, Ilse <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Outlaw, William N. &lt(b6) va.gov>, O'Toole, Thomas P. <(b6) va.gov>
Cc: Valentino, Michael (VACO) &lt(b6) @va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>, Law, Cassandra M. &lt(b6) va.gov>, Boyd, Teresa D. <(b6) va.gov>, Meyer, Laurence <(b6) va.gov>, Denietolis, Angela L. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
I agree. I wonder if low dose trazodone could be excluded.
Also, do we know how many patients receive ECT? That group would ostensibly meet criteria for this modality of treatment as well.

AMERICAN OVERSIGHT

From: Wiechers, Ilse
Sent: Monday, March 11, 2019 9:28 AM
To: Llorente, Maria D. <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. &lt(b6) va.gov>; O'Toole, Thomas P. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>; Meyer, Laurence <(b6) va.gov>; Denietolis, Angela L. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Yes, our methods are overly inclusive in capturing antidepressant Rx, and some of the “trials” with a class could be things like low dose trazodone for insomnia. I don’t have a great way to exclude that, other than to completely remove certain drugs from the data run. That might make sense for trazodone, but not for things like mirtazapine or TCAs, where I suspect we have substantial use for both sleep and depression treatment.

Sent with BlackBerry Work
(www.blackberry.com)

From: Llorente, Maria D. <(b6) va.gov>
Date: Monday, Mar 11, 2019, 5:02 AM
To: Wiechers, Ilse <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Outlaw, William N. &lt(b6) va.gov>, O'Toole, Thomas P. &lt(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>, Law, Cassandra M. <(b6) va.gov>, Boyd, Teresa D. <(b6) va.gov>, Meyer, Laurence <(b6) va.gov>, Denietolis, Angela L. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Thank you very much. Could some of these be individuals for whom a sedating antidepressant was added for sleep (trazadone added to SSRIs, for example?). Those prescriptions would be treating a side effect, rather than a reflection of a treatment resistance.

From: Wiechers, Ilse
Sent: Sunday, March 10, 2019 10:06 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. <(b6) va.gov>; O'Toole, Thomas P. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>; Meyer, Laurence <(b6) va.gov>; Denietolis, Angela L. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Hello everyone –

AMERICAN OVERSIGHT

Here is what I’ve been able to pull together with PERC to answer the request “define the universe of patients that may meet the criteria for prescribing of Spravato®.”

(b) (5)



Ilse

From: Emmendorfer, Thomas (PBM)
Sent: Friday, March 08, 2019 12:57 PM
To: Llorente, Maria D. <(b6) va.gov>; Wiechers, Ilse <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. <(b6) va.gov>; O'Toole, Thomas P. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>; Meyer, Laurence <(b6) va.gov>; Denietolis, Angela L. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression
Summary of Actions for Spravato® (esketamine) to date
OPEN:

1. • CMO Call:

AMERICAN OVERSIGHT

a. • ACTIONS: (b) (5)

AMERICAN OVERSIGHT

a. • ((b) (5)

[redacted]

From: "Llorente, Maria D." <(b6) va.gov>
Date: Friday, March 8, 2019 at 1:47 PM
To: "Wiechers, Ilse" <(b6) va.gov>, Thomas Emmendorfer <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Outlaw, William N." <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Very helpful. Thank you!

From: Wiechers, Ilse
Sent: Friday, March 8, 2019 1:47 PM
To: Llorente, Maria D. <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Will do.

I’ve spoken to several private ketamine clinics in recent years, and the only physician

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type missing on your list that I have heard about is ED physicians. I also know of several clinics using APRNs under the supervision of one of those physicians listed below.

From: Llorente, Maria D.
Sent: Friday, March 08, 2019 10:43 AM
To: Wiechers, Ilse <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. <(b6) @va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. &lt(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Yes, if you could. My understanding is that in private sector, psychiatrists, anesthesiologists, neurologists, and pain medicine providers may administer. This is in part because IV ketamine is also used for intractable pain.

From: Wiechers, Ilse
Sent: Friday, March 8, 2019 1:29 PM
To: Llorente, Maria D. <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
We do not have information on that. I can follow up on the responses to the Somatic Treatment Field Assessment and reach out to facilities that report providing IV ketamine and ask them.

From: Llorente, Maria D.
Sent: Friday, March 08, 2019 10:23 AM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Wiechers, Ilse <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. &lt(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. &lt(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Ilse, do you know if all the current VA providers who administer IV ketamine for treatment resistant depression are psychiatrists? Do we have any anesthesiologists for example?

From: Emmendorfer, Thomas (PBM)
Sent: Friday, March 8, 2019 12:50 PM
To: Llorente, Maria D. <(b6) va.gov>; Wiechers, Ilse <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. &lt(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. &lt(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression
Thank you Ilse!
I just sent the internal communications document to Jenn for review (setup as a FAQ). When she is done with her review and edits she will send it over to you.
Tom

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From: "Llorente, Maria D." <(b6) va.gov>
Date: Friday, March 8, 2019 at 12:08 PM
To: "Wiechers, Ilse" <(b6) va.gov>, Thomas Emmendorfer <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Outlaw, William N." <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Thank you all very much.

From: Wiechers, Ilse
Sent: Friday, March 8, 2019 12:04 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Tom –
I’ll reach out to Ethics to get things started. Happy to look at draft documents whenever you and Jenn have something ready to share.
Best,
Ilse

From: Emmendorfer, Thomas (PBM)
Sent: Friday, March 08, 2019 8:02 AM
To: Wiechers, Ilse <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. &lt(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. &lt(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression
Hi Ilse,
Dave and I spoke this morning after the briefing to Dr. Stone. Action items

- • Mental Health and PBM to start working together with the Comms team to develop internal/external communication.
    - • NEXT STEPS: Jenn Z. and I can work with you on the communication. Jenn and I will send you over a draft document to review.
- • iMed Consent: At morning report-Ethics asked if Spravato will need an iMed Consent.
    - • NEXT STEPS: Could you contact Ethics and work with them to determine and develop an imed consent (if needed) for Spravato?

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Bill,
I adding you to the e-mail as well as we will need your assistance with getting the external communication through the process.
Thank you!

Tom

From: "Wiechers, Ilse" <(b6) va.gov>
Date: Thursday, March 7, 2019 at 10:04 AM
To: Thomas Emmendorfer <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Yes – self reported data from the field.
Attached is a copy of the full Somatic Treatment Field Assessment – ketamine for MH is section III.

From: Emmendorfer, Thomas (PBM)
Sent: Thursday, March 07, 2019 7:00 AM
To: Wiechers, Ilse <(b6) va.gov>; Carroll, David (VACO) &lt(b6) @va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression
Hi Ilse,
Thank you very much for the information below!
Will the updated data also include any info on number of Veterans that have received ketamine for treatment of MH conditions?
Tom

From: "Wiechers, Ilse" <(b6) va.gov>
Date: Thursday, March 7, 2019 at 9:55 AM
To: "Carroll, David (VACO)" <(b6) va.gov>, Thomas Emmendorfer <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Below are the sites reporting use in FY15 from the assessment we did of the field back in fall 2016. The 2019 assessment went to the field in Feb and we are working to gather the final data from sites now. Hope to have updated data about sites using IV ketamine for treatment of MH conditions sometime later this month.

1-(689) VA Connecticut HCS, CT

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18-(501) New Mexico HCS

23-(618) Minneapolis, MN

1-(523) VA Boston HCS, MA

6-(659) Salisbury, NC

12-(607) Madison, WI

16-(580) Houston, TX

21-(662) San Francisco, CA
Best,
Ilse

From: Carroll, David (VACO)
Sent: Thursday, March 07, 2019 6:39 AM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Wiechers, Ilse <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
I do not. Ilse may have a list or can otherwise find out.

From: Emmendorfer, Thomas (PBM)
Sent: Thursday, March 7, 2019 9:25 AM
To: Carroll, David (VACO) <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. &lt(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression
Hi Dave,
The briefing went very well. By chance, do you have a list of known VA medical facilities that are using intravenous ketamine for the treatment of refractory depression?
Thank you,
Tom

From: Thomas Emmendorfer <(b6) va.gov>
Date: Thursday, March 7, 2019 at 7:45 AM
To: Jon Jensen <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Beck, Lucille B." &(b6) @va.gov>, "Howard, Kristi" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

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Will do.

From: Jon Jensen <(b6) va.gov>
Date: Thursday, March 7, 2019 at 7:41 AM
To: Thomas Emmendorfer <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Beck, Lucille B." <(b6) va.gov>, "Howard, Kristi" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Tom, can you come to Morning Report today to discuss? Starts at 9:30.

From: Emmendorfer, Thomas (PBM)
Sent: Wednesday, March 06, 2019 10:15 PM
To: Jensen, Jon M. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Howard, Kristi <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Hi Jon,

I hope all is going well. Below is the information that Jenn, Mike, and I pulled together for you. Let us know if you need anything else.

Tom

(b) (5)



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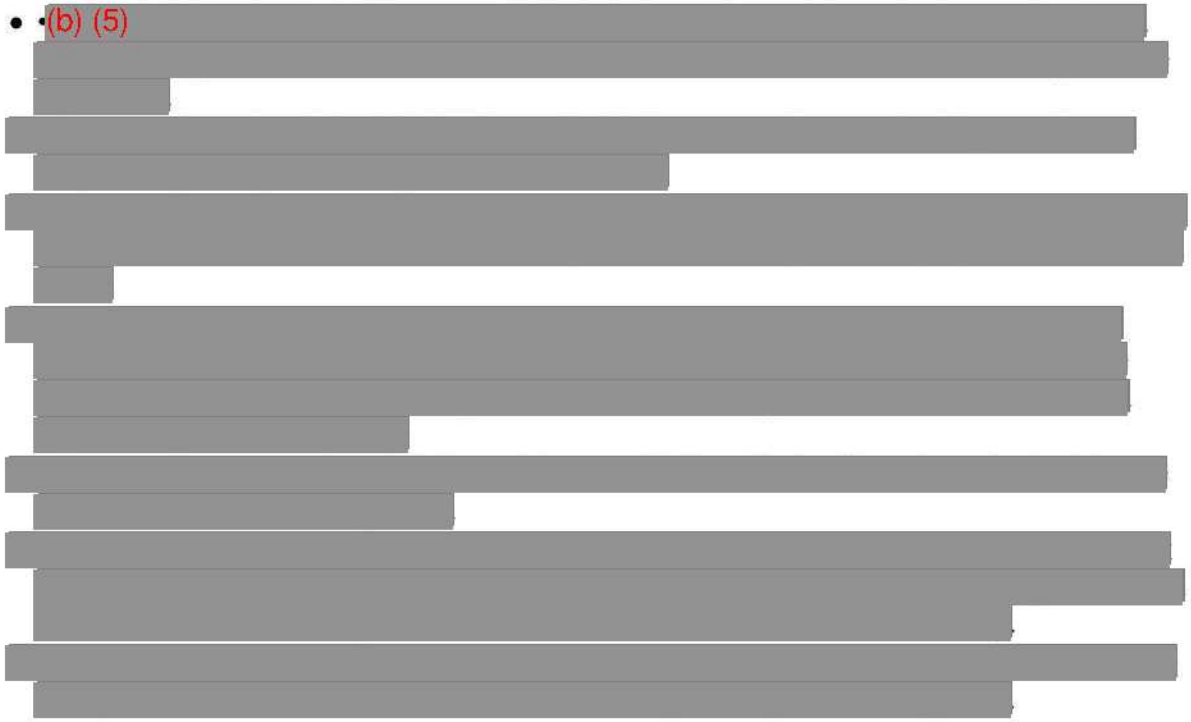
- (b) (5)



From: Jensen, Jon M.
Sent: Wednesday, March 06, 2019 7:50 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Howard, Kristi <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Thanks Tom!

Jon Jensen
VHA Acting Deputy Chief of Staff
W:(b6)
(b6)

From: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:49 PM
To: Jensen, Jon M. &lt(b6) va.gov>, Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression
Hi Jon,
We will work on it and get a response back.
Tom

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Sent with BlackBerry Work
(www.blackberry.com)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:34 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Adding Jennifer

Jon Jensen
VHA Acting Deputy Chief of Staff
W:(b6)
(b6)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:27 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Just spoke to Dr Stone. We need to get something a little earlier than 10. As soon as you can would be fantastic.
Secva has asked for an update.

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 5:40 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: HHS bought a nasal spray for depression

Good evening, need some information on a nasal spray used for depression? POTUS heard HHS recently purchased and he felt it would be great for us. That’s all I got. Can you pull info on what it would be, if we purchase currently, if we are looking into it etc. would sure appreciate anything you could provide by 10am.

Jon Jensen
VHA Acting Deputy Chief of Staff

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W(b6)
(b6)

Sender:	Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) va.gov>
Recipient:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) @va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Outlaw, William N. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3e1067978634fbf96a382bdcd5c1115-Outlaw, Wil (b6) @va.gov>; O'Toole, Thomas P.(b6) va.gov </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c5a34d8a4b294e9986ef6e1aa8009b3f-O'Toole, Th>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>; Law, Cassandra M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f888d507d6c54eb5a92fc44199eb5838-Law, Cassan <(b6) va.gov>; Boyd, Teresa D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6886a7d555a43e0bee23c1e40e1c234-Boyd, Teres <(b6) va.gov>; Meyer, Laurence /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=56f0ba2c110d4e60863b66f9728f669d-Meyer, Laur <(b6) va.gov>; Denietolis, Angela L. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b51b87cff64f4354b78eb943f97b47f3-Denietolis, <(b6) va.gov>
Sent Date:	2019/03/11 20:25:45
Delivered Date:	2019/03/11 20:25:47
Message Flags:	Unread

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From:	Wiechers, Ilse /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0C7B1428D9E4233A641F125C5B6FC4F-WIECHERS, I (b6) s@va.gov>
To:	Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>
CC:	Trafton, Jodie A /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bd911ff80678434dbf23ab0f78ad4722-Trafton, Jo (b6) @va.gov>; Smith, Clifford A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b729882079394f37af66f66722f99400-Smith, Clif <(b6) va.gov>
Subject:	RE: HHS bought a nasal spray for depression
Date:	2019/03/08 11:13:32
Priority:	Normal
Type:	Note

No problem, happy to help work with Tom &Jenn on this.
Ilse

From: Carroll, David (VACO)
Sent: Friday, March 08, 2019 8:12 AM
To: Wiechers, Ilse <(b6) v>
Cc: Trafton, Jodie A <(b6) @va.gov>; Smith, Clifford A. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Hi Ilse. I had hoped to write to you before Tom reached out. My apologies. It would be fabulous if you could be our lead on this. Thank you.
Dave

From: Emmendorfer, Thomas (PBM)
Sent: Friday, March 8, 2019 11:02 AM
To: Wiechers, Ilse (b6) @va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Hi Ilse,

Dave and I spoke this morning after the briefing to Dr. Stone. Action items

- • Mental Health and PBM to start working together with the Comms team to develop internal/external communication.

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- ○ • NEXT STEPS: Jenn Z. and I can work with you on the communication. Jenn and I will send you over a draft document to review.
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I adding you to the e-mail as well as we will need your assistance with getting the external communication through the process.

Thank you!

Tom

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Date: Thursday, March 7, 2019 at 10:04 AM
To: Thomas Emmendorfer <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Yes – self reported data from the field.

Attached is a copy of the full Somatic Treatment Field Assessment – ketamine for MH is section III.

From: Emmendorfer, Thomas (PBM)
Sent: Thursday, March 07, 2019 7:00 AM
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Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Hi Ilse,

Thank you very much for the information below!

Will the updated data also include any info on number of Veterans that have received ketamine for treatment of MH conditions?

Tom

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From: "Wiechers, Ilse" (b6) @va.gov>
Date: Thursday, March 7, 2019 at 9:55 AM
To: "Carroll, David (VACO)" <(b6) va.gov>, Thomas Emmendorfer <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

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23-(618) Minneapolis, MN
1-(523) VA Boston HCS, MA
6-(659) Salisbury, NC
12-(607) Madison, WI
16-(580) Houston, TX
21-(662) San Francisco, CA

Best,
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Subject: RE: HHS bought a nasal spray for depression

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Subject: Re: HHS bought a nasal spray for depression

Hi Dave,

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The briefing went very well. By chance, do you have a list of known VA medical facilities that are using intravenous ketamine for the treatment of refractory depression?

Thank you,

Tom

From: Thomas Emmendorfer <(b6) va.gov>
Date: Thursday, March 7, 2019 at 7:45 AM
To: Jon Jensen <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Beck, Lucille B." <(b6) va.gov>, "Howard, Kristi" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Will do.

From: Jon Jensen <(b6) va.gov>
Date: Thursday, March 7, 2019 at 7:41 AM
To: Thomas Emmendorfer <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Beck, Lucille B." <(b6) va.gov>, "Howard, Kristi" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

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From: Emmendorfer, Thomas (PBM)
Sent: Wednesday, March 06, 2019 10:15 PM
To: Jensen, Jon M. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Howard, Kristi <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Hi Jon,

I hope all is going well. Below is the information that Jenn, Mike, and I pulled together for you. Let us know if you need anything else.

Tom

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(b) (5)

[redacted]

From: Jensen, Jon M.
Sent: Wednesday, March 06, 2019 7:50 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Howard, Kristi <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

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Thanks Tom!

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:49 PM
To: Jensen, Jon M. <(b6) va.gov>, Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Hi Jon,

We will work on it and get a response back.

Tom

Sent with BlackBerry Work
(www.blackberry.com)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:34 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Adding Jennifer

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:27 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Just spoke to Dr Stone. We need to get something a little earlier than 10. As soon as you can would be fantastic.

AMERICAN OVERSIGHT

Secva has asked for an update.

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 5:40 PM
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Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

Sender:	Wiechers, Ilse /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0C7B1428D9E4233A641F125C5B6FC4F-WIECHERS, I (b6) @va.gov>
Recipient:	Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Trafton, Jodie A /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bd911ff80678434dbf23ab0f78ad4722-Trafton, Jo <(b6) a.gov>; Smith, Clifford A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b729882079394f37af66f66722f99400-Smith, Clif <(b6) va.gov>
Sent Date:	2019/03/08 11:13:31
Delivered Date:	2019/03/08 11:13:32

AMERICAN OVERSIGHT

From:	Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd. (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO,>
To:	Beck, Lucille B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=845480228a8b43e7a5fef5716ded04c2-Beck, Lucil <(b6) va.gov>
Subject:	RE: HHS bought a nasal spray for depression
Date:	2019/03/06 22:13:03
Priority:	Normal
Type:	Note

This product is likely more hype than hope as compared to ketamine (the "es" in the name essentially means it is one half of the ketamine molecule). And we already use ketamine in VA. And it is cheap!

Sent with BlackBerry Work
(www.blackberry.com)

From: Beck, Lucille B. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 9:06 PM
To: Valentino, Michael (VACO) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Thanks so much, I know you all are on it.

Sent with BlackBerry Work
(www.blackberry.com)

From: Valentino, Michael (VACO) <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 10:04 PM
To: Beck, Lucille B. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Full response with background coming momentarily

Sent with BlackBerry Work
(www.blackberry.com)

From: Beck, Lucille B. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 9:00 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>, Law, Cassandra M. <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Cc: Llorente, Maria D. <(b6) va.gov>, Valentino, Michael (VACO) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

AMERICAN OVERSIGHT

Washington Post article today reported that the spray was just approved by the FDA scientific panel for severe depressionwhen other drugs have not been effective.
The drug has some potentially serious side effects and the panel's recommendation is to administer in controlled environments with patient surveillance.

Sent with BlackBerry Work
(www.blackberry.com)

From: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 8:48 PM
To: Law, Cassandra M. <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Cc: Llorente, Maria D. <(b6) va.gov>, Valentino, Michael (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Hi Cassie,

Jenn and I are on the phone together and we are working on the request now. I called Jon about 30 minutes ago to make sure what we are working on…is what they are looking for….we will send the info as soon as we are done.

Thank you,

Tom

From: Law, Cassandra M.
Sent: Wednesday, March 06, 2019 8:46 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Zacher, Jennifer L. (PBM) (b6) @va.gov>
Cc: Llorente, Maria D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>
Subject: FW: HHS bought a nasal spray for depression

Good evening Tom and Jennifer. I am reaching out to you per Mike's Out of Office regarding the SECVA request for information for tomorrow morning (Jon Jensen email).

Sorry for the late outreach, but since information is requested for early tomorrow morning, trying to cover all bases to gain insight. Jennifer, the number in the Out of Office for Mike does not appear to be yours so I did not leave a voice mail message.

This may be a MH / Dave Carrol question regarding awareness and efficacy and potential VA interest, but want to be sure we weigh-in with any relevant information.

Thank you for any assistance, Cassie

AMERICAN OVERSIGHT

From: Law, Cassandra M.
Sent: Wednesday, March 06, 2019 8:28 PM
To: Jensen, Jon M. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Howard, Kristi <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Thanks Jon. While this is not what SECVA needs for tomorrow, it may be useful. I just read an article on this yesterday in the NY Times (see link below). It's a nasal spray version of the drug ketamine called esketamine. It was developed by a branch of J&J and is to be marketed under the name Spravato.

There is a National Institute of Mental Health Chief / researcher involved so no surprise with HHS backing. I am not aware of VA pursuit, but will see if Mike/Tom and Dave C have additional more relevant insight.

https://www.nytimes.com/2019/03/05/health/depression-treatment-ketamine-fda.html?smid=nytcore-ios-share

Cassie

From: Jensen, Jon M.
Sent: Wednesday, March 06, 2019 7:48 PM
To: Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Howard, Kristi <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

And Cassie

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:34 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Adding Jennifer

AMERICAN OVERSIGHT

Jon Jensen
VHA Acting Deputy Chief of Staff
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(b6)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:27 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
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Secva has asked for an update.

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 5:40 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: HHS bought a nasal spray for depression

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Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

Sender:	Valentino, Michael (VACO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO,>
Recipient:	Beck, Lucille B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=845480228a8b43e7a5fef5716ded04c2-Beck, Lucil <(b6) va.gov>
Sent Date:	2019/03/06 22:13:02
Delivered Date:	2019/03/06 22:13:03

AMERICAN OVERSIGHT

From:	Valentino, Michael (VACO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO,>
To:	Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>
Subject:	RE: HHS bought a nasal spray for depression
Date:	2019/03/06 21:41:36
Priority:	Normal
Type:	Note

Yes, (b) (5)

Sent with BlackBerry Work
(www.blackberry.com)

From: Zacher, Jennifer L. (PBM) <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 8:33 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Hi Mike,
We are working on the edits now and are almost done....(b) (5) ?

We have the rest in the works
JZ

From: Valentino, Michael (VACO)
Sent: Wednesday, March 06, 2019 8:31 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Looks great guys.

As we discussed Tom, (b) (5)

AMERICAN OVERSIGHT

(b) (5) [redacted]

Sent with BlackBerry Work
(www.blackberry.com)

From: Emmendorfer, Thomas (PBM) <(b6) [redacted] va.gov>
Date: Wednesday, Mar 06, 2019, 8:06 PM
To: Zacher, Jennifer L. (PBM) <(b6) [redacted] va.gov>, Valentino, Michael (VACO) <(b6) [redacted] va.gov>
Subject: FW: HHS bought a nasal spray for depression

I called Jon and the SecVA and maybe Dr. Stone have a meeting at White House tomorrow and Trump wants to meet with President of Johnson and Johnson. I told him we could give a very high level talking point and some background bullet points.

Jenn and I pulled the Background Info bullet points from the FDA Immediate Release on the approval:
https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm632761.htm

(b) (5) [redacted]

From: Jensen, Jon M.
Sent: Wednesday, March 06, 2019 7:50 PM
To: Emmendorfer, Thomas (PBM) <(b6) [redacted] va.gov>; Valentino, Michael (VACO) <(b6) [redacted] va.gov>; Carroll, David (VACO) <(b6) [redacted] va.gov>; Beck, Lucille B. <(b6) [redacted] va.gov>; Howard, Kristi <(b6) [redacted] va.gov>; Zacher, Jennifer L. (PBM)

AMERICAN OVERSIGHT

<(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Thanks Tom!

Jon Jensen
VHA Acting Deputy Chief of Staff
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(b6)

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Subject: RE: HHS bought a nasal spray for depression

Adding Jennifer

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(b6)

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Date: Wednesday, Mar 06, 2019, 7:27 PM

AMERICAN OVERSIGHT

To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
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VHA Acting Deputy Chief of Staff
(b6)
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Date: Wednesday, Mar 06, 2019, 5:40 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
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VHA Acting Deputy Chief of Staff
W(b6)
(b6)

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Recipient:	Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>
Sent Date:	2019/03/06 21:41:35
Delivered Date:	2019/03/06 21:41:36

AMERICAN OVERSIGHT

From:	Emmendorfer, Thomas (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC96BB44E7AE2C94C43B55D094-EMMENDORFER <(b6) va.gov>
To:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>
Subject:	RE: HHS bought a nasal spray for depression
Date:	2019/03/06 22:05:00
Priority:	Normal
Type:	Note

No problem and thank you Jenn for helping on this with just getting home from DC!

From: Valentino, Michael (VACO)
Sent: Wednesday, March 06, 2019 10:04 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Excellent, thanks!

Please send to Jon and copy all on the original message. Please ensure Lu Beck, Maria Llorente, Cassie and I are all on the message if not already there.

Thanks much for doing this....

Sent with BlackBerry Work
(www.blackberry.com)

From: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 8:58 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: FW: HHS bought a nasal spray for depression

Edits in red below for your review....

(b) (5)
.

From: Emmendorfer, Thomas (PBM)
Sent: Wednesday, March 06, 2019 9:06 PM
To: Zacher, Jennifer L. (PBM) <(b6) va.gov>; Valentino, Michael (VACO)

AMERICAN OVERSIGHT

([redacted]va.gov) <[redacted]va.gov>
Subject: FW: HHS bought a nasal spray for depression

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(b) (5) [redacted]

AMERICAN OVERSIGHT

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Subject: RE: HHS bought a nasal spray for depression

Adding Jennifer

Jon Jensen
VHA Acting Deputy Chief of Staff

AMERICAN OVERSIGHT

W:(b6)
(b6)

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Date: Wednesday, Mar 06, 2019, 7:27 PM
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Recipient:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>
Sent Date:	2019/03/06 22:04:59
Delivered Date:	2019/03/06 22:05:00

AMERICAN OVERSIGHT

AMERICAN OVERSIGHT

From:	Fuller, Matthew A. (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=62D9CBB23B184CACB98895776E36A471-FULLER, MAT>
To:	Nazario, Mitchell /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e909581b30643148ba99ab7ff79cae0-Nazario, Mi (b6) va.gov>; Pomerantz, Andrew /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29a9288df9a34e84bddfd00cde79f11b-Pomerantz, (b6) @va.gov>
CC:	Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>
Subject:	RE: HHS bought a nasal spray for depression
Date:	2019/03/07 16:09:00
Priority:	Normal
Type:	Note

Hi Andrew,

I anticipate that we will have some documents for our MAP/VPE to review in a couple of months. Formulary status will depend on what the committee decides. I expect that a CFU will be needed. Thanks.

Matthew

Matthew A. Fuller, BS, Pharm.D., FASHP, BCPP
National PBM Clinical Pharmacy Program Manager – Psychiatry and Geriatrics
VHA Pharmacy Benefits Management Services (10P4P)
1st Avenue – 1 Block North of Cermak (Bldg 37)
Hines, IL 60141
(b6)

From: Nazario, Mitchell
Sent: Thursday, March 07, 2019 8:11 AM
To: Pomerantz, Andrew <(b6) va.gov>; Fuller, Matthew A. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

I'm adding my colleague, Matt Fuller to the email since he covers mental health, he may already be working on it. I have a feeling it might find its way for the treatment of acute pain.

From: Pomerantz, Andrew
Sent: Wednesday, March 06, 2019 7:46 PM
To: Nazario, Mitchell <(b6) va.gov>
Subject: FW: HHS bought a nasal spray for depression

Hi Mitch,

AMERICAN OVERSIGHT

Are we adding this to national formulary? Need criteria for use?

From: Carroll, David (VACO)
Sent: Wednesday, March 06, 2019 6:47 PM
To: Wiechers, Ilse (b6) @va.gov>; McGuire, Marsden H. <(b6) va.gov>; Pomerantz, Andrew <(b6) va.gov>; Katz, Ira R. (b6) @va.gov>
Cc: VHA 10NC5 Action <VHA10NC5Action@va.gov>
Subject: FW: HHS bought a nasal spray for depression

What do we know about this? My only info came from a New York Times article posted this morning. Although FDA approved it, I'm not sure when it will be available or the supports are in place for its use (e.g., the requirement to enter patient response information into a national database). Thanks.

https://www.nytimes.com/2019/03/05/health/depression-treatment-ketamine-fda.html

---

From: Jensen, Jon M.
Sent: Wednesday, March 6, 2019 5:41 PM
To: Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Howard, Kristi <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: HHS bought a nasal spray for depression

Good evening, need some information on a nasal spray used for depression? POTUS heard HHS recently purchased and he felt it would be great for us. That's all I got. Can you pull info on what it would be, if we purchase currently, if we are looking into it etc. would sure appreciate anything you could provide by 10am.

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

Sender:	Fuller, Matthew A. (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=62D9CBB23B184CACB98895776E36A471-FULLER, MAT>
Recipient:	Nazario, Mitchell /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e909581b30643148ba99ab7ff79cae0-Nazario, Mi <(b6) va.gov>; Pomerantz, Andrew /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29a9288df9a34e84bddfd00cde79f11b-Pomerantz, (b6) @va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>
Sent Date:	2019/03/07 16:09:07
Delivered Date:	2019/03/07 16:09:00

AMERICAN OVERSIGHT

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From:	Emmendorfer, Thomas (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC96BB44E7AE2C94C43B55D094-EMMENDORFER <(b6) va.gov>
To:	Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>
Subject:	Re: HHS bought a nasal spray for depression
Date:	2019/03/07 09:58:03
Priority:	Normal
Type:	Note

Yep ☺

From: Jennifer Zacher <(b6) va.gov>
Date: Thursday, March 7, 2019 at 9:55 AM
To: Thomas Emmendorfer <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Woohoo! PBM dream team!

From: Emmendorfer, Thomas (PBM)
Sent: Thursday, March 07, 2019 8:55 AM
To: Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Dr. Stone gave very high praise to our documents last night and also to PBM in general!!!

From: Jennifer Zacher <(b6) va.gov>
Date: Thursday, March 7, 2019 at 9:42 AM
To: Thomas Emmendorfer <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

thanks

From: Emmendorfer, Thomas (PBM)
Sent: Thursday, March 07, 2019 8:21 AM
To: Zacher, Jennifer L. (PBM) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Hi Jenn,

The briefing went very well. Dr. Stone said he we provide us an update after the meeting happens.

AMERICAN OVERSIGHT

Tom

From: Jennifer Zacher <(b6) va.gov>
Date: Thursday, March 7, 2019 at 8:54 AM
To: Thomas Emmendorfer <(b6) va.gov>, Michael Valentino <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

They don't know yet. He said they are waiting for the info to be updated in daily med and then will come up with a date. Interestingly, it will be available through McKesson. He wants to set up a time to talk about the operational side of it, but it will have to wait until after the meeting next week, unless you think I need to talk to him sooner in light of these questions…..Let me know

---

From: Emmendorfer, Thomas (PBM)
Sent: Wednesday, March 06, 2019 9:30 PM
To: Valentino, Michael (VACO) <(b6) va.gov>
Cc: Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Jenn sent a message to the J&J Federal Account Manager tonight with that question.

Sent with BlackBerry Work
(www.blackberry.com)

From: Valentino, Michael (VACO) <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 10:28 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Cc: Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Do we know when this will be available to order?

Sent with BlackBerry Work
(www.blackberry.com)

From: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 9:14 PM
To: Jensen, Jon M. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi (b6) l@va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>, Llorente, Maria D. <(b6) va.gov>, Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Hi Jon,

AMERICAN OVERSIGHT

I hope all is going well. Below is the information that Jenn, Mike, and I pulled together for you. Let us know if you need anything else.

Tom

Bottom Line Up Front:
Spravato® will be available to VA providers to administer to Veterans based on their clinical assessment and the individual medical needs of our nation's Veterans.

Background Information:

- • The Food and Drug Administration (FDA) approved Spravato® on March 5, 2019.
- • Spravato's® chemical name is esketamine which is a S(+) enantiomer, a slightly different version of ketamine, and provides similar therapeutic effects to ketamine.
- • Intravenous ketamine has been used for several years in the United States for treatment refractory depression based on the body of medical evidence published in the literature.
- • Intravenous ketamine is FDA approved as an anesthetic agent for diagnostic and surgical procedures that do not require skeletal muscle relaxation and has been used for several decades.
- • Intravenous ketamine has been used for several years in the United States for treatment resistant depression and intractable neuropathic pain based on the body of medical evidence published in the literature.
- • VA Pharmacy Benefits Management (PBM) Services has developed a national protocol for the use of intravenous ketamine in treatment resistant depression and severe suicidal ideation which was published in December 2017 (attached).
- • VA PBM developed Guidance on Off Label Prescribing of drugs in August 2013 and the national protocol for the use of intravenous ketamine is consistent with this guidance (attached).
- • Spravato® is a Schedule III Controlled Substance and cannot be dispensed as an outpatient prescription for a patient to take home.
- • The patient self-administers Spravato® nasal spray under the supervision of a health care provider in a certified doctor's office or clinic, and the spray cannot be taken home.
- • Unlike ketamine which VA medical facilities can purchase unrestricted through the pharmaceutical prime vendor with next day delivery, Spravato® is only available through a restricted distribution system, under an FDA approved Risk Evaluation and Mitigation Strategy (REMS).
- • Spravato® must be administered in a certified medical office where the health care provider can monitor the patient.
- • Spravato® labeling contains a Boxed Warning that cautions that patients are at risk for sedation and difficulty with attention, judgment and thinking (dissociation), abuse and misuse, and suicidal thoughts and behaviors after administration of the drug.
- • Because of the risk of sedation and dissociation, patients must be monitored by a health care provider for at least two hours after receiving their Spravato® dose.

From: Jensen, Jon M.
Sent: Wednesday, March 06, 2019 7:50 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Valentino, Michael (VACO)

AMERICAN OVERSIGHT

<(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Howard, Kristi <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Thanks Tom!

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:49 PM
To: Jensen, Jon M. <(b6) va.gov>, Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Hi Jon,

We will work on it and get a response back.

Tom

Sent with BlackBerry Work
(www.blackberry.com)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:34 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Adding Jennifer

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

AMERICAN OVERSIGHT

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:27 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi (b6) @va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Just spoke to Dr Stone. We need to get something a little earlier than 10. As soon as you can would be fantastic.
Secva has asked for an update.

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 5:40 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: HHS bought a nasal spray for depression

Good evening, need some information on a nasal spray used for depression? POTUS heard HHS recently purchased and he felt it would be great for us. That's all I got. Can you pull info on what it would be, if we purchase currently, if we are looking into it etc. would sure appreciate anything you could provide by 10am.

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

Sender:	Emmendorfer, Thomas (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC96BB44E7AE2C94C43B55D094-EMMENDORFER <(b6) va.gov>
Recipient:	Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>
Sent Date:	2019/03/07 09:58:04
Delivered Date:	2019/03/07 09:58:03

AMERICAN OVERSIGHT

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From:	Wiechers, Ilse /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0C7B1428D9E4233A641F125C5B6FC4F-WIECHERS, I (b6) @va.gov>
To:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>
CC:	Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>
Subject:	RE: HHS bought a nasal spray for depression
Date:	2019/03/08 13:10:34
Priority:	Normal
Type:	Note

Np. I'm on West Coast time, so plenty of hours left in my workday!

I've emailed the IMED Consent group email, awaiting a response re next steps.

From: Emmendorfer, Thomas (PBM)
Sent: Friday, March 08, 2019 9:56 AM
To: Wiechers, Ilse (b6) @va.gov>
Cc: Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Hi Ilse,

It will probably be 2 hours before Jenn gets you the document…she has a physical therapy appointment that she is on her way too right now.

Tom

From: "Wiechers, Ilse" (b6) @va.gov>
Date: Friday, March 8, 2019 at 12:03 PM
To: Thomas Emmendorfer <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Outlaw, William N." (b6) @va.gov>
Cc: Michael Valentino <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Tom –

I'll reach out to Ethics to get things started. Happy to look at draft documents whenever you and Jenn have something ready to share.

Best,
Ilse

AMERICAN OVERSIGHT

From: Emmendorfer, Thomas (PBM)
Sent: Friday, March 08, 2019 8:02 AM
To: Wiechers, Ilse (b6) @va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. (b6) @va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Hi Ilse,

Dave and I spoke this morning after the briefing to Dr. Stone. Action items

- • Mental Health and PBM to start working together with the Comms team to develop internal/external communication.
    - • NEXT STEPS: Jenn Z. and I can work with you on the communication. Jenn and I will send you over a draft document to review.
- • iMed Consent: At morning report-Ethics asked if Spravato will need an iMed Consent.
    - • NEXT STEPS: Could you contact Ethics and work with them to determine and develop an imed consent (if needed) for Spravato?

Bill,

I adding you to the e-mail as well as we will need your assistance with getting the external communication through the process.

Thank you!

Tom

From: "Wiechers, Ilse" <(b6) @va.gov>
Date: Thursday, March 7, 2019 at 10:04 AM
To: Thomas Emmendorfer <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Yes – self reported data from the field.

Attached is a copy of the full Somatic Treatment Field Assessment – ketamine for MH is section III.

AMERICAN OVERSIGHT

From: Emmendorfer, Thomas (PBM)
Sent: Thursday, March 07, 2019 7:00 AM
To: Wiechers, Ilse (b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Hi Ilse,

Thank you very much for the information below!

Will the updated data also include any info on number of Veterans that have received ketamine for treatment of MH conditions?

Tom

From: "Wiechers, Ilse" (b6) @va.gov>
Date: Thursday, March 7, 2019 at 9:55 AM
To: "Carroll, David (VACO)" <(b6) va.gov>, Thomas Emmendorfer <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Below are the sites reporting use in FY15 from the assessment we did of the field back in fall 2016. The 2019 assessment went to the field in Feb and we are working to gather the final data from sites now. Hope to have updated data about sites using IV ketamine for treatment of MH conditions sometime later this month.

1-(689) VA Connecticut HCS, CT
18-(501) New Mexico HCS
23-(618) Minneapolis, MN
1-(523) VA Boston HCS, MA
6-(659) Salisbury, NC
12-(607) Madison, WI
16-(580) Houston, TX
21-(662) San Francisco, CA

Best,
Ilse

From: Carroll, David (VACO)
Sent: Thursday, March 07, 2019 6:39 AM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Wiechers, Ilse (b6) @va.gov>

AMERICAN OVERSIGHT

Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

I do not. Ilse may have a list or can otherwise find out.

From: Emmendorfer, Thomas (PBM)
Sent: Thursday, March 7, 2019 9:25 AM
To: Carroll, David (VACO) <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Hi Dave,

The briefing went very well. By chance, do you have a list of known VA medical facilities that are using intravenous ketamine for the treatment of refractory depression?

Thank you,

Tom

From: Thomas Emmendorfer <(b6) va.gov>
Date: Thursday, March 7, 2019 at 7:45 AM
To: Jon Jensen <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Beck, Lucille B." <(b6) va.gov>, "Howard, Kristi" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Will do.

From: Jon Jensen <(b6) va.gov>
Date: Thursday, March 7, 2019 at 7:41 AM
To: Thomas Emmendorfer <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Beck, Lucille B." <(b6) va.gov>, "Howard, Kristi" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

AMERICAN OVERSIGHT

Tom, can you come to Morning Report today to discuss? Starts at 9:30.

From: Emmendorfer, Thomas (PBM)
Sent: Wednesday, March 06, 2019 10:15 PM
To: Jensen, Jon M. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Howard, Kristi <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Hi Jon,

I hope all is going well. Below is the information that Jenn, Mike, and I pulled together for you. Let us know if you need anything else.

Tom

(b) (5)

AMERICAN OVERSIGHT

- (b) (5)

From: Jensen, Jon M.
Sent: Wednesday, March 06, 2019 7:50 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Howard, Kristi <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Thanks Tom!

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:49 PM
To: Jensen, Jon M. <(b6) va.gov>, Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Hi Jon,

We will work on it and get a response back.

Tom

Sent with BlackBerry Work
(www.blackberry.com)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:34 PM

AMERICAN OVERSIGHT

To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Adding Jennifer

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:27 PM
To: Valentino, Michael (VACO) (b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Just spoke to Dr Stone. We need to get something a little earlier than 10. As soon as you can would be fantastic.
Secva has asked for an update.

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 5:40 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: HHS bought a nasal spray for depression

Good evening, need some information on a nasal spray used for depression? POTUS heard HHS recently purchased and he felt it would be great for us. That's all I got. Can you pull info on what it would be, if we purchase currently, if we are looking into it etc. would sure appreciate anything you could provide by 10am.

Jon Jensen

AMERICAN OVERSIGHT

VHA Acting Deputy Chief of Staff
(b6)
(b6)

Sender:	Wiechers, Ilse /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0C7B1428D9E4233A641F125C5B6FC4F-WIECHERS, I <(b6) va.gov>
Recipient:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>
Sent Date:	2019/03/08 13:10:33
Delivered Date:	2019/03/08 13:10:34

AMERICAN OVERSIGHT

From:	Emmendorfer, Thomas (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC96BB44E7AE2C94C43B55D094-EMMENDORFER <(b6) va.gov>
To:	Howard, Kristi /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8d0afc371994181883d8861127791c3-Howard, Kri <(b6) va.gov>; Beck, Lucille B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=845480228a8b43e7a5fef5716ded04c2-Beck, Lucil <(b6) va.gov>; Jensen, Jon M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddeb735ace76400db5c3f10603188a14-Jensen, Jon <(b6) va.gov>
CC:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) @va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) va.gov>; Law, Cassandra M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f888d507d6c54eb5a92fc44199eb5838-Law, Cassan <(b6) va.gov>
Subject:	Re: HHS bought a nasal spray for depression
Date:	2019/03/07 08:08:29
Priority:	Normal
Type:	Note

Yes.

From: "Howard, Kristi" <(b6) va.gov>
Date: Thursday, March 7, 2019 at 8:08 AM
To: Thomas Emmendorfer <(b6) va.gov>, "Beck, Lucille B." <(b6) va.gov>, Jon Jensen <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>, "Howard, Kristi" <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Dr. Stone is actually going up to talk to the Secretary about this at 9:30am, so can you come at 9am to discuss? We will send a calendar invite. Thanks!

From: Emmendorfer, Thomas (PBM)
Sent: Thursday, March 07, 2019 8:07 AM
To: Beck, Lucille B. <(b6) va.gov>; Jensen, Jon M. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO)

AMERICAN OVERSIGHT

<(b6) va.gov>; Howard, Kristi <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Thank you Lu.

From: "Beck, Lucille B." <(b6) va.gov>
Date: Thursday, March 7, 2019 at 8:05 AM
To: Jon Jensen <(b6) va.gov>, Thomas Emmendorfer <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Howard, Kristi" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Questions being asked?

So, will it be available in VA?

Is it now?

What training is needed to implement?

Lucille B. Beck, Ph.D.
Deputy Under Secretary for Health
for Policy and Services (10P)
VA Central Office
Phone (b6)

Sent with BlackBerry Work
(www.blackberry.com).

From: Jensen, Jon M. <(b6) va.gov>
Date: Thursday, Mar 07, 2019, 7:41 AM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>, Llorente, Maria D. <(b6) va.gov>, Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

AMERICAN OVERSIGHT

Tom, can you come to Morning Report today to discuss? Starts at 9:30.

From: Emmendorfer, Thomas (PBM)
Sent: Wednesday, March 06, 2019 10:15 PM
To: Jensen, Jon M. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Howard, Kristi <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Hi Jon,

I hope all is going well. Below is the information that Jenn, Mike, and I pulled together for you. Let us know if you need anything else.

Tom

(b) (5)

AMERICAN OVERSIGHT

- (b) (5)

From: Jensen, Jon M.
Sent: Wednesday, March 06, 2019 7:50 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Howard, Kristi <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Thanks Tom!

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:49 PM
To: Jensen, Jon M. <(b6) va.gov>, Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Hi Jon,

We will work on it and get a response back.

Tom

Sent with BlackBerry Work
(www.blackberry.com)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:34 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

AMERICAN OVERSIGHT

Adding Jennifer

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:27 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Just spoke to Dr Stone. We need to get something a little earlier than 10. As soon as you can would be fantastic.
Secva has asked for an update.

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 5:40 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Krist(b6) @va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: HHS bought a nasal spray for depression

Good evening, need some information on a nasal spray used for depression? POTUS heard HHS recently purchased and he felt it would be great for us. That's all I got. Can you pull info on what it would be, if we purchase currently, if we are looking into it etc. would sure appreciate anything you could provide by 10am.

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

Sender:	Emmendorfer, Thomas (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC96BB44E7AE2C94C43B55D094-EMMENDORFER <(b6) va.gov>
Recipient:	Howard, Kristi /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8d0afc371994181883d8861127791c3-Howard, Kri

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	<(b6) va.gov>; Beck, Lucille B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=845480228a8b43e7a5fef5716ded04c2-Beck, Lucil <(b6) va.gov>; Jensen, Jon M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddeb735ace76400db5c3f10603188a14-Jensen, Jon <(b6) va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) va.gov>; Law, Cassandra M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f888d507d6c54eb5a92fc44199eb5838-Law, Cassan <(b6) va.gov>
Sent Date:	2019/03/07 08:08:27
Delivered Date:	2019/03/07 08:08:29

AMERICAN OVERSIGHT

From:	Carroll, David (VACO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=95E14EBD3B6745C8952A823B04DABFF5-CARROLL, DA>
To:	Boyd, Teresa D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6886a7d555a43e0bee23c1e40e1c234-Boyd, Teres <(b6) va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) va.gov>; Outlaw, William N. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3e1067978634fbf96a382bdcd5c1115-Outlaw, Wil <(b6) va.gov>; O'Toole, Thomas P.(b6) va.gov </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c5a34d8a4b294e9986ef6e1aa8009b3f-O'Toole, Th>
CC:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>; Law, Cassandra M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f888d507d6c54eb5a92fc44199eb5838-Law, Cassan <(b6) va.gov>; Meyer, Laurence /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=56f0ba2c110d4e60863b66f9728f669d-Meyer, Laur <(b6) va.gov>; Denietolis, Angela L. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b51b87cff64f4354b78eb943f97b47f3-Denietolis, <(b6) va.gov>
Subject:	RE: HHS bought a nasal spray for depression
Date:	2019/03/11 07:48:00
Priority:	Normal
Type:	Note

Great analysis using the data we have available. Interested to see the breakdown by station. Thanks.

From: Boyd, Teresa D.
Sent: Monday, March 11, 2019 5:17 AM
To: Wiechers, Ilse <(b6) @va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N.(b6) 2@va.gov>; O'Toole, Thomas P. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. (b6) va.gov>; Meyer, Laurence <(b6) va.gov>; Denietolis, Angela L. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

AMERICAN OVERSIGHT

Great work, Ilse! Gives the agency the overall potential demand (and costing), and suspect sites will want to know their potential local demand. Really appreciate the great work by PBM to coordinate this work and Dr. Llorente.

Teresa

Sent with BlackBerry Work
(www.blackberry.com)

From: Wiechers, Ilse (b6) va.gov>
Date: Sunday, Mar 10, 2019, 10:05 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>, Llorente, Maria D. <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Outlaw, William N. <(b6) va.gov>, O'Toole, Thomas P. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>, Law, Cassandra M. <(b6) va.gov>, Boyd, Teresa D. <(b6) va.gov>, Meyer, Laurence <(b6) va.gov>, Denietolis, Angela L. <(b6) s@va.gov>
Subject: RE: HHS bought a nasal spray for depression

Hello everyone –

Here is what I've been able to pull together with PERC to answer the request "define the universe of patients that may meet the criteria for prescribing of Spravato®."

(b) (5)

AMERICAN OVERSIGHT

If this seems like a reasonable approach, we will run this data by homestation, which will give us the #s for each VAMC.

Ilse

From: Emmendorfer, Thomas (PBM)
Sent: Friday, March 08, 2019 12:57 PM
To: Llorente, Maria D. <(b6) va.gov>; Wiechers, Ilse (b6) @va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. <(b6) va.gov>; O'Toole, Thomas P. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>; Meyer, Laurence <(b6) va.gov>; Denietolis, Angela L. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Summary of Actions for Spravato® (esketamine) to date

OPEN:

1. • CMO Call:
    a. • (b) (5) [redacted]

AMERICAN OVERSIGHT

i. (b) (5) [redacted]

[redacted]

From: "Llorente, Maria D." <(b6) va.gov>
Date: Friday, March 8, 2019 at 1:47 PM
To: "Wiechers, Ilse" (b6) @va.gov>, Thomas Emmendorfer <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Outlaw, William N." (b6) @va.gov>
Cc: Michael Valentino <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Very helpful. Thank you!

From: Wiechers, Ilse
Sent: Friday, March 8, 2019 1:47 PM
To: Llorente, Maria D. <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. <William.Outlaw2@va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Will do.

AMERICAN OVERSIGHT

I've spoken to several private ketamine clinics in recent years, and the only physician type missing on your list that I have heard about is ED physicians. I also know of several clinics using APRNs under the supervision of one of those physicians listed below.

From: Llorente, Maria D.
Sent: Friday, March 08, 2019 10:43 AM
To: Wiechers, Ilse (b6) @va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Yes, if you could. My understanding is that in private sector, psychiatrists, anesthesiologists, neurologists, and pain medicine providers may administer. This is in part because IV ketamine is also used for intractable pain.

From: Wiechers, Ilse
Sent: Friday, March 8, 2019 1:29 PM
To: Llorente, Maria D. <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. (b6) @va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

We do not have information on that. I can follow up on the responses to the Somatic Treatment Field Assessment and reach out to facilities that report providing IV ketamine and ask them.

From: Llorente, Maria D.
Sent: Friday, March 08, 2019 10:23 AM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Wiechers, Ilse (b6) @va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. (b6) @va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Ilse, do you know if all the current VA providers who administer IV ketamine for treatment resistant depression are psychiatrists? Do we have any anesthesiologists for example?

From: Emmendorfer, Thomas (PBM)
Sent: Friday, March 8, 2019 12:50 PM
To: Llorente, Maria D. <(b6) va.gov>; Wiechers, Ilse (b6) .gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. (b6) @va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM)

AMERICAN OVERSIGHT

<(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Thank you Ilse!

I just sent the internal communications document to Jenn for review (setup as a FAQ). When she is done with her review and edits she will send it over to you.

Tom

From: "Llorente, Maria D." <(b6) va.gov>
Date: Friday, March 8, 2019 at 12:08 PM
To: "Wiechers, Ilse" (b6) @va.gov>, Thomas Emmendorfer <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Outlaw, William N." <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Thank you all very much.

From: Wiechers, Ilse
Sent: Friday, March 8, 2019 12:04 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Tom –

I'll reach out to Ethics to get things started. Happy to look at draft documents whenever you and Jenn have something ready to share.

Best,
Ilse

From: Emmendorfer, Thomas (PBM)
Sent: Friday, March 08, 2019 8:02 AM
To: Wiechers, Ilse <(b6) @va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William (b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

AMERICAN OVERSIGHT

Hi Ilse,

Dave and I spoke this morning after the briefing to Dr. Stone. Action items

- • Mental Health and PBM to start working together with the Comms team to develop internal/external communication.
    - • NEXT STEPS: Jenn Z. and I can work with you on the communication. Jenn and I will send you over a draft document to review.
- • iMed Consent: At morning report-Ethics asked if Spravato will need an iMed Consent.
    - • NEXT STEPS: Could you contact Ethics and work with them to determine and develop an imed consent (if needed) for Spravato?

Bill,

I adding you to the e-mail as well as we will need your assistance with getting the external communication through the process.

Thank you!

Tom

From: "Wiechers, Ilse" (b6) @va.gov>
Date: Thursday, March 7, 2019 at 10:04 AM
To: Thomas Emmendorfer <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Yes – self reported data from the field.

Attached is a copy of the full Somatic Treatment Field Assessment – ketamine for MH is section III.

From: Emmendorfer, Thomas (PBM)
Sent: Thursday, March 07, 2019 7:00 AM
To: Wiechers, Ilse <(b6) s@va.gov>; Carroll, David (VACO) <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Hi Ilse,

Thank you very much for the information below!

AMERICAN OVERSIGHT

Will the updated data also include any info on number of Veterans that have received ketamine for treatment of MH conditions?

Tom

From: "Wiechers, Ilse" <I(b6) @va.gov>
Date: Thursday, March 7, 2019 at 9:55 AM
To: "Carroll, David (VACO)" (b6) va.gov>, Thomas Emmendorfer <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." (b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Below are the sites reporting use in FY15 from the assessment we did of the field back in fall 2016. The 2019 assessment went to the field in Feb and we are working to gather the final data from sites now. Hope to have updated data about sites using IV ketamine for treatment of MH conditions sometime later this month.

1-(689) VA Connecticut HCS, CT
18-(501) New Mexico HCS
23-(618) Minneapolis, MN
1-(523) VA Boston HCS, MA
6-(659) Salisbury, NC
12-(607) Madison, WI
16-(580) Houston, TX
21-(662) San Francisco, CA

Best,
Ilse

From: Carroll, David (VACO)
Sent: Thursday, March 07, 2019 6:39 AM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Wiechers, Ilse (b6) .@va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

I do not. Ilse may have a list or can otherwise find out.

From: Emmendorfer, Thomas (PBM)
Sent: Thursday, March 7, 2019 9:25 AM
To: Carroll, David (VACO) <(b6) va.gov>

AMERICAN OVERSIGHT

Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Hi Dave,

The briefing went very well. By chance, do you have a list of known VA medical facilities that are using intravenous ketamine for the treatment of refractory depression?

Thank you,

Tom

From: Thomas Emmendorfer <(b6) va.gov>
Date: Thursday, March 7, 2019 at 7:45 AM
To: Jon Jensen <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Beck, Lucille B." <(b6) va.gov>, "Howard, Kristi" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Will do.

From: Jon Jensen <(b6) va.gov>
Date: Thursday, March 7, 2019 at 7:41 AM
To: Thomas Emmendorfer <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Beck, Lucille B." <(b6) va.gov>, "Howard, Kristi" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Tom, can you come to Morning Report today to discuss? Starts at 9:30.

From: Emmendorfer, Thomas (PBM)
Sent: Wednesday, March 06, 2019 10:15 PM
To: Jensen, Jon M. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Howard, Kristi <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

AMERICAN OVERSIGHT

Hi Jon,

I hope all is going well. Below is the information that Jenn, Mike, and I pulled together for you. Let us know if you need anything else.

Tom

(b) (5)

[redacted]

From: Jensen, Jon M.
Sent: Wednesday, March 06, 2019 7:50 PM

AMERICAN OVERSIGHT

To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Howard, Kristi <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Thanks Tom!

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:49 PM
To: Jensen, Jon M. <(b6) va.gov>, Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Hi Jon,

We will work on it and get a response back.

Tom

Sent with BlackBerry Work
(www.blackberry.com)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:34 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Adding Jennifer

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:27 PM

AMERICAN OVERSIGHT

To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Just spoke to Dr Stone. We need to get something a little earlier than 10. As soon as you can would be fantastic.
Secva has asked for an update.

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 5:40 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: HHS bought a nasal spray for depression

Good evening, need some information on a nasal spray used for depression? POTUS heard HHS recently purchased and he felt it would be great for us. That's all I got. Can you pull info on what it would be, if we purchase currently, if we are looking into it etc. would sure appreciate anything you could provide by 10am.

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

Sender:	Carroll, David (VACO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=95E14EBD3B6745C8952A823B04DABFF5-CARROLL, DA>
Recipient:	Boyd, Teresa D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6886a7d555a43e0bee23c1e40e1c234-Boyd, Teres <(b6) va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b6) @va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) va.gov>; Outlaw, William N. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3e1067978634fbf96a382bdcd5c1115-Outlaw, Wil <(b6) va.gov>; O'Toole, Thomas P.(b6) va.gov </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c5a34d8a4b294e9986ef6e1aa8009b3f-O'Toole, Th>;

AMERICAN OVERSIGHT

	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>; Law, Cassandra M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f888d507d6c54eb5a92fc44199eb5838-Law, Cassan <(b6) va.gov>; Meyer, Laurence /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=56f0ba2c110d4e60863b66f9728f669d-Meyer, Laur <(b6) va.gov>; Denietolis, Angela L. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b51b87cff64f4354b78eb943f97b47f3-Denietolis, <(b6) va.gov>
Sent Date:	2019/03/11 07:48:20
Delivered Date:	2019/03/11 07:48:00

AMERICAN OVERSIGHT

From:	Llorente, Maria D. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F5C91F577D894BD9A0F09305DB34DD4F-LLORENTE, M <(b6) va.gov>
To:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; O'Toole, Thomas P.(b6) va.gov </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c5a34d8a4b294e9986ef6e1aa8009b3f-O'Toole, Th>
CC:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Boyd, Teresa D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6886a7d555a43e0bee23c1e40e1c234-Boyd, Teres <(b6) va.gov>; Davis, Lashelle (VHACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0c9bffd03b3b47daa8b6db6f8933a7e7-Davis, Lash (l(b6) va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>
Subject:	RE: HHS bought a nasal spray for depression
Date:	2019/03/08 16:52:56
Priority:	Normal
Type:	Note

Thank you all very much.

From: Emmendorfer, Thomas (PBM)
Sent: Friday, March 8, 2019 4:16 PM
To: O'Toole, Thomas P. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>; Davis, Lashelle (VHACO) (l(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Thank you Tom!

Lashelle,

Could you please send the calendar invite to Maria, Mike, and Dave as well?

Topic: Spravato® (esketamine)
Time: 15 minutes

Slides/Handouts: Work in progress.

AMERICAN OVERSIGHT

From: "O'Toole, Thomas P." <(b6) va.gov>
Date: Friday, March 8, 2019 at 4:11 PM
To: Thomas Emmendorfer <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, "Boyd, Teresa D." <(b6) va.gov>, "Davis, Lashelle (VHACO)" <(b6) a.gov>
Subject: RE: HHS bought a nasal spray for depression

Good - we'll make it work.

Lashelle - can you please add Dr. Emmendorfer to the agenda.
Tom - if you have any slides or handouts, please forward to Lashelle Davis and she can get them out to the group.

Sent with BlackBerry Work
(www.blackberry.com)

From: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Date: Friday, Mar 08, 2019, 4:08 PM
To: O'Toole, Thomas P. <(b6) va.gov>, Llorente, Maria D. <(b6) va.gov>, Wiechers, Ilse <(b6) @va.gov>, Carroll, David (VACO) <(b6) va.gov>, Outlaw, William N. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>, Law, Cassandra M. <(b6) va.gov>, Boyd, Teresa D. <(b6) va.gov>, Meyer, Laurence <(b6) va.gov>, Denietolis, Angela L. <(b6) va.gov>, Davis, Lashelle (VHACO) <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Hi Tom,

This topic is pretty hot so this upcoming Monday will work.

Thank you!

Tom

From: "O'Toole, Thomas P." <(b6) va.gov>
Date: Friday, March 8, 2019 at 4:01 PM
To: Thomas Emmendorfer <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Wiechers, Ilse" <(b6) @va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Outlaw, William N." (b6) @va.gov>
Cc: Michael Valentino <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>, "Boyd, Teresa D." <(b6) va.gov>, "Meyer, Laurence" <(b6) va.gov>, "Denietolis, Angela L." <(b6) va.gov>, "Davis, Lashelle (VHACO)" <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

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Hi Tom - we can definitely get you on the CMO call for this upcoming Monday at 2pm- if you think you need more prep time, let me know and we can push it back to the 18th
Ton

Sent with BlackBerry Work
(www.blackberry.com)

From: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Date: Friday, Mar 08, 2019, 3:57 PM
To: Llorente, Maria D. <(b6) va.gov>, Wiechers, Ilse (b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Outlaw, William N. (b6) @va.gov>, O'Toole, Thomas P. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>, Law, Cassandra M. <(b6) va.gov>, Boyd, Teresa D. <(b6) va.gov>, Meyer, Laurence <(b6) va.gov>, Denietolis, Angela L. (b6) .gov>
Subject: Re: HHS bought a nasal spray for depression

Summary of Actions for Spravato® (esketamine) to date

OPEN:

1. • CMO Call:
    a. • (b) (5)

AMERICAN OVERSIGHT



From: "Llorente, Maria D." <(b6) va.gov>
Date: Friday, March 8, 2019 at 1:47 PM
To: "Wiechers, Ilse" (b6) va.gov>, Thomas Emmendorfer <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Outlaw, William N." <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Very helpful. Thank you!

From: Wiechers, Ilse
Sent: Friday, March 8, 2019 1:47 PM
To: Llorente, Maria D. <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. (b6) @va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM)

AMERICAN OVERSIGHT

<(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Will do.

I've spoken to several private ketamine clinics in recent years, and the only physician type missing on your list that I have heard about is ED physicians. I also know of several clinics using APRNs under the supervision of one of those physicians listed below.

From: Llorente, Maria D.
Sent: Friday, March 08, 2019 10:43 AM
To: Wiechers, Ilse(b6) .gov>; Emmendorfer, Thomas (PBM)
<(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N.
(b6) @va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM)
<(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Yes, if you could. My understanding is that in private sector, psychiatrists, anesthesiologists, neurologists, and pain medicine providers may administer. This is in part because IV ketamine is also used for intractable pain.

From: Wiechers, Ilse
Sent: Friday, March 8, 2019 1:29 PM
To: Llorente, Maria D. <(b6) va.gov>; Emmendorfer, Thomas (PBM)
<(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N.
(b6) @va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM)
<(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

We do not have information on that. I can follow up on the responses to the Somatic Treatment Field Assessment and reach out to facilities that report providing IV ketamine and ask them.

From: Llorente, Maria D.
Sent: Friday, March 08, 2019 10:23 AM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Wiechers, Ilse
(b6) @va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N.
(b6) @va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM)
<(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Ilse, do you know if all the current VA providers who administer IV ketamine for treatment resistant depression are psychiatrists? Do we have any anesthesiologists for example?

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From: Emmendorfer, Thomas (PBM)
Sent: Friday, March 8, 2019 12:50 PM
To: Llorente, Maria D. <(b6) va.gov>; Wiechers, Ilse (b6) a.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. (b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Thank you Ilse!

I just sent the internal communications document to Jenn for review (setup as a FAQ). When she is done with her review and edits she will send it over to you.

Tom

From: "Llorente, Maria D." <(b6) va.gov>
Date: Friday, March 8, 2019 at 12:08 PM
To: "Wiechers, Ilse" (b6) @va.gov>, Thomas Emmendorfer <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Outlaw, William N." <(b6) @va.gov>
Cc: Michael Valentino <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Thank you all very much.

From: Wiechers, Ilse
Sent: Friday, March 8, 2019 12:04 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. <William.Outlaw2@va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Tom –

I'll reach out to Ethics to get things started. Happy to look at draft documents whenever you and Jenn have something ready to share.

Best,
Ilse

From: Emmendorfer, Thomas (PBM)
Sent: Friday, March 08, 2019 8:02 AM
To: Wiechers, Ilse (b6) gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw,

AMERICAN OVERSIGHT

William N. (b6) 2@va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Hi Ilse,

Dave and I spoke this morning after the briefing to Dr. Stone. Action items

- • Mental Health and PBM to start working together with the Comms team to develop internal/external communication.
    - • NEXT STEPS: Jenn Z. and I can work with you on the communication. Jenn and I will send you over a draft document to review.
- • iMed Consent: At morning report-Ethics asked if Spravato will need an iMed Consent.
    - • NEXT STEPS: Could you contact Ethics and work with them to determine and develop an imed consent (if needed) for Spravato?

Bill,

I adding you to the e-mail as well as we will need your assistance with getting the external communication through the process.

Thank you!

Tom

From: "Wiechers, Ilse" (b6) .gov>
Date: Thursday, March 7, 2019 at 10:04 AM
To: Thomas Emmendorfer <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Yes – self reported data from the field.

Attached is a copy of the full Somatic Treatment Field Assessment – ketamine for MH is section III.

From: Emmendorfer, Thomas (PBM)
Sent: Thursday, March 07, 2019 7:00 AM
To: Wiechers, Ilse (b6) @va.gov>; Carroll, David (VACO) <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M.

AMERICAN OVERSIGHT

<(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Hi Ilse,

Thank you very much for the information below!

Will the updated data also include any info on number of Veterans that have received ketamine for treatment of MH conditions?

Tom

From: "Wiechers, Ilse" (b6) ov>
Date: Thursday, March 7, 2019 at 9:55 AM
To: "Carroll, David (VACO)" <(b6) va.gov>, Thomas Emmendorfer <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Below are the sites reporting use in FY15 from the assessment we did of the field back in fall 2016. The 2019 assessment went to the field in Feb and we are working to gather the final data from sites now. Hope to have updated data about sites using IV ketamine for treatment of MH conditions sometime later this month.

1-(689) VA Connecticut HCS, CT
18-(501) New Mexico HCS
23-(618) Minneapolis, MN
1-(523) VA Boston HCS, MA
6-(659) Salisbury, NC
12-(607) Madison, WI
16-(580) Houston, TX
21-(662) San Francisco, CA

Best,
Ilse

From: Carroll, David (VACO)
Sent: Thursday, March 07, 2019 6:39 AM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Wiechers, Ilse (b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

I do not. Ilse may have a list or can otherwise find out.

From: Emmendorfer, Thomas (PBM)
Sent: Thursday, March 7, 2019 9:25 AM
To: Carroll, David (VACO) <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Hi Dave,

The briefing went very well. By chance, do you have a list of known VA medical facilities that are using intravenous ketamine for the treatment of refractory depression?

Thank you,

Tom

From: Thomas Emmendorfer <(b6) va.gov>
Date: Thursday, March 7, 2019 at 7:45 AM
To: Jon Jensen <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Beck, Lucille B." <(b6) va.gov>, "Howard, Kristi" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Will do.

From: Jon Jensen <(b6) va.gov>
Date: Thursday, March 7, 2019 at 7:41 AM
To: Thomas Emmendorfer <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Beck, Lucille B." <(b6) va.gov>, "Howard, Kristi" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Tom, can you come to Morning Report today to discuss? Starts at 9:30.

From: Emmendorfer, Thomas (PBM)
Sent: Wednesday, March 06, 2019 10:15 PM
To: Jensen, Jon M. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO)

AMERICAN OVERSIGHT

<(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Howard, Kristi <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Hi Jon,

I hope all is going well. Below is the information that Jenn, Mike, and I pulled together for you. Let us know if you need anything else.

Tom

(b) (5)

AMERICAN OVERSIGHT

- (b) (5) [redacted]

From: Jensen, Jon M.
Sent: Wednesday, March 06, 2019 7:50 PM
To: Emmendorfer, Thomas (PBM) <(b6) [redacted]va.gov>; Valentino, Michael (VACO) <(b6) [redacted]va.gov>; Carroll, David (VACO) <(b6) [redacted]va.gov>; Beck, Lucille B. <(b6) [redacted]va.gov>; Howard, Kristi <(b6) [redacted]va.gov>; Zacher, Jennifer L. (PBM) <(b6) [redacted]va.gov>
Subject: RE: HHS bought a nasal spray for depression

Thanks Tom!

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6) [redacted]
(b6) [redacted]

From: Emmendorfer, Thomas (PBM) <(b6) [redacted]va.gov>
Date: Wednesday, Mar 06, 2019, 7:49 PM
To: Jensen, Jon M. <(b6) [redacted]va.gov>, Valentino, Michael (VACO) <(b6) [redacted]va.gov>, Carroll, David (VACO) <(b6) [redacted]va.gov>, Beck, Lucille B. <(b6) [redacted]va.gov>, Howard, Kristi <(b6) [redacted]va.gov>, Zacher, Jennifer L. (PBM) <(b6) [redacted]va.gov>
Subject: RE: HHS bought a nasal spray for depression

Hi Jon,

We will work on it and get a response back.

Tom

Sent with BlackBerry Work
(www.blackberry.com)

From: Jensen, Jon M. <(b6) [redacted]va.gov>
Date: Wednesday, Mar 06, 2019, 7:34 PM
To: Valentino, Michael (VACO) <(b6) [redacted]va.gov>, Carroll, David (VACO) <(b6) [redacted]va.gov>, Beck, Lucille B. <(b6) [redacted]va.gov>, Howard, Kristi <(b6) [redacted]va.gov>, Emmendorfer, Thomas (PBM) <(b6) [redacted]va.gov>, Zacher, Jennifer L. (PBM) <(b6) [redacted]va.gov>
Subject: RE: HHS bought a nasal spray for depression

Adding Jennifer

Jon Jensen

AMERICAN OVERSIGHT

VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:27 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Just spoke to Dr Stone. We need to get something a little earlier than 10. As soon as you can would be fantastic.
Secva has asked for an update.

Jon Jensen
VHA Acting Deputy Chief of Staff
W:(b6)
(b6)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 5:40 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: HHS bought a nasal spray for depression

Good evening, need some information on a nasal spray used for depression? POTUS heard HHS recently purchased and he felt it would be great for us. That's all I got. Can you pull info on what it would be, if we purchase currently, if we are looking into it etc. would sure appreciate anything you could provide by 10am.

Jon Jensen
VHA Acting Deputy Chief of Staff
W:(b6)
(b6)

Sender:	Llorente, Maria D. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F5C91F577D894BD9A0F09305DB34DD4F-LLORENTE, M <(b6) va.gov>
Recipient:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; O'Toole, Thomas P.(b6) va.gov </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c5a34d8a4b294e9986ef6e1aa8009b3f-O'Toole, Th>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Boyd, Teresa D. /o=ExchangeLabs/ou=Exchange Administrative Group

AMERICAN OVERSIGHT

	(FYDIBOHF23SPDLT)/cn=Recipients/cn=f6886a7d555a43e0bee23c1e40e1c234-Boyd, Teres <(b6) va.gov>; Davis, Lashelle (VHACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0c9bffd03b3b47daa8b6db6f8933a7e7-Davis, Lash <(b6) va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>
Sent Date:	2019/03/08 16:52:55
Delivered Date:	2019/03/08 16:52:56

AMERICAN OVERSIGHT

From:	Carroll, David (VACO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=95E14EBD3B6745C8952A823B04DABFF5-CARROLL, DA>
To:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>
Subject:	RE: HHS bought a nasal spray for depression
Date:	2019/03/11 19:32:00
Priority:	Normal
Type:	Note

Thank you!

From: Wiechers, Ilse
Sent: Monday, March 11, 2019 7:30 PM
To: Llorente, Maria D. <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. (b6) @va.gov>; O'Toole, Thomas P. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>; Meyer, Laurence <(b6) va.gov>; Denietolis, Angela L. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Updates on data:

(b) (5)

).

Please let me know if you have any questions.

Ilse

From: Llorente, Maria D.
Sent: Monday, March 11, 2019 9:13 AM
To: Wiechers, Ilse (b6) Emmendorfer, Thomas (PBM)

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(b6)
va.gov>; O'Toole, Thomas P. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>; Meyer, Laurence <(b6) va.gov>; Denietolis, Angela L. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

HI, this is extremely helpful. Thank you.

From: Wiechers, Ilse
Sent: Monday, March 11, 2019 12:01 PM
To: Llorente, Maria D. <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. (b6) @va.gov>; O'Toole, Thomas P. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>; Meyer, Laurence <(b6) va.gov>; Denietolis, Angela L. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

(b) (5)

Ilse

From: Llorente, Maria D.
Sent: Monday, March 11, 2019 6:57 AM
To: Wiechers, Ilse (b6) @va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. <(b6) @va.gov>; O'Toole, Thomas P. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>; Meyer, Laurence <(b6) va.gov>; Denietolis, Angela L.

AMERICAN OVERSIGHT

<(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Great, thank you!!

From: Wiechers, Ilse
Sent: Monday, March 11, 2019 9:50 AM
To: Llorente, Maria D. <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. <(b6) va.gov>; O'Toole, Thomas P. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>; Meyer, Laurence <(b6) va.gov>; Denietolis, Angela L. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

I will have PERC rerun the national numbers with and without trazodone. And I have facility reported data on ECT use and also know NEPEC has pulled data based on CPT codes in the past. I'll work on getting those as well.

Ilse

Sent with BlackBerry Work
(www.blackberry.com)

From: Llorente, Maria D. <(b6) va.gov>
Date: Monday, Mar 11, 2019, 6:30 AM
To: Wiechers, Ilse (b6) @va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Outlaw, William N. <(b6) va.gov>, O'Toole, Thomas P. <(b6) va.gov>
Cc: Valentino, Michael (VACO) (b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>, Law, Cassandra M. <(b6) va.gov>, Boyd, Teresa D. <(b6) va.gov>, Meyer, Laurence <(b6) va.gov>, Denietolis, Angela L. (b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

I agree. (b) (5)
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From: Wiechers, Ilse
Sent: Monday, March 11, 2019 9:28 AM
To: Llorente, Maria D. <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. <(b6) 2@va.gov>; O'Toole, Thomas P. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>; Meyer, Laurence <(b6) va.gov>; Denietolis, Angela L.

AMERICAN OVERSIGHT

<(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

(b) (5)
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Sent with BlackBerry Work
(www.blackberry.com)

From: Llorente, Maria D. <(b6) va.gov>
Date: Monday, Mar 11, 2019, 5:02 AM
To: Wiechers, Ilse (b6) @va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Outlaw, William N. <(b6) va.gov>, O'Toole, Thomas P. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>, Law, Cassandra M. <(b6) va.gov>, Boyd, Teresa D. <(b6) va.gov>, Meyer, Laurence <(b6) va.gov>, Denietolis, Angela L. (b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Thank you very much. (b) (5)
.

From: Wiechers, Ilse
Sent: Sunday, March 10, 2019 10:06 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. (b6) @va.gov>; O'Toole, Thomas P. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>; Meyer, Laurence <(b6) va.gov>; Denietolis, Angela L. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Hello everyone –

Here is what I've been able to pull together with PERC to answer the request "define the universe of patients that may meet the criteria for prescribing of Spravato®."

(b) (5)

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- (b) (5) [redacted]

If this seems like a reasonable approach, we will run this data by homestation, which will give us the #s for each VAMC.

Ilse

From: Emmendorfer, Thomas (PBM)
Sent: Friday, March 08, 2019 12:57 PM
To: Llorente, Maria D. <(b6) [redacted]va.gov>; Wiechers, Ilse (b6) [redacted]@va.gov>; Carroll, David (VACO) <(b6) [redacted]va.gov>; Outlaw, William N. (b6) [redacted]@va.gov>; O'Toole, Thomas P. <(b6) [redacted]va.gov>
Cc: Valentino, Michael (VACO) <(b6) [redacted]va.gov>; Zacher, Jennifer L. (PBM) <(b6) [redacted]va.gov>; Law, Cassandra M. <(b6) [redacted]va.gov>; Boyd, Teresa D. <(b6) [redacted]va.gov>; Meyer, Laurence <(b6) [redacted]va.gov>; Denietolis, Angela L. <(b6) [redacted]va.gov>
Subject: Re: HHS bought a nasal spray for depression

Summary of Actions for Spravato® (esketamine) to date

OPEN:

1. (b) (5) [redacted]

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From: "Llorente, Maria D." <(b6) va.gov>
Date: Friday, March 8, 2019 at 1:47 PM
To: "Wiechers, Ilse" (b6) @va.gov>, Thomas Emmendorfer
<(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Outlaw,

AMERICAN OVERSIGHT

William N." (b6) @va.gov>
Cc: Michael Valentino <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Very helpful. Thank you!

From: Wiechers, Ilse
Sent: Friday, March 8, 2019 1:47 PM
To: Llorente, Maria D. <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. (b6) @va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Will do.

I've spoken to several private ketamine clinics in recent years, and the only physician type missing on your list that I have heard about is ED physicians. I also know of several clinics using APRNs under the supervision of one of those physicians listed below.

From: Llorente, Maria D.
Sent: Friday, March 08, 2019 10:43 AM
To: Wiechers, Ilse (b6) @va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. (b6) 2@va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Yes, if you could. My understanding is that in private sector, psychiatrists, anesthesiologists, neurologists, and pain medicine providers may administer. This is in part because IV ketamine is also used for intractable pain.

From: Wiechers, Ilse
Sent: Friday, March 8, 2019 1:29 PM
To: Llorente, Maria D. <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. (b6) 2@va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

We do not have information on that. I can follow up on the responses to the Somatic Treatment Field Assessment and reach out to facilities that report providing IV ketamine and ask them.

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From: Llorente, Maria D.
Sent: Friday, March 08, 2019 10:23 AM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Wiechers, Ilse (b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. (b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Ilse, do you know if all the current VA providers who administer IV ketamine for treatment resistant depression are psychiatrists? Do we have any anesthesiologists for example?

From: Emmendorfer, Thomas (PBM)
Sent: Friday, March 8, 2019 12:50 PM
To: Llorente, Maria (b6) va.gov>; Wiechers, Ilse (b6) @va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. (b6) @va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Thank you Ilse!

I just sent the internal communications document to Jenn for review (setup as a FAQ). When she is done with her review and edits she will send it over to you.

Tom

From: "Llorente, Maria D." <(b6) va.gov>
Date: Friday, March 8, 2019 at 12:08 PM
To: "Wiechers, Ilse" (b6) @va.gov>, Thomas Emmendorfer <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Outlaw, William N." (b6) @va.gov>
Cc: Michael Valentino <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Thank you all very much.

From: Wiechers, Ilse
Sent: Friday, March 8, 2019 12:04 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. (b6) @va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

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Tom –

I'll reach out to Ethics to get things started. Happy to look at draft documents whenever you and Jenn have something ready to share.

Best,
Ilse

From: Emmendorfer, Thomas (PBM)
Sent: Friday, March 08, 2019 8:02 AM
To: Wiechers, Ilse (b6) @va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. (b6) @va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Hi Ilse,

Dave and I spoke this morning after the briefing to Dr. Stone. Action items

- • Mental Health and PBM to start working together with the Comms team to develop internal/external communication.
    - • NEXT STEPS: Jenn Z. and I can work with you on the communication. Jenn and I will send you over a draft document to review.
- • iMed Consent: At morning report-Ethics asked if Spravato will need an iMed Consent.
    - • NEXT STEPS: Could you contact Ethics and work with them to determine and develop an imed consent (if needed) for Spravato?

Bill,

I adding you to the e-mail as well as we will need your assistance with getting the external communication through the process.

Thank you!

Tom

From: "Wiechers, Ilse" (b6) va.gov>
Date: Thursday, March 7, 2019 at 10:04 AM
To: Thomas Emmendorfer <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

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Yes – self reported data from the field.

Attached is a copy of the full Somatic Treatment Field Assessment – ketamine for MH is section III.

From: Emmendorfer, Thomas (PBM)
Sent: Thursday, March 07, 2019 7:00 AM
To: Wiechers, Ilse (b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Hi Ilse,

Thank you very much for the information below!

Will the updated data also include any info on number of Veterans that have received ketamine for treatment of MH conditions?

Tom

From: "Wiechers, Ilse" (b6) @va.gov>
Date: Thursday, March 7, 2019 at 9:55 AM
To: "Carroll, David (VACO)" <(b6) va.gov>, Thomas Emmendorfer <(b6) @va.gov>
Cc: Michael Valentino <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Below are the sites reporting use in FY15 from the assessment we did of the field back in fall 2016. The 2019 assessment went to the field in Feb and we are working to gather the final data from sites now. Hope to have updated data about sites using IV ketamine for treatment of MH conditions sometime later this month.

1-(689) VA Connecticut HCS, CT
18-(501) New Mexico HCS
23-(618) Minneapolis, MN
1-(523) VA Boston HCS, MA
6-(659) Salisbury, NC
12-(607) Madison, WI
16-(580) Houston, TX
21-(662) San Francisco, CA

Best,
Ilse

AMERICAN OVERSIGHT

From: Carroll, David (VACO)
Sent: Thursday, March 07, 2019 6:39 AM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Wiechers, Ilse (b6) @va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

I do not. Ilse may have a list or can otherwise find out.

From: Emmendorfer, Thomas (PBM)
Sent: Thursday, March 7, 2019 9:25 AM
To: Carroll, David (VACO) <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Hi Dave,

The briefing went very well. By chance, do you have a list of known VA medical facilities that are using intravenous ketamine for the treatment of refractory depression?

Thank you,

Tom

From: Thomas Emmendorfer <(b6) va.gov>
Date: Thursday, March 7, 2019 at 7:45 AM
To: Jon Jensen <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Beck, Lucille B." <(b6) va.gov>, "Howard, Kristi" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Will do.

From: Jon Jensen <(b6) va.gov>
Date: Thursday, March 7, 2019 at 7:41 AM
To: Thomas Emmendorfer <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)"

AMERICAN OVERSIGHT

<(b6) va.gov>, "Beck, Lucille B." <(b6) va.gov>, "Howard, Kristi" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Tom, can you come to Morning Report today to discuss? Starts at 9:30.

From: Emmendorfer, Thomas (PBM)
Sent: Wednesday, March 06, 2019 10:15 PM
To: Jensen, Jon M. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Howard, Kristi <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Hi Jon,

I hope all is going well. Below is the information that Jenn, Mike, and I pulled together for you. Let us know if you need anything else.

Tom

(b) (5)

AMERICAN OVERSIGHT

- (b) (5) [redacted]

From: Jensen, Jon M.
Sent: Wednesday, March 06, 2019 7:50 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Howard, Kristi <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Thanks Tom!

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:49 PM
To: Jensen, Jon M. <(b6) va.gov>, Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Hi Jon,

We will work on it and get a response back.

Tom

Sent with BlackBerry Work
(www.blackberry.com)

AMERICAN OVERSIGHT

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:34 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Adding Jennifer

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:27 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Just spoke to Dr Stone. We need to get something a little earlier than 10. As soon as you can would be fantastic.
Secva has asked for an update.

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 5:40 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: HHS bought a nasal spray for depression

Good evening, need some information on a nasal spray used for depression? POTUS heard HHS recently purchased and he felt it would be great for us. That's all I got. Can you pull info on what it would be, if we purchase currently, if we are looking into it etc. would sure appreciate anything you could provide by 10am.

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

AMERICAN OVERSIGHT

Sender:	Carroll, David (VACO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=95E14EBD3B6745C8952A823B04DABFF5-CARROLL, DA>
Recipient:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>
Sent Date:	2019/03/11 19:32:57
Delivered Date:	2019/03/11 19:32:00

AMERICAN OVERSIGHT

From:	Wiechers, Ilse /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0C7B1428D9E4233A641F125C5B6FC4F-WIECHERS, I <(b6) va.gov>
To:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; Boyd, Teresa D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6886a7d555a43e0bee23c1e40e1c234-Boyd, Teres <(b6) va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Outlaw, William N. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3e1067978634fbf96a382bdcd5c1115-Outlaw, Wil <(b6) va.gov>; O'Toole, Thomas P.(b6) va.gov </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c5a34d8a4b294e9986ef6e1aa8009b3f-O'Toole, Th>
CC:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>; Law, Cassandra M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f888d507d6c54eb5a92fc44199eb5838-Law, Cassan <(b6) va.gov>; Meyer, Laurence /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=56f0ba2c110d4e60863b66f9728f669d-Meyer, Laur <(b6) va.gov>; Denietolis, Angela L. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b51b87cff64f4354b78eb943f97b47f3-Denietolis, <(b6) va.gov>
Subject:	RE: HHS bought a nasal spray for depression
Date:	2019/03/11 09:30:43
Priority:	Normal
Type:	Note

Tom,
We don't really have a good way to pull the data on IV ketamine use. That is in part why we conducted the somatic treatment field assessment back in 2016 and now again this past month. I'll have data on reported number of patients treated with IV ketamine from the recent survey sometime soon. But the number reportedly treated in FY15 was 43 Veterans.
Ilse

Sent with BlackBerry Work
(www.blackberry.com)

From: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Date: Monday, Mar 11, 2019, 4:56 AM

AMERICAN OVERSIGHT

To: Boyd, Teresa D. <(b6) va.gov>, Wiechers, Ilse <(b6) va.gov>, Llorente, Maria D. <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Outlaw, William N. <(b6) va.gov>, O'Toole, Thomas P. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>, Law, Cassandra M. <(b6) va.gov>, Meyer, Laurence <(b6) va.gov>, Denietolis, Angela L. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Ilse,

This is great work. Could the PERC run a query for IV Ketamine users for treatment refractory depression?

We are getting requests for these data as well.

Thank you,

Tom

From: "Boyd, Teresa D." <(b6) va.gov>
Date: Monday, March 11, 2019 at 5:16 AM
To: "Wiechers, Ilse" <(b6) @va.gov>, Thomas Emmendorfer <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Outlaw, William N." <(b6) va.gov>, "O'Toole, Thomas P." <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>, "Meyer, Laurence" <(b6) va.gov>, "Denietolis, Angela L." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Great work, Ilse! Gives the agency the overall potential demand (and costing), and suspect sites will want to know their potential local demand. Really appreciate the great work by PBM to coordinate this work and Dr. Llorente.

Teresa

Sent with BlackBerry Work
(www.blackberry.com)

From: Wiechers, Ilse (b6) @va.gov>
Date: Sunday, Mar 10, 2019, 10:05 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>, Llorente, Maria D. <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Outlaw, William N. <(b6) va.gov>, O'Toole, Thomas P. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>, Law, Cassandra M. <(b6) va.gov>, Boyd, Teresa D.

AMERICAN OVERSIGHT

<(b6) va.gov>, Meyer, Laurence <(b6) va.gov>, Denietolis, Angela L. <(b6) .gov>
Subject: RE: HHS bought a nasal spray for depression

Hello everyone –

Here is what I've been able to pull together with PERC to answer the request "define the universe of patients that may meet the criteria for prescribing of Spravato®."

(b) (5)



If this seems like a reasonable approach, we will run this data by homestation, which will give us the #s for each VAMC.

Ilse

From: Emmendorfer, Thomas (PBM)
Sent: Friday, March 08, 2019 12:57 PM
To: Llorente, Maria D. <(b6) va.gov>; Wiechers, Ilse (b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. <(b6) @va.gov>; O'Toole, Thomas P. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>; Meyer, Laurence <(b6) va.gov>; Denietolis, Angela L. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Summary of Actions for Spravato® (esketamine) to date

AMERICAN OVERSIGHT

OPEN:

1. • (b) (5) [redacted]



AMERICAN OVERSIGHT

1. • (b) (5) [redacted]

From: "Llorente, Maria D." <(b6) [redacted] va.gov>
Date: Friday, March 8, 2019 at 1:47 PM
To: "Wiechers, Ilse" (b6) [redacted] @va.gov>, Thomas Emmendorfer <(b6) [redacted] va.gov>, "Carroll, David (VACO)" <(b6) [redacted] va.gov>, "Outlaw, William N." (b6) [redacted] @va.gov>
Cc: Michael Valentino <(b6) [redacted] va.gov>, Jennifer Zacher <(b6) [redacted] va.gov>, "Law, Cassandra M." <(b6) [redacted] va.gov>
Subject: RE: HHS bought a nasal spray for depression

Very helpful. Thank you!

From: Wiechers, Ilse
Sent: Friday, March 8, 2019 1:47 PM
To: Llorente, Maria D. <(b6) [redacted] va.gov>; Emmendorfer, Thomas (PBM) <(b6) [redacted] va.gov>; Carroll, David (VACO) <(b6) [redacted] va.gov>; Outlaw, William N. (b6) [redacted] @va.gov>
Cc: Valentino, Michael (VACO) <(b6) [redacted] va.gov>; Zacher, Jennifer L. (PBM) <(b6) [redacted] va.gov>; Law, Cassandra M. <(b6) [redacted] va.gov>
Subject: RE: HHS bought a nasal spray for depression

Will do.

I've spoken to several private ketamine clinics in recent years, and the only physician type missing on your list that I have heard about is ED physicians. I also know of several clinics using APRNs under the supervision of one of those physicians listed below.

From: Llorente, Maria D.
Sent: Friday, March 08, 2019 10:43 AM
To: Wiechers, Ilse (b6) [redacted] @va.gov>; Emmendorfer, Thomas (PBM) <(b6) [redacted] va.gov>; Carroll, David (VACO) <(b6) [redacted] va.gov>; Outlaw, William N. <(b6) [redacted] va.gov>
Cc: Valentino, Michael (VACO) <(b6) [redacted] va.gov>; Zacher, Jennifer L. (PBM) <(b6) [redacted] va.gov>; Law, Cassandra M. <(b6) [redacted] va.gov>
Subject: RE: HHS bought a nasal spray for depression

Yes, if you could. My understanding is that in private sector, psychiatrists, anesthesiologists, neurologists, and pain medicine providers may administer. This is in part because IV ketamine is also used for intractable pain.

AMERICAN OVERSIGHT

From: Wiechers, Ilse
Sent: Friday, March 8, 2019 1:29 PM
To: Llorente, Maria D. <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

We do not have information on that. I can follow up on the responses to the Somatic Treatment Field Assessment and reach out to facilities that report providing IV ketamine and ask them.

From: Llorente, Maria D.
Sent: Friday, March 08, 2019 10:23 AM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Wiechers, Ilse (b6) @va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. (b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Ilse, do you know if all the current VA providers who administer IV ketamine for treatment resistant depression are psychiatrists? Do we have any anesthesiologists for example?

From: Emmendorfer, Thomas (PBM)
Sent: Friday, March 8, 2019 12:50 PM
To: Llorente, Maria D. <(b6) va.gov>; Wiechers, Ilse (b6) >; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Thank you Ilse!

I just sent the internal communications document to Jenn for review (setup as a FAQ). When she is done with her review and edits she will send it over to you.

Tom

From: "Llorente, Maria D." <(b6) va.gov>
Date: Friday, March 8, 2019 at 12:08 PM
To: "Wiechers, Ilse" (b6) @va.gov>, Thomas Emmendorfer <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Outlaw, William N." (b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>,

AMERICAN OVERSIGHT

"Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Thank you all very much.

From: Wiechers, Ilse
Sent: Friday, March 8, 2019 12:04 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. (b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Tom –

I'll reach out to Ethics to get things started. Happy to look at draft documents whenever you and Jenn have something ready to share.

Best,
Ilse

From: Emmendorfer, Thomas (PBM)
Sent: Friday, March 08, 2019 8:02 AM
To: Wiechers, Ilse (b6) .gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. (b6) .gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Hi Ilse,

Dave and I spoke this morning after the briefing to Dr. Stone. Action items

- • Mental Health and PBM to start working together with the Comms team to develop internal/external communication.
    - • NEXT STEPS: Jenn Z. and I can work with you on the communication. Jenn and I will send you over a draft document to review.
- • iMed Consent: At morning report-Ethics asked if Spravato will need an iMed Consent.
    - • NEXT STEPS: Could you contact Ethics and work with them to determine and develop an imed consent (if needed) for Spravato?

Bill,

I adding you to the e-mail as well as we will need your assistance with getting the external communication through the process.

AMERICAN OVERSIGHT

Thank you!

Tom

From: "Wiechers, Ilse" (b6) va.gov>
Date: Thursday, March 7, 2019 at 10:04 AM
To: Thomas Emmendorfer <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Yes – self reported data from the field.

Attached is a copy of the full Somatic Treatment Field Assessment – ketamine for MH is section III.

From: Emmendorfer, Thomas (PBM)
Sent: Thursday, March 07, 2019 7:00 AM
To: Wiechers, Ilse (b6) a.gov>; Carroll, David (VACO) <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Hi Ilse,

Thank you very much for the information below!

[redacted]?

Tom

From: "Wiechers, Ilse" (b6) @va.gov>
Date: Thursday, March 7, 2019 at 9:55 AM
To: "Carroll, David (VACO)" <(b6) va.gov>, Thomas Emmendorfer <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Below are the sites reporting use in FY15 from the assessment we did of the field back in fall 2016. The 2019 assessment went to the field in Feb and we are working to gather the final data from sites now.

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Hope to have updated data about sites using IV ketamine for treatment of MH conditions sometime later this month.

1-(689) VA Connecticut HCS, CT
18-(501) New Mexico HCS
23-(618) Minneapolis, MN
1-(523) VA Boston HCS, MA
6-(659) Salisbury, NC
12-(607) Madison, WI
16-(580) Houston, TX
21-(662) San Francisco, CA

Best,
Ilse

From: Carroll, David (VACO)
Sent: Thursday, March 07, 2019 6:39 AM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Wiechers, Ilse (b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

I do not. Ilse may have a list or can otherwise find out.

From: Emmendorfer, Thomas (PBM)
Sent: Thursday, March 7, 2019 9:25 AM
To: Carroll, David (VACO) <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Hi Dave,

The briefing went very well. By chance, do you have a list of known VA medical facilities that are using intravenous ketamine for the treatment of refractory depression?

Thank you,

Tom

From: Thomas Emmendorfer <(b6) va.gov>
Date: Thursday, March 7, 2019 at 7:45 AM
To: Jon Jensen <(b6) va.gov>

AMERICAN OVERSIGHT

Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Beck, Lucille B." <(b6) va.gov>, "Howard, Kristi" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Will do.

From: Jon Jensen <(b6) va.gov>
Date: Thursday, March 7, 2019 at 7:41 AM
To: Thomas Emmendorfer <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Beck, Lucille B." <(b6) va.gov>, "Howard, Kristi" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Tom, can you come to Morning Report today to discuss? Starts at 9:30.

From: Emmendorfer, Thomas (PBM)
Sent: Wednesday, March 06, 2019 10:15 PM
To: Jensen, Jon M. (b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Howard, Kristi <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Hi Jon,

I hope all is going well. Below is the information that Jenn, Mike, and I pulled together for you. Let us know if you need anything else.

Tom

(b) (5)

AMERICAN OVERSIGHT

- (b) (5) [redacted]

From: Jensen, Jon M.
Sent: Wednesday, March 06, 2019 7:50 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Howard, Kristi <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Thanks Tom!

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:49 PM

AMERICAN OVERSIGHT

To: Jensen, Jon M. <(b6) va.gov>, Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Hi Jon,

We will work on it and get a response back.

Tom

Sent with BlackBerry Work
(www.blackberry.com)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:34 PM
To: Valentino, Michael (VACO) (b6) gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Adding Jennifer

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:27 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Just spoke to Dr Stone. We need to get something a little earlier than 10. As soon as you can would be fantastic.
Secva has asked for an update.

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 5:40 PM

AMERICAN OVERSIGHT

To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: HHS bought a nasal spray for depression

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Jon Jensen
VHA Acting Deputy Chief of Staff
W:(b6)
(b6)

Sender:	Wiechers, Ilse /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0C7B1428D9E4233A641F125C5B6FC4F-WIECHERS, I <(b6) va.gov>
Recipient:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; Boyd, Teresa D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6886a7d555a43e0bee23c1e40e1c234-Boyd, Teres <(b6) va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Outlaw, William N. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3e1067978634fbf96a382bdcd5c1115-Outlaw, Wil <(b6) va.gov>; O'Toole, Thomas P.(b6) va.gov </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c5a34d8a4b294e9986ef6e1aa8009b3f-O'Toole, Th>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>; Law, Cassandra M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f888d507d6c54eb5a92fc44199eb5838-Law, Cassan <(b6) va.gov>; Meyer, Laurence /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=56f0ba2c110d4e60863b66f9728f669d-Meyer, Laur <(b6) va.gov>; Denietolis, Angela L. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b51b87cff64f4354b78eb943f97b47f3-Denietolis, <(b6) va.gov>
Sent Date:	2019/03/11 09:30:41
Delivered Date:	2019/03/11 09:30:43

AMERICAN OVERSIGHT

From:	Jensen, Jon M. </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DDEB735ACE76400DB5C3F10603188A14-JENSEN, JON>
To:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>
Subject:	RE: HHS bought a nasal spray for depression
Date:	2019/03/07 07:46:00
Priority:	Normal
Type:	Note

Thank you!

From: Emmendorfer, Thomas (PBM)
Sent: Thursday, March 07, 2019 7:45 AM
To: Jensen, Jon M. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Howard, Kristi <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Will do.

From: Jon Jensen <(b6) va.gov>
Date: Thursday, March 7, 2019 at 7:41 AM
To: Thomas Emmendorfer <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Beck, Lucille B." <(b6) va.gov>, "Howard, Kristi" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Tom, can you come to Morning Report today to discuss? Starts at 9:30.

From: Emmendorfer, Thomas (PBM)
Sent: Wednesday, March 06, 2019 10:15 PM
To: Jensen, Jon M. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Howard, Kristi <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Hi Jon,

AMERICAN OVERSIGHT

I hope all is going well. Below is the information that Jenn, Mike, and I pulled together for you. Let us know if you need anything else.

Tom

(b) (5)

[redacted]

From: Jensen, Jon M.
Sent: Wednesday, March 06, 2019 7:50 PM
To: Emmendorfer, Thomas (PBM) <(b6) [redacted] va.gov>; Valentino, Michael (VACO) <(b6) [redacted] va.gov>; Carroll, David (VACO) <(b6) [redacted] va.gov>; Beck, Lucille B.

AMERICAN OVERSIGHT

<(b6) va.gov>; Howard, Kristi <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>
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Thanks Tom!

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:49 PM
To: Jensen, Jon M. <(b6) va.gov>, Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
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Sent with BlackBerry Work
(www.blackberry.com)

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Subject: RE: HHS bought a nasal spray for depression

Adding Jennifer

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

AMERICAN OVERSIGHT

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:27 PM
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(b6)

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Sent Date:	2019/03/07 07:46:17
Delivered Date:	2019/03/07 07:46:00

AMERICAN OVERSIGHT

From:	Jensen, Jon M. </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DDEB735ACE76400DB5C3F10603188A14-JENSEN, JON>
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CC:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>
Subject:	RE: HHS bought a nasal spray for depression
Date:	2019/03/11 15:51:39
Priority:	Normal
Type:	Note

Many thanks. Great job by PBM!

Jon Jensen
VHA Acting Deputy Chief of Staff
W:(b6)
(b6)

From: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Date: Monday, Mar 11, 2019, 3:22 PM
To: Jensen, Jon M. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>
Subject: FW: HHS bought a nasal spray for depression

Hi Jon,

This is just a heads up that the draft External Communication for Spravato® is going through the review process now.

Tom

From: Thomas Emmendorfer <(b6) va.gov>
Date: Monday, March 11, 2019 at 3:20 PM
To: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Cc: "Llorente, Maria D." <(b6) va.gov>, "Outlaw, William N." (b6) @va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Wiechers, Ilse" <(b6) va.gov>
Subject: FW: HHS bought a nasal spray for depression

The attached external press release has been developed in coordination with 10P4P and 10NC5. We left a place holder in for a potential quote from Dr. Stone.

AMERICAN OVERSIGHT

Request clearance to 10P for review.

From: Thomas Emmendorfer <(b6) va.gov>
Date: Thursday, March 7, 2019 at 7:45 AM
To: Jon Jensen <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Beck, Lucille B." <(b6) va.gov>, "Howard, Kristi" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Will do.

From: Jon Jensen <(b6) va.gov>
Date: Thursday, March 7, 2019 at 7:41 AM
To: Thomas Emmendorfer <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Beck, Lucille B." <(b6) va.gov>, "Howard, Kristi" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
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Cc: Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Howard, Kristi <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
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Tom

(b) (5)

AMERICAN OVERSIGHT

- (b) (5) [redacted]

From: Jensen, Jon M.
Sent: Wednesday, March 06, 2019 7:50 PM
To: Emmendorfer, Thomas (PBM) <(b6) [redacted]va.gov>; Valentino, Michael (VACO) <(b6) [redacted]va.gov>; Carroll, David (VACO) <(b6) [redacted]va.gov>; Beck, Lucille B. <(b6) [redacted]va.gov>; Howard, Kristi <(b6) [redacted]va.gov>; Zacher, Jennifer L. (PBM) <(b6) [redacted]va.gov>
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Jon Jensen
VHA Acting Deputy Chief of Staff

AMERICAN OVERSIGHT

W:(b6)
(b6)

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(www.blackberry.com)

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Subject: RE: HHS bought a nasal spray for depression

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Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
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Date: Wednesday, Mar 06, 2019, 7:27 PM
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VHA Acting Deputy Chief of Staff

AMERICAN OVERSIGHT

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Recipient:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>
Sent Date:	2019/03/11 15:51:39

AMERICAN OVERSIGHT

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Subject:	RE: HHS bought a nasal spray for depression
Date:	2019/03/07 05:51:37
Priority:	Normal
Type:	Note

Thank you all so much. Truly appreciate everyone's efforts to get this done so quickly. Will provide to the boss and go from there.
Thank you
Jon

Jon Jensen
VHA Acting Deputy Chief of Staff
W:(b6)
(b6)

From: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 10:14 PM
To: Jensen, Jon M. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>, Llorente, Maria D. <(b6) va.gov>, Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

AMERICAN OVERSIGHT

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AMERICAN OVERSIGHT

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AMERICAN OVERSIGHT

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Recipient:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino,

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	<(b6) va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Beck, Lucille B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=845480228a8b43e7a5fef5716ded04c2-Beck, Lucil <(b6) va.gov>; Howard, Kristi /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8d0afc371994181883d8861127791c3-Howard, Kri <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) va.gov>; Law, Cassandra M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f888d507d6c54eb5a92fc44199eb5838-Law, Cassan <(b6) va.gov>
Sent Date:	2019/03/07 05:51:36
Delivered Date:	2019/03/07 05:51:37

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From:	Smith, Avery /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9471C2D02A8B472B8543E09CB140085F-SMITH, AVER (b6) @va.gov>
To:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>; Adams, Thomas /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b14426432f64ccdb3a92cff690a1807-Adams, Thom <(b6) @va.gov>
CC:	Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) @va.gov>; Outlaw, William N. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3e1067978634fbf96a382bdcd5c1115-Outlaw, Wil <(b6) va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>
Subject:	RE: HHS bought a nasal spray for depression
Date:	2019/03/11 15:24:39
Priority:	Normal
Type:	Note

Adding communications team!

From: Emmendorfer, Thomas (PBM)
Sent: Monday, March 11, 2019 3:21 PM
To: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Cc: Llorente, Maria D. <(b6) va.gov>; Outlaw, William N.(b6) @va.gov>; Carroll, David (VACO) <(b6) va.gov>; Wiechers, Ilse (b6) va.gov>
Subject: FW: HHS bought a nasal spray for depression

The attached external press release has been developed in coordination with 10P4P and 10NC5. We left a place holder in for a potential quote from Dr. Stone.

Request clearance to 10P for review.

From: Thomas Emmendorfer <(b6) va.gov>
Date: Thursday, March 7, 2019 at 7:45 AM
To: Jon Jensen <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Beck, Lucille B." <(b6) va.gov>, "Howard, Kristi" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D."

AMERICAN OVERSIGHT

<(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Will do.

From: Jon Jensen <(b6) va.gov>
Date: Thursday, March 7, 2019 at 7:41 AM
To: Thomas Emmendorfer <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Beck, Lucille B." <(b6) va.gov>, "Howard, Kristi" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Tom, can you come to Morning Report today to discuss? Starts at 9:30.

From: Emmendorfer, Thomas (PBM)
Sent: Wednesday, March 06, 2019 10:15 PM
To: Jensen, Jon M. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Howard, Kristi <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Hi Jon,

I hope all is going well. Below is the information that Jenn, Mike, and I pulled together for you. Let us know if you need anything else.

Tom

(b) (5)

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- (b) (5) [redacted]



From: Jensen, Jon M.
Sent: Wednesday, March 06, 2019 7:50 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Howard, Kristi <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Thanks Tom!

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:49 PM
To: Jensen, Jon M. <(b6) va.gov>, Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

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Hi Jon,

We will work on it and get a response back.

Tom

Sent with BlackBerry Work
(www.blackberry.com)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:34 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi (b6) @va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Adding Jennifer

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:27 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi (b6) @va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Just spoke to Dr Stone. We need to get something a little earlier than 10. As soon as you can would be fantastic.
Secva has asked for an update.

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 5:40 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: HHS bought a nasal spray for depression

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Good evening, need some information on a nasal spray used for depression? POTUS heard HHS recently purchased and he felt it would be great for us. That's all I got. Can you pull info on what it would be, if we purchase currently, if we are looking into it etc. would sure appreciate anything you could provide by 10am.

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

Sender:	Smith, Avery /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9471C2D02A8B472B8543E09CB140085F-SMITH, AVER (b6) @va.gov>
Recipient:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>; Adams, Thomas /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b14426432f64ccdb3a92cff690a1807-Adams, Thom (b6) @va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) va.gov>; Outlaw, William N. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3e1067978634fbf96a382bdcd5c1115-Outlaw, Wil (b6) @va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>
Sent Date:	2019/03/11 15:24:37
Delivered Date:	2019/03/11 15:24:39

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From:	Llorente, Maria D. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F5C91F577D894BD9A0F09305DB34DD4F-LLORENTE, M <(b6) va.gov>
To:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b6) @va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Outlaw, William N. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3e1067978634fbf96a382bdcd5c1115-Outlaw, Wil (b6) @va.gov>; O'Toole, Thomas P.(b6) va.gov </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c5a34d8a4b294e9986ef6e1aa8009b3f-O'Toole, Th>
CC:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>; Law, Cassandra M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f888d507d6c54eb5a92fc44199eb5838-Law, Cassan <(b6) va.gov>; Boyd, Teresa D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6886a7d555a43e0bee23c1e40e1c234-Boyd, Teres <(b6) va.gov>; Meyer, Laurence /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=56f0ba2c110d4e60863b66f9728f669d-Meyer, Laur <(b6) va.gov>; Denietolis, Angela L. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b51b87cff64f4354b78eb943f97b47f3-Denietolis, <(b6) va.gov>
Subject:	RE: HHS bought a nasal spray for depression
Date:	2019/03/11 12:13:09
Priority:	Normal
Type:	Note

HI, this is extremely helpful. Thank you.

From: Wiechers, Ilse
Sent: Monday, March 11, 2019 12:01 PM
To: Llorente, Maria (b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. <W(b6) 2@va.gov>; O'Toole, Thomas P. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>; Meyer, Laurence <(b6) va.gov>; Denietolis, Angela L. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

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ECT data is below. This on captures ECT provided at VA facilities. There are likely some number of patients who need ECT and receive care at the 85 facilities that do not provide service on site, who subsequently get referred to care in the community for their ECT.

FY15
# of facilities providing on site ECT = 55 out of 140
# of unique Veterans receiving ECT = 849

FY17 (most recent year we have data)
# of facilities providing on site ECT = unknown
# of unique Veterans receiving ECT = 852

I asked NEPEC to re-run the # of uniques for FY18 and I'll have # of facilities later this month once we have the completed Somatic Treatment Field Assessment.

Ilse

From: Llorente, Maria D.
Sent: Monday, March 11, 2019 6:57 AM
To: Wiechers, Ilse <(b6) @va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. (b6) @va.gov>; O'Toole, Thomas P. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>; Meyer, Laurence <(b6) va.gov>; Denietolis, Angela L. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Great, thank you!!

From: Wiechers, Ilse
Sent: Monday, March 11, 2019 9:50 AM
To: Llorente, Maria D. <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) (b6) gov>; Outlaw, William N. (b6) @va.gov>; O'Toole, Thomas P. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>; Meyer, Laurence <(b6) va.gov>; Denietolis, Angela L. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

(b) (5)
.

Ilse

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Sent with BlackBerry Work
(www.blackberry.com)

From: Llorente, Maria D. <(b6) va.gov>
Date: Monday, Mar 11, 2019, 6:30 AM
To: Wiechers, Ilse (b6) @va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Outlaw, William N. (b6) @va.gov>, O'Toole, Thomas P. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>, Law, Cassandra M. <(b6) va.gov>, Boyd, Teresa D. <(b6) va.gov>, Meyer, Laurence <(b6) va.gov>, Denietolis, Angela L. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

I agree. (b) (5)

From: Wiechers, Ilse
Sent: Monday, March 11, 2019 9:28 AM
To: Llorente, Maria D. <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. (b6) @va.gov>; O'Toole, Thomas P. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>; Meyer, Laurence <(b6) va.gov>; Denietolis, Angela L. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

(b) (5)

Sent with BlackBerry Work
(www.blackberry.com)

From: Llorente, Maria D. <(b6) va.gov>
Date: Monday, Mar 11, 2019, 5:02 AM
To: Wiechers, Ilse (b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Outlaw, William N. (b6) va.gov>, O'Toole, Thomas P. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>, Law, Cassandra M. (b6) va.gov>, Boyd, Teresa D. <(b6) va.gov>, Meyer, Laurence <(b6) va.gov>, Denietolis, Angela L. <(b6) va.gov>

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Subject: RE: HHS bought a nasal spray for depression

Thank you very much. (b) (5) .

From: Wiechers, Ilse
Sent: Sunday, March 10, 2019 10:06 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. (b6) @va.gov>; O'Toole, Thomas P. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>; Meyer, Laurence <(b6) va.gov>; Denietolis, Angela L. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Hello everyone –

(b) (5)

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Ilse

From: Emmendorfer, Thomas (PBM)
Sent: Friday, March 08, 2019 12:57 PM
To: Llorente, Maria D. <(b6) va.gov>; Wiechers, Ilse (b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. (b6) @va.gov>; O'Toole, Thomas P. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. (b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>; Meyer, Laurence <(b6) va.gov>; Denietolis, Angela L. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Summary of Actions for Spravato® (esketamine) to date

OPEN:

1. (b) (5)

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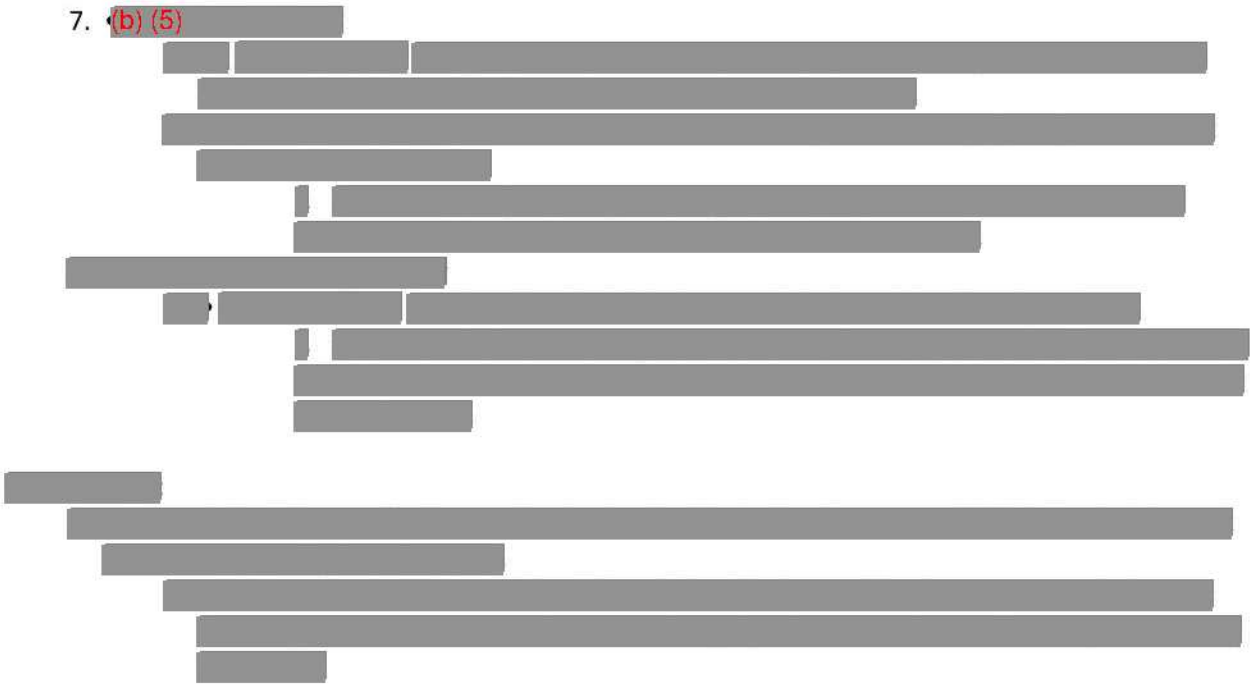
7. (b) (5) [redacted]



From: "Llorente, Maria D." <(b6) va.gov>
Date: Friday, March 8, 2019 at 1:47 PM
To: "Wiechers, Ilse" (b6) @va.gov>, Thomas Emmendorfer <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Outlaw, William N." (b6) @va.gov>
Cc: Michael Valentino <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Very helpful. Thank you!

From: Wiechers, Ilse
Sent: Friday, March 8, 2019 1:47 PM
To: Llorente, Maria D. <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Will do.

I've spoken to several private ketamine clinics in recent years, and the only physician type missing on your list that I have heard about is ED physicians. I also know of several clinics using APRNs under the supervision of one of those physicians listed below.

AMERICAN OVERSIGHT

From: Llorente, Maria D.
Sent: Friday, March 08, 2019 10:43 AM
To: Wiechers, Ilse (b6) @va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. (b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Yes, if you could. My understanding is that in private sector, psychiatrists, anesthesiologists, neurologists, and pain medicine providers may administer. This is in part because IV ketamine is also used for intractable pain.

From: Wiechers, Ilse
Sent: Friday, March 8, 2019 1:29 PM
To: Llorente, Maria D. <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. (b6) @va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

We do not have information on that. I can follow up on the responses to the Somatic Treatment Field Assessment and reach out to facilities that report providing IV ketamine and ask them.

From: Llorente, Maria D.
Sent: Friday, March 08, 2019 10:23 AM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Wiechers, Ilse (b6) @va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. (b6) @va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Ilse, do you know if all the current VA providers who administer IV ketamine for treatment resistant depression are psychiatrists? Do we have any anesthesiologists for example?

From: Emmendorfer, Thomas (PBM)
Sent: Friday, March 8, 2019 12:50 PM
To: Llorente, Maria D. <(b6) va.gov>; Wiechers, Ilse (b6) @va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Thank you Ilse!

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I just sent the internal communications document to Jenn for review (setup as a FAQ). When she is done with her review and edits she will send it over to you.

Tom

From: "Llorente, Maria D." <(b6) va.gov>
Date: Friday, March 8, 2019 at 12:08 PM
To: "Wiechers, Ilse" (b6) @va.gov>, Thomas Emmendorfer <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Outlaw, William N." (b6) @va.gov>
Cc: Michael Valentino <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Thank you all very much.

From: Wiechers, Ilse
Sent: Friday, March 8, 2019 12:04 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Tom –

I'll reach out to Ethics to get things started. Happy to look at draft documents whenever you and Jenn have something ready to share.

Best,
Ilse

From: Emmendorfer, Thomas (PBM)
Sent: Friday, March 08, 2019 8:02 AM
To: Wiechers, Ilse (b6) .gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Hi Ilse,

Dave and I spoke this morning after the briefing to Dr. Stone. Action items

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- • Mental Health and PBM to start working together with the Comms team to develop internal/external communication.
    - • NEXT STEPS: Jenn Z. and I can work with you on the communication. Jenn and I will send you over a draft document to review.
- • iMed Consent: At morning report-Ethics asked if Spravato will need an iMed Consent.
    - • NEXT STEPS: Could you contact Ethics and work with them to determine and develop an imed consent (if needed) for Spravato?

Bill,

I adding you to the e-mail as well as we will need your assistance with getting the external communication through the process.

Thank you!

Tom

From: "Wiechers, Ilse" (b6) @va.gov>
Date: Thursday, March 7, 2019 at 10:04 AM
To: Thomas Emmendorfer <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Yes – self reported data from the field.

Attached is a copy of the full Somatic Treatment Field Assessment – ketamine for MH is section III.

From: Emmendorfer, Thomas (PBM)
Sent: Thursday, March 07, 2019 7:00 AM
To: Wiechers, Ilse (b6) @va.gov>; Carroll, David (VACO) <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Hi Ilse,

Thank you very much for the information below!

Will the updated data also include any info on number of Veterans that have received ketamine for treatment of MH conditions?

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Tom

From: "Wiechers, Ilse" (b6) @va.gov>
Date: Thursday, March 7, 2019 at 9:55 AM
To: "Carroll, David (VACO)" <(b6) va.gov>, Thomas Emmendorfer <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Below are the sites reporting use in FY15 from the assessment we did of the field back in fall 2016. The 2019 assessment went to the field in Feb and we are working to gather the final data from sites now. Hope to have updated data about sites using IV ketamine for treatment of MH conditions sometime later this month.

1-(689) VA Connecticut HCS, CT
18-(501) New Mexico HCS
23-(618) Minneapolis, MN
1-(523) VA Boston HCS, MA
6-(659) Salisbury, NC
12-(607) Madison, WI
16-(580) Houston, TX
21-(662) San Francisco, CA

Best,
Ilse

From: Carroll, David (VACO)
Sent: Thursday, March 07, 2019 6:39 AM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Wiechers, Ilse (b6) @va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

I do not. Ilse may have a list or can otherwise find out.

From: Emmendorfer, Thomas (PBM)
Sent: Thursday, March 7, 2019 9:25 AM
To: Carroll, David (VACO) <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

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Hi Dave,

The briefing went very well. By chance, do you have a list of known VA medical facilities that are using intravenous ketamine for the treatment of refractory depression?

Thank you,

Tom

From: Thomas Emmendorfer <(b6) va.gov>
Date: Thursday, March 7, 2019 at 7:45 AM
To: Jon Jensen <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Beck, Lucille B." <(b6) va.gov>, "Howard, Kristi" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Will do.

From: Jon Jensen <(b6) va.gov>
Date: Thursday, March 7, 2019 at 7:41 AM
To: Thomas Emmendorfer <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Beck, Lucille B." <(b6) va.gov>, "Howard, Kristi" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Tom, can you come to Morning Report today to discuss? Starts at 9:30.

From: Emmendorfer, Thomas (PBM)
Sent: Wednesday, March 06, 2019 10:15 PM
To: Jensen, Jon M. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Howard, Kristi <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Hi Jon,

I hope all is going well. Below is the information that Jenn, Mike, and I pulled together for you. Let us know if you need anything else.

AMERICAN OVERSIGHT

Tom

(b) (5) [redacted]

(b) (5) [redacted]



From: Jensen, Jon M.
Sent: Wednesday, March 06, 2019 7:50 PM
To: Emmendorfer, Thomas (PBM) <(b6) [redacted]va.gov>; Valentino, Michael (VACO) <(b6) [redacted]va.gov>; Carroll, David (VACO) <(b6) [redacted]va.gov>; Beck, Lucille B. <(b6) [redacted]va.gov>; Howard, Kristi <(b6) [redacted]va.gov>; Zacher, Jennifer L. (PBM)

AMERICAN OVERSIGHT

<(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Thanks Tom!

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:49 PM
To: Jensen, Jon M. <(b6) va.gov>, Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Hi Jon,

We will work on it and get a response back.

Tom

Sent with BlackBerry Work
(www.blackberry.com)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:34 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Adding Jennifer

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:27 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

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Just spoke to Dr Stone. We need to get something a little earlier than 10. As soon as you can would be fantastic.
Secva has asked for an update.

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 5:40 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: HHS bought a nasal spray for depression

Good evening, need some information on a nasal spray used for depression? POTUS heard HHS recently purchased and he felt it would be great for us. That's all I got. Can you pull info on what it would be, if we purchase currently, if we are looking into it etc. would sure appreciate anything you could provide by 10am.

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

Sender:	Llorente, Maria D. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F5C91F577D894BD9A0F09305DB34DD4F-LLORENTE, M <(b6) va.gov>
Recipient:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) @va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Outlaw, William N. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3e1067978634fbf96a382bdcd5c1115-Outlaw, Wil (b6) @va.gov>; O'Toole, Thomas P.(b6) va.gov </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c5a34d8a4b294e9986ef6e1aa8009b3f-O'Toole, Th>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b6) @va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen (b6) @va.gov>; Law, Cassandra M. /o=ExchangeLabs/ou=Exchange Administrative Group

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	(FYDIBOHF23SPDLT)/cn=Recipients/cn=f888d507d6c54eb5a92fc44199eb5838-Law, Cassan <(b6) va.gov>; Boyd, Teresa D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6886a7d555a43e0bee23c1e40e1c234-Boyd, Teres <(b6) va.gov>; Meyer, Laurence /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=56f0ba2c110d4e60863b66f9728f669d-Meyer, Laur <(b6) va.gov>; Denietolis, Angela L. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b51b87cff64f4354b78eb943f97b47f3-Denietolis, <(b6) va.gov>
Sent Date:	2019/03/11 12:13:01
Delivered Date:	2019/03/11 12:13:09

AMERICAN OVERSIGHT

From:	Llorente, Maria D. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F5C91F577D894BD9A0F09305DB34DD4F-LLORENTE, M <(b6) va.gov>
To:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b6) @va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Outlaw, William N. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3e1067978634fbf96a382bdcd5c1115-Outlaw, Wil (b6) @va.gov>; O'Toole, Thomas P.(b6) va.gov </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c5a34d8a4b294e9986ef6e1aa8009b3f-O'Toole, Th>
CC:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>; Law, Cassandra M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f888d507d6c54eb5a92fc44199eb5838-Law, Cassan <(b6) va.gov>; Boyd, Teresa D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6886a7d555a43e0bee23c1e40e1c234-Boyd, Teres <(b6) va.gov>; Meyer, Laurence /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=56f0ba2c110d4e60863b66f9728f669d-Meyer, Laur <(b6) va.gov>; Denietolis, Angela L. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b51b87cff64f4354b78eb943f97b47f3-Denietolis, <(b6) va.gov>
Subject:	RE: HHS bought a nasal spray for depression
Date:	2019/03/11 20:25:47
Priority:	Normal
Type:	Note

Thank you. OMHSP has been extremely responsive!

From: Wiechers, Ilse
Sent: Monday, March 11, 2019 7:30 PM
To: Llorente, Maria (b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. (b6) 2@va.gov>; O'Toole, Thomas P. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>; Meyer, Laurence <(b6) va.gov>; Denietolis, Angela L. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Updates on data:

AMERICAN OVERSIGHT

(b) (5) [redacted]

Please let me know if you have any questions.

Ilse

From: Llorente, Maria D.
Sent: Monday, March 11, 2019 9:13 AM
To: Wiechers, Ilse (b6) [redacted]@va.gov>; Emmendorfer, Thomas (PBM) <(b6) [redacted]va.gov>; Carroll, David (VACO) <(b6) [redacted]va.gov>; Outlaw, William N. (b6) [redacted]@va.gov>; O'Toole, Thomas P. <(b6) [redacted]va.gov>
Cc: Valentino, Michael (VACO) <(b6) [redacted]va.gov>; Zacher, Jennifer L. (PBM) <(b6) [redacted]va.gov>; Law, Cassandra M. <(b6) [redacted]va.gov>; Boyd, Teresa D. <(b6) [redacted]va.gov>; Meyer, Laurence <(b6) [redacted]va.gov>; Denietolis, Angela L. <(b6) [redacted]va.gov>
Subject: RE: HHS bought a nasal spray for depression

HI, this is extremely helpful. Thank you.

From: Wiechers, Ilse
Sent: Monday, March 11, 2019 12:01 PM
To: Llorente, Maria D. <(b6) [redacted]va.gov>; Emmendorfer, Thomas (PBM) <(b6) [redacted]va.gov>; Carroll, David (VACO) <(b6) [redacted]va.gov>; Outlaw, William N. (b6) [redacted]@va.gov>; O'Toole, Thomas P. <(b6) [redacted]va.gov>
Cc: Valentino, Michael (VACO) <(b6) [redacted]va.gov>; Zacher, Jennifer L. (PBM) <(b6) [redacted]va.gov>; Law, Cassandra M. <(b6) [redacted]va.gov>; Boyd, Teresa D. <(b6) [redacted]va.gov>; Meyer, Laurence <(b6) [redacted]va.gov>; Denietolis, Angela L. <(b6) [redacted]va.gov>
Subject: RE: HHS bought a nasal spray for depression

ECT data is below. This on captures ECT provided at VA facilities. There are likely some number of patients who need ECT and receive care at the 85 facilities that do not provide service on site, who subsequently get referred to care in the community for their ECT.

FY15
# of facilities providing on site ECT = 55 out of 140

AMERICAN OVERSIGHT

# of unique Veterans receiving ECT = 849

FY17 (most recent year we have data)
# of facilities providing on site ECT = unknown
# of unique Veterans receiving ECT = 852

I asked NEPEC to re-run the # of uniques for FY18 and I'll have # of facilities later this month once we have the completed Somatic Treatment Field Assessment.

Ilse

From: Llorente, Maria D.
Sent: Monday, March 11, 2019 6:57 AM
To: Wiechers, Ilse (b6) @va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. (b6) @va.gov>; O'Toole, Thomas P. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>; Meyer, Laurence <(b6) va.gov>; Denietolis, Angela L. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Great, thank you!!

From: Wiechers, Ilse
Sent: Monday, March 11, 2019 9:50 AM
To: Llorente, Maria D. <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. (b6) @va.gov>; O'Toole, Thomas P. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>; Meyer, Laurence <(b6) va.gov>; Denietolis, Angela L. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

I (b) (5)
ell.

Ilse

Sent with BlackBerry Work
(www.blackberry.com)

From: Llorente, Maria D. <(b6) va.gov>
Date: Monday, Mar 11, 2019, 6:30 AM

AMERICAN OVERSIGHT

To: Wiechers, Ilse (b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Outlaw, William N. <(b6) va.gov>, O'Toole, Thomas P. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>, Law, Cassandra M. <(b6) va.gov>, Boyd, Teresa D. <(b6) va.gov>, Meyer, Laurence <(b6) va.gov>, Denietolis, Angela L. (b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

I agree. (b) (5)
.

From: Wiechers, Ilse
Sent: Monday, March 11, 2019 9:28 AM
To: Llorente, Maria D. <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) (b6) >; Outlaw, William N. <(b6) @va.gov>; O'Toole, Thomas P. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>; Meyer, Laurence <(b6) va.gov>; Denietolis, Angela L. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

(b) (5)
.

Sent with BlackBerry Work
(www.blackberry.com)

From: Llorente, Maria D. <(b6) va.gov>
Date: Monday, Mar 11, 2019, 5:02 AM
To: Wiechers, Ilse (b6) @va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Outlaw, William N. <(b6) va.gov>, O'Toole, Thomas P. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>, Law, Cassandra M. <(b6) va.gov>, Boyd, Teresa D. <(b6) va.gov>, Meyer, Laurence <(b6) va.gov>, Denietolis, Angela L. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Thank you very much. (b) (5)

AMERICAN OVERSIGHT

From: Wiechers, Ilse
Sent: Sunday, March 10, 2019 10:06 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. (b6) @va.gov>; O'Toole, Thomas P. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>; Meyer, Laurence <(b6) va.gov>; Denietolis, Angela L. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Hello everyone –

(b) (5)

Ilse

From: Emmendorfer, Thomas (PBM)
Sent: Friday, March 08, 2019 12:57 PM
To: Llorente, Maria D. <(b6) va.gov>; Wiechers, Ilse (b6) @va.gov>; Carroll, David

AMERICAN OVERSIGHT

(VACO) <(b6) va.gov>; Outlaw, William N. <(b6) va.gov>; O'Toole, Thomas P. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>; Meyer, Laurence <(b6) va.gov>; Denietolis, Angela L. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Summary of Actions for Spravato® (esketamine) to date

OPEN:

1. (b) (5)

AMERICAN OVERSIGHT

i. (b) (5) [redacted]

From: "Llorente, Maria D." <(b6) va.gov>
Date: Friday, March 8, 2019 at 1:47 PM
To: "Wiechers, Ilse" (b6) @va.gov>, Thomas Emmendorfer <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Outlaw, William N." (b6) @va.gov>
Cc: Michael Valentino <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Very helpful. Thank you!

From: Wiechers, Ilse
Sent: Friday, March 8, 2019 1:47 PM
To: Llorente, Maria D. <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. (b6) @va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. (b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Will do.

I've spoken to several private ketamine clinics in recent years, and the only physician type missing on your list that I have heard about is ED physicians. I also know of several clinics using APRNs under the supervision of one of those physicians listed below.

From: Llorente, Maria D.
Sent: Friday, March 08, 2019 10:43 AM
To: Wiechers, Ilse (b6) @va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N.

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(b6) @va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Yes, if you could. My understanding is that in private sector, psychiatrists, anesthesiologists, neurologists, and pain medicine providers may administer. This is in part because IV ketamine is also used for intractable pain.

From: Wiechers, Ilse
Sent: Friday, March 8, 2019 1:29 PM
To: Llorente, Maria D. <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. (b6) @va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

We do not have information on that. I can follow up on the responses to the Somatic Treatment Field Assessment and reach out to facilities that report providing IV ketamine and ask them.

From: Llorente, Maria D.
Sent: Friday, March 08, 2019 10:23 AM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Wiechers, Ilse (b6) @va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. (b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Ilse, do you know if all the current VA providers who administer IV ketamine for treatment resistant depression are psychiatrists? Do we have any anesthesiologists for example?

From: Emmendorfer, Thomas (PBM)
Sent: Friday, March 8, 2019 12:50 PM
To: Llorente, Maria D. <(b6) va.gov>; Wiechers, Ilse (b6) @va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William (b6) @va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Thank you Ilse!

I just sent the internal communications document to Jenn for review (setup as a FAQ). When she is done with her review and edits she will send it over to you.

Tom

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From: "Llorente, Maria D." <(b6) va.gov>
Date: Friday, March 8, 2019 at 12:08 PM
To: "Wiechers, Ilse" (b6) @va.gov>, Thomas Emmendorfer <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Outlaw, William N.' (b6) @va.gov>
Cc: Michael Valentino <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Thank you all very much.

From: Wiechers, Ilse
Sent: Friday, March 8, 2019 12:04 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. (b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Tom –

I'll reach out to Ethics to get things started. Happy to look at draft documents whenever you and Jenn have something ready to share.

Best,
Ilse

From: Emmendorfer, Thomas (PBM)
Sent: Friday, March 08, 2019 8:02 AM
To: Wiechers, Ilse (b6) @va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Hi Ilse,

Dave and I spoke this morning after the briefing to Dr. Stone. Action items

- • Mental Health and PBM to start working together with the Comms team to develop internal/external communication.
    - • NEXT STEPS: Jenn Z. and I can work with you on the communication. Jenn and I will send you over a draft document to review.
- • iMed Consent: At morning report-Ethics asked if Spravato will need an iMed Consent.

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- • NEXT STEPS: Could you contact Ethics and work with them to determine and develop an imed consent (if needed) for Spravato?

Bill,

I adding you to the e-mail as well as we will need your assistance with getting the external communication through the process.

Thank you!

Tom

From: "Wiechers, Ilse" (b6) @va.gov>
Date: Thursday, March 7, 2019 at 10:04 AM
To: Thomas Emmendorfer <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Yes – self reported data from the field.

Attached is a copy of the full Somatic Treatment Field Assessment – ketamine for MH is section III.

From: Emmendorfer, Thomas (PBM)
Sent: Thursday, March 07, 2019 7:00 AM
To: Wiechers, Ilse (b6) @va.gov>; Carroll, David (VACO) <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Hi Ilse,

Thank you very much for the information below!

Will the updated data also include any info on number of Veterans that have received ketamine for treatment of MH conditions?

Tom

From: "Wiechers, Ilse" (b6) @va.gov>
Date: Thursday, March 7, 2019 at 9:55 AM

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To: "Carroll, David (VACO)" <(b6) va.gov>, Thomas Emmendorfer <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Below are the sites reporting use in FY15 from the assessment we did of the field back in fall 2016. The 2019 assessment went to the field in Feb and we are working to gather the final data from sites now. Hope to have updated data about sites using IV ketamine for treatment of MH conditions sometime later this month.

1-(689) VA Connecticut HCS, CT
18-(501) New Mexico HCS
23-(618) Minneapolis, MN
1-(523) VA Boston HCS, MA
6-(659) Salisbury, NC
12-(607) Madison, WI
16-(580) Houston, TX
21-(662) San Francisco, CA

Best,
Ilse

From: Carroll, David (VACO)
Sent: Thursday, March 07, 2019 6:39 AM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Wiechers, Ilse (b6) @va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

I do not. Ilse may have a list or can otherwise find out.

From: Emmendorfer, Thomas (PBM)
Sent: Thursday, March 7, 2019 9:25 AM
To: Carroll, David (VACO) <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Hi Dave,

The briefing went very well. By chance, do you have a list of known VA medical facilities that are using intravenous ketamine for the treatment of refractory depression?

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Thank you,

Tom

From: Thomas Emmendorfer <(b6) va.gov>
Date: Thursday, March 7, 2019 at 7:45 AM
To: Jon Jensen <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Beck, Lucille B." <(b6) va.gov>, "Howard, Kristi" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Will do.

From: Jon Jensen <(b6) va.gov>
Date: Thursday, March 7, 2019 at 7:41 AM
To: Thomas Emmendorfer <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Beck, Lucille B." <(b6) va.gov>, "Howard, Kristi" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Tom, can you come to Morning Report today to discuss? Starts at 9:30.

From: Emmendorfer, Thomas (PBM)
Sent: Wednesday, March 06, 2019 10:15 PM
To: Jensen, Jon M. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Howard, Kristi <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Hi Jon,

I hope all is going well. Below is the information that Jenn, Mike, and I pulled together for you. Let us know if you need anything else.

Tom

(b) (5)

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(b) (5)



From: Jensen, Jon M.
Sent: Wednesday, March 06, 2019 7:50 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Howard, Kristi <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Thanks Tom!

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Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:49 PM
To: Jensen, Jon M. <(b6) va.gov>, Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Hi Jon,

We will work on it and get a response back.

Tom

Sent with BlackBerry Work
(www.blackberry.com)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:34 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Adding Jennifer

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:27 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Just spoke to Dr Stone. We need to get something a little earlier than 10. As soon as you can would be fantastic.
Secva has asked for an update.

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Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 5:40 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: HHS bought a nasal spray for depression

Good evening, need some information on a nasal spray used for depression? POTUS heard HHS recently purchased and he felt it would be great for us. That's all I got. Can you pull info on what it would be, if we purchase currently, if we are looking into it etc. would sure appreciate anything you could provide by 10am.

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

Sender:	Llorente, Maria D. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F5C91F577D894BD9A0F09305DB34DD4F-LLORENTE, M <(b6) va.gov>
Recipient:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Outlaw, William N. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3e1067978634fbf96a382bdcd5c1115-Outlaw, Wil <(b6) va.gov>; O'Toole, Thomas P.(b6) va.gov </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c5a34d8a4b294e9986ef6e1aa8009b3f-O'Toole, Th>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>; Law, Cassandra M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f888d507d6c54eb5a92fc44199eb5838-Law, Cassan <(b6) va.gov>; Boyd, Teresa D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6886a7d555a43e0bee23c1e40e1c234-Boyd, Teres <(b6) va.gov>; Meyer, Laurence /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=56f0ba2c110d4e60863b66f9728f669d-Meyer, Laur

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	<(b6) va.gov>; Denietolis, Angela L. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b51b87cff64f4354b78eb943f97b47f3-Denietolis, <(b6) va.gov>
Sent Date:	2019/03/11 20:25:45
Delivered Date:	2019/03/11 20:25:47

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From:	Wiechers, Ilse /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0C7B1428D9E4233A641F125C5B6FC4F-WIECHERS, I (b6) @va.gov>
To:	Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Outlaw, William N. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3e1067978634fbf96a382bdcd5c1115-Outlaw, Wil (b6) @va.gov>; O'Toole, Thomas P.(b6) va.gov </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c5a34d8a4b294e9986ef6e1aa8009b3f-O'Toole, Th>
CC:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>; Law, Cassandra M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f888d507d6c54eb5a92fc44199eb5838-Law, Cassan <(b6) va.gov>; Boyd, Teresa D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6886a7d555a43e0bee23c1e40e1c234-Boyd, Teres <(b6) va.gov>; Meyer, Laurence /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=56f0ba2c110d4e60863b66f9728f669d-Meyer, Laur <(b6) va.gov>; Denietolis, Angela L. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b51b87cff64f4354b78eb943f97b47f3-Denietolis, <(b6) va.gov>
Subject:	RE: HHS bought a nasal spray for depression
Date:	2019/03/11 19:29:47
Priority:	Normal
Type:	Note

Updates on data:

(b) (5)

).

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Please let me know if you have any questions.

Ilse

From: Llorente, Maria D.
Sent: Monday, March 11, 2019 9:13 AM
To: Wiechers, Ilse <Ilse.Wiechers@va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. <(b6) va.gov>; O'Toole, Thomas P. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>; Meyer, Laurence <(b6) va.gov>; Denietolis, Angela L. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

HI, this is extremely helpful. Thank you.

From: Wiechers, Ilse
Sent: Monday, March 11, 2019 12:01 PM
To: Llorente, Maria D. <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. (b6) 2@va.gov>; O'Toole, Thomas P. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>; Meyer, Laurence <(b6) va.gov>; Denietolis, Angela L. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

ECT data is below. This on captures ECT provided at VA facilities. There are likely some number of patients who need ECT and receive care at the 85 facilities that do not provide service on site, who subsequently get referred to care in the community for their ECT.

FY15
# of facilities providing on site ECT = 55 out of 140
# of unique Veterans receiving ECT = 849

FY17 (most recent year we have data)
# of facilities providing on site ECT = unknown
# of unique Veterans receiving ECT = 852

I asked NEPEC to re-run the # of uniques for FY18 and I'll have # of facilities later this month once we have the completed Somatic Treatment Field Assessment.

Ilse

From: Llorente, Maria D.
Sent: Monday, March 11, 2019 6:57 AM

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To: Wiechers, Ilse <Ilse.Wiechers@va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. (b6) @va.gov>; O'Toole, Thomas P. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>; Meyer, Laurence <(b6) va.gov>; Denietolis, Angela L. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Great, thank you!!

From: Wiechers, Ilse
Sent: Monday, March 11, 2019 9:50 AM
To: Llorente, Maria D. <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. (b6) va.gov>; O'Toole, Thomas P. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>; Meyer, Laurence <(b6) va.gov>; Denietolis, Angela L. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

I will have PERC rerun the national numbers with and without trazodone. And I have facility reported data on ECT use and also know NEPEC has pulled data based on CPT codes in the past. I'll work on getting those as well.

Ilse

Sent with BlackBerry Work
(www.blackberry.com)

From: Llorente, Maria D. <(b6) va.gov>
Date: Monday, Mar 11, 2019, 6:30 AM
To: Wiechers, Ilse (b6) @va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Outlaw, William N. <(b6) va.gov>, O'Toole, Thomas P. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>, Law, Cassandra M. <(b6) va.gov>, Boyd, Teresa D. <(b6) va.gov>, Meyer, Laurence <(b6) va.gov>, Denietolis, Angela L. <Angela.Denietolis@va.gov>
Subject: RE: HHS bought a nasal spray for depression

I agree. I wonder if low dose trazodone could be excluded.
Also, do we know how many patients receive ECT? That group would ostensibly meet criteria for this modality of treatment as well.

From: Wiechers, Ilse
Sent: Monday, March 11, 2019 9:28 AM

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To: Llorente, Maria D. <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. <(b6) @va.gov>; O'Toole, Thomas P. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>; Meyer, Laurence <(b6) va.gov>; Denietolis, Angela L. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

(b) (5)
[redacted]
.

Sent with BlackBerry Work
(www.blackberry.com)

From: Llorente, Maria D. <(b6) va.gov>
Date: Monday, Mar 11, 2019, 5:02 AM
To: Wiechers, Ilse (b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Outlaw, William N. <(b6) va.gov>, O'Toole, Thomas P. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>, Law, Cassandra M. <(b6) va.gov>, Boyd, Teresa D. <(b6) va.gov>, Meyer, Laurence <(b6) va.gov>, Denietolis, Angela L. <Angela.Denietolis@va.gov>
Subject: RE: HHS bought a nasal spray for depression

Thank you very much. (b) (5)
[redacted]
.

From: Wiechers, Ilse
Sent: Sunday, March 10, 2019 10:06 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. (b6) @va.gov>; O'Toole, Thomas P. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>; Meyer, Laurence <(b6) va.gov>; Denietolis, Angela L. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Hello everyone –

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(b) (5)

If this seems like a reasonable approach, we will run this data by homestation, which will give us the #s for each VAMC.

Ilse

From: Emmendorfer, Thomas (PBM)
Sent: Friday, March 08, 2019 12:57 PM
To: Llorente, Maria D. <(b6) va.gov>; Wiechers, Ilse (b6) @va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. (b6) @va.gov>; O'Toole, Thomas P. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>; Meyer, Laurence <(b6) va.gov>; Denietolis, Angela L. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Summary of Actions for Spravato® (esketamine) to date

OPEN:

1. (b) (5)

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From: "Llorente, Maria D." <(b6) va.gov>
Date: Friday, March 8, 2019 at 1:47 PM
To: "Wiechers, Ilse" (b6) @va.gov>, Thomas Emmendorfer <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Outlaw, William N." (b6) @va.gov>
Cc: Michael Valentino <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Very helpful. Thank you!

From: Wiechers, Ilse
Sent: Friday, March 8, 2019 1:47 PM
To: Llorente, Maria D. <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. (b6) @va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Will do.

I've spoken to several private ketamine clinics in recent years, and the only physician type missing on your list that I have heard about is ED physicians. I also know of several clinics using APRNs under the supervision of one of those physicians listed below.

From: Llorente, Maria D.
Sent: Friday, March 08, 2019 10:43 AM
To: Wiechers, Ilse (b6) @va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. <(b6) @va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Yes, if you could. My understanding is that in private sector, psychiatrists, anesthesiologists, neurologists, and pain medicine providers may administer. This is in part because IV ketamine is also used for intractable pain.

From: Wiechers, Ilse
Sent: Friday, March 8, 2019 1:29 PM
To: Llorente, Maria D. <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. (b6) @va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM)

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<(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

We do not have information on that. I can follow up on the responses to the Somatic Treatment Field Assessment and reach out to facilities that report providing IV ketamine and ask them.

From: Llorente, Maria D.
Sent: Friday, March 08, 2019 10:23 AM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Wiechers, Ilse (b6) @va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. (b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Ilse, do you know if all the current VA providers who administer IV ketamine for treatment resistant depression are psychiatrists? Do we have any anesthesiologists for example?

From: Emmendorfer, Thomas (PBM)
Sent: Friday, March 8, 2019 12:50 PM
To: Llorente, Maria D. <(b6) va.gov>; Wiechers, Ilse <(b6) @va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. (b6) @va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Thank you Ilse!

I just sent the internal communications document to Jenn for review (setup as a FAQ). When she is done with her review and edits she will send it over to you.

Tom

From: "Llorente, Maria D." <(b6) va.gov>
Date: Friday, March 8, 2019 at 12:08 PM
To: "Wiechers, Ilse" (b6) va.gov>, Thomas Emmendorfer <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Outlaw, William N." <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Thank you all very much.

From: Wiechers, Ilse
Sent: Friday, March 8, 2019 12:04 PM

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To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. (b6) @va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Tom –

I'll reach out to Ethics to get things started. Happy to look at draft documents whenever you and Jenn have something ready to share.

Best,
Ilse

From: Emmendorfer, Thomas (PBM)
Sent: Friday, March 08, 2019 8:02 AM
To: Wiechers, Ilse (b6) @va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. <(b6) @va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Hi Ilse,

Dave and I spoke this morning after the briefing to Dr. Stone. Action items

- • Mental Health and PBM to start working together with the Comms team to develop internal/external communication.
    - • NEXT STEPS: Jenn Z. and I can work with you on the communication. Jenn and I will send you over a draft document to review.
- • iMed Consent: At morning report-Ethics asked if Spravato will need an iMed Consent.
    - • NEXT STEPS: Could you contact Ethics and work with them to determine and develop an imed consent (if needed) for Spravato?

Bill,

I adding you to the e-mail as well as we will need your assistance with getting the external communication through the process.

Thank you!

Tom

From: "Wiechers, Ilse" (b6) @va.gov>
Date: Thursday, March 7, 2019 at 10:04 AM

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To: Thomas Emmendorfer <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Yes – self reported data from the field.

Attached is a copy of the full Somatic Treatment Field Assessment – ketamine for MH is section III.

From: Emmendorfer, Thomas (PBM)
Sent: Thursday, March 07, 2019 7:00 AM
To: Wiechers, Ilse (b6) a.gov>; Carroll, David (VACO) <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Hi Ilse,

Thank you very much for the information below!

Will the updated data also include any info on number of Veterans that have received ketamine for treatment of MH conditions?

Tom

From: "Wiechers, Ilse" (b6) @va.gov>
Date: Thursday, March 7, 2019 at 9:55 AM
To: "Carroll, David (VACO)" <(b6) va.gov>, Thomas Emmendorfer <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Below are the sites reporting use in FY15 from the assessment we did of the field back in fall 2016. The 2019 assessment went to the field in Feb and we are working to gather the final data from sites now. Hope to have updated data about sites using IV ketamine for treatment of MH conditions sometime later this month.

1-(689) VA Connecticut HCS, CT
18-(501) New Mexico HCS
23-(618) Minneapolis, MN
1-(523) VA Boston HCS, MA

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6-(659) Salisbury, NC
12-(607) Madison, WI
16-(580) Houston, TX
21-(662) San Francisco, CA

Best,
Ilse

From: Carroll, David (VACO)
Sent: Thursday, March 07, 2019 6:39 AM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Wiechers, Ilse (b6) @va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

I do not. Ilse may have a list or can otherwise find out.

From: Emmendorfer, Thomas (PBM)
Sent: Thursday, March 7, 2019 9:25 AM
To: Carroll, David (VACO) <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Hi Dave,

The briefing went very well. By chance, do you have a list of known VA medical facilities that are using intravenous ketamine for the treatment of refractory depression?

Thank you,

Tom

From: Thomas Emmendorfer <(b6) va.gov>
Date: Thursday, March 7, 2019 at 7:45 AM
To: Jon Jensen <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Beck, Lucille B." <(b6) va.gov>, "Howard, Kristi" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

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Will do.

From: Jon Jensen <(b6) va.gov>
Date: Thursday, March 7, 2019 at 7:41 AM
To: Thomas Emmendorfer <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Beck, Lucille B." <(b6) va.gov>, "Howard, Kristi" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Tom, can you come to Morning Report today to discuss? Starts at 9:30.

From: Emmendorfer, Thomas (PBM)
Sent: Wednesday, March 06, 2019 10:15 PM
To: Jensen, Jon M. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Howard, Kristi <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Hi Jon,

I hope all is going well. Below is the information that Jenn, Mike, and I pulled together for you. Let us know if you need anything else.

Tom

(b) (5)

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- (b) (5) [redacted]

From: Jensen, Jon M.
Sent: Wednesday, March 06, 2019 7:50 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Howard, Kristi (b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Thanks Tom!

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:49 PM
To: Jensen, Jon M. <(b6) va.gov>, Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi (b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Hi Jon,

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We will work on it and get a response back.

Tom

Sent with BlackBerry Work
(www.blackberry.com)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:34 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Adding Jennifer

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:27 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Just spoke to Dr Stone. We need to get something a little earlier than 10. As soon as you can would be fantastic.
Secva has asked for an update.

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 5:40 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi (b6) .gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: HHS bought a nasal spray for depression

Good evening, need some information on a nasal spray used for depression? POTUS heard HHS recently purchased and he felt it would be great for us. That's all I got. Can you pull info on what it

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would be, if we purchase currently, if we are looking into it etc. would sure appreciate anything you could provide by 10am.

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

Sender:	Wiechers, Ilse /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0C7B1428D9E4233A641F125C5B6FC4F-WIECHERS, I <(b6) va.gov>
Recipient:	Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Outlaw, William N. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3e1067978634fbf96a382bdcd5c1115-Outlaw, Wil (b6) @va.gov>; O'Toole, Thomas P.(b6) va.gov </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c5a34d8a4b294e9986ef6e1aa8009b3f-O'Toole, Th>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>; Law, Cassandra M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f888d507d6c54eb5a92fc44199eb5838-Law, Cassan <(b6) va.gov>; Boyd, Teresa D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6886a7d555a43e0bee23c1e40e1c234-Boyd, Teres <(b6) va.gov>; Meyer, Laurence /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=56f0ba2c110d4e60863b66f9728f669d-Meyer, Laur <(b6) va.gov>; Denietolis, Angela L. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b51b87cff64f4354b78eb943f97b47f3-Denietolis, <(b6) va.gov>
Sent Date:	2019/03/11 19:29:45
Delivered Date:	2019/03/11 19:29:47

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From:	Pomerantz, Andrew /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=29A9288DF9A34E84BDDFD00CDE79F11B-POMERANTZ, (b6) @va.gov>
To:	Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b6) @va.gov>; McGuire, Marsden H. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29e9d648c29f4885828c10446fdd7379-McGuire, Ma (b6) @va.gov>; Katz, Ira R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=65f4e28aa7574641932c29fed7c0b4b8-Katz, Ira R <(b6) va.gov>
CC:	VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>
Subject:	RE: HHS bought a nasal spray for depression
Date:	2019/03/06 19:44:15
Priority:	Normal
Type:	Note

I think we'll need to talk with PBM. It would need to be added to the VA formulary. In the meantime facilities will get a lot of NF requests. I can contact Mitch Nazario, as he manages their mh drugs

---

From: Carroll, David (VACO)
Sent: Wednesday, March 06, 2019 6:47 PM
To: Wiechers, Ilse (b6) @va.gov>; McGuire, Marsden H. <(b6) va.gov>; Pomerantz, Andrew <(b6) va.gov>; Katz, Ira R. (b6) @va.gov>
Cc: VHA 10NC5 Action <VHA10NC5Action@va.gov>
Subject: FW: HHS bought a nasal spray for depression

What do we know about this? My only info came from a New York Times article posted this morning. Although FDA approved it, I'm not sure when it will be available or the supports are in place for its use (e.g., the requirement to enter patient response information into a national database). Thanks.

https://www.nytimes.com/2019/03/05/health/depression-treatment-ketamine-fda.html

---

From: Jensen, Jon M.
Sent: Wednesday, March 6, 2019 5:41 PM
To: Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Howard, Kristi <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: HHS bought a nasal spray for depression

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Good evening, need some information on a nasal spray used for depression? POTUS heard HHS recently purchased and he felt it would be great for us. That's all I got. Can you pull info on what it would be, if we purchase currently, if we are looking into it etc. would sure appreciate anything you could provide by 10am.

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

Sender:	Pomerantz, Andrew /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=29A9288DF9A34E84BDDFD00CDE79F11B-POMERANTZ, <(b6) @va.gov>
Recipient:	Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>; McGuire, Marsden H. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29e9d648c29f4885828c10446fdd7379-McGuire, Ma <(b6) va.gov>; Katz, Ira R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=65f4e28aa7574641932c29fed7c0b4b8-Katz, Ira R <(b6) va.gov>; VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>
Sent Date:	2019/03/06 19:44:14
Delivered Date:	2019/03/06 19:44:15

AMERICAN OVERSIGHT

From:	Jensen, Jon M. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DDEB735ACE76400DB5C3F10603188A14-JENSEN, JON <(b6) va.gov>
To:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Beck, Lucille B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=845480228a8b43e7a5fef5716ded04c2-Beck, Lucil <(b6) va.gov>; Howard, Kristi /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8d0afc371994181883d8861127791c3-Howard, Kri <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>
Subject:	RE: HHS bought a nasal spray for depression
Date:	2019/03/06 19:50:19
Priority:	Normal
Type:	Note

Thanks Tom!

Jon Jensen
VHA Acting Deputy Chief of Staff
W:(b6)
(b6)

From: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:49 PM
To: Jensen, Jon M. <(b6) va.gov>, Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Hi Jon,
We will work on it and get a response back.
Tom

Sent with BlackBerry Work
(www.blackberry.com)

From: Jensen, Jon M. <(b6) va.gov>

AMERICAN OVERSIGHT

Date: Wednesday, Mar 06, 2019, 7:34 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Adding Jennifer

Jon Jensen
VHA Acting Deputy Chief of Staff
W:(b6)
(b6)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:27 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Just spoke to Dr Stone. We need to get something a little earlier than 10. As soon as you can would be fantastic.
Secva has asked for an update.

Jon Jensen
VHA Acting Deputy Chief of Staff
W:(b6)
(b6)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 5:40 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: HHS bought a nasal spray for depression

Good evening, need some information on a nasal spray used for depression? POTUS heard HHS recently purchased and he felt it would be great for us. That's all I got. Can you pull info on what it would be, if we purchase currently, if we are looking into it etc. would sure appreciate anything you could provide by 10am.

AMERICAN OVERSIGHT

Jon Jensen
VHA Acting Deputy Chief of Staff
W: (b6)
(b6)

Sender:	Jensen, Jon M. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DDEB735ACE76400DB5C3F10603188A14-JENSEN, JON <(b6) va.gov>
Recipient:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Beck, Lucille B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=845480228a8b43e7a5fef5716ded04c2-Beck, Lucil <(b6) va.gov>; Howard, Kristi /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8d0afc371994181883d8861127791c3-Howard, Kri <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>
Sent Date:	2019/03/06 19:50:18
Delivered Date:	2019/03/06 19:50:19

AMERICAN OVERSIGHT

From:	Llorente, Maria D. </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F5C91F577D894BD9A0F09305DB34DD4F-LLORENTE, M>
To:	Beck, Lucille B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=845480228a8b43e7a5fef5716ded04c2-Beck, Lucil <(b6) va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; Law, Cassandra M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f888d507d6c54eb5a92fc44199eb5838-Law, Cassan <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>
CC:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>
Subject:	RE: HHS bought a nasal spray for depression
Date:	2019/03/06 23:03:07
Priority:	Normal
Type:	Note

This medication is chemically similar to ketamine, can only be administered in medical office due to possible adverse effects. My understanding is that the patient will have to be monitored for approx 2 hours.

(b) (5)

Sent with BlackBerry Work
(www.blackberry.com)

From: Beck, Lucille B. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 10:00 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>, Law, Cassandra M. <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Cc: Llorente, Maria D. <(b6) va.gov>, Valentino, Michael (VACO) <(b6) va.gov>

AMERICAN OVERSIGHT

Subject: RE: HHS bought a nasal spray for depression

Washington Post article today reported that the spray was just approved by the FDA scientific panel for severe depressionwhen other drugs have not been effective.
The drug has some potentially serious side effects and the panel's recommendation is to administer in controlled environments with patient surveillance.

Sent with BlackBerry Work
(www.blackberry.com)

From: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 8:48 PM
To: Law, Cassandra M. <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Cc: Llorente, Maria D. <(b6) va.gov>, Valentino, Michael (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Hi Cassie,

Jenn and I are on the phone together and we are working on the request now. I called Jon about 30 minutes ago to make sure what we are working on…is what they are looking for….we will send the info as soon as we are done.

Thank you,

Tom

From: Law, Cassandra M.
Sent: Wednesday, March 06, 2019 8:46 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>
Cc: Llorente, Maria D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>
Subject: FW: HHS bought a nasal spray for depression

Good evening Tom and Jennifer. I am reaching out to you per Mike's Out of Office regarding the SECVA request for information for tomorrow morning (Jon Jensen email).

Sorry for the late outreach, but since information is requested for early tomorrow morning, trying to cover all bases to gain insight. Jennifer, the number in the Out of Office for Mike does not appear to be yours so I did not leave a voice mail message.

This may be a MH / Dave Carrol question regarding awareness and efficacy and potential VA interest, but want to be sure we weigh-in with any relevant information.

Thank you for any assistance, Cassie

AMERICAN OVERSIGHT

From: Law, Cassandra M.
Sent: Wednesday, March 06, 2019 8:28 PM
To: Jensen, Jon M. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Howard, Kristi <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Thanks Jon. While this is not what SECVA needs for tomorrow, it may be useful. I just read an article on this yesterday in the NY Times (see link below). It's a nasal spray version of the drug ketamine called esketamine. It was developed by a branch of J&J and is to be marketed under the name Spravato.

There is a National Institute of Mental Health Chief / researcher involved so no surprise with HHS backing. I am not aware of VA pursuit, but will see if Mike/Tom and Dave C have additional more relevant insight.

https://www.nytimes.com/2019/03/05/health/depression-treatment-ketamine-fda.html?smid=nytcore-ios-share

Cassie

From: Jensen, Jon M.
Sent: Wednesday, March 06, 2019 7:48 PM
To: Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Howard, Kristi <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

And Cassie

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:34 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

AMERICAN OVERSIGHT

Adding Jennifer

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:27 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Just spoke to Dr Stone. We need to get something a little earlier than 10. As soon as you can would be fantastic.
Secva has asked for an update.

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 5:40 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: HHS bought a nasal spray for depression

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Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

Sender:	Llorente, Maria D. </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F5C91F577D894BD9A0F09305DB34DD4F-LLORENTE, M>
Recipient:	Beck, Lucille B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=845480228a8b43e7a5fef5716ded04c2-Beck, Lucil <(b6) va.gov>;

AMERICAN OVERSIGHT

	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; Law, Cassandra M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f888d507d6c54eb5a92fc44199eb5838-Law, Cassan <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) @va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b6) @va.gov>
Sent Date:	2019/03/06 23:03:06
Delivered Date:	2019/03/06 23:03:07

AMERICAN OVERSIGHT

From:	Meyer, Laurence /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=56F0BA2C110D4E60863B66F9728F669D-MEYER, LAUR <(b6) va.gov>
To:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; Boyd, Teresa D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6886a7d555a43e0bee23c1e40e1c234-Boyd, Teres <(b6) va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Outlaw, William N. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3e1067978634fbf96a382bdcd5c1115-Outlaw, Wil <(b6) va.gov>; O'Toole, Thomas P.(b6) va.gov </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c5a34d8a4b294e9986ef6e1aa8009b3f-O'Toole, Th>; Tenhula, Wendy /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1dfacf744064e4c8590533bbccdd73c-Tenhula, We <(b6) @va.gov>
CC:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>; Law, Cassandra M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f888d507d6c54eb5a92fc44199eb5838-Law, Cassan <(b6) va.gov>; Denietolis, Angela L. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b51b87cff64f4354b78eb943f97b47f3-Denietolis, <(b6) va.gov>; Ramoni, Rachel /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fe9b81d214fe4c6facd2c08857b83f7a-Ramoni, Rac (b6) @va.gov>
Subject:	RE: HHS bought a nasal spray for depression
Date:	2019/03/11 08:31:45
Priority:	Normal
Type:	Note

This might be a place where the VA could run a comparative effectiveness study. The only difference between ketamine and esketamine is a racemic v. enantiomeric drug (and the nasal v. IV administration). Unless the asymmetric carbon affects receptor binding they could be entirely equivalent. I have not seen the pricing, but I would guess ketamine is significantly less expensive.

Laurence J. Meyer, PhD, MD
Chief Officer Specialty Care
(b6)

AMERICAN OVERSIGHT

From: Emmendorfer, Thomas (PBM)
Sent: Monday, March 11, 2019 7:56 AM
To: Boyd, Teresa D. <(b6) va.gov>; Wiechers, Ilse (b6) @va.gov>; Llorente, Maria D. <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. <(b6) 2@va.gov>; O'Toole, Thomas P. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>; Meyer, Laurence <(b6) va.gov>; Denietolis, Angela L. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Ilse,

This is great work. Could the PERC run a query for IV Ketamine users for treatment refractory depression?

We are getting requests for these data as well.

Thank you,

Tom

From: "Boyd, Teresa D." <(b6) va.gov>
Date: Monday, March 11, 2019 at 5:16 AM
To: "Wiechers, Ilse" (b6) @va.gov>, Thomas Emmendorfer <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Outlaw, William N." <(b6) va.gov>, "O'Toole, Thomas P." <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>, "Meyer, Laurence" <(b6) va.gov>, "Denietolis, Angela L." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Great work, Ilse! Gives the agency the overall potential demand (and costing), and suspect sites will want to know their potential local demand. Really appreciate the great work by PBM to coordinate this work and Dr. Llorente.

Teresa

Sent with BlackBerry Work
(www.blackberry.com)

From: Wiechers, Ilse (b6) @va.gov>
Date: Sunday, Mar 10, 2019, 10:05 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>, Llorente, Maria D. <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Outlaw, William N. <(b6) va.gov>, O'Toole, Thomas P. <(b6) va.gov>

AMERICAN OVERSIGHT

Cc: Valentino, Michael (VACO) <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>, Law, Cassandra M. <(b6) va.gov>, Boyd, Teresa D. <(b6) va.gov>, Meyer, Laurence <(b6) va.gov>, Denietolis, Angela L. (b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Hello everyone –

Here is what I've been able to pull together with PERC to answer the request "define the universe of patients that may meet the criteria for prescribing of Spravato®."

(b) (5)

If this seems like a reasonable approach, we will run this data by homestation, which will give us the #s for each VAMC.

Ilse

From: Emmendorfer, Thomas (PBM)
Sent: Friday, March 08, 2019 12:57 PM
To: Llorente, Maria D. <(b6) va.gov>; Wiechers, Ilse <(b6) @va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. (b6) @va.gov>; O'Toole, Thomas P. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>; Meyer, Laurence <(b6) va.gov>; Denietolis, Angela L. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

AMERICAN OVERSIGHT

Summary of Actions for Spravato® (esketamine) to date

OPEN:

(b) (5)



AMERICAN OVERSIGHT

COMPLETED:

1. (b) (5) [redacted]

From: "Llorente, Maria D." <(b6) va.gov>
Date: Friday, March 8, 2019 at 1:47 PM
To: "Wiechers, Ilse" (b6) @va.gov>, Thomas Emmendorfer <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Outlaw, William N." <(b6) @va.gov>
Cc: Michael Valentino <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Very helpful. Thank you!

From: Wiechers, Ilse
Sent: Friday, March 8, 2019 1:47 PM
To: Llorente, Maria D. <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Will do.

I've spoken to several private ketamine clinics in recent years, and the only physician type missing on your list that I have heard about is ED physicians. I also know of several clinics using APRNs under the supervision of one of those physicians listed below.

From: Llorente, Maria D.
Sent: Friday, March 08, 2019 10:43 AM
To: Wiechers, Ilse (b6) @va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Yes, if you could. My understanding is that in private sector, psychiatrists, anesthesiologists, neurologists, and pain medicine providers may administer. This is in part because IV ketamine is also used for intractable pain.

AMERICAN OVERSIGHT

From: Wiechers, Ilse
Sent: Friday, March 8, 2019 1:29 PM
To: Llorente, Maria D. <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. <(b6) @va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

We do not have information on that. I can follow up on the responses to the Somatic Treatment Field Assessment and reach out to facilities that report providing IV ketamine and ask them.

From: Llorente, Maria D.
Sent: Friday, March 08, 2019 10:23 AM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Wiechers, Ilse (b6) @va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Ilse, do you know if all the current VA providers who administer IV ketamine for treatment resistant depression are psychiatrists? Do we have any anesthesiologists for example?

From: Emmendorfer, Thomas (PBM)
Sent: Friday, March 8, 2019 12:50 PM
To: Llorente, Maria D. <(b6) va.gov>; Wiechers, Ilse (b6) @va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. (b6) @va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Thank you Ilse!

I just sent the internal communications document to Jenn for review (setup as a FAQ). When she is done with her review and edits she will send it over to you.

Tom

From: "Llorente, Maria D." <(b6) va.gov>
Date: Friday, March 8, 2019 at 12:08 PM
To: "Wiechers, Ilse" (b6) @va.gov>, Thomas Emmendorfer <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Outlaw, William N." <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>,

AMERICAN OVERSIGHT

"Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Thank you all very much.

From: Wiechers, Ilse
Sent: Friday, March 8, 2019 12:04 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. (b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Tom –

I'll reach out to Ethics to get things started. Happy to look at draft documents whenever you and Jenn have something ready to share.

Best,
Ilse

From: Emmendorfer, Thomas (PBM)
Sent: Friday, March 08, 2019 8:02 AM
To: Wiechers, Ilse (b6) .gov>; Carroll, David (VACO) <(b6) va.gov>; Outlaw, William N. (b6) .gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Hi Ilse,

Dave and I spoke this morning after the briefing to Dr. Stone. Action items

- • Mental Health and PBM to start working together with the Comms team to develop internal/external communication.
    - • NEXT STEPS: Jenn Z. and I can work with you on the communication. Jenn and I will send you over a draft document to review.
- • iMed Consent: At morning report-Ethics asked if Spravato will need an iMed Consent.
    - • NEXT STEPS: Could you contact Ethics and work with them to determine and develop an imed consent (if needed) for Spravato?

Bill,

I adding you to the e-mail as well as we will need your assistance with getting the external communication through the process.

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Thank you!

Tom

From: "Wiechers, Ilse" (b6) va.gov>
Date: Thursday, March 7, 2019 at 10:04 AM
To: Thomas Emmendorfer <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Yes – self reported data from the field.

Attached is a copy of the full Somatic Treatment Field Assessment – ketamine for MH is section III.

From: Emmendorfer, Thomas (PBM)
Sent: Thursday, March 07, 2019 7:00 AM
To: Wiechers, Ilse (b6) a.gov>; Carroll, David (VACO) <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Hi Ilse,

Thank you very much for the information below!

(b) (5)
?

Tom

From: "Wiechers, Ilse" (b6) @va.gov>
Date: Thursday, March 7, 2019 at 9:55 AM
To: "Carroll, David (VACO)" <(b6) va.gov>, Thomas Emmendorfer <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Below are the sites reporting use in FY15 from the assessment we did of the field back in fall 2016. The 2019 assessment went to the field in Feb and we are working to gather the final data from sites now.

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Hope to have updated data about sites using IV ketamine for treatment of MH conditions sometime later this month.

1-(689) VA Connecticut HCS, CT
18-(501) New Mexico HCS
23-(618) Minneapolis, MN
1-(523) VA Boston HCS, MA
6-(659) Salisbury, NC
12-(607) Madison, WI
16-(580) Houston, TX
21-(662) San Francisco, CA

Best,
Ilse

From: Carroll, David (VACO)
Sent: Thursday, March 07, 2019 6:39 AM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Wiechers, Ilse (b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

I do not. Ilse may have a list or can otherwise find out.

From: Emmendorfer, Thomas (PBM)
Sent: Thursday, March 7, 2019 9:25 AM
To: Carroll, David (VACO) <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Hi Dave,

The briefing went very well. By chance, do you have a list of known VA medical facilities that are using intravenous ketamine for the treatment of refractory depression?

Thank you,

Tom

From: Thomas Emmendorfer <(b6) va.gov>
Date: Thursday, March 7, 2019 at 7:45 AM
To: Jon Jensen <(b6) va.gov>

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Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Beck, Lucille B." <(b6) va.gov>, "Howard, Kristi" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: Re: HHS bought a nasal spray for depression

Will do.

From: Jon Jensen <(b6) va.gov>
Date: Thursday, March 7, 2019 at 7:41 AM
To: Thomas Emmendorfer <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, "Carroll, David (VACO)" <(b6) va.gov>, "Beck, Lucille B." <(b6) va.gov>, "Howard, Kristi" <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>, "Llorente, Maria D." <(b6) va.gov>, "Law, Cassandra M." <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Tom, can you come to Morning Report today to discuss? Starts at 9:30.

From: Emmendorfer, Thomas (PBM)
Sent: Wednesday, March 06, 2019 10:15 PM
To: Jensen, Jon M. (b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Howard, Kristi <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Hi Jon,

I hope all is going well. Below is the information that Jenn, Mike, and I pulled together for you. Let us know if you need anything else.

Tom

(b) (5)

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- (b) (5) [redacted]

From: Jensen, Jon M.
Sent: Wednesday, March 06, 2019 7:50 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Howard, Kristi <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Thanks Tom!

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:49 PM

AMERICAN OVERSIGHT

To: Jensen, Jon M. <(b6) va.gov>, Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Hi Jon,

We will work on it and get a response back.

Tom

Sent with BlackBerry Work
(www.blackberry.com)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:34 PM
To: Valentino, Michael (VACO) (b6) gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Adding Jennifer

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 7:27 PM
To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: HHS bought a nasal spray for depression

Just spoke to Dr Stone. We need to get something a little earlier than 10. As soon as you can would be fantastic.
Secva has asked for an update.

Jon Jensen
VHA Acting Deputy Chief of Staff
(b6)
(b6)

From: Jensen, Jon M. <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 5:40 PM

AMERICAN OVERSIGHT

To: Valentino, Michael (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Beck, Lucille B. <(b6) va.gov>, Howard, Kristi <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: HHS bought a nasal spray for depression

Good evening, need some information on a nasal spray used for depression? POTUS heard HHS recently purchased and he felt it would be great for us. That's all I got. Can you pull info on what it would be, if we purchase currently, if we are looking into it etc. would sure appreciate anything you could provide by 10am.

Jon Jensen
VHA Acting Deputy Chief of Staff
W:(b6)
(b6)

Sender:	Meyer, Laurence /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=56F0BA2C110D4E60863B66F9728F669D-MEYER, LAUR (b6) r@va.gov>
Recipient:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; Boyd, Teresa D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6886a7d555a43e0bee23c1e40e1c234-Boyd, Teres <(b6) va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Outlaw, William N. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3e1067978634fbf96a382bdcd5c1115-Outlaw, Wil (b6) @va.gov>; O'Toole, Thomas P.(b6) va.gov </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c5a34d8a4b294e9986ef6e1aa8009b3f-O'Toole, Th>; Tenhula, Wendy /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1dfacf744064e4c8590533bbccdd73c-Tenhula, We (b6) @va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>; Law, Cassandra M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f888d507d6c54eb5a92fc44199eb5838-Law, Cassan <(b6) va.gov>; Denietolis, Angela L. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b51b87cff64f4354b78eb943f97b47f3-Denietolis, <(b6) va.gov>; Ramoni, Rachel /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fe9b81d214fe4c6facd2c08857b83f7a-Ramoni, Rac (b6) va.gov>
Sent Date:	2019/03/11 08:31:44
Delivered Date:	2019/03/11 08:31:45

AMERICAN OVERSIGHT

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From:	Llorente, Maria D. </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F5C91F577D894BD9A0F09305DB34DD4F-LLORENTE, M>
To:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>
Subject:	RE: Group just voted to change ketamine to match Esketamine
Date:	2019/06/20 14:49:35
Priority:	Normal
Type:	Note

Agreed and that is consistent with wording namely that ECT is considered, not necessarily used.

Sent with BlackBerry Work
(www.blackberry.com)

From: Wiechers, Ilse <(b6) va.gov>
Date: Thursday, Jun 20, 2019, 1:47 PM
To: Llorente, Maria D. <(b6) va.gov>
Subject: RE: Group just voted to change ketamine to match Esketamine

Noted, and reasonable. Considering an existing evidence-based treatment for TRD prior to moving to esketamine or ketamine is totally reasonable. That said, not all patients are going to be willing to try ECT, but I think having that discussion with them should be part of a process of walking through treatment steps.

From: Llorente, Maria D.
Sent: Thursday, June 20, 2019 11:44 AM
To: Wiechers, Ilse (b6) @va.gov>
Subject: Group just voted to change ketamine to match Esketamine

Just as an FYI

Sent with BlackBerry Work
(www.blackberry.com)

Sender:	Llorente, Maria D. </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F5C91F577D894BD9A0F09305DB34DD4F-LLORENTE, M>
Recipient:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>
Sent Date:	2019/06/20 14:49:35

AMERICAN OVERSIGHT

From:	Capehart, Bruce P. DURVAMC /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6866EFF4E9DF4A48846D056A02044C38-CAPEHART, B <(b6) va.gov>
To:	Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat <(b6) va.gov>
Subject:	RE: gabapentinoids and suicide
Date:	2019/06/21 08:10:47
Priority:	Normal
Type:	Note

Matthew,

That's interesting. I saw the abstract but didn't read the whole paper until this AM.

Looks like pregabalin is the main culprit.

Should we examine this question with Fran's dataset?

Regards,

Bruce

From: Fuller, Matthew A. (PBM)
Sent: Tuesday, June 18, 2019 8:21 AM
To: Capehart, Bruce P. DURVAMC <(b6) va.gov>
Subject: gabapentinoids and suicide

Bruce,

FYI, something other than esketamine….

Matthew

Sender:	Capehart, Bruce P. DURVAMC /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6866EFF4E9DF4A48846D056A02044C38-CAPEHART, B <(b6) va.gov>
Recipient:	Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat <(b6) va.gov>
Sent Date:	2019/06/21 08:10:46
Delivered Date:	2019/06/21 08:10:47

AMERICAN OVERSIGHT

From:	Schreiber, Matthew A. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DB4D0324BF0945F183F33816C7FD1DB0-SCHREIBER, (b6) va.gov>
To:	Glassman, Peter A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90608d43ef14423db308fb6c71ed750b-Glassman, P (b6) va.gov>; Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat <(b6) va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Capehart, Bruce P. DURVAMC /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6866eff4e9df4a48846d056a02044c38-Capehart, B <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>
Subject:	RE: From today's news clips
Date:	2019/06/26 10:22:58
Priority:	Normal
Type:	Note

(b) (5) [redacted]

From: Glassman, Peter A.
Sent: Wednesday, June 26, 2019 7:14 AM
To: Fuller, Matthew A. (PBM) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Capehart, Bruce P. DURVAMC <(b6) va.gov>; Schreiber, Matthew A. (b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: From today's news clips

That was my thought as well. (b6) [redacted]

(b) (5) [redacted]

P

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(www.blackberry.com)

AMERICAN OVERSIGHT

From: Fuller, Matthew A. (PBM) <(b6) va.gov>
Date: Wednesday, Jun 26, 2019, 6:42 AM
To: Valentino, Michael (VACO) <(b6) va.gov>, Capehart, Bruce P. DURVAMC <(b6) va.gov>, Glassman, Peter A. <(b6) va.gov>, Schreiber, Matthew A. <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: From today's news clips

Hi Mike,

I believe they are referring to the SUSTAIN-1 trial that showed that: those patients in stable remission or with stable response who continued treatment with esketamine plus an oral antidepressant experienced a statistically significantly longer time to relapse of depressive symptoms than patients on placebo nasal spray plus an oral antidepressant. However, as noted in the FDA briefing document, the faster rate of relapse in those patients who were randomized to placebo nasal spray plus and oral antidepressant could reflect functional unblinding, with subjects realizing that they are no longer on esketamine after switching to placebo. Hope this helps.

Matthew

From: Valentino, Michael (VACO)
Sent: Wednesday, June 26, 2019 9:31 AM
To: Capehart, Bruce P. DURVAMC <(b6) va.gov>; Fuller, Matthew A. (PBM) <(b6) va.gov>; Glassman, Peter A. <(b6) va.gov>; Schreiber, Matthew A. <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: From today's news clips

Hmm…..

What "…..proven…..long-term benefits of the drug" could J&J be referencing in the quote at the end of the article?

Mike

2.10 - FiercePharma: J&J depression drug Spravato gets half-hearted backing from VA doctors despite Trump's zeal (24 June, Eric Sagonowsky, 121k uvm; Washington, DC)

Despite unconventional support from President Donald Trump, Johnson &Johnson's Spravato didn't win broad backing at the U.S. Department of Veterans Affairs. Agency clinicians instead approved the depression spray's use on a limited basis, requiring patients to try other options first.

A team of VA clinicians last week voted against putting the drug on the VA's formulary, an agency spokeswoman said. Instead, the VA will require a process similar to prior authorizations for patients seeking treatment with the med. Aside from that limitation, the drug also carries strict administration requirements, such as a stipulation that doctors must monitor patients for two hours after dosing.

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Spravato is an altered form of ketamine, which is used legally in anesthesia and illegally as a street drug. The med, also known as esketamine, won FDA approval earlier this year in patients who have tried and failed on at least two other depression medications.

“These evidence-based processes will ensure the medication is prioritized for use in veterans who have not previously responded to adequate trials of other available treatments for major depression,” a VA spokeswoman told FiercePharma.

A J&J representative said the company is "committed to working with public and private payers, including the U.S. Department of Veteran Affairs, to ensure access to Spravato for patients who need it."

"We firmly believe that people suffering from treatment-resistant depression, including our nation’s veterans, deserve the opportunity to benefit from this breakthrough medicine," she added.

The run-up to the VA vote generated considerable media attention, particularly after Trump praised the drug in a meeting this month with Veterans Affairs Secretary Robert Wilkie. Trump told Wilkie he believed J&J would be “generous” on pricing, and that the drug could lead to an “incredible” reduction in veteran suicides, Bloomberg reported. He also offered to negotiate the drug’s price.

Adding to the scrutiny was a recent report by the Guardian and the Center for Public Integrity that the VA hurried its review and potential implementation of the med based on interest from the president.

Reacting in a statement to those headlines, House Committee on Veterans' Affairs chairman Mark Takano said he's "incredibly alarmed by reporting today that suggests Spravato, a controversial new drug, is being rushed through critical reviews and may be prescribed to veterans before fully vetting the potential risks and benefits."

The drug’s price has also generated criticism. Spravato costs $4,720 to $6,785 before discounts for the first month, and up to $3,450 for additional months. Last week, cost watchdog ICER called the drug overpriced, saying the company would have to slash its price by 25% to 52% to make it cost-effective, while a J&J spokeswoman said the analysis “underestimates the proven short- and long-term benefits” of the drug.

Spravato won approval in March and is one of several new or upcoming launches J&J has touted as a potential blockbuster.

Michael A. Valentino, R.Ph., MHSA
Chief Consultant, Pharmact Benefits Management Services
Department of Veterans Affairs
Room 982
810 Vermont Avenue NW
Washington DC

(b6)

AMERICAN OVERSIGHT

Sender:	Schreiber, Matthew A. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DB4D0324BF0945F183F33816C7FD1DB0-SCHREIBER, <(b6) va.gov>
Recipient:	Glassman, Peter A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90608d43ef14423db308fb6c71ed750b-Glassman, P <(b6) va.gov>; Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat <(b6) va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Capehart, Bruce P. DURVAMC /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6866eff4e9df4a48846d056a02044c38-Capehart, B <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>
Sent Date:	2019/06/26 10:22:57
Delivered Date:	2019/06/26 10:22:58
Message Flags:	Unread

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From:	Glassman, Peter A. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90608D43EF14423DB308FB6C71ED750B-GLASSMAN, P <(b6) va.gov>
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Date:	2019/06/26 13:25:28
Priority:	Normal
Type:	Note

One also has to look at SUSTAIN-1 and the underlying hypothesis being tested to frame this correctly. In the initial efficacy trials the hypothesis was that adding de novo esketamine to a de novo antidepressant would provide benefit in terms of less depression symptoms. One trial confirmed this hypothesis, and two did not.

In the SUSTAIN-1 trial, the underlying hypothesis being tested is in a highly selected population of responders (those who had had efficacy already demonstrated) would continuation of esketamine benefit (versus anti-depressant alone). That trial showed a benefit, essentially telling us that those who already have a benefit from therapy continue to benefit with prolonged use. This trial has more practical implications for those already on esketamine rather than telling us about de novo efficacy.

But, there are some substantive things to consider along the way:

1. • The SUSTAIN-1 patient population is a very selected group of high responders (e.g., >or + to 50% responders on MADRS) either in stable remission or having a stable response
2. • The prespecified primary analysis stated that they looked at those in stable remission (not stable response) and that part of the study only included 176 individuals (Figure 1)
3. • The preponderance of participants in stable remission were younger (average age around mid 40's) and mostly (white, European) women—about a third were men (i.e., in the stable remission group there were a total of 59 men [see Table 1)
4. • The average duration of MDD was about 110 to 112 weeks (stable remission patients) with most (about 79%) having had 2 or fewer oral antidepressants before screening (Table 1)

So, in this younger group of mostly white, European women with long durations of depression (more than 2 years) who were often tried on only 1 or 2 antidepressant drugs (about 74-79% in the stable remission group) during those episodes the continuation of esketmaine on highly selected and substantial responders had a benefit in terms of the number of relapses. While this could be considered

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"long term" follow-up findings, the study's small population (particularly with such a small numbers of males) does not equate to "proven" benefits of the drug, at least not In my calculation, in a population similar to our VA population. "Proven" drugs, for depression anyway, have long term use, with widespread clinical experience, in large diverse populations—or at the very least large properly conducted RCTs to base evidence upon. Moreover, while not seen in this study, this has to be viewed in the context of the prior efficacy studies (modest findings given the 2 negative "short-term" trials) and the potential, cumulative suicide signal.

Just my two cents.

p

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Sent: Wednesday, June 26, 2019 8:07 AM
To: Valentino, Michael (VACO) <(b6) va.gov>; Capehart, Bruce P. DURVAMC <(b6) va.gov>; Glassman, Peter A. <(b6) va.gov>; Schreiber, Matthew A. <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>
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(b6)

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Subject:	RE: From today's news clips
Date:	2019/06/26 13:10:12
Priority:	Normal
Type:	Note

Before VA went to spend money on an esketamine CSP – which would take years to report results – we are very likely to find useful information from esketamine use. Assuming Fran has the CPRS template note in place, we should have better information than most naturalistic real-world retrospective studies. Data from that use could inform the need for a CSP, or further refine CSP hypotheses.

The functional unblinding mentioned below by Matthew F is very important. The IV ketamine effect sizes change depending upon the control group. Saline control yields a rather large effect size, IV midazolam less so.

Any VA study should include an active control. Returning to history from decades ago, alprazolam looked more like an antidepressant when compared only to amitriptyline. When compared to a TCA, lorazepam, and placebo, the two benzos performed similarly, beating placebo but not performing as well as the TCA. It was the end of company's "unique triazolo-ring structure" marketing campaign. That shift also helped psychiatry see alprazolam as just another benzodiazepine, making it seem less like an antidepressant.

Recent residency graduates are unaware alprazolam ever was considered an antidepressant. (b6)

(b6)

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Adding to the scrutiny was a recent report by the Guardian and the Center for Public Integrity that the VA hurried its review and potential implementation of the med based on interest from the president.

Reacting in a statement to those headlines, House Committee on Veterans' Affairs chairman Mark Takano said he's "incredibly alarmed by reporting today that suggests Spravato, a controversial new drug, is being rushed through critical reviews and may be prescribed to veterans before fully vetting the potential risks and benefits."

The drug’s price has also generated criticism. Spravato costs $4,720 to $6,785 before discounts for the first month, and up to $3,450 for additional months. Last week, cost watchdog ICER called the drug overpriced, saying the company would have to slash its price by 25% to 52% to make it cost-effective, while a J&J spokeswoman said the analysis “underestimates the proven short- and long-term benefits” of the drug.

Spravato won approval in March and is one of several new or upcoming launches J&J has touted as a potential blockbuster.

Michael A. Valentino, R.Ph., MHSA
Chief Consultant, Pharmact Benefits Management Services
Department of Veterans Affairs
Room 982
810 Vermont Avenue NW
Washington DC

(b6)

Recipient:	Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat <(b6) va.gov>; Capehart, Bruce P. DURVAMC /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6866eff4e9df4a48846d056a02044c38-Capehart, B <(b6) va.gov>; Glassman, Peter A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90608d43ef14423db308fb6c71ed750b-Glassman, P <(b6) va.gov>; Schreiber, Matthew A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=db4d0324bf0945f183f33816c7fd1db0-Schreiber, <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen (b6) @va.gov>
Sent Date:	2019/06/26 09:48:31
Delivered Date:	2019/06/26 10:15:11
Message Flags:	Unread Unsent

AMERICAN OVERSIGHT

From:	Sales, Marie /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0903DEC780A4A718D49602777FA5643-SALES, MARI <(b6) va.gov>
To:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>
Subject:	RE: Frequently Asked Questions (FAQ): Esketamine (Spravato®)
Date:	2019/03/15 14:57:38
Priority:	Normal
Type:	Note

Great! Happy to help!

From: Emmendorfer, Thomas (PBM)
Sent: Friday, March 15, 2019 1:55 PM
To: Sales, Marie <(b6) va.gov>
Subject: RE: Frequently Asked Questions (FAQ): Esketamine (Spravato®)

That's okay Marie…If they get two message…thank you for doing this again for us!!

I owe you one.

From: Sales, Marie
Sent: Friday, March 15, 2019 2:40 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: Frequently Asked Questions (FAQ): Esketamine (Spravato®)

Hi Tom,

Wanted to run something by you. For those messages that were already opened and could not be recalled, I was thinking of adding "Updated Message" (as highlighted below) to the top to differentiate it from the previously sent message. Thoughts?

Thanks,
Marie

UPDATED MESSAGE

Attached is the **Frequently Asked Questions (FAQ)** sheet addressing the newly FDA-approved **esketamine (Spravato®)** nasal spray for treatment-resistant depression published by the VA Pharmacy Benefits Management Services and Office of Mental Health and Suicide Prevention. This FAQ sheet will also be available online at the following link https://vaww.cmopnational.va.gov/cmop/pbm/default.aspx (pending posting).

The purpose of this FAQ sheet is to:

AMERICAN OVERSIGHT

- • Disseminate new drug information to the provider-level regarding esketamine (Spravato®)
- • Provide answers on availability and accessibility of esketamine (Spravato®) within VA

From: Sales, Marie
Sent: Friday, March 15, 2019 1:34 PM
To: Emmendorfer, Thomas (PBM) <{b6} va.gov>
Subject: RE: Frequently Asked Questions (FAQ): Esketamine (Spravato®)

HI Tom,

Saw this message after seeing your IM. I have recalled the message and will send out a new one.

Thanks,
Marie

From: Emmendorfer, Thomas (PBM)
Sent: Friday, March 15, 2019 1:05 PM
To: Sales, Marie <{b6} va.gov>
Subject: RE: Frequently Asked Questions (FAQ): Esketamine (Spravato®)

Hi Marie—I hate to do this…could you recall the message and resend with the following edit (we don't know exactly when the VA's New Release will go out).

Thank you! This communication looks great!

Attached is the **Frequently Asked Questions (FAQ)** sheet addressing the newly FDA-approved **esketamine (Spravato®)** nasal spray for treatment-resistant depression published by the VA Pharmacy Benefits Management Services and Office of Mental Health and Suicide Prevention. This FAQ sheet ~~accompanies VA's News Release and~~ will also be available online at the following link https://vaww.cmopnational.va.gov/cmop/pbm/default.aspx (pending posting).

The purpose of this FAQ sheet is to:

- • Disseminate new drug information to the provider-level regarding esketamine (Spravato®)
- • Provide answers on availability and accessibility of esketamine (Spravato®) within VA

From: Sales, Marie
Sent: Friday, March 15, 2019 1:55 PM
To: VHAPBM MAP Committee <pbm.map@med.va.gov>; VHAPBM VISN Pharmacist Executives

AMERICAN OVERSIGHT

<VISNPharmacyExecs@va.gov>; VHAPBM Pharmacy Chiefs <PharmacyChiefs@va.gov>; VHAPBM PMO <PMO@va.gov>
Subject: Frequently Asked Questions (FAQ): Esketamine (Spravato®)
Importance: High

Attached is the **Frequently Asked Questions (FAQ)** sheet addressing the newly FDA-approved **esketamine (Spravato®)** nasal spray for treatment-resistant depression published by the VA Pharmacy Benefits Management Services and Office of Mental Health and Suicide Prevention. This FAQ sheet accompanies VA's News Release and will also be available online at the following link https://vaww.cmopnational.va.gov/cmop/pbm/default.aspx (pending posting).

The purpose of this FAQ sheet is to:

- • Disseminate new drug information to the provider-level regarding esketamine (Spravato®)
- • Provide answers on availability and accessibility of esketamine (Spravato®) within VA

Sender:	Sales, Marie /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0903DEC780A4A718D49602777FA5643-SALES, MARI <(b6) va.gov>
Recipient:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>
Sent Date:	2019/03/15 14:57:37
Delivered Date:	2019/03/15 14:57:38

AMERICAN OVERSIGHT

From:	Valentino, Michael (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO, <(b6) va.gov>
To:	Stone, Richard A., MD /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bd16619615d64adea22e45e63ff6462a-Stone, Rich <(b6) va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) va.gov>; Beck, Lucille B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=845480228a8b43e7a5fef5716ded04c2-Beck, Lucil <(b6) va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; Jensen, Jon M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddeb735ace76400db5c3f10603188a14-Jensen, Jon <(b6) va.gov>; Connell, Lawrence B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a3e7233376344045980ad214122389f4-Connell, La (b6) @va.gov>
Subject:	RE: Follow Up: HHS Nasal Spray
Date:	2019/03/07 16:44:18
Priority:	Normal
Type:	Note

Courtesy copy of the draft slides for tomorrow morning's discussion about VA's drug rep policy attached.

Official cleared slides will come through after 10P4 and 10P concurrence.

Mike

-----Original Appointment-----
From: Howard, Kristi **On Behalf Of** Stone, Richard A., MD
Sent: Thursday, March 07, 2019 2:35 PM
To: Llorente, Maria D.; Beck, Lucille B.; Emmendorfer, Thomas (PBM); Jensen, Jon M.; Valentino, Michael (VACO); Connell, Lawrence B.
Subject: Follow Up: HHS Nasal Spray
When: Friday, March 08, 2019 8:30 AM-9:00 AM (UTC-05:00) Eastern Time (US &Canada).
Where: VACO 802 or VANTS 1-800-767-1750 A/C 22021

Follow up from Thursday's morning meeting.

Sender:	Valentino, Michael (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO, <(b6) va.gov>
Recipient:	Stone, Richard A., MD /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bd16619615d64adea22e45e63ff6462a-Stone, Rich <(b6) va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group

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	(FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) va.gov>; Beck, Lucille B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=845480228a8b43e7a5fef5716ded04c2-Beck, Lucil <(b6) va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; Jensen, Jon M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddeb735ace76400db5c3f10603188a14-Jensen, Jon <(b6) va.gov>; Connell, Lawrence B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a3e7233376344045980ad214122389f4-Connell, La (b6) @va.gov>
Sent Date:	2019/03/07 16:44:16
Delivered Date:	2019/03/07 16:44:18

AMERICAN OVERSIGHT

From:	Valentino, Michael (VACO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO,>
To:	Kraemer, John E /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a2a0091f85ff4e6e8042219f6027a842-Kraemer, Jo (b6) @va.gov>
Subject:	RE: Follow Up: HHS Nasal Spray
Date:	2019/03/07 16:44:00
Priority:	Normal
Type:	Note

Yes, please

From: Kraemer, John E
Sent: Thursday, March 07, 2019 3:43 PM
To: Valentino, Michael (VACO) <(b6) va.gov>
Subject: RE: Follow Up: HHS Nasal Spray

Do you want this to go through 10P4 PCS Clearance?

From: Valentino, Michael (VACO)
Sent: Thursday, March 07, 2019 4:40 PM
To: VHA 10P4 Actions <VHA10P4Actions@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Cc: Llorente, Maria D. <(b6) va.gov>; Beck, Lucille B. <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: Follow Up: HHS Nasal Spray

For review and clearance for an 8:30am meeting tomorrow morning

-----Original Appointment-----
From: Howard, Kristi **On Behalf Of** Stone, Richard A., MD
Sent: Thursday, March 07, 2019 2:35 PM
To: Llorente, Maria D.; Beck, Lucille B.; Emmendorfer, Thomas (PBM); Jensen, Jon M.; Valentino, Michael (VACO); Connell, Lawrence B.
Subject: Follow Up: HHS Nasal Spray
When: Friday, March 08, 2019 8:30 AM-9:00 AM (UTC-05:00) Eastern Time (US &Canada).
Where: VACO 802 or VANTS 1-800-767-1750 A/C 22021

Follow up from Thursday's morning meeting.

Sender:	Valentino, Michael (VACO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO,>
Recipient:	Kraemer, John E /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a2a0091f85ff4e6e8042219f6027a842-Kraemer, Jo (b6) @va.gov>
Sent Date:	2019/03/07 16:44:51
Delivered Date:	2019/03/07 16:44:00

AMERICAN OVERSIGHT

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From:	Capehart, Bruce P. DURVAMC /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6866EFF4E9DF4A48846D056A02044C38-CAPEHART, B <(b6) va.gov>
To:	Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat <(b6) va.gov>; Schreiber, Matthew A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=db4d0324bf0945f183f33816c7fd1db0-Schreiber, <(b6) va.gov>
Subject:	RE: F2F meeting follow up
Date:	2019/06/21 13:36:24
Priority:	Normal
Type:	Note

Matthew,

You are most welcome. I can safely say I've learned more about ketamine in the last 3 months than I ever knew before, and picked up some valuable info on depression along the way.

I'm confident we'll revisit esketamine as the company plans additional indications. All of this knowledge will be useful the next time around.

Regards,

Bruce

From: Fuller, Matthew A. (PBM)
Sent: Friday, June 21, 2019 10:05 AM
To: Capehart, Bruce P. DURVAMC <(b6) va.gov>; Schreiber, Matthew A. <(b6) va.gov>
Subject: F2F meeting follow up

Hi Bruce and Matt,

Just wanted to say Thank-You for all your efforts to get the esketamine monograph, CFU, and national protocol guidance approved! While I know that this is not the end of the esketamine discussion, it is none the less a major hurdle. Please accept my thanks.

Regards,

Matthew

Sender:	Capehart, Bruce P. DURVAMC /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6866EFF4E9DF4A48846D056A02044C38-CAPEHART, B <(b6) va.gov>
Recipient:	Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat <(b6) va.gov>;

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	Schreiber, Matthew A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=db4d0324bf0945f183f33816c7fd1db0-Schreiber, <(b6) va.gov>
Sent Date:	2019/06/21 13:36:22
Delivered Date:	2019/06/21 13:36:24
Message Flags:	Unread

AMERICAN OVERSIGHT

From:	Fuller, Matthew A. (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=62D9CBB23B184CACB98895776E36A471-FULLER, MAT>
To:	Dailey, Janet /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=64678944a5aa4b4b8ba1c93d93d63534-Dailey, Jan <(b6) va.gov>
Subject:	RE: EZ minutes
Date:	2019/06/27 09:19:00
Priority:	Normal
Type:	Note

Hi Janet,

I have recently learned that academic detailing has reached out to EES to see what their options are before collaborating with PBM and OMHSP on esketamine education. I am waiting further instruction from Jenn as she has been working with both groups.

Matthew

From: Dailey, Janet
Sent: Monday, June 24, 2019 5:28 PM
To: Fuller, Matthew A. (PBM) <(b6) va.gov>
Subject: RE: EZ minutes

Hi Matthew,

A couple of thoughts..

I was interested in making sure the providers were aware the steps they needed to be do i.e. ….how to complete the forms etc. in order to prescribe esketamine. In addition to that, depending on space, explaining what you believe providers need to know about the drug PRIOR to ordering it which would of course include providing a brief overview of the evidence. What would you want providers to know and as a result, what decisions were made by the VA National Formulary Committee supporting the evidence.

I think a more detailed discussion might be more suited for the Ez Minutes Video which would be taped in late July. For that, I would review your slides, draft a script, send it to Dan (moderator) to add his spin and then have you review the script. Of course, I would be interested in letting the field know that VA Med SAFE was also monitoring the usage etc. if permitted.

Ez Minutes Newsletter is scheduled to be released Tues, Aug. 7th. The date for taping of the July Ez Minutes video is pending.

Open to thoughts/suggestions. If you have a date of the webinar that you spoke about, we could easily leverage that information.

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If you OR someone else would like to use the PBM Monthly Webinar platform to explain the agent to the field, I could make that happen. Right now, Aug. 20th might be available (will know in about a week) but Sept 17th is wide open.

Janet

Janet H. Dailey PharmD
National PBM Clinical Pharmacy Program Manager-Education/Insomnia
Chair, PBM Education Advisory Committee
VHA Pharmacy Benefits Management Services (10P4P)
(b6) va.gov (b6) (CT)
VA Pharmacy On-line Classroom (AKA Moodle site)
NEW! VA PBM Education SharePoint Site



cid:image002.jpg@01CE28E5.E9A17EE0

From: Fuller, Matthew A. (PBM)
Sent: Monday, June 24, 2019 10:26 AM
To: Dailey, Janet <(b6) va.gov>
Subject: EZ minutes

Hi Janet,

At the F2F meeting you wrote me a note about including information on esketamine for the EZ minutes. Can you say more about what you are interested in? Thanks.

Matthew

Sender:	Fuller, Matthew A. (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=62D9CBB23B184CACB98895776E36A471-FULLER, MAT>
Recipient:	Dailey, Janet /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=64678944a5aa4b4b8ba1c93d93d63534-Dailey, Jan <(b6) va.gov>
Sent Date:	2019/06/27 09:19:38
Delivered Date:	2019/06/27 09:19:00

AMERICAN OVERSIGHT

From:	Llorente, Maria D. </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F5C91F577D894BD9A0F09305DB34DD4F-LLORENTE, M>
To:	Hastings, Patricia R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a504fbfe766048a5a65461c45f28e9de-Hastings, P (b6) @va.gov>
Subject:	RE: Excerpt from President Trumps Mission Act phone call:
Date:	2019/06/26 18:59:00
Priority:	Normal
Type:	Note

That is consistent with what I witnessed.

From: Hastings, Patricia R.
Sent: Wednesday, June 26, 2019 7:59 AM
To: Llorente, Maria (b6) va.gov>
Subject: Excerpt from President Trumps Mission Act phone call:

https://www.military.com/daily-news/2019/06/25/trump-touts-mission-act-record-phone-call-thousands-veterans.html

Excerpt from President Trumps Mission Act phone call:

He also touted the newly available medication Spravato, a ketamine-based nasal spray made by Janssen Pharmaceuticals, a Johnson &Johnson subsidiary, that was fast-tracked earlier this year by the FDA for patients with treatment-resistant depression.

VA is in the process of treating some patients with the novel medication, which is based on an anesthetic (and well-known party drug) ketamine.

"I thought it was so fantastic," Trump said. "I heard about it -- I remember I read something, I saw something, and I immediately called [Wilkie] and said, please call the head of the company, of Johnson &Johnson, and let's see what we can do for the vets."

Sender:	Llorente, Maria D. </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F5C91F577D894BD9A0F09305DB34DD4F-LLORENTE, M>
Recipient:	Hastings, Patricia R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a504fbfe766048a5a65461c45f28e9de-Hastings, P (b6) @va.gov>
Sent Date:	2019/06/26 18:59:17
Delivered Date:	2019/06/26 18:59:00

AMERICAN OVERSIGHT

From:	Zacher, Jennifer L. (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9027C425646E4DE8A7D196908016331B-ZACHER, JEN <(b6) va.gov>
To:	Jensen, Benjamin D. (VHAANC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2193f62e7ced42178eaff63fe691bbc1-Jensen, Ben (b6) @va.gov>; VHAPBM Ask PBM Clinical /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=82b40b5f582040959b9edcf353b2a433-VHAPBH Ask <AskPBMClinical@va.gov>
CC:	Fisher, Lucy L. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=50224c15fcfe4a1fae5c8f6ae2334dab-Curtiss, Lu (b6) @va.gov>; Rudisill, Jamie R ASHVAMC /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b1d5d784b4e24249a92e4d0e68f1bab5-Rudisill, J (b6) @va.gov>; LaDue, Brenda (V20) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e1dd346fefa7472ca42c13026324d67d-LaDue, Bren (b6) va.gov>
Subject:	RE: esketamine?
Date:	2019/03/12 16:41:36
Priority:	Normal
Type:	Note

PBM anticipates that the review of the product will be completed by the national formulary committee in May 2019. PBM is working on REMS guidance for the field as we do with every other REMS product, and that should be ready as soon as J&J has the program fully implemented. This product will be available through McKesson once the facility and pharmacy are REMS certified.

More to come once the product is available.

From: Jensen, Benjamin D. (VHAANC)
Sent: Tuesday, March 12, 2019 3:38 PM
To: VHAPBM Ask PBM Clinical <AskPBMClinical@va.gov>
Cc: Fisher, Lucy L. (b6) @va.gov>; Rudisill, Jamie R ASHVAMC (b6) @va.gov>; LaDue, Brenda (V20) (b6) @va.gov>
Subject: FW: esketamine?

I called Janssen, they won't have the med available until the end of this month at the earliest. There is a REMS program: https://www.spravatorems.com/.
I'm not sure what the VA has planned for this med as far as VA Criteria For Use or a special ordering pathway. Adding the clinical email group.

Ben

From: Fisher, Lucy L.
Sent: Tuesday, March 12, 2019 12:02 PM
To: Jensen, Benjamin D. (VHAANC) (b6) @va.gov>; Rudisill, Jamie R ASHVAMC (b6) @va.gov>
Subject: esketamine?

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I have a patient with severe treatment resistant depression who is asking about esketamine. It appears that there is a REMS process. Is this something we can do within the VA?
If not, are you familiar with local providers we can refer to?

Thanks.

Sender:	Zacher, Jennifer L. (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9027C425646E4DE8A7D196908016331B-ZACHER, JEN <(b6) va.gov>
Recipient:	Jensen, Benjamin D. (VHAANC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2193f62e7ced42178eaff63fe691bbc1-Jensen, Ben (b6) @va.gov>; VHAPBM Ask PBM Clinical /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=82b40b5f582040959b9edcf353b2a433-VHAPBH Ask <AskPBMClinical@va.gov>; Fisher, Lucy L. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=50224c15fcfe4a1fae5c8f6ae2334dab-Curtiss, Lu (b6) @va.gov>; Rudisill, Jamie R ASHVAMC /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b1d5d784b4e24249a92e4d0e68f1bab5-Rudisill, J <(b6) @va.gov>; LaDue, Brenda (V20) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e1dd346fefa7472ca42c13026324d67d-LaDue, Bren (b6) va.gov>
Sent Date:	2019/03/12 16:41:32
Delivered Date:	2019/03/12 16:41:36

AMERICAN OVERSIGHT

From:	Boyd, Teresa D. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F6886A7D555A43E0BEE23C1E40E1C234-BOYD, TERES <(b6) va.gov>
To:	Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b6) va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>; Smith, Clifford A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b729882079394f37af66f66722f99400-Smith, Clif <(b6) va.gov>
Subject:	RE: esketamine updates for week of June 3rd
Date:	2019/06/10 05:41:47
Priority:	Normal
Type:	Note

Great work all!
Agree with same procedure re the other sites.
I unfortunately will be at the airport but please send me an invite for Wed - will dial in schedule permitting. Thank you!
As soon as we are firm with Boston, I want to give Dr. Stone heads' up - appreciate it.
Teresa

Sent with BlackBerry Work
(www.blackberry.com)

From: Carroll, David (VACO) <(b6) va.gov>
Date: Friday, Jun 07, 2019, 8:11 PM
To: Wiechers, Ilse (b6) @va.gov>, Boyd, Teresa D. <(b6) va.gov>, Valentino, Michael (VACO) <(b6) @va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>, Smith, Clifford A. <(b6) va.gov>
Subject: RE: esketamine updates for week of June 3rd

(b) (5)
[redacted]

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Thanks.

AMERICAN OVERSIGHT

From: Wiechers, Ilse
Sent: Friday, June 07, 2019 4:54 PM
To: Boyd, Teresa D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Smith, Clifford A. <(b6) @va.gov>
Subject: esketamine updates for week of June 3rd

Hello everyone – below are key updates on our progress with esketamine roll out for this week. I would greatly appreciate your input on the 2 items I have **flagged**, but welcome input on any of the items below.

Thanks,
Ilse

- (b) (5)

AMERICAN OVERSIGHT

- (b) (5)

***

Ilse R. Wiechers, MD, MPP, MHS
National Director, Psychotropic Drug Safety Initiative (PDSI)
Associate Director, Northeast Program Evaluation Center
Office of Mental Health and Suicide Prevention (10NC5), Department of Veterans Affairs
Assistant Clinical Professor of Psychiatry, Yale University School of Medicine
cell (b6)
email: (b6) @va.gov | (b6) yale.edu

Sender:	Boyd, Teresa D. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F6886A7D555A43E0BEE23C1E40E1C234-BOYD, TERES <(b6) va.gov>
Recipient:	Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>; Smith, Clifford A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b729882079394f37af66f66722f99400-Smith, Clif <(b6) va.gov>
Sent Date:	2019/06/10 05:41:46
Delivered Date:	2019/06/10 05:41:47

AMERICAN OVERSIGHT

From:	Fuller, Matthew A. (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=62D9CBB23B184CACB98895776E36A471-FULLER, MAT>
To:	Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>
Subject:	RE: esketamine updates for week of June 3rd
Date:	2019/06/10 09:15:00
Priority:	Normal
Type:	Note

Can't wait ☺

From: Zacher, Jennifer L. (PBM)
Sent: Monday, June 10, 2019 9:14 AM
To: Fuller, Matthew A. (PBM) <(b6) va.gov>
Subject: RE: esketamine updates for week of June 3rd

Perfect. You also get to be the PBM cheerleader for how "excited" we are to work on this.....

From: Fuller, Matthew A. (PBM)
Sent: Monday, June 10, 2019 8:13 AM
To: Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: esketamine updates for week of June 3rd

Hi Jenn,

Yes, it is on my calendar. I already told Ilse that I would provide an update on current status of esketamine documents for the call.

Matthew

From: Zacher, Jennifer L. (PBM)
Sent: Monday, June 10, 2019 9:08 AM
To: Fuller, Matthew A. (PBM) <(b6) va.gov>
Subject: FW: esketamine updates for week of June 3rd

Hi,
Are you able to dial into Ilse's esketamine call on Wednesday at 2pm your time?
JZ

From: Valentino, Michael (VACO)
Sent: Monday, June 10, 2019 8:07 AM
To: Zacher, Jennifer L. (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Wiechers, Ilse <(b6) @va.gov>; Boyd, Teresa D. <(b6) va.gov>; Smith, Clifford A.

AMERICAN OVERSIGHT

<(b6) va.gov>
Subject: RE: esketamine updates for week of June 3rd

How about Matt? Would he be available?

From: Zacher, Jennifer L. (PBM)
Sent: Monday, June 10, 2019 9:02 AM
To: Valentino, Michael (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Wiechers, Ilse (b6) @va.gov>; Boyd, Teresa D. <(b6) va.gov>; Smith, Clifford A. <(b6) va.gov>
Subject: RE: esketamine updates for week of June 3rd

Hi Mike,
I actually have a conflict at that time as well.
JZ

From: Valentino, Michael (VACO)
Sent: Monday, June 10, 2019 7:06 AM
To: Carroll, David (VACO) <(b6) va.gov>; Wiechers, Ilse (b6) @va.gov>; Boyd, Teresa D. <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Smith, Clifford A. <(b6) va.gov>
Subject: RE: esketamine updates for week of June 3rd

Hi Ilse,

The Community of Practice call is the same time as the 10P Town Hall meeting here in VACO, so neither Tom nor I would be able to join.

Jenn,

Are you planning on dialing in to the Town Hall? If not, would you be able to dial in for this call?

Mike

From: Carroll, David (VACO)
Sent: Friday, June 7, 2019 8:11 PM
To: Wiechers, Ilse (b6) @va.gov>; Boyd, Teresa D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Smith, Clifford A. <(b6) va.gov>
Subject: RE: esketamine updates for week of June 3rd

(b) (5)

AMERICAN OVERSIGHT

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Thanks.

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Sent: Friday, June 07, 2019 4:54 PM
To: Boyd, Teresa D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Smith, Clifford A. <(b6) va.gov>
Subject: esketamine updates for week of June 3rd

Hello everyone – below are key updates on our progress with esketamine roll out for this week. I would greatly appreciate your input on the 2 items I have **flagged**, but welcome input on any of the items below.

Thanks,
Ilse

- (b) (5)

AMERICAN OVERSIGHT

- (b) (5) [redacted]

[redacted]

***

Ilse R. Wiechers, MD, MPP, MHS
National Director, Psychotropic Drug Safety Initiative (PDSI)
Associate Director, Northeast Program Evaluation Center
Office of Mental Health and Suicide Prevention (10NC5), Department of Veterans Affairs
Assistant Clinical Professor of Psychiatry, Yale University School of Medicine
cell (b6) [redacted]
email (b6) [redacted]@va.gov | (b6) [redacted]yale.edu

Sender:	Fuller, Matthew A. (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=62D9CBB23B184CACB98895776E36A471-FULLER, MAT>
Recipient:	Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) [redacted]va.gov>
Sent Date:	2019/06/10 09:15:01
Delivered Date:	2019/06/10 09:15:00

AMERICAN OVERSIGHT

From:	Zacher, Jennifer L. (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9027C425646E4DE8A7D196908016331B-ZACHER, JEN <(b6) va.gov>
To:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Boyd, Teresa D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6886a7d555a43e0bee23c1e40e1c234-Boyd, Teres <(b6) va.gov>; Smith, Clifford A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b729882079394f37af66f66722f99400-Smith, Clif <(b6) va.gov>
Subject:	RE: esketamine updates for week of June 3rd
Date:	2019/06/10 11:06:32
Priority:	Normal
Type:	Note

He will be on the call, and he can also represent PBM leadership on my behalf.
Thanks!
JZ

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Sent: Monday, June 10, 2019 9:07 AM
To: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>; Smith, Clifford A. <(b6) va.gov>
Subject: RE: esketamine updates for week of June 3rd

I believe Matt intends to join, as I've asked him to update people on the status of the CFU and other PBM policy documents.

Sent with BlackBerry Work
(www.blackberry.com)

From: Valentino, Michael (VACO) <(b6) va.gov>
Date: Monday, Jun 10, 2019, 6:06 AM
To: Zacher, Jennifer L. (PBM) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Wiechers, Ilse (b6) @va.gov>, Boyd, Teresa D. <(b6) va.gov>, Smith, Clifford A. <(b6) va.gov>
Subject: RE: esketamine updates for week of June 3rd

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Sent: Friday, June 7, 2019 8:11 PM
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AMERICAN OVERSIGHT

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Associate Director, Northeast Program Evaluation Center
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Sent Date:	2019/06/10 11:06:31
Delivered Date:	2019/06/10 11:06:32

AMERICAN OVERSIGHT

From:	Boyd, Teresa D. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F6886A7D555A43E0BEE23C1E40E1C234-BOYD, TERES <(b6) va.gov>
To:	Drexler, Karen MD (Atlanta) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c456a9bf391415bb4bdb9b6f88bdf45-Drexler, Ka <(b6) va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; McGuire, Marsden H. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29e9d648c29f4885828c10446fdd7379-McGuire, Ma <(b6) va.gov>; Smith, Clifford A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b729882079394f37af66f66722f99400-Smith, Clif <(b6) va.gov>; Pomerantz, Andrew /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29a9288df9a34e84bddfd00cde79f11b-Pomerantz, <(b6) va.gov>; Katz, Ira R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=65f4e28aa7574641932c29fed7c0b4b8-Katz, Ira R <(b6) va.gov>
CC:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>; Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat <(b6) va.gov>
Subject:	RE: esketamine updates
Date:	2019/06/20 14:45:25
Priority:	Normal
Type:	Note

Indeed great news and what wonderful multi-disciplinary teamwork! Congratulations!

Teresa

From: Drexler, Karen MD (Atlanta)
Sent: Thursday, June 20, 2019 1:37 PM
To: Wiechers, Ilse (b6) @va.gov>; Carroll, David (VACO) <(b6) va.gov>; McGuire, Marsden H. <(b6) va.gov>; Smith, Clifford A. <(b6) va.gov>; Pomerantz, Andrew <(b6) va.gov>; Katz, Ira R. (b6) @va.gov>
Cc: Boyd, Teresa D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Fuller, Matthew A. (PBM) <(b6) va.gov>
Subject: RE: esketamine updates

AMERICAN OVERSIGHT

Terrific news. Thank you, Ilse, for your leadership on this and to all of our partners for your collaboration and support! -Karen

---

From: Wiechers, Ilse
Sent: Thursday, June 20, 2019 1:35 PM
To: Carroll, David (VACO) <(b6) va.gov>; McGuire, Marsden H. <(b6) va.gov>; Smith, Clifford A. <(b6) va.gov>; Pomerantz, Andrew <(b6) va.gov>; Katz, Ira R. (b6) @va.gov>; Drexler, Karen MD (Atlanta) <(b6) va.gov>
Cc: Boyd, Teresa D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Fuller, Matthew A. (PBM) <(b6) va.gov>
Subject: esketamine updates

Hi everyone –

This morning at the MAP/VPE Committee meeting the following determinations regarding esketamine were approved:

1. • Nonformulary status confirmed (both MAP and VPE had voted to approve this status at their individual May meetings).
2. • Approved Do not promote status – what this means (from Mike Valentino): "Our current Handbook allows promotion of drugs as long as it is consistent with our formulary objectives, so making this drug non-promotable is an additional restriction. The rationale is that your office and my office reserve the right to educate VA staff about how this drug will be used in VA and how staff will be educated about that. We don't need the manufacturer sending conflicting messages." Take home: Jansen cannot promote at VA.
3. • Extended the data collection mandate of the Medication Use Evaluation (MUE) to include both IV ketamine and IN esketamine. We currently have an operational MUE for IV ketamine, but it is not mandatory to use it. Now it will be. What this means is we will be gathering more robust data on safety and efficacy on BOTH ketamine and esketamine, which will facilitate comparisons (right now we have no idea how they compare).
4. • Approved Criteria for Use (CFU), with multiple revisions on the most recent draft considered. I'm awaiting the final version, but most of the changes as I heard them discussed added content that bolstered safety and monitoring concerns.
5. • Approved National Protocol Guidance, also with multiple revisions of a similar nature to those made to the CFU.

I will be talking with Jen Zacher tomorrow afternoon to fully debrief and review everything that transpired. I will work with her determine how best to share these updates with both our Pharmacy and Mental Health colleagues in the field.

Best,
Ilse

***

Ilse R. Wiechers, MD, MPP, MHS
National Director, Psychotropic Drug Safety Initiative (PDSI)
Associate Director, Northeast Program Evaluation Center

AMERICAN OVERSIGHT

Office of Mental Health and Suicide Prevention (10NC5), Department of Veterans Affairs
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email: (b6) @va.gov | (b6) yale.edu

Sender:	Boyd, Teresa D. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F6886A7D555A43E0BEE23C1E40E1C234-BOYD, TERES <(b6) va.gov>
Recipient:	Drexler, Karen MD (Atlanta) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c456a9bf391415bb4bdb9b6f88bdf45-Drexler, Ka <(b6) va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; McGuire, Marsden H. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29e9d648c29f4885828c10446fdd7379-McGuire, Ma <(b6) va.gov>; Smith, Clifford A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b729882079394f37af66f66722f99400-Smith, Clif <(b6) va.gov>; Pomerantz, Andrew /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29a9288df9a34e84bddfd00cde79f11b-Pomerantz, <(b6) @va.gov>; Katz, Ira R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=65f4e28aa7574641932c29fed7c0b4b8-Katz, Ira R <(b6) va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>; Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat <(b6) va.gov>
Sent Date:	2019/06/20 14:45:24
Delivered Date:	2019/06/20 14:45:25

AMERICAN OVERSIGHT

From:	Llorente, Maria D. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F5C91F577D894BD9A0F09305DB34DD4F-LLORENTE, M <(b6) va.gov>
To:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b6) @va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; McGuire, Marsden H. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29e9d648c29f4885828c10446fdd7379-McGuire, Ma <(b6) va.gov>; Smith, Clifford A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b729882079394f37af66f66722f99400-Smith, Clif <(b6) va.gov>; Pomerantz, Andrew /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29a9288df9a34e84bddfd00cde79f11b-Pomerantz, <(b6) @va.gov>; Katz, Ira R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=65f4e28aa7574641932c29fed7c0b4b8-Katz, Ira R <(b6) va.gov>; Drexler, Karen MD (Atlanta) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c456a9bf391415bb4bdb9b6f88bdf45-Drexler, Ka <(b6) va.gov>
CC:	Boyd, Teresa D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6886a7d555a43e0bee23c1e40e1c234-Boyd, Teres <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>; Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat <(b6) va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>
Subject:	RE: esketamine updates
Date:	2019/06/20 14:26:35
Priority:	Normal
Type:	Note

Thank you very much for the summary and your thoughtful review and representation during the meeting.

Sent with BlackBerry Work
(www.blackberry.com)

From: Valentino, Michael (VACO) <(b6) @va.gov>
Date: Thursday, Jun 20, 2019, 1:03 PM
To: Wiechers, Ilse (b6) @va.gov>, Carroll, David (VACO) <(b6) va.gov>, McGuire, Marsden H. <(b6) va.gov>, Smith, Clifford A. <(b6) va.gov>, Pomerantz, Andrew <(b6) va.gov>, Katz, Ira R. (b6) @va.gov>, Drexler, Karen MD (Atlanta) <(b6) va.gov>

AMERICAN OVERSIGHT

Cc: Boyd, Teresa D. <{b6} va.gov>, Zacher, Jennifer L. (PBM) <{b6} va.gov>, Fuller, Matthew A. (PBM) <{b6} va.gov>, Emmendorfer, Thomas (PBM) <{b6} va.gov>, Llorente, Maria D. <{b6} va.gov>
Subject: RE: esketamine updates

Excellent summary Ilse.....thanks for putting this together...

Sent with BlackBerry Work
(www.blackberry.com)

From: Wiechers, Ilse <{b6} va.gov>
Date: Thursday, Jun 20, 2019, 12:35 PM
To: Carroll, David (VACO) <{b6} va.gov>, McGuire, Marsden H. <{b6} va.gov>, Smith, Clifford A. <{b6} va.gov>, Pomerantz, Andrew <{b6} va.gov>, Katz, Ira R. {b6} @va.gov>, Drexler, Karen MD (Atlanta) <{b6} va.gov>
Cc: Boyd, Teresa D. <{b6} va.gov>, Valentino, Michael (VACO) <{b6} va.gov>, Zacher, Jennifer L. (PBM) <{b6} va.gov>, Fuller, Matthew A. (PBM) <{b6} va.gov>
Subject: esketamine updates

Hi everyone –

This morning at the MAP/VPE Committee meeting the following determinations regarding esketamine were approved:

1. • Nonformulary status confirmed (both MAP and VPE had voted to approve this status at their individual May meetings).
2. • Approved Do not promote status – what this means (from Mike Valentino): "Our current Handbook allows promotion of drugs as long as it is consistent with our formulary objectives, so making this drug non-promotable is an additional restriction. The rationale is that your office and my office reserve the right to educate VA staff about how this drug will be used in VA and how staff will be educated about that. We don't need the manufacturer sending conflicting messages." Take home: Jansen cannot promote at VA.
3. • Extended the data collection mandate of the Medication Use Evaluation (MUE) to include both IV ketamine and IN esketamine. We currently have an operational MUE for IV ketamine, but it is not mandatory to use it. Now it will be. What this means is we will be gathering more robust data on safety and efficacy on BOTH ketamine and esketamine, which will facilitate comparisons (right now we have no idea how they compare).
4. • Approved Criteria for Use (CFU), with multiple revisions on the most recent draft considered. I'm awaiting the final version, but most of the changes as I heard them discussed added content that bolstered safety and monitoring concerns.
5. • Approved National Protocol Guidance, also with multiple revisions of a similar nature to those made to the CFU.

I will be talking with Jen Zacher tomorrow afternoon to fully debrief and review everything that transpired. I will work with her determine how best to share these updates with both our Pharmacy and Mental Health colleagues in the field.

Best,

AMERICAN OVERSIGHT

Ilse

***

Ilse R. Wiechers, MD, MPP, MHS
National Director, Psychotropic Drug Safety Initiative (PDSI)
Associate Director, Northeast Program Evaluation Center
Office of Mental Health and Suicide Prevention (10NC5), Department of Veterans Affairs
Assistant Clinical Professor of Psychiatry, Yale University School of Medicine
cell (b6)
email: (b6) @va.gov | (b6) yale.edu

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Sent Date:	2019/06/20 14:26:34
Delivered Date:	2019/06/20 14:26:35

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To:	Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>
Subject:	RE: esketamine site visits - travel proposal
Date:	2019/06/25 12:44:50
Priority:	Normal
Type:	Note

I defer to you Jenn but in my opinion, I don't think it is necessary to ask Matthew, Michelle or Jeanne to participate.

My reasoning is:

- (b6)

So…..completely your call…..

Mike

From: Zacher, Jennifer L. (PBM)
Sent: Tuesday, June 25, 2019 12:34 PM
To: Valentino, Michael (VACO) <(b6) va.gov>
Subject: FW: esketamine site visits - travel proposal

Hi Mike,
So, Ilse mentioned that she was sending this proposal to OMHSP when I spoke with her on Friday. She wants to set up several site visits to the VA sites that will be piloting esketamine, and also some community sites that are already doing ketamine/esketamine in order to strengthen the plan for implementation within VA. She would like for a PBM rep to come on the visits with her so that the pharmacy perspective is covered. I told her that while I didn't have an issue with sending someone from my staff, I wanted to discuss with you before committing…..

Looks like her proposal got approved, so was wondering what your thoughts were about sending someone out with her? Matthew Fuller is the most obvious choice from my staff, but was thinking that it might help to have Michelle or Jeanne go on at least one trip too to look at it from a pharmacy operations standpoint and how the controlled substance is being monitoring/dispensed in clinics.

AMERICAN OVERSIGHT

Thoughts?
JZ

From: Wiechers, Ilse
Sent: Tuesday, June 25, 2019 8:59 AM
To: Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: FW: esketamine site visits - travel proposal

I've got the green light to move forward with the site visits. Most urgent in terms of planning is Cleveland, since I will be there visiting family in a month and hoped to swing by the VA for a day during that visit. I've already back channeled with Matthew and he has a hold on the days on his calendar, to be on the safe side.

I'll work to nail down dates with the other sites in the next week, but you can see the locations and tentative dates in the word doc attached. That may help you identify some staff on your end.

Ilse

From: Carroll, David (VACO)
Sent: Tuesday, June 25, 2019 4:34 AM
To: Wiechers, Ilse (b6) @va.gov>
Cc: Gavin, Stacy <(b6) va.gov>; Strmiska, Jon G. <(b6) va.gov>
Subject: RE: esketamine site visits - travel proposal

Approved. Thanks for putting this together. We can fund.

From: Wiechers, Ilse
Sent: Monday, June 24, 2019 2:25 PM
To: Carroll, David (VACO) <(b6) va.gov>
Cc: Gavin, Stacy <(b6) va.gov>
Subject: esketamine site visits - travel proposal

Dear Dave –

I have developed a proposal with budget for a series of 5 esketamine site visits, to include a total of 9 sites (6 VA sites, 2 academic sites, 1 community provider site). Details can be found in the attached document, but highlights are below.

- • Requesting OMHSP funding for 2 people to attend each site visit
- • Schedule in document serves as an example of the amount of time spent at sites. Final dates and details of which site is visited on which date TBD following coordination with local sites.
- • PBM anticipates sending a representative along with us to these site visits, and will fund travel for their representative.
- • Total estimated budget expenses: **$12,622**

AMERICAN OVERSIGHT

Please let me know if you have any questions about the proposal, I would be happy to talk with you about it further if you like.

Thanks,
Ilse

***

Ilse R. Wiechers, MD, MPP, MHS
National Director, Psychotropic Drug Safety Initiative (PDSI)
Associate Director, Northeast Program Evaluation Center
Office of Mental Health and Suicide Prevention (10NC5), Department of Veterans Affairs
Assistant Clinical Professor of Psychiatry, Yale University School of Medicine
cell (b6)
email: (b6) @va.gov | (b6) yale.edu

Suicide Prevention is Everyone's Business. *#BeThere.*



VCL

Recipient:	Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>
Sent Date:	2019/06/25 12:44:53
Delivered Date:	2019/06/25 12:44:50
Message Flags:	Unread Unsent

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From:	Zacher, Jennifer L. (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9027C425646E4DE8A7D196908016331B-ZACHER, JEN <(b6) va.gov>
To:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>
Subject:	RE: esketamine site visits - travel proposal
Date:	2019/06/25 13:47:37
Priority:	Normal
Type:	Note

I am so glad you said that. I was feeling the same way. I think as a compromise, I will have Matthew join Ilse when she's at the Cleveland VAMC, since it is local for him. We'll see how that goes, and then likely gracefully bow out of all the other visits.
JZ

From: Valentino, Michael (VACO)
Sent: Tuesday, June 25, 2019 11:49 AM
To: Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: esketamine site visits - travel proposal

I defer to you Jenn but in my opinion, I don't think it is necessary to ask Matthew, Michelle or Jeanne to participate.

My reasoning is:

- (b6) [redacted]

So…..completely your call if we go , don't go, if we do, who is the logical choice (assuming they are OK with it)…..

Mike

From: Zacher, Jennifer L. (PBM)
Sent: Tuesday, June 25, 2019 12:34 PM

AMERICAN OVERSIGHT

To: Valentino, Michael (VACO) <(b6) va.gov>
Subject: FW: esketamine site visits - travel proposal

Hi Mike,
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Thoughts?
JZ

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Sent: Tuesday, June 25, 2019 8:59 AM
To: Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: FW: esketamine site visits - travel proposal

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I'll work to nail down dates with the other sites in the next week, but you can see the locations and tentative dates in the word doc attached. That may help you identify some staff on your end.

Ilse

From: Carroll, David (VACO)
Sent: Tuesday, June 25, 2019 4:34 AM
To: Wiechers, Ilse (b6) @va.gov>
Cc: Gavin, Stacy <(b6) va.gov>; Strmiska, Jon G. <(b6) va.gov>
Subject: RE: esketamine site visits - travel proposal

Approved. Thanks for putting this together. We can fund.

From: Wiechers, Ilse
Sent: Monday, June 24, 2019 2:25 PM
To: Carroll, David (VACO) <(b6) va.gov>

AMERICAN OVERSIGHT

Cc: Gavin, Stacy <(b6) va.gov>
Subject: esketamine site visits - travel proposal

Dear Dave –

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- • PBM anticipates sending a representative along with us to these site visits, and will fund travel for their representative.
- • Total estimated budget expenses: **$12,622**

Please let me know if you have any questions about the proposal, I would be happy to talk with you about it further if you like.

Thanks,
Ilse

***
Ilse R. Wiechers, MD, MPP, MHS
National Director, Psychotropic Drug Safety Initiative (PDSI)
Associate Director, Northeast Program Evaluation Center
Office of Mental Health and Suicide Prevention (10NC5), Department of Veterans Affairs
Assistant Clinical Professor of Psychiatry, Yale University School of Medicine
cell (b6)
email: (b6) @va.gov | (b6) yale.edu

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VCL

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Sent Date:	2019/06/25 13:47:35
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To:	Strmiska, Jon G. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9872f41bf2844c8085d371e21482b635-Strmiska, J <(b6) va.gov>
CC:	Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>
Subject:	RE: esketamine site visits - travel proposal
Date:	2019/06/25 09:56:31
Priority:	Normal
Type:	Note

Thanks, Dave!

Will keep you posted, Jon. Appreciate your help with this (in advance).

Ilse

From: Strmiska, Jon G.
Sent: Tuesday, June 25, 2019 4:42 AM
To: Wiechers, Ilse (b6) @va.gov>
Cc: Carroll, David (VACO) <(b6) va.gov>
Subject: RE: esketamine site visits - travel proposal

When you have finalized who will be going on the visits, please let me know the following information and I will get the funding sent out.

Thanks!

- • Station number
- • Staff Member's name
- • Type of funding (medical admin or medical services) I will assume medical services if the staff traveling are at facilities and clinicians.
- • Amount of funding needed:

Jon G. Strmiska
Business Operations Manager (10NC5)
VA Central Office – Washington, DC
Phone: (b6)
FAX: 202.495.5933

From: Carroll, David (VACO)
Sent: Tuesday, June 25, 2019 7:34 AM
To: Wiechers, Ilse (b6) @va.gov>

AMERICAN OVERSIGHT

Cc: Gavin, Stacy <(b6) va.gov>; Strmiska, Jon G. <(b6) va.gov>
Subject: RE: esketamine site visits - travel proposal

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VCL

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Sent Date:	2019/06/25 09:56:31

AMERICAN OVERSIGHT

From:	Davis, Lashelle (VHACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0C9BFFD03B3B47DAA8B6DB6F8933A7E7-DAVIS, LASH (b6) va.gov>
To:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>
CC:	Charness, Michael /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=20da3e82762e464a9b7e52370fde4674-Charness, M (b6) va.gov>; VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>
Subject:	RE: Esketamine roll out/COS Monthly Schedule
Date:	2019/08/14 08:15:44
Priority:	Normal
Type:	Note

Received and incorporated.

A meeting invite was sent. Please confirm receipt.

Thank you,

Lashelle

From: Wiechers, Ilse
Sent: Tuesday, August 13, 2019 8:09 PM
To: Davis, Lashelle (VHACO) (b6) va.gov>
Cc: Charness, Michael (b6) va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>
Subject: RE: Esketamine roll out/COS Monthly Schedule

Please find attached the slides I will walk through on the COS call tomorrow.

Could you please forward me the meeting invite or call information at your earliest convenience?

Thanks,
Ilse

From: Davis, Lashelle (VHACO)
Sent: Tuesday, August 13, 2019 11:01 AM
To: Wiechers, Ilse (b6) @va.gov>
Cc: Charness, Michael (b6) va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>; Davis, Lashelle (VHACO) (b6) va.gov>
Subject: RE: Esketamine roll out/COS Monthly Schedule

AMERICAN OVERSIGHT

4:00– 4:30PM ET should work, but if you can call in sooner that would be great. Each presenter has 15 minutes = 10 minutes presentation and 5 minutes for discussion. Please submit the slide deck before or by 10:00 a.m., Est tomorrow.

Adding Dr. Charness for awareness.

Thank you,

Lashelle

From: Wiechers, Ilse
Sent: Tuesday, August 13, 2019 1:45 PM
To: Davis, Lashelle (VHACO) <(b6) va.gov>
Cc: Charness, Michael <(b6) va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>
Subject: RE: Esketamine roll out/COS Monthly Schedule

Hello Lashelle –

I am available from 4-4:30 pm ET tomorrow to join the call. Will that work with the National COS call schedule? Please let me know how much time I can anticipate having for the briefing. I am updating slides now and can forward to you by COB Pacific today.

CC'ing 10NC5 Action group for their awareness.

Best,
Ilse

From: Davis, Lashelle (VHACO)
Sent: Tuesday, August 13, 2019 8:17 AM
To: Wiechers, Ilse (b6) @va.gov>
Cc: Charness, Michael <(b6) va.gov>; Davis, Lashelle (VHACO) <(b6) va.gov>
Subject: FW: Esketamine roll out/COS Monthly Schedule

Good Day, Dr. Wiechers

Would you be available to present the roll out clinical esketamine service on the National COS call, Wednesday, August 14, 2019, 3:30 – 4:30 PM, ET?

Thank you,

Lashelle

AMERICAN OVERSIGHT

Lashelle Davis

Health System Specialist,
Assistant Deputy Under Secretary for Health for Clinical Operations (10NC)
(202) (b6) Office
(b6)
(b6) va.gov

From: Wiechers, Ilse
Sent: Thursday, May 16, 2019 8:27 AM
To: Charness, Michael <(b6) va.gov>; Smith, Clifford A. <(b6) va.gov>; O'Toole, Thomas P. <(b6) va.gov>
Cc: Davis, Lashelle (VHACO) <(b6) va.gov>
Subject: RE: Esketamine roll out

Dr. Charness,

I'm happy to join a call in July or August to update the COS group on our efforts to roll out clinical esketamine service. If you could please let me know when the call regularly occurs, I will put a hold on my calendar to ensure I'm available whenever works best with the group's schedule.

Best,
Ilse

***

Ilse R. Wiechers, MD, MPP, MHS
National Director, Psychotropic Drug Safety Initiative (PDSI)
Associate Director, Northeast Program Evaluation Center
Office of Mental Health and Suicide Prevention (10NC5), Department of Veterans Affairs
Assistant Clinical Professor of Psychiatry, Yale University School of Medicine
cell (b6)
email: (b6) @va.gov | (b6) yale.edu

From: Charness, Michael
Sent: Wednesday, May 15, 2019 6:04 PM
To: Smith, Clifford A. <(b6) va.gov>; O'Toole, Thomas P. <(b6) va.gov>; Wiechers, Ilse (b6) @va.gov>
Cc: Davis, Lashelle (VHACO) <(b6) va.gov>
Subject: RE: Esketamine roll out

Dear Cliff,

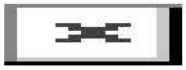
AMERICAN OVERSIGHT

Thanks for the heads up. I suspect that we will have time again on one of our calls during the summer. We're currently committing all of our calls to Mission Act. I'll make a note to include Dr. Wiechers on a call in July or August if that would work.

Best,

Michael

Michael E. Charness, M.D.
Chief of Staff,
VA Boston Healthcare System



cid:image001.png@01CBA291.A3714C20

1400 VFW Parkway, West Roxbury MA 02132
Tel: (857) 203-6011; Fax: (857) 203-5500

From: Smith, Clifford A.
Sent: Wednesday, May 15, 2019 6:04 PM
To: Charness, Michael <(b6) va.gov>; O'Toole, Thomas P. <(b6) va.gov>; Wiechers, Ilse (b6) @va.gov>
Subject: Esketamine roll out

Dr Charness,

Dr Wiechers is heading up the roll out of esKetamine for mental health. Recognizing the national interest in this, I wanted to connect you two for opportunities to keep COS community informed.

Cliff

Sent with BlackBerry Work
(www.blackberry.com)

Sender:	Davis, Lashelle (VHACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0C9BFFD03B3B47DAA8B6DB6F8933A7E7-DAVIS, LASH <(b6) va.gov>
Recipient:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>; Charness, Michael /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=20da3e82762e464a9b7e52370fde4674-Charness, M <(b6) va.gov>; VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>
Sent Date:	2019/08/14 08:15:43
Delivered Date:	2019/08/14 08:15:44

AMERICAN OVERSIGHT

To:	Cunningham, Fran /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=613f0d8e535d46af95fed310f100dcbc-Cunningham, <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>
Subject:	RE: esketamine question
Date:	2019/03/25 09:30:42
Priority:	Normal
Type:	Note

Hi Fran

From: Cunningham, Fran
Sent: Monday, March 25, 2019 9:22 AM
To: Zacher, Jennifer L. (PBM) <(b6) va.gov>; Fuller, Matthew A. (PBM) <(b6) va.gov>
Subject: RE: esketamine question

Hi Jennifer and Matthew – We can definitely have Tom set up a call to discuss the overall esketamine project in detail. In the meantime Matthew we can chat briefly to get the ball rolling on what patients to look at so we don't lose time. Please let me know if you're free this morning. I just finished my 830 meeting and am free until 10.

Thanks,
Fran

From: Zacher, Jennifer L. (PBM)
Sent: Friday, March 22, 2019 2:48 PM
To: Fuller, Matthew A. (PBM) <(b6) va.gov>
Cc: Cunningham, Fran <(b6) va.gov>
Subject: RE: esketamine question

Yes. Adding Fran…I think that the three of us should talk this through and come up with a solid way to look at this…..

Fran, is it okay if I have Tom set up a call?

From: Fuller, Matthew A. (PBM)
Sent: Wednesday, March 20, 2019 3:15 PM
To: Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: esketamine question

Jenn,

AMERICAN OVERSIGHT

As you know, the short term esketamine trial resulting in its approval treated pts who had not adequately responded to at least two different antidepressant of adequate dose and duration. Would it be helpful for us to take a look at this pt population in the VA so that we have it ready for presentation? If so, should I ask Ashir, Fran, someone else? Thanks.

Matthew

Recipient:	Cunningham, Fran /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=613f0d8e535d46af95fed310f100dcbc-Cunningham, <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>
Sent Date:	2019/03/25 09:30:49
Delivered Date:	2019/03/25 09:30:42
Message Flags:	Unread Unsent

AMERICAN OVERSIGHT

From:	Fuller, Matthew A. (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=62D9CBB23B184CACB98895776E36A471-FULLER, MAT>
To:	Cunningham, Fran /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=613f0d8e535d46af95fed310f100dcbc-Cunningham, <(b6) va.gov>
Subject:	RE: esketamine question
Date:	2019/03/26 16:33:00
Priority:	Normal
Type:	Note

Thanks!

From: Cunningham, Fran
Sent: Tuesday, March 26, 2019 4:32 PM
To: Fuller, Matthew A. (PBM) <(b6) va.gov>
Subject: RE: esketamine question

Hi Matthew, we can. That will let us know if the definition we used for "tx resistant" based on the number of medications, dose and duration are a good marker.

Fran

From: Fuller, Matthew A. (PBM)
Sent: Tuesday, March 26, 2019 4:26 PM
To: Cunningham, Fran <(b6) va.gov>
Subject: RE: esketamine question

I'm very interested to see what we find.
According to the literature, about 1/3 of pts with MDD are considered "treatment-resistant". Is there a way we can capture this as a way a validating our data? Ie pts with treatment-resistance/total # of pts with MDD? Thoughts?

From: Cunningham, Fran
Sent: Tuesday, March 26, 2019 4:23 PM
To: Fuller, Matthew A. (PBM) <(b6) va.gov>
Subject: RE: esketamine question

Thank you!!

From: Fuller, Matthew A. (PBM)
Sent: Tuesday, March 26, 2019 4:22 PM
To: Cunningham, Fran <(b6) va.gov>
Subject: RE: esketamine question

I think that is a reasonable place to start. Thanks.

AMERICAN OVERSIGHT

From: Cunningham, Fran
Sent: Tuesday, March 26, 2019 4:20 PM
To: Fuller, Matthew A. (PBM) <(b6) va.gov>
Subject: RE: esketamine question

Thanks Matthew – this helps a great deal!

One final questions…For the highlighted section below. How far back do we look? Are you okay with going back 24 months from the index date of MDD and capturing the 2 trials in succession?

From: Fuller, Matthew A. (PBM)
Sent: Tuesday, March 26, 2019 4:14 PM
To: Cunningham, Fran <(b6) va.gov>
Subject: RE: esketamine question

Hi Fran,

We are interested in treatment resistant depression. However, I doubt providers will list it that way. If you are using ICD-10 codes I would use F32.xx, if you are using ICD-9 codes I would use 296.xx.
Current dx = currently depressed and have had at least two trials of antidepressants in succession either as individual agents or in combination.
An adequate trial can be defined as 8 or 12 weeks so we will look at both.
Hope this helps.

Matthew

From: Cunningham, Fran
Sent: Tuesday, March 26, 2019 3:56 PM
To: Fuller, Matthew A. (PBM) <(b6) va.gov>
Subject: RE: esketamine question
Importance: High

Thanks Matthew – I'm finishing the Abstract for the analysis and I have a couple of questions.

1. • We have all depression defined in our depression dx cohort. Do you have specific dx codes that you want us to use for major depressive disorder only?
2. • We will identify "current dx of major depressive disorder" as patients with a dx in the most recent 12 months. How far back do you want to look for the >/= 2 antidepressants? I think it should be more than just the most recent 12 months… I was thinking the MDD index date this year and looking within the previous 12 or 24 months for the medications but will go with your guidance.
3. • Within that time period we will at look at patients that were on the agents for 8 weeks duration only or 12 weeks duration only. Please let me know if this is what we agreed to or if it's too rigid.

AMERICAN OVERSIGHT

From: Fuller, Matthew A. (PBM)
Sent: Monday, March 25, 2019 11:30 AM
To: Cunningham, Fran <(b6) va.gov>
Cc: Fuller, Matthew A. (PBM) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: esketamine question

Hi Fran,

Below is a list of antidepressants and the minimum dosage we want to use for our data pull. Thanks.

Matthew

Amitriptyline 150 mg
Amoxapine 300 mg
Bupropion 300 mg
Citalopram 40 mg
Clomipramine 150 mg
Desipramine 150 mg
Desvenlafaxine 100 mg
Doxepin 150 mg
Duloxetine 60 mg
Escitalopram 20 mg
Fluoxetine 40 mg
Fluvoxamine 150 mg
Imipramine 150 mg
Levomilnacipran 60 mg
Maprotiline 150 mg
Mirtazapine 45 mg
Nefazodone 300 mg
Nortriptyline 75 mg
Paroxetine 40 mg
Protriptyline 30 mg
Sertraline 200 mg
Trazodone 400 mg
Trimipramine 150 mg
Venlafaxine 225 mg
Vilazodone 20 mg
Vortioxetine 20 mg

From: Cunningham, Fran
Sent: Monday, March 25, 2019 9:35 AM
To: Fuller, Matthew A. (PBM) <(b6) va.gov>
Subject: RE: esketamine question

Perfect! You can reach me at (b6) (b6)

AMERICAN OVERSIGHT

Thanks,
Fran

From: Fuller, Matthew A. (PBM)
Sent: Monday, March 25, 2019 8:32 AM
To: Cunningham, Fran <(b6) va.gov>
Subject: RE: esketamine question

Hi Fran,

I have time this morning. If you provide a number I can call you. Thanks.

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Thanks,
Fran

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Sent: Friday, March 22, 2019 2:48 PM
To: Fuller, Matthew A. (PBM) <(b6) va.gov>
Cc: Cunningham, Fran <(b6) va.gov>
Subject: RE: esketamine question

Yes. Adding Fran…I think that the three of us should talk this through and come up with a solid way to look at this…..

Fran, is it okay if I have Tom set up a call?

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Sent: Wednesday, March 20, 2019 3:15 PM
To: Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: esketamine question

Jenn,

AMERICAN OVERSIGHT

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Recipient:	Cunningham, Fran /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=613f0d8e535d46af95fed310f100dcbc-Cunningham, <(b6) va.gov>
Sent Date:	2019/03/26 16:33:24
Delivered Date:	2019/03/26 16:33:00

AMERICAN OVERSIGHT

From:	Fuller, Matthew A. (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=62D9CBB23B184CACB98895776E36A471-FULLER, MAT>
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Subject:	RE: esketamine question
Date:	2019/03/26 16:15:00
Priority:	Normal
Type:	Note

Hi Fran, I think we need to capture both.

From: Cunningham, Fran
Sent: Tuesday, March 26, 2019 4:13 PM
To: Fuller, Matthew A. (PBM) <(b6) va.gov>
Subject: RE: esketamine question

Hi Matthew – Here are the codes we have for MDD.
Icd10 for MDD: F32 (single episode), F33 (recurrent)

From: Cunningham, Fran
Sent: Tuesday, March 26, 2019 3:56 PM
To: Fuller, Matthew A. (PBM) <(b6) va.gov>
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Cc: Fuller, Matthew A. (PBM) <(b6) va.gov>; Zacher, Jennifer L. (PBM)

AMERICAN OVERSIGHT

<(b6) va.gov>
Subject: RE: esketamine question

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Escitalopram 20 mg
Fluoxetine 40 mg
Fluvoxamine 150 mg
Imipramine 150 mg
Levomilnacipran 60 mg
Maprotiline 150 mg
Mirtazapine 45 mg
Nefazodone 300 mg
Nortriptyline 75 mg
Paroxetine 40 mg
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AMERICAN OVERSIGHT

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Subject: RE: esketamine question

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AMERICAN OVERSIGHT

Matthew

Sender:	Fuller, Matthew A. (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=62D9CBB23B184CACB98895776E36A471-FULLER, MAT>
Recipient:	Cunningham, Fran /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=613f0d8e535d46af95fed310f100dcbc-Cunningham, <(b6) va.gov>
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AMERICAN OVERSIGHT

From:	Fuller, Matthew A. (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=62D9CBB23B184CACB98895776E36A471-FULLER, MAT>
To:	Wadhwani, Audrey M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bf43e7e703cb4dd78dabc095d26ab6f3-Wadhwani, A (b6) @va.gov>
CC:	Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat <(b6) va.gov>
Subject:	RE: Esketamine Nasal Spray
Date:	2019/06/25 13:31:00
Priority:	Normal
Type:	Note

Hi Audrey,

I believe you are referring to the implementation plan that Dr Wiechers presented (i.e. round 1, 2 and 3 sites). The plan that she presented is being rolled out nation wide with round 1 sites (those using IV ketamine + volunteers) going first followed by round 2 and 3 sites at a later date. In May 2019 the PBM MAP/VPE committee voted to keep esketamine nonformulary with CFU. The CFU and National protocol guidance have been developed and were approved this month. Therefore, while implementation will take place over time, sites can use as a nonformulary agent but will require following REMS and VA CFU. Hope this helps.

Matthew

From: Wadhwani, Audrey M.
Sent: Tuesday, June 25, 2019 12:26 PM
To: Fuller, Matthew A. (PBM) <(b6) va.gov>
Subject: Esketamine Nasal Spray

Good morning Matthew,

My name is Audrey Wadhwani I'm a pharmacy resident at the Roseburg VA in Oregon. The Chief of Pharmacy here, Dan Neal, has asked me to reach out to you after listening to the Esketamine presentation a couple weeks ago. We would like to know what we should tell our medical staff and patients when they ask if they can prescribe/use this medication. Do we information them that this medication will not be available for use until 2020 after pilot VA's complete their trial?

Thank you for your time,

Audrey

Sender:	Fuller, Matthew A. (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=62D9CBB23B184CACB98895776E36A471-FULLER, MAT>
Recipient:	Wadhwani, Audrey M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bf43e7e703cb4dd78dabc095d26ab6f3-Wadhwani, A (b6) @va.gov>; Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat

AMERICAN OVERSIGHT

	<(b6) va.gov>
Sent Date:	2019/06/25 13:31:37
Delivered Date:	2019/06/25 13:31:00

AMERICAN OVERSIGHT

From:	Fuller, Matthew A. (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=62D9CBB23B184CACB98895776E36A471-FULLER, MAT>
To:	Schreiber, Matthew A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=db4d0324bf0945f183f33816c7fd1db0-Schreiber, <(b6) va.gov>; Capehart, Bruce P. DURVAMC /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6866eff4e9df4a48846d056a02044c38-Capehart, B <(b6) va.gov>
Subject:	RE: esketamine monograph
Date:	2019/03/25 08:54:00
Priority:	Normal
Type:	Note

Hi Matt and Bruce,

My first thought was to present this at an upcoming F2F meeting but we were told it will be on the May agenda. (b6) ; (b6) ; (b6) . On Friday, I had a call with Ilse Wiechers who has been charged with implementing the REMS for esketamine nationally. Seems this is going to happen. I am interested to see what ends up happening with this drug.

Regards,

Matthew

From: Schreiber, Matthew A.
Sent: Friday, March 22, 2019 5:09 PM
To: Fuller, Matthew A. (PBM) <(b6) va.gov>; Capehart, Bruce P. DURVAMC <(b6) va.gov>
Subject: RE: esketamine monograph

Hi Matthew,
(b6)
.

(b6)

In any case, I understand the urgency so I will take a look at this over the weekend and let you know if I have any comments as early next week as possible. Hope you are doing well and thanks for sending this.
Matt

From: Fuller, Matthew A. (PBM)
Sent: Friday, March 22, 2019 1:55 PM

AMERICAN OVERSIGHT

To: Schreiber, Matthew A. <(b6) va.gov>; Capehart, Bruce P. DURVAMC <(b6) va.gov>
Cc: Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: esketamine monograph

Hi Bruce and Matt,

Please find attached the DRAFT esketamine monograph. I appreciate you taking a look at it and providing feedback prior to it being sent to the field for review. Thanks.

Matthew

Sender:	Fuller, Matthew A. (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=62D9CBB23B184CACB98895776E36A471-FULLER, MAT>
Recipient:	Schreiber, Matthew A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=db4d0324bf0945f183f33816c7fd1db0-Schreiber, <(b6) va.gov>; Capehart, Bruce P. DURVAMC /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6866eff4e9df4a48846d056a02044c38-Capehart, B <(b6) va.gov>
Sent Date:	2019/03/25 08:54:47
Delivered Date:	2019/03/25 08:54:00

AMERICAN OVERSIGHT

From:	Zacher, Jennifer L. (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9027C425646E4DE8A7D196908016331B-ZACHER, JEN <(b6) va.gov>
To:	Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat <(b6) va.gov>
Subject:	RE: esketamine monograph
Date:	2019/03/22 17:03:21
Priority:	Normal
Type:	Note

You are a ROCK STAR for getting that done so quickly!
JZ

From: Fuller, Matthew A. (PBM)
Sent: Friday, March 22, 2019 3:55 PM
To: Schreiber, Matthew A. <(b6) va.gov>; Capehart, Bruce P. DURVAMC <(b6) va.gov>
Cc: Zacher, Jennifer L. (PBM) <(b6) va.gov>
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Sent Date:	2019/03/22 17:03:20
Delivered Date:	2019/03/22 17:03:21
Message Flags:	Unread

AMERICAN OVERSIGHT

From:	Goodman, Francine /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EC164D1255644AC4BB4AF7B812F0A6FB-GOODMAN, FR (b6) va.gov>
To:	Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat <(b6) va.gov>
Subject:	RE: Esketamine in DDA
Date:	2019/06/24 15:23:20
Priority:	Normal
Type:	Note

Oh! The National Protocol for esketamine goes under Other Announcements too.

I'm out of the DDA now.

Francine Goodman | National Clinical Pharmacy Program Manager | VHA PBM Services (10P4P)

From: Fuller, Matthew A. (PBM)
Sent: Monday, June 24, 2019 3:17 PM
To: Goodman, Francine (b6) va.gov>
Subject: RE: Esketamine in DDA

Sounds good. Thanks.

From: Goodman, Francine
Sent: Monday, June 24, 2019 2:51 PM
To: Fuller, Matthew A. (PBM) <(b6) va.gov>
Subject: Esketamine in DDA

Hi Matthew,

I was adding my topics to the DDA and noticed that you placed the esketamine documents under **Drugs Not Added** to the VA National Formulary. Since we didn't make the nonformulary decision in June (it was made in May and should have been listed in the May DDA), the monograph and CFU belong under Other Announcements. I haven't made any changes to the DDA, (b) (5) is:

5. • (b) (5)

AMERICAN OVERSIGHT

(b6)
!

Francine Goodman, PharmD, BCPS
National Clinical Pharmacy Program Manager – Formulary
Pharmacy Benefits Management Services (10P4P)
T: (b6)
www.va.pbm.gov

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Sent Date:	2019/06/24 15:23:19
Delivered Date:	2019/06/24 15:23:20
Message Flags:	Unread

AMERICAN OVERSIGHT

From:	Goodman, Francine /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EC164D1255644AC4BB4AF7B812F0A6FB-GOODMAN, FR <(b6) va.gov>
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Subject:	RE: Esketamine in DDA
Date:	2019/06/24 15:19:04
Priority:	Normal
Type:	Note

I'll be out of the DDA in about 2 minutes. ☺

Francine Goodman | National Clinical Pharmacy Program Manager | VHA PBM Services (10P4P)

From: Fuller, Matthew A. (PBM)
Sent: Monday, June 24, 2019 3:17 PM
To: Goodman, Francine <(b6) va.gov>
Subject: RE: Esketamine in DDA

Sounds good. Thanks.

From: Goodman, Francine
Sent: Monday, June 24, 2019 2:51 PM
To: Fuller, Matthew A. (PBM) <(b6) va.gov>
Subject: Esketamine in DDA

Hi Matthew,

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AMERICAN OVERSIGHT

(b6)

Francine Goodman, PharmD, BCPS
National Clinical Pharmacy Program Manager – Formulary
Pharmacy Benefits Management Services (10P4P)
T: (b6)
www.va.pbm.gov

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Sent Date:	2019/06/24 15:19:03
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AMERICAN OVERSIGHT

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To:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>
Subject:	RE: Esketamine Community of Practice call tomorrow @ 2 pm ET
Date:	2019/06/12 14:52:21
Priority:	Normal
Type:	Note

Yep, I should be free any time after 3pm central

From: Valentino, Michael (VACO)
Sent: Wednesday, June 12, 2019 1:49 PM
To: Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: Esketamine Community of Practice call tomorrow @ 2 pm ET

Something else....

I'm in a The PCS Town Hall now....can I call you later?

Sent with BlackBerry Work
(www.blackberry.com)

From: Zacher, Jennifer L. (PBM) <(b6) va.gov>
Date: Wednesday, Jun 12, 2019, 2:25 PM
To: Valentino, Michael (VACO) <(b6) va.gov>
Subject: RE: Esketamine Community of Practice call tomorrow @ 2 pm ET

Already have that covered Mike. Fran and I are working with the REMS program so that MedSAFE will submit all of the REMS documents on behalf of VA through MedSAFE/the MUET. That will force the MUET as mandatory and will also allow us to force collection of all the data points that we need....We already met with the J&J REMS coordinator to get the ball rolling.

Is that what you are talking about or something else???

From: Valentino, Michael (VACO)
Sent: Wednesday, June 12, 2019 11:53 AM
To: Fuller, Matthew A. (PBM) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: Esketamine Community of Practice call tomorrow @ 2 pm ET

Not particularly Matt.

AMERICAN OVERSIGHT

If it comes up, you might want to give an update on the formulary actions:

- • CFU, monograph, etc. drafted, disseminated to the field and discussed at length at the last formulary meeting
- • On the agenda for this month's meeting and we anticipate the documents will be finalized and that a formulary decision "might" be made
- • Discussions pending about mandatory data collection and submission to PBM for IN esketamine and IV ketamine administration to assess comparative safety and efficacy

I know the last bullet is likely news to you both but I am fairly certain this will come up at next week's meeting. (b6) . I envision we could do this like we did with the coverage with evidence development we did with Drotrecogan Alfa (SP?) i.e. Xigris.

Mike

From: Fuller, Matthew A. (PBM)
Sent: Wednesday, June 12, 2019 12:46 PM
To: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: Esketamine Community of Practice call tomorrow @ 2 pm ET

Hi Mike and Jenn,

Is there anything in particular you would like me to say on behalf of PBM during welcome?

Matthew

From: Wiechers, Ilse
Sent: Wednesday, June 12, 2019 2:24 AM
To: Carroll, David (VACO) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Fuller, Matthew A. (PBM) <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>
Subject: Esketamine Community of Practice call tomorrow @ 2 pm ET

Hi everyone –

A quick reminder of the call in information for those able to join tomorrow. Please use the MODERATOR code listed below, as I anticipate we may need to mute the audience due to large number of participants.

Matthew – I will turn it over to you for slides 18-19 on updates re PBM policies. Please feel free to edit those slides if you like and send me revised slides tomorrow by 1 pm ET.

Join Skype Meeting (Trouble Joining? Try Skype Web App)
Join audio by VANTS at 1-800-767-1750, moderator 13331#

AMERICAN OVERSIGHT

Thanks,
Ilse

***

Ilse R. Wiechers, MD, MPP, MHS
National Director, Psychotropic Drug Safety Initiative (PDSI)
Associate Director, Northeast Program Evaluation Center
Office of Mental Health and Suicide Prevention (10NC5), Department of Veterans Affairs
Assistant Clinical Professor of Psychiatry, Yale University School of Medicine
cell (b6)
email: (b6) @va.gov | (b6) yale.edu

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Subject:	RE: Esketamine Community of Practice call tomorrow @ 2 pm ET
Date:	2019/06/12 13:16:28
Priority:	Normal
Type:	Note

Agree….just let them know we are working hard to get the guidance out THROUGH OUR NORMAL CHANNELS…there seems to be a perception that we are treating this drug differently….

From: Fuller, Matthew A. (PBM)
Sent: Wednesday, June 12, 2019 11:55 AM
To: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: Esketamine Community of Practice call tomorrow @ 2 pm ET

Noted. Thanks.

From: Valentino, Michael (VACO)
Sent: Wednesday, June 12, 2019 12:53 PM
To: Fuller, Matthew A. (PBM) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>
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Thanks,
Ilse

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Associate Director, Northeast Program Evaluation Center
Office of Mental Health and Suicide Prevention (10NC5), Department of Veterans Affairs
Assistant Clinical Professor of Psychiatry, Yale University School of Medicine
cell (b6)
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	<(b6) va.gov>
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Subject:	RE: Esketamine Community of Practice call tomorrow @ 2 pm ET
Date:	2019/06/12 08:48:00
Priority:	Normal
Type:	Note

Hi Ilse,

Minor edits added. Thanks.

Matthew

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To: Carroll, David (VACO) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Fuller, Matthew A. (PBM) <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>
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Sent Date:	2019/06/12 08:47:57
Delivered Date:	2019/06/12 08:48:00

AMERICAN OVERSIGHT

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To:	Boyd, Teresa D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6886a7d555a43e0bee23c1e40e1c234-Boyd, Teres <(b6) va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>
Subject:	RE: Esketamine Community of Practice call tomorrow @ 2 pm ET
Date:	2019/06/12 15:20:05
Priority:	Normal
Type:	Note

John Bradley is the Chief of Psychiatry at Boston and would be able to pull in others as needed.

From: Boyd, Teresa D.
Sent: Wednesday, June 12, 2019 6:12 AM
To: Wiechers, Ilse <Ilse.Wiechers@va.gov>
Cc: Carroll, David (VACO) <(b6) va.gov>
Subject: RE: Esketamine Community of Practice call tomorrow @ 2 pm ET

I will be en route to the airport with others - my apologies but please express my appreciation to all. Look forward to hearing any outcome to call.

Also, would like to give comms a heads' up about Boston as initial site - a good news story. Who do you all work with usually?

Thanks again! Great work/heavy lift.

Teresa

Sent with BlackBerry Work
(www.blackberry.com)

From: Wiechers, Ilse (b6) @va.gov>
Date: Wednesday, Jun 12, 2019, 2:23 AM
To: Carroll, David (VACO) <(b6) va.gov>, Valentino, Michael (VACO) <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>, Fuller, Matthew A. (PBM) <(b6) va.gov>, Boyd, Teresa D. <(b6) va.gov>
Subject: Esketamine Community of Practice call tomorrow @ 2 pm ET

Hi everyone –

A quick reminder of the call in information for those able to join tomorrow. Please use the MODERATOR code listed below, as I anticipate we may need to mute the audience due to large number of participants.

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Matthew – I will turn it over to you for slides 18-19 on updates re PBM policies. Please feel free to edit those slides if you like and send me revised slides tomorrow by 1 pm ET.

Join Skype Meeting (Trouble Joining? Try Skype Web App)
Join audio by VANTS at 1-800-767-1750, moderator 13331#

Thanks,
Ilse

***

Ilse R. Wiechers, MD, MPP, MHS
National Director, Psychotropic Drug Safety Initiative (PDSI)
Associate Director, Northeast Program Evaluation Center
Office of Mental Health and Suicide Prevention (10NC5), Department of Veterans Affairs
Assistant Clinical Professor of Psychiatry, Yale University School of Medicine
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Recipient:	Boyd, Teresa D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6886a7d555a43e0bee23c1e40e1c234-Boyd, Teres <(b6) va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>
Sent Date:	2019/06/12 15:20:06
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From:	Butler, Brooke /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4C01305E4FE24027828970A10090E946-BUTLER, BRO (b6) va.gov>
To:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>; Hobbs, Deborah /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f927338db84e46dcbc32de9fcfc2772b-Hobbs, Debo <(b6) va.gov>; Blalock, Meredith J. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=049248ff499341cd951ebde4dca87bd7-Blalock, Me <(b6) @va.gov>; VHA National Psychiatry Chiefs /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eb44f48927b74432829cd2cc99374596-VHA Nationa <VHANationalPsychiatryChiefs@va.gov>; VHACLE BVAC Group /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=22c1aa8521d14717a1ccc0cc1ab55c6e-VHACLE BVAC <VHACLEBVACGroup@va.gov>; VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>; Shiroma, Paulo R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cae9fb698bb245669c11a3564784e24e-Shiroma, Pa <(b6) va.gov>; McGuire, Marsden H. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29e9d648c29f4885828c10446fdd7379-McGuire, Ma (b6) @va.gov>; Drexler, Karen MD (Atlanta) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c456a9bf391415bb4bdb9b6f88bdf45-Drexler, Ka <(b6) va.gov>; Pomerantz, Andrew /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29a9288df9a34e84bddfd00cde79f11b-Pomerantz, <(b6) @va.gov>; Katz, Ira R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=65f4e28aa7574641932c29fed7c0b4b8-Katz, Ira R <(b6) va.gov>; Yoon, Gihyun /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aec946e46a224f4ea66ce2078a8115d3-Yoon, Gihyu <(b6) va.gov>; Mathew, Sanjay (HOU) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=67422a5cc3904b40bff8fca2b9cd1b48-Mathew, San <(b6) va.gov>; Mohamed, Somaia /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=37831d1786914522b90bb85b2a8e1441-Mohamed, So <(b6) va.gov>; Ranganathan, Mohini /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a929509685bd4ad2895c66775c05d7b5-Ranganathan <(b6) va.gov>; Krystal, John /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3d5500f300d74e0dba7f8b30a5b42f02-Krystal, Jo (b6) va.gov>; Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat <(b6) va.gov>; Cunningham, Fran /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=613f0d8e535d46af95fed310f100dcbc-Cunningham, <(b6) va.gov>; Moore, Tera /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=443b30ba02cc4630a7567d54c649a771-Moore, Tera <(b6) @va.gov>; Czekanski, Elizabeth R /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aee7f346873e4a84a863e6c1d28bac48-Czekanski, <(b6) va.gov>;

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	Myrick, Donald L. (Hugh) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ffec881db4394259b082b76436cdc904-Myrick, Don <(b6) va.gov>; National Mental Health Facility Leaders /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=19747ced1df743daba0cc87d8778c400-National Me <MHFacilityLeaders@med.va.gov>; Kapral, Troy /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e68ba4ade95347e48cf8d79cee1ffde4-Kapral, Tro <(b6) @va.gov>; Duncan, Erica MD /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=600b2f4d20cd4d6ab196263a4eb0ce43-Duncan, Eri <(b6) @va.gov>; Mostaghimi Tehrani, Ladan /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2a7a2811cd4842d29d5d1eadd83b34d9-Mostaghimi- <(b6) @va.gov>; Wingerson, Dane K /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d232b4f06a104867938173cdf4c23a0a-Wingerson, <(b6) @va.gov>; Eddy, Emily A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e1e60648d0784caaade53e3846a96d76-Eddy, Emily (b6) @va.gov>; Nuhic, Safiye /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=64d1a7f343194595aed6030b5b0a6927-Nuhic, Safi (b6) va.gov>; Dieperink, Michael /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=da1de3a4d6404f1ab79e6a87a702991a-Dieperink, (b6) @va.gov>; Keane, Terry /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f3737ec08294cbe992a5b233fba367f-Keane, Terr <(b6) @va.gov>; Hurley, Robin A SBYVAMC /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=72e3630f60004829b3f8fb44d19557e7-Hurley, Rob <(b6) y@va.gov>; Tubbs, Rhamey /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a44dee7cabb14f709963e2172176e6b2-Tubs, Rhame (b6) @va.gov>; Baldwin-Thomas, Valerie (ROS) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b293cd6d9d3649559f0f07301119f6e0-Baldwin-Tho (b6) @va.gov>; <??>; ; ; ; ;
CC:	McGuire, Lisa L. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=220cd4e14c6e42e09b15a2f0888f1efe-McGuire, Li <(b6) @va.gov>; Dunaway, Kristen M (Portland) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=593cc385e9c1486ca5b71d4efcf5c327-Dunaway, Kr <(b6) @va.gov>; Parisien, Karen M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=55f48ed3c5e7450bb198a54da788ad4f-Parisien, K <(b6) @va.gov>; Lowman, Cheryl A. Ph.d. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6c940f7024c945629f5bb87a3f283a3a-Lowman, Che (b6))@va.gov>; Cork, Travis J. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=11caa312168f421bb4145bba3d4d92ad-Cork, Travi (b6) @va.gov>; Jaume, Alyssia J. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=32b1e043722a40b69204e39ca10b9ba2-Jaume, Alys (b6) e@va.gov>; VHA VISN 04 BH Committee /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c717b1992e794206a8a817bd05aa4cf6-VHA VISN 04 <BHCommittee@med.va.gov>; Keen, Angela D /o=ExchangeLabs/ou=Exchange Administrative Group

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{b6} @va.gov>;
Leinbach, Jonathan E DURVAMC /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e9f36c898fc246d4bce7481a6432bd7a-Leinbach, J
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<{b6} va.gov>;
Mohamed, Somaia {b6} yale.edu) <{b6} yale.edu>;
Oslin, Dave (Philadelphia VAMC) /o=ExchangeLabs/ou=Exchange Administrative Group
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VISN 23 MH Site Directors /o=ExchangeLabs/ou=Exchange Administrative Group
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Ross, Debra (V23) /o=ExchangeLabs/ou=Exchange Administrative Group
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Hiett, Erica H /o=ExchangeLabs/ou=Exchange Administrative Group
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Brown, Keith L /o=ExchangeLabs/ou=Exchange Administrative Group
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Dahlinger, Rosanna J. /o=ExchangeLabs/ou=Exchange Administrative Group
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Spollen, John J. III /o=ExchangeLabs/ou=Exchange Administrative Group
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Dunn, Walter /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=dd06b6b345fe4e25871d6ff0e6b94471-Dunn, Walte
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Golier, Julia A. /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ffef8d04a1a04d8d8ce3c4ff57351e34-Golier, Jul
{b6} @va.gov>;
David, Daniella (MIAMI VA) /o=ExchangeLabs/ou=Exchange Administrative Group
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Siegel, Mary K /o=ExchangeLabs/ou=Exchange Administrative Group
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<{b6} @va.gov>;

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Lache, Daniel J. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f68dc7b53f44f9e82cc5b4020131004-Lache, Dani (b6) @va.gov>;
Sivak, Kim A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8f72debca022442a921e59b6efe89def-Sivak, Kim (b6) @va.gov>;
Hagler, Jennifer E. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3dd99ed364b745e5ace2a59479f5d641-Hagler, Jen <(b6) @va.gov>;
Gottumukkala, Aruna (HOU) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01f07e1e0ed24c979ba15bab668e3196-Gottumukkal <(b6) @va.gov>;
Hahn-Mowry, Angela J. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17ce2b0d0f4147b9ae95c18c19301950-Hahn-Mowry, <(b6) @va.gov>;
Montautti, Silvana L. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83b36db36ebf48ca90ed8e0dad57478b-Montautti, (b6) @va.gov>;
Weddle, Jessica /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48f321dbbd91419793ff980811f7df6f-Weddle, Jes (b6) @va.gov>;
Drexler, Michael /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e10af3d4ce04d558cd5db0d376086f1-Drexler, Mi <(b6) @va.gov>;
Kilgore, Heath M /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90dc4cf50df2413bbc05adc92feea138-Kilgore, He <(b6) @va.gov>;
VHAMIW Psychiatry /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3b1d0fd2754f48d2a2a7e2a8444e9fcb-VHAMIW Psyc <VHAMIWPsychiatry@med.va.gov>;
Desai, Nitigna /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7bb9e26d62d24ccdba71a3f4558fc5c3-Desai, Niti (b6) @va.gov>;
Hauser, Peter /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb84c51ec5364f8fbff6676791460f8a-Hauser, Pet <(b6) va.gov>;
VHAHAM Psychiatrists & MD /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2274c14cb2554d1796a514f5833afb77-VHAHAM Psyc <VHAHAMPsychatrists&MD@va.gov>;
Singh, Maninder HAMVAMC /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b9cb0b4a5491475690cadf674a7e624e-Singh, Mani (b6) @va.gov>;
Hooshyar, Dina /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0822b5df331a4b4593eb7572087e5321-Hooshyar, D <(b6) @va.gov>;
Varma, Anjali SAMVAMC /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f99a28f2fec844aca34b50c6613f41b1-Varma, Anja (b6) a.gov>;
Saleh, Elaine M /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=813e403c9efe4ca6be5f3d8fa6d9d573-Saleh, Elai (b6) @va.gov>;
Marx, Brian /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df3b82149db745e0bfe1d9a3f50096bf-Marx, Brian (b6) @va.gov>;
Nimgaonkar, Vishwajit L. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2539341a259846b4b3560a81e2b6aa03-Nimgaonkar, (b6) @va.gov>;
Cooper, Marc A. SBYVAMC /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=601f7783e51e4cd5b77fe484244bca91-Cooper, Mar (b6) @va.gov>;
Samples, Jessica C. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=105fdf480ede44838cc0e7c84d0b4421-Samples, Je (b6) @va.gov>;
Schmidt, Clark P. (Walla Walla) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fc3f7945a4e34abf875501e261eb24ae-Schmidt, Cl (b6) @va.gov>;

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Sood-Khandpur, Roopam HAMVAMC /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b52796acee488ab43b93e14a9cc769-Sood-Khandp (b6) @va.gov>;
MacPhee, Edward R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=190e432f2c9342d0899d7c55892df23c-MacPhee, Ed (b6) @va.gov>;
Smith, Lisa C. (ECH) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7c6bda337d6146bcafdb6ff67bcce05c-Smith, Lisa <(b6) @va.gov>;
Whittaker, Kevin C. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e137d726f6448b0a6a2804f39a1e35f-Whittaker, (b6) @va.gov>;
Ford, Lovetta /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=640c4f933da44a3aaded83da1a144902-Ford, Lovet (b6) va.gov>;
Smith, Tammy J SBYVAMC /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=42a70b0687d34781b69143b842cc31e3-Smith, Tamm (b6) @va.gov>;
Brown, Thomas W. SBYVAMC /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=519c14650eb547ff997b2cdcd4424ecb-Brown, Thom <(b6) @va.gov>;
Khan, Amer H HAMVAMC /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=432c79833c3a4e4393e0c9eedb135f30-Khan, Amer <(b6) @va.gov>;
Payne, Annette /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5388ec8437274963adbebfaebcc65ec2-Payne, Anne (b6) @va.gov>;
Costa, Nicole M /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ff5f1eacbe234bfab2e07ec9312680a5-Costa, Nico (b6) va.gov>;
Stromberg, Nicole /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd0d18f974f34dcf8d4aa27edafa1909-Stromberg, <(b6) @va.gov>;
Siegrist, Joy H HAMVAMC /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba53bc963a3346838192a4b24ea5349b-Siegrist, J <(b6) @va.gov>;
Griffin, John HAMVAMC /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=604a91ad4b6b498bb4137358bf86f43f-Griffin, Jo <(b6) @va.gov>;
Haider, Naveed /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e357f25071cf4f4cb28fac2d6bd187fc-Haider, Nav <(b6) @va.gov>;
Buckley, Timothy J /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7fd8344b327b4b3f8be31d719625c634-Buckley, Ti <(b6) @va.gov>;
Tsao, Carol I. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f449bb1333f94f088e1c96f192c20697-Tsao, Carol (b6) @va.gov>;
Mankad, Mehul V. DURVAMC /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ccf31a0ab89347c4926bb2d729669ae9-Mankad, Meh (b6) va.gov>;
Gabrielson, Amanda B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e113cc3f200243528f65d449383e9f37-Gabrielson, <A(b6) @va.gov>;
Kuo, Irving /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4cf261f46b1a4dad979c0574a6ba90c6-Kuo, Irving (b6) @va.gov>;
Ventura, Jose Victor M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=032df0dc5f884cb4b6d44ae38da934fe-Ventura, Jo (b6) @va.gov>;
VHAPBM Pharmacy Chiefs /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b3bdd525bd2340749ff69f86d2e657f0-VHAPBH Phar <PharmacyChiefs@va.gov>;
VHA Psychiatric Pharmacists /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90cb74f2975346fc8ad14f8c9a05a521-VHA Psychia <PsychiatricPharmacists@va.gov>;

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VHAPBM Academic Detailing Collaboration /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08f999dbd97248e5903e3f600de27b56-VHAPBH Acad <AcademicDetailingCollaboration@va.gov>;
VHAPBM VPE Formulary Committee /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fcba1f4b52e048838d3053091f54eb4e-VHAPBH VPE <VPEFormularyCommittee@va.gov>;
VHA Clinical Pharmacists /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=feeeb2640db54aeebeeb57c1e0f534ea-VHA Clinica <vha.clinical.pharmacists@va.gov>;
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Burrell, Bruce /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c32c8383add0443b8a7bba232304a809-Burrell, Br (b6) @va.gov>;
Borba, Brett /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=84477462c7284667903f9cfbdd8c7997-Borba, Bret (b6) @va.gov>;
Cunningham-Stonewall, Ashlee /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a00756e2b5db4c748d1a54e481494461-Thomas, Ash (b6) @va.gov>;
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Lucas, Tori M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e90190e502644c5e945cecbc4a8c1472-Lucas, Tori (b6) va.gov>;
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Folstad, Jon E SBYVAMC /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=30b071eb845149f085a7b7aa26dc53d7-Folstad, Jo <(b6) a.gov>;
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Segraves, Ann M /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b6ed1a0b0aa64a50a2a025193bea1c78-Segraves1, (b6) @va.gov>;
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Jones, Rebecca L /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03f1d8d1334b41cfb5ccf622bd8a3ad1-Jones1, Reb (b6) @va.gov>;

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Kellermann, Mary-Jean /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6e656b92001b4962b040409e9b63f8a4-Kellermann, <(b6) va.gov>;
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Sweet, Gary D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=454af259fc264558bbeb628425928175-Sweet, Gary <(b6) a.gov>;
Hillman, Ashley D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eb19afd311cf41958deeffaa1efa8fad-Hillman, As <(b6) va.gov>;
Ramsdell, Taylor H /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=66663bd3cebb4e5c92c9b08fa5773600-Ramsdell, T <(b6) ll@va.gov>;
Saghaian, Ali Z. (White City/VISN20) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c86f1526bfde4766832a62d490b7e4a1-Saghaian, A <(b6) @va.gov>;
Jain, Vivek /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45b3c49bd4674c7eb48316176b43b9b0-Jain, Vivek <(b6) .gov>;
Su, Eugenia A. (ROS) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0ff8c8c41474c1d9d2d59edf8f478a6-Su, Eugenia <(b6) gov>;
Villasenor, David /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95ba4163b9564309bcdc46b77aec60e1-Villasenor, <(b6) @va.gov>;
Spence, Earlene (Orlando) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=543218c38bef447b96ae1ddb48e6fd70-Spence, Ear <(b6) va.gov>;
Milanovich, Dragan /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ea1f1eb4957d40d39f96089ce1023b45-Milanovich, <(b6) a.gov>;
VHALAS PHARM MHC /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b54bc07fae984d72aeed74a81135a2e2-VHALAS PHAR <VHALASPHARMMHC@va.gov>;
Love-Dubeau, Lauren L. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=776978a8b0cd47d7a5f36d2dbefe612d-Love-Dubeau <(b6) a.gov>;

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Wallen, Christopher J /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=784ad8325e45435d8a86d0ca37ba69af-Wallen, Chr (b6) va.gov>;
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Johnston, Christine (NCHCS) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86bd183519d149e5a7ddc83d48a11873-Johnston, C (b6) @va.gov>;
Ward, Kristina /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98f538e34fad4cac84f8f393957e0156-Ward, Krist (b6) ov>;
Porter, Heather /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=75da4441ee8c4758822a081c06f43400-Porter, Hea (b6) @va.gov>;
Fabo, Karyn FNCVAMC /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6f761990badc470d93907dc404a716f4-Fabo, Karyn (b6) va.gov>;
Meyer, Rebecca /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=25f63e8d1fd84115a8b60d45763c0064-Meyer, Rebe (b6) va.gov>;
Morgan, Joni H. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40a7df230d04466486d8f326ee422550-Morgan, Jon (b6) va.gov>;
Griffith, June /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43341869684d4805b542dc14e42e0cd9-Griffith, J (b6) @va.gov>;
Paul E. Holtzheimer <(b6) hitchcock.org>;
Alholail, Ayman M. (ROS) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae4b6084cd9348ad983a896d71b4f137-Alholail, A <(b6) @va.gov>;
Winder, Marquita Bradshaw /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a4d390eed8d34361ad5ff7d5f82572cc-Winder, Mar (b6) @va.gov>;
Congdon, Ardsley P. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=530acb9f3579498ab39ee30039dca4bd-Condgon Iii <(b6) va.gov>;
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Mackenna, Holly (NOLA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=42bd105e71844bd1b514ebeea7a1e798-Mackenna, H (b6) @va.gov>;
Lionas, Michelle J. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb17ae9d1c584fbe9bcba298b6c27de6-Lionas, Mic (b6) gov>;
Trang, Peter T. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=94808db4f9c441be9a52f6c9afe1c2ab-Trang, Pete (b6) @va.gov>;
VHANOL MHS PSYCHIATRY /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7e1fcedd1612419c8bfd429f22a2b407-VHANOL MHS <VHANOLMHSPSYCHIATRY@va.gov>;
Curry, Brent Weston /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45fcc90ac8b44dadb9e7fa36133e0feb-Curry, Bren (b6) va.gov>;
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LI, CHENGQING (KCVA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e24f36df79d945e392234bf1570c1e64-LI, CHENGQI (b6) @va.gov>;

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Peters, Jennifer L. RICVAMC /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=14458a4a3cd74f98b00f614046e5bcc5-Peters, Jen (b6) @va.gov>;
Lezer, Ryan D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=af981608e9a84fa59ecc0db5b8d694d6-Lezer, Ryan (b6) a.gov>;
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Maurstad, Jeremy L /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3b002481729d4b4d98289e90038e82cc-Maurstad, J (b6) @va.gov>;
Hibbs, Jennifer L.(White City/VISN20/) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d85c109cca3e4a9c879efb881fcd594a-Hibbs, Jenn (b6) a.gov>;
Werner, Katherine E. (SPO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac03fc5a0f9c419eb2d38576d44f70aa-Werner, Kat (b6) @va.gov>;
Kesgen, Carl V. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8f7a8584e42e40b585834f5564a583ee-Kesgen, Car (b6) @va.gov>;
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Vespia, Judith /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f228107701c94902a3f1234b59364b9f-Glaskin, Ju (b6) @va.gov>;
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Christopher, Melissa L (VHASDC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a542daad1277489fb77c0b3d08454521-Christopher <(b6) @va.gov>;
Shenfield, Angela /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1f4127d9ccc740ec861921e6833cef3f-Shenfield, (b6) a.gov>;
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Massari-Ortiz, Raisha /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=467cce3a57fa41f7ab9ab331a4ea3466-Massari-Ort (b6) va.gov>;
Jensen, Benjamin D. (VHAANC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2193f62e7ced42178eaff63fe691bbc1-Jensen, Ben (b6) @va.gov>;
Basanese, Lisa A. VHAIRO /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d1652a71de844574b75ce324eb29cf75-Basanese, L (b6) >;
Shayegani, Ramona /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=96e75488fe45492cb7045f4146512887-Shayegani, (b6) @va.gov>;
Doebler, Tammy E. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f095d9996074d9aa7ae80717f769472-Doebler, Ta (b6) @va.gov>;
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Allen, Clayton E. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d7985623d1a436bb4645657cf05b195-Allen, Clay
(b6) @va.gov>;
Shikwana, Sara S /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fcd51f3a4712422087c55bbdf57e8a0b-Shikwana, S
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Mendes, Margaret A /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=99156a1abbd84345a5f5de328985805c-Mendes, Mar
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Havelka, Carolyn /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5332a6050cca4e78b8455c621c112729-Havelka, Ca
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Miller, Janice (ELP VAMC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4f9431585a04d3888983d9e71c4903b-Miller, Jan
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Graham, Rebecca L. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1dc6c8b897a344ae93fdbbe2f5579aa8-Graham, Reb
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Crumb, Meredith W. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1bbb16a7e68493d80faf5979493dcdf-Crumb, Mere
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Carnes, Paul A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17034a0b74804db7b3b851f8ce3007b3-Carnes, Pau
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Holsinger, Tracey DURVAMC /o=ExchangeLabs/ou=Exchange Administrative Group
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AMERICAN OVERSIGHT

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AMERICAN OVERSIGHT

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AMERICAN OVERSIGHT

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AMERICAN OVERSIGHT

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AMERICAN OVERSIGHT

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Subject:	RE: Esketamine Community of Practice
Date:	2019/08/15 07:33:34
Priority:	Normal
Type:	Note

Please disregard the last message. Sorry that wasn't supposed to go to everybody on the list, just my supervisors to help adjust my schedule.

-----Original Appointment-----
From: Butler, Brooke **On Behalf Of** Wiechers, Ilse
Sent: Thursday, August 15, 2019 7:28 AM
To: Hobbs, Deborah
Subject: FW: Esketamine Community of Practice

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When: Occurs the second Wednesday of every 1 month(s) effective 6/12/2019 from 11:00 AM to 12:00 PM (UTC-08:00) Pacific Time (US &Canada).
Where: Skype for online meeting VANTS for audio at 1-800767-1750, 45914#

I have patients scheduled on Wednesdays from 2-3. What should I do?

-----Original Appointment-----
From: Wiechers, Ilse
Sent: Thursday, May 30, 2019 10:53 AM
To: Wiechers, Ilse; Butler, Brooke; Blalock, Meredith J.; Hobbs, Deborah; VHA National Psychiatry Chiefs; VHACLE BVAC Group; VHA 10NC5 Action; Zacher, Jennifer L. (PBM); Shiroma, Paulo R.; McGuire, Marsden H.; Drexler, Karen MD (Atlanta); Pomerantz, Andrew; Katz, Ira R.; Yoon, Gihyun; Mathew, Sanjay (HOU); Mohamed, Somaia; Ranganathan, Mohini; Krystal, John; Fuller, Matthew A. (PBM); Cunningham, Fran; Moore, Tera; Czekanski, Elizabeth R; Myrick, Donald L. (Hugh); National Mental Health Facility Leaders; Kapral, Troy; Duncan, Erica MD; Mostaghimi Tehrani, Ladan; Wingerson, Dane K; Eddy, Emily A.; Nuhic, Safiye; Dieperink, Michael; Keane, Terry; Hurley, Robin A SBYVAMC; Tubbs, Rhamey; Baldwin-Thomas, Valerie (ROS)
Cc: McGuire, Lisa L.; Dunaway, Kristen M (Portland); Parisien, Karen M.; Lowman, Cheryl A. Ph.d.; Cork, Travis J.; Jaume, Alyssia J.; VHA VISN 04 BH Committee; Keen, Angela D; Walker, Paul J.; Leinbach, Jonathan E DURVAMC; Gibson, Carri-Ann M.; Chemerinski, Eran; Hillier, Shannon L.; (b6) ((b6) yale.edu); Oslin, Dave (Philadelphia VAMC); VISN 23 MH Site Directors; Ross, Debra (V23); Minor, Donna; Le, Vu H.; Hiett, Erica H; Brown, Keith L; Dahlinger, Rosanna J.; Spollen, John J. III; Dunn, Walter; Poole, Ronald D.; Golier, Julia A.; David, Daniella (MIAMI VA); Siegel, Mary K; Dev, Deepak; McGuire, Kevin; Lache, Daniel J.; Sivak, Kim A.; Hagler, Jennifer E.; Gottumukkala, Aruna (HOU); Hahn-Mowry, Angela J.; Montautti, Silvana L.; Weddle, Jessica; Drexler, Michael; Kilgore, Heath M; VHAMIW Psychiatry; Desai, Nitigna; Hauser, Peter; VHAHAM Psychiatrists &MD; Singh, Maninder HAMVAMC; Hooshyar, Dina; Varma, Anjali SAMVAMC; Saleh, Elaine M; Marx, Brian; Nimgaonkar, Vishwajit L.; Cooper, Marc A. SBYVAMC; Samples, Jessica C.; Schmidt, Clark P. (Walla Walla); Sood-Khandpur, Roopam HAMVAMC; MacPhee, Edward R.; Smith, Lisa C. (ECH); Whittaker, Kevin C.; Ford, Lovetta; Smith, Tammy J SBYVAMC; Brown, Thomas W. SBYVAMC; Khan, Amer H HAMVAMC; Payne, Annette; Costa, Nicole M; Stromberg, Nicole; Siegrist, Joy H HAMVAMC; Griffin, John HAMVAMC; Haider, Naveed; Buckley, Timothy J; Tsao, Carol I.; Mankad, Mehul V. DURVAMC; Gabrielson, Amanda B.; Kuo, Irving; Ventura, Jose Victor M.; VHAPBM Pharmacy Chiefs; VHA Psychiatric Pharmacists; VHAPBM Clinical Pharmacy Practice Office (CPPO); VHAPBM Academic Detailing Collaboration; VHAPBM VPE Formulary Committee; VHA Clinical Pharmacists; Taylor, Suzanne; Burrell, Bruce; Borba, Brett; Cunningham-Stonewall, Ashlee; Dalton, Shawn M.; Hardee, Jillaine G., DURVAMC; Elias, Willishea J.; Lucas, Tori M.; Stefanelli, Rita; Vernon, Martein; VHASBY Clinical Pharmacy Staff Psychiatry; Folstad, Jon E SBYVAMC; Hill, Zachary D.; Jodocy, Andrew P.; Guerra, Melinda B.; Segraves, Ann M; Koller, Katherine L; Jones, Rebecca L; Ho, Angela; Gaballah, Adel; Wells, Daina L.; Anadu, Ifeanyi O.; Butler, Brooke; Blalock, Meredith J.; Abudia, Jade L.; Fackler, Sondralyn M.; Miller, Laura (Dublin, Ga); Geurkink, Eric; Eberly, Mary E.; Kellermann, Mary-Jean; Shaban, Hanan M.; Sweet, Gary D.; Hillman, Ashley D.; Ramsdell, Taylor H; Saghaian, Ali Z. (White City/VISN20); Jain, Vivek; Su, Eugenia A. (ROS); Villasenor, David; Spence, Earlene (Orlando); Milanovich, Dragan; VHALAS PHARM MHC; Love-Dubeau, Lauren L.; O'Connor, Kevin R.; Wallen, Christopher J; Chen, Jacqueline S.; Johnston, Christine (NCHCS); Ward, Kristina; Porter, Heather; Fabo, Karyn FNCVAMC; Meyer, Rebecca; Morgan, Joni H.; Griffith, June; Paul E. Holtzheimer; Alholail, Ayman M. (ROS); Winder, Marquita Bradshaw; Congdon, Ardsley P.; Ward, Sarah; Houranieh, Antoun; Mackenna, Holly (NOLA); Lionas, Michelle J.; Trang, Peter T.; VHANOL MHS PSYCHIATRY; Curry, Brent Weston; Snyder, Morgan; LI, CHENGQING (KCVA); Gibbs, Eric D. ASHVAMC;

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Walter, Andrea N. (VA NWI); Bishop, Kristen L.; Frazer, Justin M.; Coniglio, Jenifer R.; Jesse, Sarah J.; VISN 23 Pharmacy Chiefs; Awan, Sundus S. FHCC Lovell; Didion, Rachel K. FHCC Lovell; Haake, Elizabeth R. VHAREN; Urick Perez, Lois BECVAMC; Perry, Richard J. (ROS); Rodriguez, William E. (Miami VAMC); VHAWAS MHMD; Coakley, Christina; Franck, Jessica B.; Zumberg, Lisa; Chung, Haemy; Ang, Gordon W.; Rickert, Leah M.; Wilmer, Sonya R (HOU); Melde, Stephen L; De Peralta, Sharon B.; Lehman, David; Printz, David; Ramanathan, Dhakshin; Beizai, Kristin S.; Cooley, Allyson M.; MacWhorter, Carrie; Suazo, Michelle T. (Miami VA); Jensen, Aimee N.; Thomas, Kevin; Duquette, Meghan Q.; Buyck, David W SAMVAMC; Sangutei, Brian RICVAMC; Tubbs, Traviss A.; Schmidt, Robert W RICVAMC; Mathis, Erin R. RICVAMC; Wonson, Erica RICVAMC; Del Rio, Manuel (Miami VA); Pazzaglia, Peggy J.; Ritz, Stacy R.; Nwabuzor, Emeke B.; Larew, Janel M.; Hershey, Benjamin; Praus, Julie M.; Nwokoro, Stella; Jackson, John K (NOLA); Genesio, Kimberly (NOLA); Kokett, Gerard J.; Lundell, Ryan D.; Barber, Joseph A. LEBVAMC; Sanft, Ryan; Summerville, Michele R.; Miller, Christopher W.; Sherif, Mohamed; Monsour, Sophia A.; Forman, Steven D; Vajjhala, Vinay T; Carradine, Lauren E; Speerhas, Lucy E; Bennett, Sevim; Forshee, Judith A.; Gaber, Lea M.; Smith, Jordan O; Vandaele, Madeline A.; Ali, Sarah S.; Roche, Jennifer (VHACLE); Allen, Sarah M.; Saeed, Mohammad A; Jones, Ellen A.; Fox, Mark; Sophinos, Jeffrey; Mitchell, Brian G. (HOU); Karow, Matthew J.; Campbell, Tamara, VHACIN; Lehrer, Douglas S., VHACIN; Taxeras, Heather D.; Pencea, Viorica; Lipp, Sharon, DVHACS; Oshita, Monica I.; Jobin, Timothy; Turner, Ted J.; Tuck, Katie A.; Leeson, Michael; Maksimowski, Michael; Elliott, William J. FNCVAMC; Gossett, Anne K; McCoy, Thomas; HEISSLER, JAIME T.; Owenby, Ryan K DURVAMC; Duquaine, Susan M. (KCVA); Hunt, Lindsey (Boise); Bahrey, Stephanie J., VHACIN; Chau, Suzanne T. FHCC Lovell
Subject: FW: Esketamine Community of Practice
When: Occurs the second Wednesday of every 1 month(s) effective 6/12/2019 from 11:00 AM to 12:00 PM (UTC-08:00) Pacific Time (US &Canada).
Where: Skype for online meeting VANTS for audio at 1-800767-1750, 45914#

Good morning! I did not know if you all received this invite? If someone from pharmacy could represent us on the call that would be most appreciated. Thanks so much! I will not be able to dial in due to Joint Commission's visit. Take care. I hope that everyone has a good day!

Sondralyn

-----Original Appointment-----
From: Wiechers, Ilse
Sent: Thursday, May 30, 2019 10:58 AM
To: Wiechers, Ilse; VHA National Psychiatry Chiefs; VHACLE BVAC Group; VHA 10NC5 Action; Zacher, Jennifer L. (PBM); Shiroma, Paulo R.; McGuire, Marsden H.; Drexler, Karen MD (Atlanta); Pomerantz, Andrew; Katz, Ira R.; Yoon, Gihyun; Mathew, Sanjay (HOU); Mohamed, Somaia; Ranganathan, Mohini; Krystal, John; Fuller, Matthew A. (PBM); Cunningham, Fran; Moore, Tera; Czekanski, Elizabeth R; Myrick, Donald L. (Hugh); National Mental Health Facility Leaders; Kapral, Troy; Duncan, Erica MD; Mostaghimi Tehrani, Ladan; Wingerson, Dane K; Eddy, Emily A.; Nuhic, Safiye; Dieperink, Michael; Keane, Terry; Hurley, Robin A SBYVAMC; Tubbs, Rhamey; Baldwin-Thomas, Valerie (ROS)
Cc: McGuire, Lisa L.; Dunaway, Kristen M (Portland); Parisien, Karen M.; Lowman, Cheryl A. Ph.d.; Cork, Travis J.; Jaume, Alyssia J.; VHA VISN 04 BH Committee; Keen, Angela D; Walker, Paul J.; Leinbach, Jonathan E DURVAMC; Gibson, Carri-Ann M.; Chemerinski, Eran; Hillier, Shannon L.; (b6) ((b6) yale.edu); Oslin, Dave (Philadelphia VAMC); VISN 23 MH Site Directors; Ross, Debra (V23); Minor, Donna; Le, Vu H.; Hiett, Erica H; Brown, Keith L; Dahlinger, Rosanna J.; Spollen, John J. III; Dunn, Walter; Poole, Ronald D.; Golier, Julia A.; David, Daniella (MIAMI VA); Siegel, Mary K; Dev, Deepak; McGuire, Kevin; Lache, Daniel J.; Sivak, Kim A.; Hagler, Jennifer E.; Gottumukkala, Aruna (HOU);

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Where: Skype for online meeting VANTS for audio at 1-800767-1750, 45914#

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-----Original Appointment-----
From: Wiechers, Ilse
Sent: Tuesday, May 28, 2019 12:32 PM
To: Wiechers, Ilse; VHA National Psychiatry Chiefs; VHACLE BVAC Group; VHA 10NC5 Action; Zacher, Jennifer L. (PBM); Shiroma, Paulo R.; McGuire, Marsden H.; Drexler, Karen MD (Atlanta); Pomerantz, Andrew; Katz, Ira R.; Yoon, Gihyun; Mathew, Sanjay (HOU); Mohamed, Somaia; Ranganathan, Mohini; Krystal, John; Fuller, Matthew A. (PBM); Cunningham, Fran; Moore, Tera; Czekanski, Elizabeth R; Myrick, Donald L. (Hugh); National Mental Health Facility Leaders
Cc: McGuire, Lisa L.; Dunaway, Kristen M (Portland); Parisien, Karen M.; Lowman, Cheryl A. Ph.d.; Cork, Travis J.; Jaume, Alyssia J.; VHA VISN 04 BH Committee; Keen, Angela D; Walker, Paul J.; Leinbach, Jonathan E DURVAMC; Gibson, Carri-Ann M.; Chemerinski, Eran; Hillier, Shannon L.; Mohamed, Somaia ((b6) yale.edu); Oslin, Dave (Philadelphia VAMC); VISN 23 MH Site Directors; Ross, Debra (V23); Minor, Donna; Le, Vu H.; Hiett, Erica H; Brown, Keith L; Dahlinger, Rosanna J.; Spollen, John J. III; Dunn, Walter; Poole, Ronald D.; Golier, Julia A.; David, Daniella (MIAMI VA); Siegel, Mary K; Dev, Deepak; McGuire, Kevin; Lache, Daniel J.; Sivak, Kim A.; Hagler, Jennifer E.; Gottumukkala, Aruna (HOU); Hahn-Mowry, Angela J.; Montautti, Silvana L.; Weddle, Jessica; Drexler, Michael; Kilgore, Heath M; VHAMIW Psychiatry; Desai, Nitigna; Hauser, Peter; VHAHAM Psychiatrists &MD; Singh, Maninder HAMVAMC; Hooshyar, Dina; Varma, Anjali SAMVAMC; Saleh, Elaine M; Marx, Brian; Nimgaonkar, Vishwajit L.; Cooper, Marc A. SBYVAMC; Samples, Jessica C.; Schmidt, Clark P. (Walla Walla); Sood-Khandpur, Roopam HAMVAMC; MacPhee, Edward R.; Smith, Lisa C. (ECH); Whittaker, Kevin C.; Ford, Lovetta; Smith, Tammy J SBYVAMC; Brown, Thomas W. SBYVAMC; Khan, Amer H HAMVAMC; Payne, Annette; Costa, Nicole M; Stromberg, Nicole; Siegrist, Joy H HAMVAMC; Griffin, John HAMVAMC; Haider, Naveed; Buckley, Timothy J; Tsao, Carol I.; Mankad, Mehul V. DURVAMC; Gabrielson, Amanda B.; Kuo, Irving; Ventura, Jose Victor M.; Leeson, Michael; Maksimowski, Michael
Subject: Esketamine Community of Practice
When: Occurs the second Wednesday of every 1 month(s) effective 6/12/2019 from 11:00 AM to 12:00 PM (UTC-08:00) Pacific Time (US &Canada).
Where: Skype for online meeting VANTS for audio at 1-800767-1750, 45914#

Join us for the

Esketamine Community of Practice

Second Wednesday of the month at 2 pm ET/11 am PT

Join Skype Meeting (Trouble Joining? Try Skype Web App)

Join audio by VANTS at 1-800-767-1750, participant code 45914#

The Esketamine Community of Practice is a monthly teleconference that supports the clinical implementation of intranasal esketamine for treatment resistant depression across VHA. The

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teleconference is open to everyone, but participation is strongly encouraged for leadership, providers, and staff working in mental health, pharmacy, and nursing at esketamine early adopter sites.

Calls will discuss progress in implementation, troubleshoot systems barriers, and develop best practices. Calls will also serve as a key venue for the Office of Mental Health and Suicide Prevention to convey updates on policies and guidance related to esketamine to the field.

For questions about this call or esketamine clinical implementation in general, please contact Dr. Ilse Wiechers with the Office of Mental Health and Suicide Prevention (b6) @va.gov

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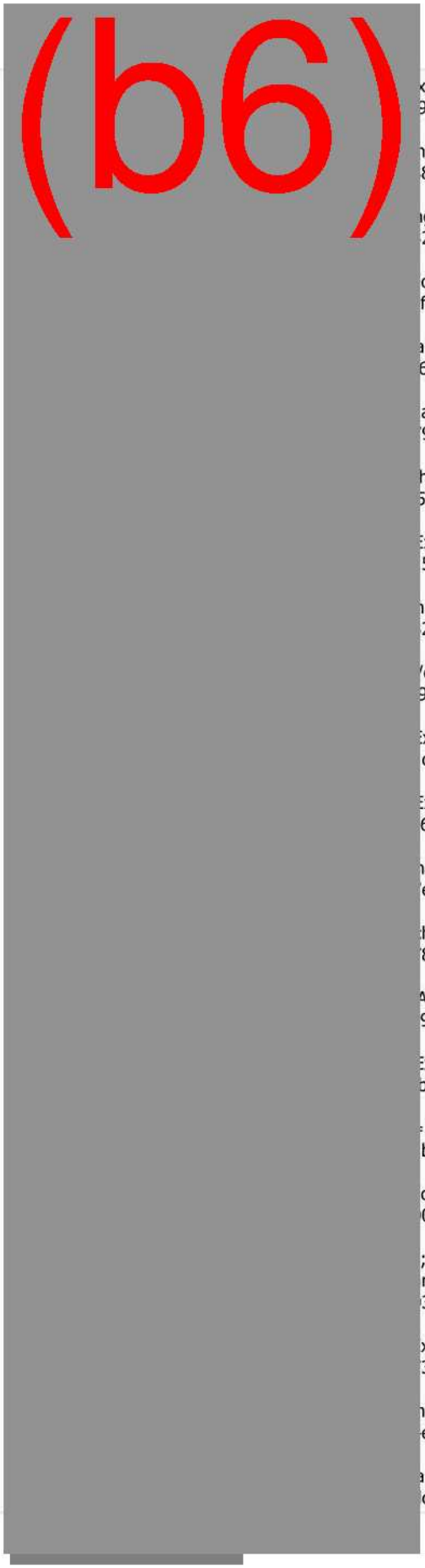

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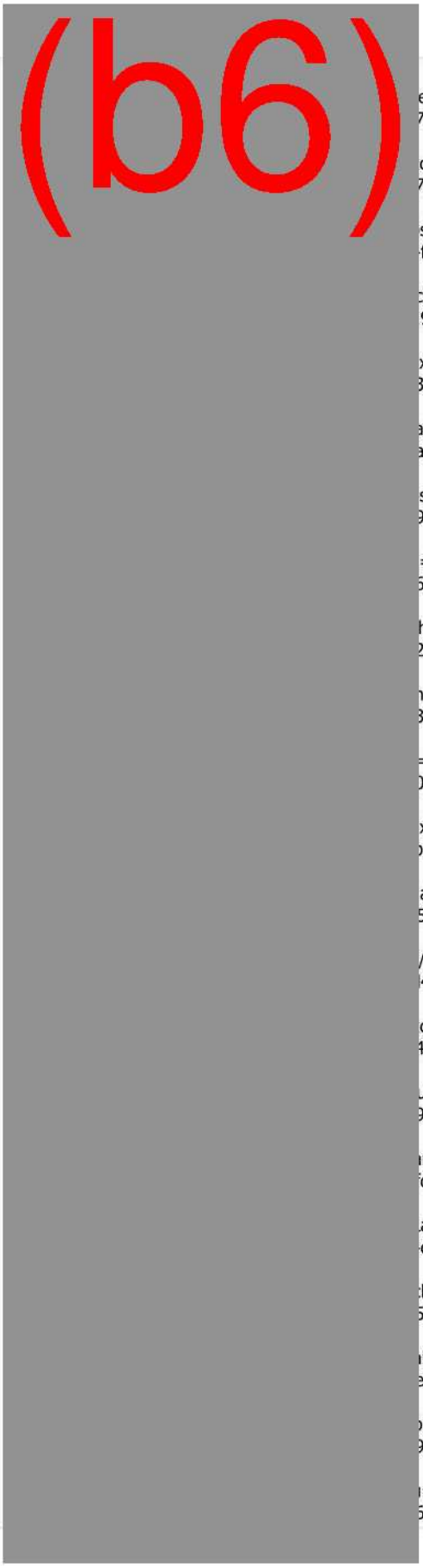

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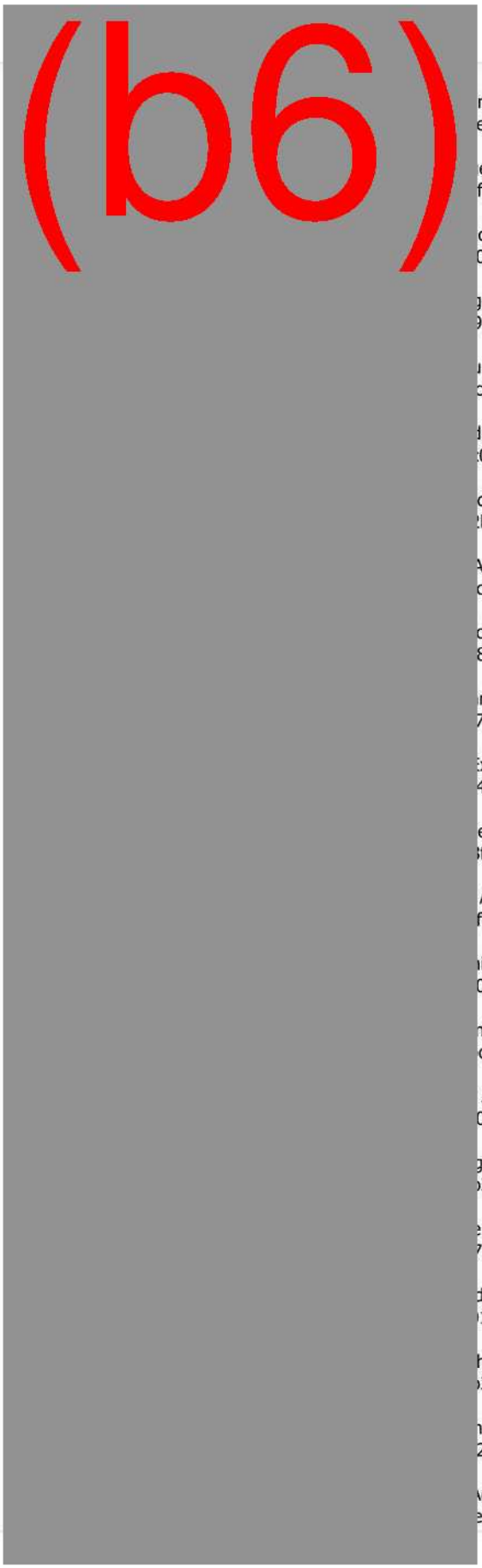

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Sent Date: 2019/08/15 07:33:02

Delivered Date: 2019/08/15 07:33:34

Message Flags: Unread

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From:	Carroll, David (VACO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=95E14EBD3B6745C8952A823B04DABFF5-CARROLL, DA>
To:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>
Subject:	RE: Esketamine Community of Practice
Date:	2019/06/12 13:34:55
Priority:	Normal
Type:	Note

Yes. Thx for reminder.

Sent with BlackBerry Work
(www.blackberry.com)

From: Wiechers, Ilse <(b6) va.gov>
Date: Wednesday, Jun 12, 2019, 1:34 PM
To: Carroll, David (VACO) <(b6) va.gov>
Subject: RE: Esketamine Community of Practice

Perfect – thanks so much. If you could also say something to highlight Dr. Boyd's support and enthusiasm for this work, that would be much appreciated.

Ilse

From: Carroll, David (VACO)
Sent: Wednesday, June 12, 2019 10:05 AM
To: Wiechers, Ilse (b6) @va.gov>
Subject: RE: Esketamine Community of Practice

Hi Ilse. FYI, I am tracking and will be on the call at 2:00 (ET). I will likely join right at 2:00 (have another call at 1:30). Let me know if you have any particular messages that you want me to give. My current thought is to address the following

- • Thanks for being willing to join this important work
- • Reflects VA's commitment to bring the latest and best science into practice
- • Acknowledging that there is much yet to learn
- • We are committed to safety and quality and will proceed in a way to honor both
- • First steps and first experience will guide further implementation plans
- • Your active engagement and dialogue is critically important

Thanks
Dave

-----Original Appointment-----
From: Wiechers, Ilse

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Sent: Tuesday, May 28, 2019 1:32 PM
To: Wiechers, Ilse; Pomerantz, Andrew; Zacher, Jennifer L. (PBM); VHA National Psychiatry Chiefs; VHACLE BVAC Group; VHA 10NC5 Action; Shiroma, Paulo R.; McGuire, Marsden H.; Katz, Ira R.; Yoon, Gihyun; Mathew, Sanjay (HOU); Mohamed, Somaia; Ranganathan, Mohini; Krystal, John; Fuller, Matthew A. (PBM); Cunningham, Fran; Moore, Tera; Czekanski, Elizabeth R; Myrick, Donald L. (Hugh); National Mental Health Facility Leaders; Drexler, Karen MD (Atlanta)
Cc: Jesse, Sarah J.; VISN 23 Pharmacy Chiefs; Awan, Sundus S. FHCC Lovell; Didion, Rachel K. FHCC Lovell; Haake, Elizabeth R. VHAREN; Urick Perez, Lois BECVAMC; Perry, Richard J. (ROS); LILLY, DEBRA L BECVAMC; Albers, Larry; Schmidt, Clark P. (Walla Walla); Whittaker, Kevin C.; Ford, Lovetta; Payne, Annette; Costa, Nicole M; Mankad, Mehul V. DURVAMC; VISN 16 MHPLAC; Kuo, Irving; Thomas, Dorothy (ALX); Smith, Lisa C. (ECH); Menard, Aja W.; Wyatt, Wendyann R.; Borba, Brett; Carnes, Paul A.; Beckey, Nick P; Cunningham-Stonewall, Ashlee; Cummins, Kelly R. (VHAJAC); Lents, Joseph; Morgan, Katherine; Vernon, Martein; Laton, Thomas M; Schoeffel, Marcia D.; Folstad, Jon E SBYVAMC; Hill, Zachary D.; Gayle, Sherrhonda; Hansen Cook, Shannon; Stoss, Thomas D.; Guerra, Melinda B.; Reed, Ellen M; Jorgenson, Terri L.; Anadu, Ifeanyi O.; Gesek, Frank; Rodriguez, Kelly R; Sagrado, Baldomero J. LCDR, FHCC Lovell; Tran, Taylor T.; Milanovich, Dragan; Mattox, Kimberly M.; Chen, Jacqueline S.; Malmstrom, Robert; Paul E. Holtzheimer; Fabo, Karyn FNCVAMC; Mccullough, Megan; Gutierrez, Cynthia A.; Ward, Sarah; Griffith, June; Augustus, DeAna A. (NOLA); Lionas, Michelle J.; Mackenna, Holly (NOLA); Curry, Brent Weston; Snyder, Morgan; Thomas-Taylor, Jennifer A (NOLA); Gibbs, Eric D. ASHVAMC; Werner, Katherine E. (SPO); Dean, Patrick D.; Kesgen, Carl V.; Christopher, Melissa L (VHASDC); Dill, Eric C; Mondiello, Taryn; Dickerson, Kimberly W.; Jensen, Benjamin D. (VHAANC); Shayegani, Ramona; Shikwana, Sara S; Mendes, Margaret A; Itebejac, Ivan S.; Havelka, Carolyn; Miller, Janice (ELP VAMC); Simon, Michelle (NOLA); Villasenor, David; Boykin, Crystal M.HAMVAMC; Cenac, Philip L (NOLA); Maurstad, Jeremy L; Doten, Amy E.; Lowe, Joette; Justice, Keri M.; Flowers, Gary C.; Graham, Paula I.; Ha, Allen RICVAMC; Mekuria, Tekikil; DeLara, Eugene; Mears, Christina (KCVA); Grabylnikov, Stanislav; Short, Delmar D SAMVAMC; Higgins, Diana Tovar (VHAMAC); Hoffman, Jonathan D. (VISN 19); 'deanoman83@gmail.com'; Moore, Troy A.; Wu, Christine; Mambourg, Scott VHAREN; Kaigle, Allie E.; Thompson, Mike FNCVAMC; Erwin, William FNCVAMC; Tunio, Javed H.; Thornhill, Frederick (OKL); McMaster-Baxter, Nicole L. (HOU); Ho, Angela; Smith, Derek M.,; Cosgrove, John C.; Kill, Jacqueline L; Mahoney, Melissa R. (Puget Sound); Baugh, Terrence B; Himsel, Andrew S.; Bell, Breanne R.; Ansara, Elayne D.; Armbrust, Jennifer J.; Shishko, Ilona; Dao, Vinh; Sartin, Carrie J. FNCVAMC; Danelisen, Daliborka FNCVAMC; Ripepi, Frances R.; Stolz, Brigitte J RICVAMC; Hansen, Elizabeth A. (Columbus); Drogemuller, Lisa; Mathew, Paige K.; Hyde, Ashley E.; Nordine, Shauna L.; Thomas, Sharon; Yates, Derek A.; Jones, Brian D.; Myers, Bonny L. (VHACLE); Lefler, James P DURVAMC; Jensen, Cory J. (IOW); Helmut, Ursula H. (Orlando); Preinitz, Jennifer K.; Son, Elizabeth K.; Strate, Margaret; Davis, Stephanie J.; Macdonald, Debra JR.; Cheung, Michael Y.; Zeier, Kathryn L. VHAIRO; Fields, Laurel; Gionet, Danielle; Frede, Elizabeth, VHACIN; Rabon, Hannah E.; Rosario-Vega, Maria N.; La, Amanda Q.; Hieber, Robin N. FHCC Lovell; Jacoby, Aaron M.; Sibert, Nancy A. CMOVAMC; Komanduri, Ramanujam V.; Bartholomew, Chad A.; Ferrill, Laine R.; Gray, Jennifer M HAMVAMC; Boakye, Ebenezer SAMVAMC; Schultz, Sarah R.; Bartlett, Carissa; Richardson, Korin A. (White City/VISN20); Kostric, Anna L RICVAMC; Burlingame, Mark; Jahangirian, Farahnaz; Thomas, Anne-Claire (Orlando); Ishino, Risa; Haskell, Sabrina; Johnson, Eric D.; Hunt, Wanda M.; Miller, Alisa K.; Anderson, Martin S.; Grooms, Kye H.; Vaughn, Kaitlin S.; Dailey, Janet; Holm, Cynthia L. (Walla Walla); Braddy, Kathryn A.; Levarity, Rashondra Bain; Huynh, Pearl; Saltz, Elizabeth A.; Pellegrino, Brian F.; Roche, Jennifer (VHACLE); Schmitz, Allison E.; Flores, Nelida; Rai, Amneet S. VHAREN; Elharar, Nicole; Gradek, Jaroslaw (Jerry); Beall, Andrea L.; Chapman, Amanda G. (FAV); Scalise, Alissa; Potoski, Laura M; Rider, Shyla K.; Hoeldtke, John; Moore, Brandon K. (ALX); Lee, Stephanie; Hughes, Kenneth D.; Miksanek, Arlene (MRN); Scholfield, Brian A. (STL); Haas, Matthew T; Stephens, Carolyn; Webb, Thomas A (NOLA); Marioni, Kay; Scholfield, Angelina M. (STL); Cole, Miranda;

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Michelle K.; Wilcox, Andrew J.; Butler, Mark E.; Vallabh, Anuja; Miller, Lacey J.; Bower, Theresa (Terri) (SPO); Taylor, Janice M.; Seeler, Dorothy A.; Chipchura, Danielle A.; Ryu, Jae M.; Cooney, Jeffrey M. (VHACLE); Burke, Timothy R; Radtke, Michelle L. SAMVAMC; LeClerc, Sheena B. (Chillicothe); Silvershein, Jamie; Marbury, Khiana; Barry, Matthew J.; Sutherland, Trent T., Greenville HCC; Egge, Jason A.; Manning, Jane M (V20); McArdle, Kaitlin; Beatty, Allison M.; Funk, Margo C.; Dailey, Alison M. (VHACLE); Pace, Shannon M.; Braun, Steven J.; Colvard, Michelle D.; Herdzina, Amanda M.; Gabel, Teri L; Walter, Andrea N. (VA NWI); Bishop, Kristen L.; Frazer, Justin M.; Coniglio, Jenifer R.; Obrian, Angela R. CMOVAMC; Burk, Jeffrey P.; Leeson, Michael; Elliott, William J. FNCVAMC; Sutherland, Michael T. (CMOP); Kellermann, Mary-Jean; McCoy, Thomas; Trang, Peter T.; Owenby, Ryan K DURVAMC; Duquaine, Susan M. (KCVA); Daum, Marian; Hsia, Stephanie; Smith, Tracey L. (HOU); Maksimowski, Michael; Gossett, Anne K; HEISSLER, JAIME T.; Hunt, Lindsey (Boise); Bahrey, Stephanie J., VHACIN; Chau, Suzanne T. FHCC Lovell
Subject: Esketamine Community of Practice
When: Wednesday, June 12, 2019 11:00 AM-12:00 PM (UTC-08:00) Pacific Time (US &Canada).
Where: Skype for online meeting VANTS for audio at 1-800767-1750, 45914#

Join us for the

Esketamine Community of Practice

Second Wednesday of the month at 2 pm ET/11 am PT

Join Skype Meeting (Trouble Joining? Try Skype Web App)

Join audio by VANTS at 1-800-767-1750, participant code 45914#

The Esketamine Community of Practice is a monthly teleconference that supports the clinical implementation of intranasal esketamine for treatment resistant depression across VHA. The teleconference is open to everyone, but participation is strongly encouraged for leadership, providers, and staff working in mental health, pharmacy, and nursing at esketamine early adopter sites.

Calls will discuss progress in implementation, troubleshoot systems barriers, and develop best practices. Calls will also serve as a key venue for the Office of Mental Health and Suicide Prevention to convey updates on policies and guidance related to esketamine to the field.

For questions about this call or esketamine clinical implementation in general, please contact Dr. Ilse Wiechers with the Office of Mental Health and Suicide Prevention at Ilse.Wiechers@va.gov

Sender:	Carroll, David (VACO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=95E14EBD3B6745C8952A823B04DABFF5-CARROLL, DA>
Recipient:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>
Sent Date:	2019/06/12 13:34:54
Delivered Date:	2019/06/12 13:34:55

AMERICAN OVERSIGHT

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From:	Wiechers, Ilse /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0C7B1428D9E4233A641F125C5B6FC4F-WIECHERS, I (b6) @va.gov>
To:	Cunningham, Fran /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=613f0d8e535d46af95fed310f100dcbc-Cunningham, <(b6) va.gov>; Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat <(b6) va.gov>
Subject:	RE: Esketamine Clinical Implementation Workgroup meeting
Date:	2019/06/26 09:47:21
Priority:	Normal
Type:	Note

Perfect! Thanks so much!

Sent with BlackBerry Work
(www.blackberry.com)

From: Cunningham, Fran <(b6) va.gov>
Date: Tuesday, Jun 25, 2019, 5:42 PM
To: Wiechers, Ilse <(b6) va.gov>, Fuller, Matthew A. (PBM) <(b6) va.gov>
Subject: RE: Esketamine Clinical Implementation Workgroup meeting

I'm ready with the old version that doesn't have the updated CFU/guidance info but covers the majority of information. I can discuss the current form and let them know we will be adding a couple of items from the CFU/guidance.

From: Wiechers, Ilse <(b6) va.gov>
Date: Tuesday, Jun 25, 2019, 2:18 PM
To: Fuller, Matthew A. (PBM) <(b6) va.gov>
Cc: Cunningham, Fran <(b6) va.gov>
Subject: RE: Esketamine Clinical Implementation Workgroup meeting

I had planned to have Fran and her team join the larger national Community of Practice call on Wed July 10th to walk through the MUE (and hopefully you can join that as well for the CFU/protocol update too, now that I think of it…)

I'm not sure if Fran will be ready for next Wed to share the MUE with the smaller implementation workgroup, but I'm going to cc her here and see what she thinks.

Ilse

From: Fuller, Matthew A. (PBM)
Sent: Tuesday, June 25, 2019 11:14 AM
To: Wiechers, Ilse (b6) @va.gov>
Subject: RE: Esketamine Clinical Implementation Workgroup meeting

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Hi Ilse,

Yes, I plan to join the call and can talk about the CFU and protocol guidance. Since the MAP/VPE committee voted to require completion of the VAMedSAFE safety form for the esketamine MUE as a condition of use, will Fran be talking about this on the call as well? I know you had that planned but could not recall when. Thanks.

Matthew

From: Wiechers, Ilse
Sent: Tuesday, June 25, 2019 1:57 PM
To: Fuller, Matthew A. (PBM) <(b6) va.gov>
Subject: RE: Esketamine Clinical Implementation Workgroup meeting

Hi Matthew –

I wanted to check and see if you are able to attend the workgroup meeting next Wednesday. I was hoping you could provide an update to everyone on the finalized versions of the CFU and national protocol guidance.

This will be our first meeting of the national workgroup and the 13 Early Adopter sites.

Ilse

-----Original Appointment-----
From: Wiechers, Ilse
Sent: Wednesday, May 15, 2019 8:53 AM
To: Wiechers, Ilse; Myrick, Donald L. (Hugh); Shiroma, Paulo R.; McGuire, Marsden H.; Drexler, Karen MD (Atlanta); Pomerantz, Andrew; Katz, Ira R.; Yoon, Gihyun; Mathew, Sanjay (HOU); Mohamed, Somaia; Ranganathan, Mohini; Krystal, John; Fuller, Matthew A. (PBM); Cunningham, Fran; Czekanski, Elizabeth R; Wells, Daina L.; Schafer, David W.; Buyck, David W SAMVAMC; Gibson, Carri-Ann M.; Burgard, Jesse, VHAV10; Landreth, Edward S.; Kuo, Irving; Indest, David W (Portland); Drexler, Michael; Kilgore, Heath M; Bradley, John; Petrakis, Ismene; Leinbach, Jonathan E DURVAMC; Cooper, Marc A. SBYVAMC; Shorter, George Wiley; Hosanagar, Avinash; Konicki, P. Eric (VHACLE); Juergens, Timothy; Marsh, Laura (HOU); Markman, Jesse D; McQuaid, John R.; Torres-Sena, Lorraine M.; Guze, Barry H.; Holsinger, Tracey DURVAMC; Brown, Thomas W. SBYVAMC; Bruijnzeel, Dawn; Salow, Marci VHABHS; Narayana, Sampath (VISN1); Borysiuk, Lydia; Coombs, Stephen J. VISN 6; Holland, Jon Todd DURVAMC; Norem, Brett SBYVAMC; Justice, Keri M.; Itebejac, Ivan S.; Ekola, Timothy A.; Neff, Melissa VHAV10; Heimann, Timothy M. (VHACLE); Leslie, Donna M.; Wilcox, Andrew J.; McMaster-Baxter, Nicole L. (HOU); Hawkins, Jason B. (V16); Chantelois, Eric P; LaDue, Brenda (V20); Dare, Donna C.; Mambourg, Scott VHAREN; Evans, Winston F. (Frank); Foster, Julie
Cc: (b6) @bcm.edu; Still, Candy L. (V16); Vaughn, Kaitlin S.; Maddix, Daniel S.; Marton, Tobias; Hoeldtke, John; Korman, Lisa B.; Zacher, Jennifer L. (PBM); Smith, Tammy J SBYVAMC; Hampton, Gwen E SBYVAMC; Hobson, Shannon K.(b6) va.gov); Frazier, Erica E.; Wilmer, Sonya R (HOU)
Subject: Esketamine Clinical Implementation Workgroup meeting

AMERICAN OVERSIGHT

When: Wednesday, July 03, 2019 11:00 AM-12:00 PM (UTC-08:00) Pacific Time (US &Canada).
Where: Skype Meeting

This invitation is for the monthly call of the Esketamine Clinical Implementation Workgroup. Initial participants will include the National Workgroup members and teams from the Round 1 Early Adopter sites. Ideally, Early Adopter sites will have representation on the call from Mental Health, Pharmacy, and Nursing. We encourage as many members of the front-line staff and providers engaged in esketamine treatment as well as facility leadership to participate in these calls. Participation by VISN MH and Pharmacy teams is also welcome.

Initial invites are being sent to MH and Pharmacy service line leads and POC at Early Adopter sites, as well as VISN CMHOs and VPEs for the associated VISNs. ***Please forward to additional staff and providers at your sites, as appropriate***.

The call will occur on the **first Wed @ 11 am PT / 2 pm ET**, tentatively through the end of calendar year 2019, with additional calls based on assessment of need and group discussion. ***Please use Skype*** to join for audio and for shared desktop functionality (link and call in # below).

Please contact Dr. Ilse Wiechers(b6) va.gov) with any questions.

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https://vaww.portal2.va.gov/sites/LYNC/SiteAssets/VALOGO.png

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Sender:	Wiechers, Ilse /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0C7B1428D9E4233A641F125C5B6FC4F-WIECHERS, I (b6) @va.gov>
Recipient:	Cunningham, Fran /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=613f0d8e535d46af95fed310f100dcbc-Cunningham, <(b6) va.gov>; Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat <(b6) va.gov>
Sent Date:	2019/06/26 09:47:19
Delivered Date:	2019/06/26 09:47:21

AMERICAN OVERSIGHT

To:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b6) va.gov>
Subject:	RE: Esketamine Clinical Implementation Workgroup meeting
Date:	2019/06/25 14:12:58
Priority:	Normal
Type:	Note

Hi Ilse,

Yes, I plan to join the call and can talk about the CFU and protocol guidance. Since the MAP/VPE committee voted for require completion of the VAMedSAFE safety form for the MUE as a condition of use, will Fran be talking about this on the call?

From: Wiechers, Ilse
Sent: Tuesday, June 25, 2019 1:57 PM
To: Fuller, Matthew A. (PBM) <(b6) va.gov>
Subject: RE: Esketamine Clinical Implementation Workgroup meeting

Hi Matthew –

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Cc: (b6) @bcm.edu; Still, Candy L. (V16); Vaughn, Kaitlin S.; Maddix, Daniel S.; Marton, Tobias; Hoeldtke, John; Korman, Lisa B.; Zacher, Jennifer L. (PBM); Smith, Tammy J SBYVAMC; Hampton, Gwen E SBYVAMC; Hobson, Shannon K. (b6) @va.gov); Frazier, Erica E.; Wilmer, Sonya R (HOU)
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When: Wednesday, July 03, 2019 11:00 AM-12:00 PM (UTC-08:00) Pacific Time (US &Canada).
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844-770-5400,,3924357896# (East)	English (United States)

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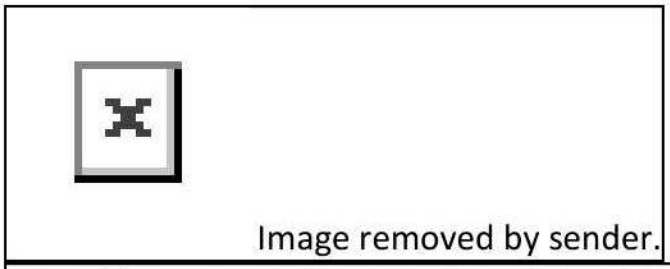

Recipient:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>
Sent Date:	2019/06/25 14:13:02
Delivered Date:	2019/06/25 14:12:58
Message Flags:	Unread Unsent

AMERICAN OVERSIGHT

From:	Fuller, Matthew A. (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=62D9CBB23B184CACB98895776E36A471-FULLER, MAT>
To:	Donahue, Mark DURVAMC /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=351153458968417988 4b5e24269a8cc8-Donahue, Ma (b6) @va.gov>; Capehart, Bruce P. DURVAMC /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6866eff4e9df4a48846d056a02044c38-Capehart, B <(b6) va.gov>; Schreiber, Matthew A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=db4d0324bf0945f183f33816c7fd1db0-Schreiber, <(b6) va.gov>
Subject:	RE: esketamine CFU
Date:	2019/03/26 14:20:00
Priority:	Normal
Type:	Note

Thanks Mark! I will make the recommended change to the CFU.

Matthew

From: Donahue, Mark DURVAMC
Sent: Tuesday, March 26, 2019 11:59 AM
To: Capehart, Bruce P. DURVAMC <(b6) va.gov>; Fuller, Matthew A. (PBM) <(b6) va.gov>; Schreiber, Matthew A. <(b6) va.gov>
Cc: Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: esketamine CFU

Thanks Bruce. (b) (5)

From: Capehart, Bruce P. DURVAMC
Sent: Tuesday, March 26, 2019 11:46 AM
To: Fuller, Matthew A. (PBM) <(b6) va.gov>; Schreiber, Matthew A. <(b6) va.gov>
Cc: Zacher, Jennifer L. (PBM) <(b6) va.gov>; Donahue, Mark DURVAMC (b6) @va.gov>
Subject: RE: esketamine CFU

Matthew,

CFU comments attached. The monograph is up for reading this afternoon.

I've copied Mark Donahue as there is one point where his input would be useful.

AMERICAN OVERSIGHT

Regards,

Bruce

From: Fuller, Matthew A. (PBM)
Sent: Monday, March 25, 2019 4:15 PM
To: Capehart, Bruce P. DURVAMC <(b6) va.gov>; Schreiber, Matthew A. <(b6) va.gov>
Cc: Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: esketamine CFU

Hi Bruce and Matt,

Attached is my first crack at writing up a CFU. I used our ketamine guidance as a guide. Please let me know what you think. I am not sure I have captured everything yet so I appreciate your eyes on this. A specific question; (b) (5) ? Thanks.

Matthew

Sender:	Fuller, Matthew A. (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=62D9CBB23B184CACB98895776E36A471-FULLER, MAT>
Recipient:	Donahue, Mark DURVAMC /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=351153458968417988 4b5e24269a8cc8-Donahue, Ma (b6) @va.gov>; Capehart, Bruce P. DURVAMC /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6866eff4e9df4a48846d056a02044c38-Capehart, B <(b6) va.gov>; Schreiber, Matthew A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=db4d0324bf0945f183f33816c7fd1db0-Schreiber, <(b6) va.gov>
Sent Date:	2019/03/26 14:20:05
Delivered Date:	2019/03/26 14:20:00

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From:	Capehart, Bruce P. DURVAMC /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6866EFF4E9DF4A48846D056A02044C38-CAPEHART, B <(b6) va.gov>
To:	Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat <(b6) va.gov>
Subject:	RE: esketamine CFU
Date:	2019/03/26 16:27:13
Priority:	Normal
Type:	Note

(b) (5)

From: Fuller, Matthew A. (PBM)
Sent: Tuesday, March 26, 2019 3:08 PM
To: Capehart, Bruce P. DURVAMC <(b6) va.gov>
Subject: RE: esketamine CFU

(b) (5) . Suggestions?

From: Fuller, Matthew A. (PBM)
Sent: Tuesday, March 26, 2019 3:02 PM
To: Capehart, Bruce P. DURVAMC <(b6) va.gov>; Schreiber, Matthew A. <(b6) va.gov>
Cc: Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: esketamine CFU

Hi Bruce,

Thanks for your comments! (b) (5)

Regards,

Matthew

From: Capehart, Bruce P. DURVAMC
Sent: Tuesday, March 26, 2019 11:46 AM
To: Fuller, Matthew A. (PBM) <(b6) va.gov>; Schreiber, Matthew A.

AMERICAN OVERSIGHT

<(b6) va.gov>
Cc: Zacher, Jennifer L. (PBM) <(b6) va.gov>; Donahue, Mark DURVAMC (b6) @va.gov>
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Matthew,

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Regards,

Bruce

From: Fuller, Matthew A. (PBM)
Sent: Monday, March 25, 2019 4:15 PM
To: Capehart, Bruce P. DURVAMC <(b6) va.gov>; Schreiber, Matthew A. <(b6) va.gov>
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Hi Bruce and Matt,

Attached is my first crack at writing up a CFU. I used our ketamine guidance as a guide. Please let me know what you think. I am not sure I have captured everything yet so I appreciate your eyes on this. A specific question; (b) (5) ? Thanks.

Matthew

Sender:	Capehart, Bruce P. DURVAMC /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6866EFF4E9DF4A48846D056A02044C38-CAPEHART, B <(b6) va.gov>
Recipient:	Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat <(b6) va.gov>
Sent Date:	2019/03/26 16:27:12
Delivered Date:	2019/03/26 16:27:13

AMERICAN OVERSIGHT

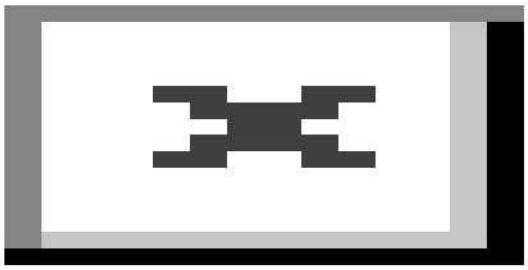
From:	Fuller, Matthew A. (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=62D9CBB23B184CACB98895776E36A471-FULLER, MAT>
To:	Connell, Robert W. (STL) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=decaccd8ce10451a8e1ace209d57fe83-Connell, Ro (b6) @va.gov>
Subject:	RE: esketamine and cocominant medications
Date:	2019/06/13 16:00:00
Priority:	Normal
Type:	Note

Thanks. I appreciate the follow up.

From: Connell, Robert W. (STL)
Sent: Thursday, June 13, 2019 3:52 PM
To: Fuller, Matthew A. (PBM) <(b6) va.gov>
Subject: RE: esketamine and cocominant medications

Hi Matt,

I'm sorry to belabor this point about opioids. I thought maybe I was misinterpreting the exclusionary criteria so I reached out to Janssen for clarification. This was their response.



From: Fuller, Matthew A. (PBM)
Sent: Thursday, June 13, 2019 10:28 AM
To: Connell, Robert W. (STL) (b6) va.gov>
Cc: Fuller, Matthew A. (PBM) <(b6) va.gov>
Subject: RE: esketamine and cocominant medications

Hi Rob,

AMERICAN OVERSIGHT

The MAP felt that if a pt was prescribed an opiate for a medication condition and the Utox was positive that would not preclude them from receiving esketamine. They did not require that the pt be willing to stop the opiate. Regarding the benzo/non-benzo restriction; we currently have in the DRAFT protocol guidance the following language: (b) (5) [redacted]

Matthew

From: Connell, Robert W. (STL)
Sent: Wednesday, June 12, 2019 3:48 PM
To: Fuller, Matthew A. (PBM) <(b6) [redacted] va.gov>
Subject: RE: esketamine and cocominant medications

Yes, that is the article that I am referring to. When you look in the supplement it gets more specific about what they excluded. It wasn't just patients with drugs of abuse. It included patients prescribed medications like opiates unless they were willing to stop it.

(b) (5) [redacted]

(b) (5) [redacted]

AMERICAN OVERSIGHT

• (b) (5) [redacted]

Rob Connell

From: Fuller, Matthew A. (PBM)
Sent: Wednesday, June 12, 2019 2:30 PM
To: Connell, Robert W. (STL) (b6) [redacted]@va.gov>
Cc: Fuller, Matthew A. (PBM) <(b6) [redacted]va.gov>
Subject: RE: esketamine and cocominant medications

Hi Rob,

The following is from the recently published "TRANSFORM-2" study (attached).

'(b) (5) [redacted]

The CFU has been updated to reflect these exclusions. Hope this helps.

Matthew

From: Connell, Robert W. (STL)
Sent: Wednesday, June 12, 2019 3:19 PM

AMERICAN OVERSIGHT

To: Fuller, Matthew A. (PBM) <(b6) va.gov>
Subject: esketamine and cocominant medications

Hi Matt,

(b) (5)
[redacted]
]?

Rob Connell PharmD, BCPP
CPS – Mental Health
Jefferson Barracks VAMC
St. Louis, MO 63125

Sender:	Fuller, Matthew A. (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=62D9CBB23B184CACB98895776E36A471-FULLER, MAT>
Recipient:	Connell, Robert W. (STL) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=decaccd8ce10451a8e1ace209d57fe83-Connell, Ro (b6) .gov>
Sent Date:	2019/06/13 16:00:33
Delivered Date:	2019/06/13 16:00:00

AMERICAN OVERSIGHT

To:	Connell, Robert W. (STL) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=decaccd8ce10451a8e1ace209d57fe83-Connell, Ro (b6) @va.gov>
Subject:	RE: esketamine and cocominant medications
Date:	2019/06/12 15:26:09
Priority:	Normal
Type:	Note

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'(b) (5)

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Sent: Wednesday, June 12, 2019 3:19 PM
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Subject: esketamine and cocominant medications

Hi Matt,

(b) (5)

Rob Connell PharmD, BCPP
CPS – Mental Health
Jefferson Barracks VAMC
St. Louis, MO 63125

AMERICAN OVERSIGHT

Recipient:	Connell, Robert W. (STL) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=decaccd8ce10451a8e1ace209d57fe83-Connell, Ro (b6) @va.gov>
Sent Date:	2019/06/12 15:26:20
Delivered Date:	2019/06/12 15:26:09
Message Flags:	Unread Unsent

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To:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>
Subject:	RE: Esketamine
Date:	2019/03/21 16:21:24
Priority:	Normal
Type:	Note

The purpose of this toolkit is to enable organizations to implement the National CLAS Standards and improve health equity. It is organized according to the enhanced National CLAS Standards, and provides practical tools and examples of CLAS, in addition to efforts to implement the National CLAS Standards that can be adapted for use by health care organizations. It is intended for organizations that have already decided to pursue CLAS, to improve equity and eliminate health care disparities; it is not a decision guide about whether to implement National CLAS Standards.

From: Valentino, Michael (VACO)
Sent: Thursday, March 21, 2019 9:38 AM
To: Wiechers, Ilse (b6) @va.gov>; Llorente, Maria D. <(b6) va.gov>
Subject: FW: Esketamine

Just an example FYI.....have had a few reports of pushback from the field....

Sent with BlackBerry Work
(www.blackberry.com)

From: Lowe, Joette <(b6) va.gov>
Date: Thursday, Mar 21, 2019, 9:14 AM
To: VHAPBM VPE Formulary Committee <VPEFormularyCommittee@va.gov>
Subject: FW: Esketamine

Just FYI on feedback from the MH side of the issue.

Joette S. Lowe, PharmD
VISN 7 Pharmacy Executive (VPE)
3701 Loop Road East
Tuscaloosa, AL 35404
(b6)

Suicide Prevention is Everyone's Business. *#BeThere.*



cid:image009.jpg@01D328A1.8C7B68A0

AMERICAN OVERSIGHT

From: Myrick, Donald L. (Hugh)
Sent: Wednesday, March 20, 2019 12:31 PM
To: Lowe, Joette <(b6) va.gov>
Subject: FW: Esketamine

Just FYI.

Hugh Myrick, MD
ACOS, Mental Health Service Line
Ralph H. Johnson VAMC
Director, Addiction Sciences Division
Director, Military Sciences Division
MUSC, Charleston SC

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http://veteranscrisisline.net/banners/public/ads/VeteransCrisisLine-Badge-Phone.gif

From: Myrick, Donald L. (Hugh)
Sent: Wednesday, March 20, 2019 1:22 PM
To: Landreth, Edward S. (b6) @va.gov>; Magnes, N. Sarah (b6) @va.gov>; Cohen, Jay L. (b6) @va.gov>; Holliday, Steve <(b6) y@va.gov>; VHACLE BVAC Group <VHACLEBVACGroup@va.gov>
Subject: RE: Esketamine

(b6)

Hugh Myrick, MD
ACOS, Mental Health Service Line
Ralph H. Johnson VAMC
Director, Addiction Sciences Division
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Subject: RE: Esketamine

Consider it done.

From: Magnes, N. Sarah
Sent: Wednesday, March 20, 2019 11:54 AM
To: Cohen, Jay L. (b6) .gov>; Holliday, Steve (b6) @va.gov>; VHACLE BVAC Group <VHACLEBVACGroup@va.gov>
Subject: RE: Esketamine

I'd like to suggest that we discuss further on both our Monday calls.
Thanks!

Sarah Magnes, PhD, LCSW, BCD
Chief Mental Health Officer
VISN 7 Southeast Network
Office (b6)
Cell (b6)



cid:image001.jpg@01D23138.866DD440

VA Core Values: Integrity, **C**ommitment, **A**dvocacy, **R**espect, **E**xcellence ("I CARE")
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From: Cohen, Jay L.
Sent: Wednesday, March 20, 2019 11:54 AM
To: Holliday, Steve (b6) @va.gov>; Magnes, N. Sarah (b6) a.gov>; VHACLE BVAC Group <VHACLEBVACGroup@va.gov>
Subject: RE: Esketamine

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Same in V23…not sure the point of the memo and the requirement to get registered within 30 days when much of the details hadn't been worked out…

Jay L. Cohen, Ph.D.
Interim Chief Mental Health Officer
VA Midwest Healthcare Network—VISN 23
(b6) @va.gov
(b6)

From: Holliday, Steve
Sent: Wednesday, March 20, 2019 11:48 AM
To: Magnes, N. Sarah <(b6) @va.gov>; VHACLE BVAC Group <VHACLEBVACGroup@va.gov>
Subject: RE: Esketamine

There were similar concerns expressed on our VISN 17 PDSI Work Group call this morning. I told them to wait until VACO rolls out the materials and training materials. That is, we are NOT providing it now and won't until these things happen.

Steve

From: Magnes, N. Sarah
Sent: Wednesday, March 20, 2019 10:45 AM
To: VHACLE BVAC Group <VHACLEBVACGroup@va.gov>
Subject: Esketamine

Good Morning,
I was wondering if anyone else has had strong pushback from pharmacy and the field on this? When the Somatic Treatment Survey came out, none of our facilities expressed an interest in providing Ketamine treatment. Besides the fast turnaround, the VISN Pharmacy Exec expressed the following concerns –

1. (b6)

Thanks, Sarah

Sarah Magnes, PhD, LCSW, BCD
Chief Mental Health Officer
VISN 7 Southeast Network
Office: (b6)

AMERICAN OVERSIGHT

Cell (b6)



cid:image001.jpg@01D23138.866DD440

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Recipient:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>
Sent Date:	2019/03/21 16:21:37
Delivered Date:	2019/03/21 16:21:24
Message Flags:	Unread Unsent

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From:	Burk, Muriel /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=38E0E5ED6A744C219E7B3AF9F9A3BF3D-BURK, MURIE (b6) @va.gov>
To:	Nazario, Mitchell /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e909581b30643148ba99ab7ff79cae0-Nazario, Mi <(b6) va.gov>; Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat <(b6) va.gov>
CC:	Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>
Subject:	RE: Esketamine
Date:	2019/03/20 11:55:35
Priority:	Normal
Type:	Note

Thank you both for your input.

Mitch, I am not aware of any requests.

Matthew, Dr. Hosanagar at Ann Arbor mentioned he received a memo yesterday on esketamine. I'm not sure of the content, but it may be the news release I found online.
https://www.va.gov/opa/pressrel/pressrelease.cfm?id=5220

I'll wait for any additional reviews to guide the MUE going forward.

From: Nazario, Mitchell
Sent: Wednesday, March 20, 2019 11:42 AM
To: Fuller, Matthew A. (PBM) <(b6) va.gov>; Burk, Muriel (b6) va.gov>
Cc: Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: Esketamine

(b6) ?

Mitch

From: Fuller, Matthew A. (PBM)
Sent: Wednesday, March 20, 2019 11:34 AM
To: Burk, Muriel (b6) @va.gov>; Nazario, Mitchell <(b6) va.gov>
Cc: Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: Esketamine

Hi Muriel,

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(b6) [redacted]

(b) (6) [redacted].

(b) (6) [redacted]h.

These are just my thoughts. The committee and others may have a different take on this. Hope this helps.

Matthew

From: Burk, Muriel
Sent: Wednesday, March 20, 2019 10:47 AM
To: Nazario, Mitchell <(b6) [redacted]va.gov>; Fuller, Matthew A. (PBM) <(b6) [redacted]va.gov>
Subject: Esketamine

Hi Matthew and Mitch,

(b) (5) [redacted]

[redacted]?

Any information or guidance you have would be greatly appreciated!

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Thanks,
Muriel

Sender:	Burk, Muriel /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=38E0E5ED6A744C219E7B3AF9F9A3BF3D-BURK, MURIE (b6) va.gov>
Recipient:	Nazario, Mitchell /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e909581b30643148ba99ab7ff79cae0-Nazario, Mi <(b6) va.gov>; Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>
Sent Date:	2019/03/20 11:55:33
Delivered Date:	2019/03/20 11:55:35

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VA | U.S. Department of Veterans Affairs

News Release

Office of Public Affairs
Media Relations

Washington, DC 20420
(202) 461-7600
www.va.gov

FOR IMMEDIATE RELEASE
March 19, 2019

VA to make new nasal spray drug available for treatment-resistant depression

WASHINGTON — Today the U.S. Department of Veterans Affairs (VA) announced its health care providers will now be able to offer the newly approved Spravato nasal spray for treatment-resistant depression.

The treatment will be made available to Veterans based on their individual medical needs combined with providers' clinical assessments.

The move follows the March 5 Food and Drug Administration (FDA) approval of Spravato (esketamine) nasal spray. Spravato was approved for use in conjunction with an oral antidepressant for the treatment of treatment-resistant depression in adults.

"We're pleased to be able to expand options for Veterans with depression who have not responded to other treatments," said VA Secretary Robert Wilkie. "It reflects our commitment to seek new ways to provide the best health care available for our nation's Veterans."

Spravato will be available through a restricted distribution system under an FDA-approved Risk Evaluation and Mitigation Strategy (REMS). The purpose of the REMS is to mitigate the risks of serious adverse outcomes and the potential abuse and misuse of Spravato.

VA health care providers will monitor Veterans for serious adverse outcomes, such as sedation and difficulty with attention, judgment and thinking (dissociation), abuse and misuse, worsening of depression and suicidal thoughts and behaviors.

Veterans will self-administer Spravato nasal spray under the direct observation of a health care provider in a certified medical facility, and then must be monitored by a health care provider for at least two hours after receiving their dose. Spravato cannot be dispensed directly to Veterans for use at home.

For additional information on access to Mental Health Support for Veterans, visit VA Mental Health. Veterans in immediate crisis may call the Veterans Crisis Line at 800-273-8255 and press 1, text to 838255 or chat online at Veterans Crisis Line.

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From:	Llorente, Maria D. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F5C91F577D894BD9A0F09305DB34DD4F-LLORENTE, M <(b6) va.gov>
To:	Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>
Subject:	RE: Esketamine
Date:	2019/03/21 12:52:08
Priority:	Normal
Type:	Note

The comments are helpful. Dr. Myrick's remarks and attachment were super helpful. I was reviewing the document. One quick question for the group:
(b) (5)
[redacted]
;?

From: Carroll, David (VACO)
Sent: Thursday, March 21, 2019 10:25 AM
To: Wiechers, Ilse (b6) @va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>
Subject: RE: Esketamine

Got it. I will make sure that we reserve time for you on the MH Leads Call on Monday.

I appreciate the concerns. It is a moment of dynamic tension – we of course want to preserve solid, evidence-based, high quality, safe approaches to care but at the same time as an organization we want to be agile and provide cutting edge care and services as well.

From: Wiechers, Ilse
Sent: Thursday, March 21, 2019 10:00 AM
To: Valentino, Michael (VACO) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>
Cc: Carroll, David (VACO) <(b6) va.gov>
Subject: RE: Esketamine

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I've had several MH Service Chiefs reach out to me directly as well asking for the "context." I anticipate being asked to join the MH VISN Leads call this coming Monday to discuss further.

Adding Dave for his awareness as well.

Ilse

From: Valentino, Michael (VACO)
Sent: Thursday, March 21, 2019 6:38 AM
To: Wiechers, Ilse (b6) @va.gov>; Llorente, Maria D. <(b6) va.gov>
Subject: FW: Esketamine

Just an example FYI.....have had a few reports of pushback from the field....

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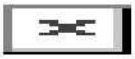
From: Lowe, Joette <(b6) va.gov>
Date: Thursday, Mar 21, 2019, 9:14 AM
To: VHAPBM VPE Formulary Committee <VPEFormularyCommittee@va.gov>
Subject: FW: Esketamine

Just FYI on feedback from the MH side of the issue.

Joette S. Lowe, PharmD
VISN 7 Pharmacy Executive (VPE)
3701 Loop Road East
Tuscaloosa, AL 35404
(b6)
Suicide Prevention is Everyone's Business. *#BeThere.*



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Sent: Wednesday, March 20, 2019 12:31 PM
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To: Landreth, Edward S. (b6) @va.gov>; Magnes, N. Sarah (b6) @va.gov>; Cohen, Jay L. (b6) .gov>; Holliday, Steve (b6) @va.gov>; VHACLE BVAC Group <VHACLEBVACGroup@va.gov>
Subject: RE: Esketamine

(b6) [redacted]

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Consider it done.

From: Magnes, N. Sarah
Sent: Wednesday, March 20, 2019 11:54 AM
To: Cohen, Jay L. (b6) .gov>; Holliday, Steve (b6) y@va.gov>; VHACLE BVAC Group <VHACLEBVACGroup@va.gov>
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I'd like to suggest that we discuss further on both our Monday calls.
Thanks!

Sarah Magnes, PhD, LCSW, BCD
Chief Mental Health Officer
VISN 7 Southeast Network
Office (b6)
(b6)



cid:image001.jpg@01D23138.866DD440

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Sent: Wednesday, March 20, 2019 11:54 AM
To: Holliday, Steve (b6) @va.gov>; Magnes, N. (b6) va.gov>; VHACLE BVAC Group <VHACLEBVACGroup@va.gov>
Subject: RE: Esketamine

Same in V23…not sure the point of the memo and the requirement to get registered within 30 days when much of the details hadn't been worked out…

Jay L. Cohen, Ph.D.
Interim Chief Mental Health Officer
VA Midwest Healthcare Network—VISN 23
(b6) *@va.gov*
(b6)

From: Holliday, Steve
Sent: Wednesday, March 20, 2019 11:48 AM

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To: Magnes, N. Sarah (b6) @va.gov>; VHACLE BVAC Group <VHACLEBVACGroup@va.gov>
Subject: RE: Esketamine

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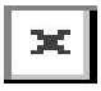
Steve

From: Magnes, N. Sarah
Sent: Wednesday, March 20, 2019 10:45 AM
To: VHACLE BVAC Group <VHACLEBVACGroup@va.gov>
Subject: Esketamine

Good Morning,
I was wondering if anyone else has had strong pushback from pharmacy and the field on this? (b) (5)

Thanks, Sarah

Sarah Magnes, PhD, LCSW, BCD
Chief Mental Health Officer
VISN 7 Southeast Network
Office: (b6)



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Sent Date:	2019/03/21 12:52:06
Delivered Date:	2019/03/21 12:52:08

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From:	Kohutynski, Cheryl /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=12B3BA8BEF60455886734005FB6952C7-KOHUTYNSKI, <(b6) @va.gov>
To:	Torphy, Lisa /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43ab37387c5c4ed6bae3006dcde84582-Torphy, Lis <(b6) va.gov>
CC:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>
Subject:	RE: Esketamine
Date:	2019/06/24 11:53:33
Priority:	Normal
Type:	Note

Hello Mike,

Spravato(esketamine) 28mg (2 x 28mg) cost:	BIG4 $437.34	FSS $581.11
Spravato(esketamine) 28mg (3 x 28mg) cost:	BIG 4 $656.03	FSS $871.66

Cheryl
Cheryl Kohutynski, RPh, MBA, COR
PBM Program Manager – Public Law
(b6)

From: Torphy, Lisa
Sent: Monday, June 24, 2019 10:44 AM
To: Kohutynski, Cheryl <(b6) @va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>
Subject: Esketamine
Importance: High

Please call or send to Mike ASAP…thank you.

From: Valentino, Michael (VACO)
Sent: Monday, June 24, 2019 10:20 AM
To: Torphy, Lisa <(b6) va.gov>; Szudarski, Lucy (PBM) (b6) @va.gov>
Subject: Is Jenn in today?

I need the current esketamine (Spravato) pricing.

If she isn't in, could you please ask someone else to send it?

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Thanks

Mike

Sent with BlackBerry Work
(www.blackberry.com)

Sender:	Kohutynski, Cheryl /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=12B3BA8BEF60455886734005FB6952C7-KOHUTYNSKI, <(b6) va.gov>
Recipient:	Torphy, Lisa /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43ab37387c5c4ed6bae3006dcde84582-Torphy, Lis <(b6) va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>
Sent Date:	2019/06/24 11:53:32
Delivered Date:	2019/06/24 11:53:33

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From:	Valentino, Michael (VACO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO,>
To:	Kohutynski, Cheryl /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12b3ba8bef60455886734005fb6952c7-Kohutynski, (b6) @va.gov>; Torphy, Lisa /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43ab37387c5c4ed6bae3006dcde84582-Torphy, Lis <(b6) va.gov>
Subject:	RE: Esketamine
Date:	2019/06/24 12:09:00
Priority:	Normal
Type:	Note

Thanks much Cheryl!

Mike

From: Kohutynski, Cheryl
Sent: Monday, June 24, 2019 11:59 AM
To: Torphy, Lisa <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>
Subject: RE: Esketamine

Hello Mike,

This is the listing in McKesson:

MCK Item #	Description	Strength	Form	NDC	AWP	Est. Net Price	Purchase Price	Unit Price	Contract #
3935830	https://orderzone2.mckesson.com/SMOnline/img/dot_clr.gif	https://orderzone2.mckesson.com/SMOnline/img/dot_clr.gif							
3935822	https://orderzone2.mckesson.com/SMOnline/img/dot_clr.gif	https://orderzone2.mckesson.com/SMOnline/img/dot_clr.gif							

Cheryl

From: Kohutynski, Cheryl
Sent: Monday, June 24, 2019 10:54 AM
To: Torphy, Lisa <(b6) va.gov>

AMERICAN OVERSIGHT

Cc: Valentino, Michael (VACO) <(b6) va.gov>
Subject: RE: Esketamine

Hello Mike,

Spravato(esketamine) 28mg (2 x 28mg) cost:	BIG4 $437.34	FSS $581.11
Spravato(esketamine) 28mg (3 x 28mg) cost:	BIG 4 $656.03	FSS $871.66

Cheryl
Cheryl Kohutynski, RPh, MBA, COR
PBM Program Manager – Public Law
(b6)

From: Torphy, Lisa
Sent: Monday, June 24, 2019 10:44 AM
To: Kohutynski, Cheryl (b6) @va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>
Subject: Esketamine
Importance: High

Please call or send to Mike ASAP…thank you.

From: Valentino, Michael (VACO)
Sent: Monday, June 24, 2019 10:20 AM
To: Torphy, Lisa <(b6) va.gov>; Szudarski, Lucy (PBM) (b6) @va.gov>
Subject: Is Jenn in today?

I need the current esketamine (Spravato) pricing.

If she isn't in, could you please ask someone else to send it?

Thanks

Mike

Sent with BlackBerry Work
(www.blackberry.com)

Sender:	Valentino, Michael (VACO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO,>
Recipient:	Kohutynski, Cheryl /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12b3ba8bef60455886734005fb6952c7-Kohutynski, (b6) va.gov>; Torphy, Lisa /o=ExchangeLabs/ou=Exchange Administrative Group

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	(FYDIBOHF23SPDLT)/cn=Recipients/cn=43ab37387c5c4ed6bae3006dcde84582-Torphy, Lis <(b6) va.gov>
Sent Date:	2019/06/24 12:09:39
Delivered Date:	2019/06/24 12:09:00

AMERICAN OVERSIGHT

From:	Kohutynski, Cheryl /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=12B3BA8BEF60455886734005FB6952C7-KOHUTYNSKI, <(b6) @va.gov>
To:	Torphy, Lisa /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43ab37387c5c4ed6bae3006dcde84582-Torphy, Lis <(b6) va.gov>
CC:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>
Subject:	RE: Esketamine
Date:	2019/06/24 11:59:08
Priority:	Normal
Type:	Note

Hello Mike,

This is the listing in McKesson:

MCK Item # Description Strength For m NDC AWP Est. Net Price Purchase Price Unit Price Contract #

3935830	https://orderzone2.mckesson.com/SMOnline/img/dot_clr.gif	https://orderzone2.mckesson.com/SMOnline/img/dot_clr.gif
3935822	https://orderzone2.mckesson.com/SMOnline/img/dot_clr.gif	https://orderzone2.mckesson.com/SMOnline/img/dot_clr.gif

Cheryl

From: Kohutynski, Cheryl
Sent: Monday, June 24, 2019 10:54 AM
To: Torphy, Lisa <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>
Subject: RE: Esketamine

Hello Mike,

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Spravato(esketamine) 28mg (3 x 28mg) cost:	BIG 4 $656.03	FSS $871.66

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Cheryl
Cheryl Kohutynski, RPh, MBA, COR
PBM Program Manager – Public Law
(b6)

From: Torphy, Lisa
Sent: Monday, June 24, 2019 10:44 AM
To: Kohutynski, Cheryl <(b6) @va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>
Subject: Esketamine
Importance: High

Please call or send to Mike ASAP…thank you.

From: Valentino, Michael (VACO)
Sent: Monday, June 24, 2019 10:20 AM
To: Torphy, Lisa <(b6) va.gov>; Szudarski, Lucy (PBM) (b6) @va.gov>
Subject: Is Jenn in today?

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Thanks

Mike

Sent with BlackBerry Work
(www.blackberry.com)

Sender:	Kohutynski, Cheryl /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=12B3BA8BEF60455886734005FB6952C7-KOHUTYNSKI, <(b6) @va.gov>
Recipient:	Torphy, Lisa /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43ab37387c5c4ed6bae3006dcde84582-Torphy, Lis <(b6) va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>
Sent Date:	2019/06/24 11:59:03
Delivered Date:	2019/06/24 11:59:08

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From:	Mole, Larry A. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A7F4EED603A543398E4E0B0BBE52CF41-MOLE, LARRY (b6) @va.gov>
To:	Bricker, David /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5012db713ab406daf228a7f5855581f-Bricker, Da (b6) @va.gov>; Andersen, Cheryl /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0933541e04e47ed9ad9a5fdb39e6175-Andersen, C (b6) n@va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>; Peppiatt, Jennifer L. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eaa77295805640b798dff496264eef73-Peppiatt, J (b6) @va.gov>; Page, Tonya Hymer /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e96620b1be3f412d93512fa0befe908f-Page, Tonya (b6) @va.gov>; Inhofe, Kerry E. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=046e71c75a554f93970467bab4f632c0-Inhofe, Ker (b6) a.gov>
CC:	Baker, K. Mitch (OCC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f894a81b872b44ac9e777151288d9a4f-Baker, Kevi (b6) @va.gov>; Cabeen, Janet /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a92cfecf7218412ea8b720fd998c7c99-Cabeen, Jan (b6) @va.gov>; Harris, Gus /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b80a4167859d483ea0ef2ed74aed8041-Harris, Gus (b6) @va.gov>; Garman, Tony A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bab07ad64f54d7d82d29cbe401ee435-Garman, Tho <(b6) n@va.gov>; DeWitt, Christopher A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1fe70ddfd93942ee9d0a4477a9a03305-DeWitt, Chr (b6) @va.gov>; Fagan, Craig A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5dce38631b74622af60602f58146a87-Fagan, Crai (b6) @va.gov>
Subject:	RE: esketamine
Date:	2019/08/16 12:22:36
Priority:	Normal
Type:	Note

Hi everyone

Tom, thanks for adding me to the conversation. VHA Policy is that our providers may not prescribe, complete forms, or recommend medical cannabis. A VHA pharmacy could not provide the product nor pay for it. So this comes down to whether a community care provider can fill out those forms and the Veteran goes to the State run location to purchase the product. Would this be allowed? I can see a visit being coded for whatever issues the Veteran is seeking coverage for (in this case PTSD) and the act of

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recommending/prescribing cannabis is unknown to us as a payor. The provider gets paid and the Veteran gains access to the State approved program cannabis product (albeit they pay for that product).

Larry

From: Bricker, David
Sent: Thursday, August 15, 2019 12:59 PM
To: Andersen, Cheryl (b6) @va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Wiechers, Ilse (b6) @va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Mole, Larry (b6) @va.gov>; Peppiatt, Jennifer L. (b6) t@va.gov>; Page, Tonya Hymer (b6) @va.gov>; Inhofe, Kerry E. (b6) va.gov>
Cc: Baker, K. Mitch (OCC) (b6) .@va.gov>; Cabeen, Janet (b6) @va.gov>; Harris, Gus <(b6) a.gov>; Garman, Tony (b6) va.gov>; DeWitt, Christopher A. <(b6) t@va.gov>; Fagan, Craig A. (b6) @va.gov>
Subject: RE: esketamine

Tom,
(b6)
(b6)

As Cheryl mentioned CI Leadership is in a better position to discuss this new Ketamine Clinic and whether a CC Mental Health provider can refer the Veterans to the clinic without a VA referral.
(b6)
er.

Dave
David J. Bricker
Project Manager
Cell (b6)

From: Andersen, Cheryl
Sent: Thursday, August 15, 2019 10:43 AM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Wiechers, Ilse (b6) .@va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Mole, Larry A. <(b6) @va.gov>; Bricker, David (b6) @va.gov>; Peppiatt, Jennifer L. (b6) @va.gov>; Page, Tonya Hymer (b6) @va.gov>; Inhofe, Kerry E. <(b6) va.gov>
Subject: RE: esketamine

Bringing in CI Leadership also to this discussion on Marijuana prescribing.

Cheryl Andersen, RN MSSL
CIPM, Clinical Integration
VHA Office of Community Care
Clinical Network Management
Telephone remote: (b6)

AMERICAN OVERSIGHT

Email: (b6) @va.gov

From: Emmendorfer, Thomas (PBM)
Sent: Thursday, August 15, 2019 11:37 AM
To: Andersen, Cheryl <(b6) @va.gov>; Wiechers, Ilse (b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Mole, Larry A (b6) e@va.gov>; Bricker, David (b6) va.gov>
Subject: RE: esketamine

Hi Cheryl/Ilse,

I have added Larry Mole to the e-mail to see if an authorized community care provider is allowed to follow a different set of rules in regards to prescribing marijuana than VA providers.

If not, I have added Dave Bricker from Office of Community Care to the e-mail as someone from OCC and assuming this a TriWest PC3 provider to ensure the appropriate action is taken.

Someone from OCC may want to review the process of reporting these type of prescribing practices with the VA Medical facilities thru the appropriate OCC channels…

Tom

From: Andersen, Cheryl
Sent: Thursday, August 15, 2019 10:30 AM
To: Wiechers, Ilse (b6) @va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: esketamine

We will have a C6 center that takes calls from those that are distant eligible and not seeing VA. There will be nurses and providers integrated to essentially do the same level of care coordination that is being done with the local office of community care teams. Thus there is clinical involvement from the VA side.

When a request for services for this care is received, a consult would need to be entered by someone with delegation of authority to approve the care.
This SEOC would then be applied.

Cheryl Andersen, RN MSSL
CIPM, Clinical Integration
VHA Office of Community Care
Clinical Network Management
Telephone remote: (b6)
Email (b6)

From: Wiechers, Ilse
Sent: Thursday, August 15, 2019 9:23 AM
To: Andersen, Cheryl (b6) @va.gov>; Emmendorfer, Thomas (PBM)

AMERICAN OVERSIGHT

<(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: FW: esketamine

Hi –

Please see the email below and the concern raised by (b) (5)

Ilse

From: Ryder, Kathryn M.
Sent: Wednesday, August 14, 2019 5:24 PM
To: Wiechers, Ilse <(b6) @va.gov>
Subject: esketamine

Thank you for your presentation on esketamine. All of our veterans in VAPIHCS are community care eligible (lack of inpatient facility). Some veterans have chosen MH in community. Those MH docs are establishing ketamine clinics. (b6) . A lot of our veterans see 1 in our community who prescribes a lot of medical marijuana for PTSD-t(b) (5) .

Kathryn Ryder, M.D., M.S.
Deputy COS
VAPIHCS
(b6)
One Team, One Ohana!

Sender:	Mole, Larry A. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A7F4EED603A543398E4E0B0BBE52CF41-MOLE, LARRY (b6) va.gov>
Recipient:	Bricker, David /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5012db713ab406daf228a7f5855581f-Bricker, Da (b6) @va.gov>; Andersen, Cheryl /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0933541e04e47ed9ad9a5fdb39e6175-Andersen, C (b6) @va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group

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	(FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>; Peppiatt, Jennifer L. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eaa77295805640b798dff496264eef73-Peppiatt, J (b6) t@va.gov>; Page, Tonya Hymer /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e96620b1be3f412d93512fa0befe908f-Page, Tonya (b6) a.gov>; Inhofe, Kerry E. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=046e71c75a554f93970467bab4f632c0-Inhofe, Ker (b6) e@va.gov>; Baker, K. Mitch (OCC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f894a81b872b44ac9e777151288d9a4f-Baker, Kevi (b6) @va.gov>; Cabeen, Janet /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a92cfecf7218412ea8b720fd998c7c99-Cabeen, Jan (b6) n@va.gov>; Harris, Gus /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b80a4167859d483ea0ef2ed74aed8041-Harris, Gus (b6) @va.gov>; Garman, Tony A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bab07ad64f54d7d82d29cbe401ee435-Garman, Tho (b6) @va.gov>; DeWitt, Christopher A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1fe70ddfd93942ee9d0a4477a9a03305-DeWitt, Chr (b6) t@va.gov>; Fagan, Craig A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5dce38631b74622af60602f58146a87-Fagan, Crai <(b6) @va.gov>
Sent Date:	2019/08/16 12:22:34
Delivered Date:	2019/08/16 12:22:36

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To:	Mitchell, Brian G. (HOU) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=26a0a4f77fd84c5eb8ad053c9cf6ebb3-Mitchell, B (b6) @va.gov>
Subject:	RE: Esketamine
Date:	2019/06/27 14:31:04
Priority:	Normal
Type:	Note

Hi Brian,

It is listed under clinical recommendations. See intranasal esketamine for treatment resistant depression.
Here is the link:

https://vaww.cmopnational.va.gov/cmop/PBM/Clinical%20Guidance/Forms/AllItems.aspx?RootFolder=%2Fcmop%2FPBM%2FClinical%20Guidance%2FClinical%20Recommendations&FolderCTID=0x0120006BA3B2280F536A41A2C5A1B0F4AFC943&View={43999405-C9A2-47A4-AE17-15518717FA3E}

Hope this helps.

Matthew

From: Mitchell, Brian G. (HOU)
Sent: Thursday, June 27, 2019 1:42 PM
To: Fuller, Matthew A. (PBM) <(b6) va.gov>
Subject: RE: Esketamine

Good afternoon Dr. Fuller,

Do you happen to know if there is a timeline for the release of the national protocol guidance?

Brian G. Mitchell, PharmD, BCPS, BCPP
Clinical Pharmacy Specialist – Psychiatry
PGY2 Psychiatric Pharmacy Residency Program Director
Michael E. DeBakey VA Medical Center
2002 Holcombe Blvd (119), Houston, TX 77030
Phone: (b6) 1 | Pager: (b6)

AMERICAN OVERSIGHT

From: Moore, Tera
Sent: Thursday, May 9, 2019 12:21 PM
To: McArdle, Kaitlin (b)(6) @va.gov>; VHA Psychiatric Pharmacists <PsychiatricPharmacists@va.gov>
Cc: Fuller, Matthew A. (PBM) (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) (b)(6) @va.gov>
Subject: RE: Esketamine

Good morning!

The PBM Formulary group will be publishing the esketamine monograph, CFU and are participating with Office of Mental Health and Suicide Prevention (OMHSP) in developing the national protocol guidance. It's recommended to wait until the CFU and protocol guidance are complete before moving forward with a local SOP.

Thank you,

Tera

Tera D. Moore, Pharm.D., BCPS, BCACP
National PBM Program Manager, Clinical Practice Integration and Model Advancement
Pharmacy Benefits Management (PBM) (10P4P), Clinical Pharmacy Practice Office (CPPO)
Cell (b)(6)

From: McArdle, Kaitlin
Sent: Thursday, May 9, 2019 9:56 AM
To: VHA Psychiatric Pharmacists <PsychiatricPharmacists@va.gov>
Subject: Esketamine

Good morning,

I know that we recently received guidance on REMS enrollment, ordering summary for the VA, and a draft of the CFU/monograph for intranasal esketamine. But has any site already developed a SOP or MCM? If so, would you mind sharing?

Thank you! Enjoy the rest of your week!

Kaitlin McArdle, PharmD, BCPS, BCPP
Mental Health Clinical Pharmacy Specialist
Iowa City VA Health Care System – Coralville VA Outpatient Clinics
520 10th Ave
Coralville, IA 52241
Phone: (b)(6)
Email: (b)(6) @va.gov

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Recipient:	Mitchell, Brian G. (HOU) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=26a0a4f77fd84c5eb8ad053c9cf6ebb3-Mitchell, B *(b)(6)* @va.gov>
Sent Date:	2019/06/27 14:31:07
Delivered Date:	2019/06/27 14:31:04
Message Flags:	Unread Unsent

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From:	Potoski, Laura M /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=45F12750BC5C43259A4F95175E2ACF34-POTOSKI, LA (b)(6) @va.gov>
To:	Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen (b)(6) @va.gov>; VHAPBM Ask PBM Clinical /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=82b40b5f582040959b9edcf353b2a433-VHAPBH Ask <AskPBMClinical@va.gov>
Subject:	RE: Esketamine
Date:	2019/03/11 14:27:04
Priority:	Normal
Type:	Note

Thank you!

From: Zacher, Jennifer L. (PBM)
Sent: Monday, March 11, 2019 2:25 PM
To: Potoski, Laura M (b)(6) @va.gov>; VHAPBM Ask PBM Clinical <AskPBMClinical@va.gov>
Subject: RE: Esketamine

Hello Laura,
It is projected that the review will be completed between May and June.

The drug is not commercially launched yet, it should be available next week. It will be available through McKesson once sites certify with the REMS. The REMS site isn't live yet, so PBM will send more information out on what to do once it is available.
Jennifer

From: Potoski, Laura M
Sent: Monday, March 11, 2019 1:02 PM
To: VHAPBM Ask PBM Clinical <AskPBMClinical@va.gov>
Subject: Esketamine

Hello
We have been getting a lot of questions about Esketamine nasal spray.
I don't see it listed on the NME list yet.
We were wondering if there was a projected date for review or any information yet to provide?
Thank you
Laura

Sender:	Potoski, Laura M /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=45F12750BC5C43259A4F95175E2ACF34-POTOSKI, LA (b)(6) @va.gov>
Recipient:	Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen (b)(6) @va.gov>; VHAPBM Ask PBM Clinical /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=82b40b5f582040959b9edcf353b2a433-VHAPBH Ask

AMERICAN OVERSIGHT

	<AskPBMClinical@va.gov>
Sent Date:	2019/03/11 14:27:02
Delivered Date:	2019/03/11 14:27:04
Message Flags:	Unread

AMERICAN OVERSIGHT

From:	Kelley, Catherine /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=62EF810523394D98AE3B91A6EF2623BC-KELLEY, CAT ·(b)(6) @va.gov>
To:	Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat (b)(6) @va.gov>
Subject:	RE: Esketamine
Date:	2019/03/25 14:03:25
Priority:	Normal
Type:	Note

☺

From: Fuller, Matthew A. (PBM)
Sent: Monday, March 25, 2019 11:02 AM
To: Kelley, Catherine (b)(6) @va.gov>
Subject: RE: Esketamine

Hi Cathy,

The short answer; it came from the top. ☺

From: Kelley, Catherine
Sent: Monday, March 25, 2019 2:00 PM
To: Fuller, Matthew A. (PBM) (b)(6) @va.gov>
Subject: RE: Esketamine

Matthew, that is so frustrating. How does that happen? This has to be confusing to the field, etc. Have you asked Pete and Jenn since this would sidestep our usual processes?

From: Fuller, Matthew A. (PBM)
Sent: Monday, March 25, 2019 10:51 AM
To: Kelley, Catherine ·(b)(6) @va.gov>
Subject: RE: Esketamine

Hi Cathy,

It's hard to control…. See news release from last week.

Matthew

From: Kelley, Catherine
Sent: Monday, March 25, 2019 1:47 PM
To: Fuller, Matthew A. (PBM) (b)(6) @va.gov>
Subject: RE: Esketamine

AMERICAN OVERSIGHT

Matthew, this person saw the same thing that I saw in VA Voice. We should talk about how the source got this incorrect information at an upcoming clinical meeting, Cathy

---

From: Fuller, Matthew A. (PBM)
Sent: Friday, March 22, 2019 10:34 AM
To: Binns, Lindsey <(b)(6) @va.gov>; VHAPBM Ask PBM Clinical <AskPBMClinical@va.gov>
Subject: RE: Esketamine

Hi Lindsey,

Thanks for your question. Formulary status for esketamine has not been determined. Esketamine is currently be reviewed by VA PBM. It should be presented to the MAP/VPE committee in the next several months for decision making. Thanks.

Matthew

Matthew A. Fuller, BS, Pharm.D., FASHP, BCPP
National PBM Clinical Pharmacy Program Manager – Psychiatry and Geriatrics
VHA Pharmacy Benefits Management Services (10P4P)
1st Avenue – 1 Block North of Cermak (Bldg 37)
Hines, IL 60141
(b)(6)

From: Binns, Lindsey
Sent: Friday, March 22, 2019 1:02 PM
To: VHAPBM Ask PBM Clinical <AskPBMClinical@va.gov>
Subject: Esketamine

I was curious about this posting we received in VA Stories of Note: March 16-March 22 today.
Military.com (San Francisco), Mar. 20: VA to Offer New Ketamine-Based Nasal Spray for Depression
The newest FDA-approved medication to treat severe depression, a nasal spray based on the anesthetic (and misused hallucinogenic party drug) ketamine, will soon be available to veterans treated within the Department of Veterans Affairs.

Clicking the link, the article reads as if it was added to the formulary, but the formulary email from yesterday does not include it. We are afraid that people are going to start asking for it and we have no guidance. Any insight?

Lindsey Binns, PharmD, BCPP
Clinical Pharmacy Specialist, Mental Health
PGY2 Psychiatric Pharmacy Residency Program Director
VA Texas Valley Coastal Bend HCS
Corpus Christi Specialty Clinic

Sender:	Kelley, Catherine /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

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	(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=62EF810523394D98AE3B91A6EF2623BC-KELLEY, CAT (b)(6) @va.gov>
Recipient:	Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat (b)(6) @va.gov>
Sent Date:	2019/03/25 14:02:58
Delivered Date:	2019/03/25 14:03:25
Message Flags:	Unread

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From:	Goodman, Francine /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EC164D1255644AC4BB4AF7B812F0A6FB-GOODMAN, FR (b)(6) @va.gov>
To:	Anderson, Brett A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93c513b102b84b4381364eea3e1afcc0-Anderson, B (b)(6) @va.gov>; VHAPBM Ask PBM Clinical /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=82b40b5f582040959b9edcf353b2a433-VHAPBH Ask <AskPBMClinical@va.gov>
Subject:	RE: esketamine
Date:	2019/03/07 15:44:56
Priority:	Normal
Type:	Note

Hi Brett,

The clinician covering this area is out of office and will address your question when he returns to the office next Monday.

Francine Goodman | National Clinical Pharmacy Program Manager | VHA PBM Services (10P4P)

From: Anderson, Brett A.
Sent: Thursday, March 07, 2019 3:25 PM
To: VHAPBM Ask PBM Clinical <AskPBMClinical@va.gov>
Subject: esketamine

https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm632761.htm

Any sense when CFU &guidance on availability will be forthcoming?

Thanks for any insight.

Brett

Sender:	Goodman, Francine /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EC164D1255644AC4BB4AF7B812F0A6FB-GOODMAN, FR (b)(6) @va.gov>
Recipient:	Anderson, Brett A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93c513b102b84b4381364eea3e1afcc0-Anderson, B (b)(6) @va.gov>;

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	VHAPBM Ask PBM Clinical /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=82b40b5f582040959b9edcf353b2a433-VHAPBH Ask <AskPBMClinical@va.gov>
Sent Date:	2019/03/07 15:44:54
Delivered Date:	2019/03/07 15:44:56

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From:	Fuller, Matthew A. (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=62D9CBB23B184CACB98895776E36A471-FULLER, MAT>
To:	Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen *(b)(6)* @va.gov>
Subject:	RE: Esketamine
Date:	2019/03/09 17:19:00
Priority:	Normal
Type:	Note

Jenn,

Thanks for the update. I will plan on moving esketamine to high priority. Given all the "interest" around this product I too thought it would be better for a F2F meeting but will now target the May call unless I hear otherwise.

Regarding aripiprazole LAI; it really does not matter what product we use. I suggest we go with the least expensive.(b) (6)
(b) (6)

Also, I will be driving all day Sunday and Monday. If something comes up in the interim please text me on my cell. Thanks.

Matthew

From: Zacher, Jennifer L. (PBM)
Sent: Saturday, March 09, 2019 2:46 PM
To: Fuller, Matthew A. (PBM) *(b)(6)* @va.gov>
Subject: RE: Esketamine

Hi,
Sorry – the day got crazy….

So, I know I will see you next week, but wanted to give you a few updates…..

1. •(b) (6) ..do you think you can target moving this to a high priority and reviewing on the May calls? I told Mike V my preference was June because there are a lot of logistical issues so a face to face meeting would be easier, but I got asked to try for May. June will be the fall back. I will fill you in on the rest when I see you.
2. • I spoke with Otsuka regarding the Aristada/Maintena issue on Friday. They told me that if we add Aristada at a parity formulary placement, the will likely lower the amount of discount that they are offering, but they won't go to full FSS price. They didn't really quantify, just gave me some vague numbers, but I will try to have some idea of the cost and will jump in when you present. They also said that if VA was willing to make some kind of initiative to call out the fact that only certain injections (including Maintena) are indicated for bipolar, they might steepen

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their discount, but again, they didn't commit to numbers. Personally, I don't think we need to do anything on that topic, but open to your thoughts....

See you next week.
JZ

From: Fuller, Matthew A. (PBM)
Sent: Thursday, March 07, 2019 7:34 AM
To: Zacher, Jennifer L. (PBM) (b)(6) @va.gov>
Subject: RE: Esketamine

Hi Jenn,

When are you available to talk?

From: Zacher, Jennifer L. (PBM)
Sent: Wednesday, March 06, 2019 9:36 PM
To: Fuller, Matthew A. (PBM) (b)(6) @va.gov>
Subject: RE: Esketamine

Let's talk in the am...I don't think we need to rush it too much. I think a few months is just fine. I don't anticipate a lot of use, and I am not even sure of the distribution model yet, since this will be for supervised administration

---

From: Fuller, Matthew A. (PBM)
Sent: Wednesday, March 06, 2019 8:13 PM
To: Zacher, Jennifer L. (PBM) (b)(6) @va.gov>
Subject: RE: Esketamine

I can give it high priority if you like. I will be back in the office after the F2F meeting. Maybe a couple months after that?

Also, looks like I got an email in my inbox for Marsden asking what PBMs position on ketamine is. I am not sure how to answer. Do we have a position?

From: Zacher, Jennifer L. (PBM)
Sent: Wednesday, March 06, 2019 9:09 PM
To: Fuller, Matthew A. (PBM) (b)(6) @va.gov>
Subject: Esketamine

Hi,
Can you give me a rough estimate on when you think you will review esketamine? The White House is already asking questions, so I just need a ballpark.
Thanks,
JZ

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Jennifer L. Zacher, PharmD, BCPP
Associate Chief Consultant
VA Pharmacy Benefits Management Services
(b)(6)
(b)(6) @va.gov

Sender:	Fuller, Matthew A. (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=62D9CBB23B184CACB98895776E36A471-FULLER, MAT>
Recipient:	Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen (b)(6) @va.gov>
Sent Date:	2019/03/09 17:19:35
Delivered Date:	2019/03/09 17:19:00

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VA-19-1109-B-001012

From:	Fuller, Matthew A. (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=62D9CBB23B184CACB98895776E36A471-FULLER, MAT>
To:	Goodman, Francine /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec164d1255644ac4bb4af7b812f0a6fb-Goodman, Fr (b)(6) @va.gov>
Subject:	RE: esketamine
Date:	2019/03/08 08:17:00
Priority:	Normal
Type:	Note

Yes!

From: Goodman, Francine
Sent: Thursday, March 07, 2019 4:13 PM
To: Fuller, Matthew A. (PBM) (b)(6) @va.gov>
Subject: RE: esketamine

(b) (6) ☺

Francine Goodman | National Clinical Pharmacy Program Manager | VHA PBM Services (10P4P)

From: Fuller, Matthew A. (PBM)
Sent: Thursday, March 07, 2019 4:05 PM
To: Anderson, Brett A. (b)(6) @va.gov>; VHAPBM Ask PBM Clinical <AskPBMClinical@va.gov>
Subject: RE: esketamine

Hi Brett,

I anticipate that we will have something available in the next couple of months.

Matthew

Matthew A. Fuller, BS, Pharm.D., FASHP, BCPP
National PBM Clinical Pharmacy Program Manager – Psychiatry and Geriatrics
VHA Pharmacy Benefits Management Services (10P4P)
1st Avenue – 1 Block North of Cermak (Bldg 37)
Hines, IL 60141
(b)(6)

From: Anderson, Brett A.
Sent: Thursday, March 07, 2019 3:25 PM
To: VHAPBM Ask PBM Clinical <AskPBMClinical@va.gov>
Subject: esketamine

https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm632761.htm

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Any sense when CFU &guidance on availability will be forthcoming?

Thanks for any insight.

Brett

Sender:	Fuller, Matthew A. (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=62D9CBB23B184CACB98895776E36A471-FULLER, MAT>
Recipient:	Goodman, Francine /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec164d1255644ac4bb4af7b812f0a6fb-Goodman, Fr *(b)(6)* @va.gov>
Sent Date:	2019/03/08 08:17:40
Delivered Date:	2019/03/08 08:17:00

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From:	Wiechers, Ilse /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0C7B1428D9E4233A641F125C5B6FC4F-WIECHERS, I (b)(6) @va.gov>
To:	Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M (b)(6) @va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>
CC:	Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da (b)(6) @va.gov>
Subject:	RE: Esketamine
Date:	2019/03/21 14:39:56
Priority:	Normal
Type:	Note

Very helpful, thanks so much, Maria.

From: Llorente, Maria D.
Sent: Thursday, March 21, 2019 11:38 AM
To: Wiechers, Ilse <(b)(6) @va.gov>; Valentino, Michael (VACO) <(b)(6) @va.gov>
Cc: Carroll, David (VACO) <(b)(6) @va.gov>
Subject: RE: Esketamine

The questions being asked are reasonable. Prior to the internal urgency, there was a tremendous amount of public media coverage of this medication. We received feedback that patients were contacting their primary care providers and asking when they might be able to come in for a prescription. So, the information is important to be able to address veteran inquiries, that then translate into provider inquiries. Further, it is important for everyone to understand the risk mitigation aspects.

That having been said, in so far as this treatment may also prove to be of benefit (albeit it may only be a handful of patients), we should assist facilities.

Because of the added logistics (cardiovascular monitoring), designated space for administration, choosing appropriate patients, consenting process, required education, and need for certification of the clinical setting, pharmacy, and patient enrollment, it makes a lot of sense to provide the information quickly so that the prep work can be started for those facilities who will be offering this unique service.

Lastly, if the facility is not able to offer the service (I think I saw at least one comment to that effect), they may be able to identify community providers who will offer the treatments, and the heads up information may facilitate working with community care contract providers.

Just a few thoughts.
Maria

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From: Wiechers, Ilse
Sent: Thursday, March 21, 2019 10:00 AM
To: Valentino, Michael (VACO) (b)(6) @va.gov>; Llorente, Maria D. (b)(6) @va.gov>
Cc: Carroll, David (VACO) (b)(6) @va.gov>
Subject: RE: Esketamine

I've had several MH Service Chiefs reach out to me directly as well asking for the "context." I anticipate being asked to join the MH VISN Leads call this coming Monday to discuss further.

Adding Dave for his awareness as well.

Ilse

From: Valentino, Michael (VACO)
Sent: Thursday, March 21, 2019 6:38 AM
To: Wiechers, Ilse (b)(6) @va.gov>; Llorente, Maria D. (b)(6) @va.gov>
Subject: FW: Esketamine

Just an example FYI.....have had a few reports of pushback from the field....

Sent with BlackBerry Work
(www.blackberry.com)

From: Lowe, Joette (b)(6) @va.gov>
Date: Thursday, Mar 21, 2019, 9:14 AM
To: VHAPBM VPE Formulary Committee <VPEFormularyCommittee@va.gov>
Subject: FW: Esketamine

Just FYI on feedback from the MH side of the issue.

Joette S. Lowe, PharmD
VISN 7 Pharmacy Executive (VPE)
3701 Loop Road East
Tuscaloosa, AL 35404
(b)(6)

Suicide Prevention is Everyone's Business. *#BeThere.*



cid:image009.jpg@01D328A1.8C7B68A0

From: Myrick, Donald L. (Hugh)
Sent: Wednesday, March 20, 2019 12:31 PM

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To: Lowe, Joette (b)(6) @va.gov>
Subject: FW: Esketamine

Just FYI.

Hugh Myrick, MD
ACOS, Mental Health Service Line
Ralph H. Johnson VAMC
Director, Addiction Sciences Division
Director, Military Sciences Division
MUSC, Charleston SC

Suicide Prevention is Everyone's Business. *#BeThere.*



http://veteranscrisisline.net/banners/public/ads/VeteransCrisisLine-Badge-Phone.gif

---

From: Myrick, Donald L. (Hugh)
Sent: Wednesday, March 20, 2019 1:22 PM
To: Landreth, Edward S. (b)(6) @va.gov>; Magnes, N. Sarah (b)(6) @va.gov>; Cohen, Jay L. (b)(6) @va.gov>; Holliday, Steve <(b)(6) @va.gov>; VHACLE BVAC Group <VHACLEBVACGroup@va.gov>
Subject: RE: Esketamine

(b) (6)
(b) (6)(b) (6)

(b) (6)

Hugh Myrick, MD
ACOS, Mental Health Service Line
Ralph H. Johnson VAMC
Director, Addiction Sciences Division
Director, Military Sciences Division
MUSC, Charleston SC

Suicide Prevention is Everyone's Business. *#BeThere.*

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http://veteranscrisisline.net/banners/public/ads/VeteransCrisisLine-Badge-Phone.gif

From: Landreth, Edward S.
Sent: Wednesday, March 20, 2019 12:54 PM
To: Magnes, N. Sarah (b)(6) @va.gov>; Cohen, Jay L. <(b)(6) @va.gov>; Holliday, Steve (b)(6) @va.gov>; VHACLE BVAC Group <VHACLEBVACGroup@va.gov>
Subject: RE: Esketamine

Consider it done.

From: Magnes, N. Sarah
Sent: Wednesday, March 20, 2019 11:54 AM
To: Cohen, Jay L. (b)(6) @va.gov>; Holliday, Steve <(b)(6) @va.gov>; VHACLE BVAC Group <VHACLEBVACGroup@va.gov>
Subject: RE: Esketamine

I'd like to suggest that we discuss further on both our Monday calls.
Thanks!

Sarah Magnes, PhD, LCSW, BCD
Chief Mental Health Officer
VISN 7 Southeast Network
Office: (b)(6)
Cell: (b)(6)



cid:image001.jpg@01D23138.866DD440

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From: Cohen, Jay L.
Sent: Wednesday, March 20, 2019 11:54 AM
To: Holliday, Steve (b)(6) @va.gov>; Magnes, N. Sarah <(b)(6) @va.gov>; VHACLE BVAC Group <VHACLEBVACGroup@va.gov>
Subject: RE: Esketamine

Same in V23...not sure the point of the memo and the requirement to get registered within 30 days when much of the details hadn't been worked out...

AMERICAN OVERSIGHT

Jay L. Cohen, Ph.D.
Interim Chief Mental Health Officer
VA Midwest Healthcare Network—VISN 23
(b)(6) @va.gov
(b)(6)

From: Holliday, Steve
Sent: Wednesday, March 20, 2019 11:48 AM
To: Magnes, N. Sarah (b)(6) @va.gov>; VHACLE BVAC Group <VHACLEBVACGroup@va.gov>
Subject: RE: Esketamine

There were similar concerns expressed on our VISN 17 PDSI Work Group call this morning. I told them to wait until VACO rolls out the materials and training materials. That is, we are NOT providing it now and won't until these things happen.

Steve

From: Magnes, N. Sarah
Sent: Wednesday, March 20, 2019 10:45 AM
To: VHACLE BVAC Group <VHACLEBVACGroup@va.gov>
Subject: Esketamine

Good Morning,
I was wondering if anyone else has had strong pushback from pharmacy and the field on this? When the Somatic Treatment Survey came out, none of our facilities expressed an interest in providing Ketamine treatment. Besides the fast turnaround, the VISN Pharmacy Exec expressed the following concerns –

(b5)

Thanks, Sarah

Sarah Magnes, PhD, LCSW, BCD
Chief Mental Health Officer
VISN 7 Southeast Network
Office: (b)(6)
Cell: (b)(6)

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cid:image001.jpg@01D23138.866DD440

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VA Core Characteristics: Trustworthy, Accessible, Quality, Innovative, Agile, Integrated

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Sender:	Wiechers, Ilse /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0C7B1428D9E4233A641F125C5B6FC4F-WIECHERS, I *(b)(6)* @va.gov>
Recipient:	Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M *(b)(6)* @va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, *(b)(6)* @va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da *(b)(6)* @va.gov>
Sent Date:	2019/03/21 14:39:55
Delivered Date:	2019/03/21 14:39:56

AMERICAN OVERSIGHT

From:	Mitchell, Brian G. (HOU) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=26A0A4F77FD84C5EB8AD053C9CF6EBB3-MITCHELL, B *(b)(6)* @va.gov>
To:	Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat *(b)(6)* @va.gov>
Subject:	RE: Esketamine
Date:	2019/06/27 14:52:05
Priority:	Normal
Type:	Note

Thanks. I really appreciate it.

BGM

From: Fuller, Matthew A. (PBM)
Sent: Thursday, June 27, 2019 1:32 PM
To: Mitchell, Brian G. (HOU) *(b)(6)* @va.gov>
Subject: RE: Esketamine

Hi Brian,

It is listed under the PBM clinical recommendations section. See intranasal esketamine for treatment resistant depression.
Here is the link:

https://vaww.cmopnational.va.gov/cmop/PBM/Clinical%20Guidance/Forms/AllItems.aspx?RootFolder=%2Fcmop%2FPBM%2FClinical%20Guidance%2FClinical%20Recommendations&FolderCTID=0x0120006BA3B2280F536A41A2C5A1B0F4AFC943&View={43999405-C9A2-47A4-AE17-15518717FA3E}

Hope this helps.

Matthew

From: Mitchell, Brian G. (HOU)
Sent: Thursday, June 27, 2019 1:42 PM
To: Fuller, Matthew A. (PBM) *(b)(6)* @va.gov>
Subject: RE: Esketamine

Good afternoon Dr. Fuller,

Do you happen to know if there is a timeline for the release of the national protocol guidance?

AMERICAN OVERSIGHT

Brian G. Mitchell, PharmD, BCPS, BCPP
Clinical Pharmacy Specialist – Psychiatry
PGY2 Psychiatric Pharmacy Residency Program Director
Michael E. DeBakey VA Medical Center
2002 Holcombe Blvd (119), Houston, TX 77030
Phone: (b)(6) | Pager:(b)(6)

From: Moore, Tera
Sent: Thursday, May 9, 2019 12:21 PM
To: McArdle, Kaitlin (b)(6) @va.gov>; VHA Psychiatric Pharmacists <PsychiatricPharmacists@va.gov>
Cc: Fuller, Matthew A. (PBM) (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) (b)(6) @va.gov>
Subject: RE: Esketamine

Good morning!

The PBM Formulary group will be publishing the esketamine monograph, CFU and are participating with Office of Mental Health and Suicide Prevention (OMHSP) in developing the national protocol guidance. It's recommended to wait until the CFU and protocol guidance are complete before moving forward with a local SOP.

Thank you,

Tera

Tera D. Moore, Pharm.D., BCPS, BCACP
National PBM Program Manager, Clinical Practice Integration and Model Advancement
Pharmacy Benefits Management (PBM) (10P4P), Clinical Pharmacy Practice Office (CPPO)
Cell (b)(6)

From: McArdle, Kaitlin
Sent: Thursday, May 9, 2019 9:56 AM
To: VHA Psychiatric Pharmacists <PsychiatricPharmacists@va.gov>
Subject: Esketamine

Good morning,

AMERICAN OVERSIGHT

I know that we recently received guidance on REMS enrollment, ordering summary for the VA, and a draft of the CFU/monograph for intranasal esketamine. But has any site already developed a SOP or MCM? If so, would you mind sharing?

Thank you! Enjoy the rest of your week!

Kaitlin McArdle, PharmD, BCPS, BCPP
Mental Health Clinical Pharmacy Specialist
Iowa City VA Health Care System – Coralville VA Outpatient Clinics
520 10th Ave
Coralville, IA 52241
Phone: (b)(6)
Email: (b)(6) @va.gov

Sender:	Mitchell, Brian G. (HOU) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=26A0A4F77FD84C5EB8AD053C9CF6EBB3-MITCHELL, B (b)(6) @va.gov>
Recipient:	Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat (b)(6) @va.gov>
Sent Date:	2019/06/27 14:52:04
Delivered Date:	2019/06/27 14:52:05
Message Flags:	Unread

AMERICAN OVERSIGHT

From:	Zacher, Jennifer L. (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9027C425646E4DE8A7D196908016331B-ZACHER, JEN (b)(6) @va.gov>
To:	Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat (b)(6) @va.gov>
Subject:	RE: Don't kill the messenger.....
Date:	2019/06/11 10:08:21
Priority:	Normal
Type:	Note

You will just be one member of a workgroup on this. They will take the lead, so you don't need to do anything until someone contacts you...sorry, I should have made that more clear!

From: Fuller, Matthew A. (PBM)
Sent: Monday, June 10, 2019 3:50 PM
To: Zacher, Jennifer L. (PBM) (b)(6) @va.gov>
Subject: RE: Don't kill the messenger.....

Ok. How will this work? Will academic detailing update and send to me to edit or do I need to track down the old module and create a new one? Thanks.

From: Zacher, Jennifer L. (PBM)
Sent: Monday, June 10, 2019 4:44 PM
To: Fuller, Matthew A. (PBM) (b)(6) @va.gov>
Subject: Don't kill the messenger.....

Hi,
Had a call with Ilse and the Academic Detailing crew.....based on all the esketamine buzz, Academic Detailing is going to move up the priority on updating their treatment resistant depression module. Instead of just looking at esketamine, it is going to look at everything.....I think there is an old module that just needs updates. They are apparently short-staffed, and Ilse and I asked them to have this done by the new year, so I graciously volunteered you to assist....they told me that wanted someone knowledgeable that can write.

Just didn't want you to be blindsided!
JZ

Jennifer L. Zacher, PharmD, BCPP
Associate Chief Consultant
VA Pharmacy Benefits Management Services
(b)(6)
(b)(6) @va.gov

AMERICAN OVERSIGHT

Sender:	Zacher, Jennifer L. (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9027C425646E4DE8A7D196908016331B-ZACHER, JEN (b)(6) @va.gov>
Recipient:	Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat (b)(6) @va.gov>
Sent Date:	2019/06/11 10:08:20
Delivered Date:	2019/06/11 10:08:21

AMERICAN OVERSIGHT

From:	Valentino, Michael (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO, (b)(6) @va.gov>
To:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b)(6) @va.gov>; Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat (b)(6) @va.gov>; Torphy, Lisa /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43ab37387c5c4ed6bae3006dcde84582-Torphy, Lis (b)(6) @va.gov>
CC:	Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen (b)(6) va.gov>
Subject:	RE: Dial-in information
Date:	2019/06/17 15:44:33
Priority:	Normal
Type:	Note

Hi Ilse,

Please feel free to speak up on the phone to comment on anything in the slides or that we discuss….we value your contributions.

Dr. Llorente will be there in person as will our 2 MAP psychiatrists, so you'll be in good company!

Mike

From: Wiechers, Ilse
Sent: Monday, June 17, 2019 2:51 PM
To: Fuller, Matthew A. (PBM) (b)(6) @va.gov>; Valentino, Michael (VACO) (b)(6) @va.gov>; Torphy, Lisa (b)(6) @va.gov>
Subject: RE: Dial-in information

Thanks! I'll dial in and be a fly on the virtual wall. Let me know if there is anything you need from me – I'll try to be online as well, so you can back channel me as needed via Skype.

From: Fuller, Matthew A. (PBM)
Sent: Monday, June 17, 2019 11:46 AM
To: Valentino, Michael (VACO) (b)(6) @va.gov>; Torphy, Lisa <(b)(6) @va.gov>
Cc: Wiechers, Ilse (b)(6) @va.gov>
Subject: RE: Dial-in information

Hi Ilse,

AMERICAN OVERSIGHT

Please see the information below. Note this is CST. Thanks.

Matthew

DATES: June 19-20 | 2019
LOCATION: Double Tree by Hilton| 1909 Spring Road | Oak Brook | IL 60523 | 630-472-6000
DIAL-IN#: 1-800-767-1750 | code: 86140

Thursday | June 20

WELCOME &INTRODUCTIONS **P. Glassman**

CONFLICTS OF INTEREST

DISCUSSION ITEMS

8:10-8:40 **Esketamine (SPRAVATO) Monograph and CFU*** **30 min**
WHO: M. Fuller
TYPE: Discussion
DISC: Follow up discussion from the May VPE and MAP committee meetings
ACTION:
STATUS: Open **[Janssen Pharmaceuticals]**

8:40-9:00 **Esketamine (SPRAVATO) National Protocol*** **20 min**
WHO: M. Fuller
TYPE: Discussion
DISC: Present esketamine National Protocol for discussion/approval
ACTION:
STATUS: Open **[Janssen Pharmaceuticals]**

From: Valentino, Michael (VACO)
Sent: Monday, June 17, 2019 1:16 PM
To: Fuller, Matthew A. (PBM) *(b)(6)* @va.gov>; Torphy, Lisa *(b)(6)* @va.gov>
Cc: Wiechers, Ilse *(b)(6)* @va.gov>
Subject: Dial-in information

Hi Matt and Lisa,

I invited Ilse to join the esketamine discussion.

Would one of you please send her the dial in information and the time and day of the call?

Ilse, the meeting is in Chicago, so the time is CST.

Mike

AMERICAN OVERSIGHT

Michael A. Valentino, R.Ph., MHSA
Chief Consultant, Pharmact Benefits Management Services
Department of Veterans Affairs
Room 982
810 Vermont Avenue NW
Washington DC

(b)(6)

Sender:	Valentino, Michael (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO, *(b)(6)* @va.gov>
Recipient:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I *(b)(6)* @va.gov>; Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat *(b)(6)* @va.gov>; Torphy, Lisa /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43ab37387c5c4ed6bae3006dcde84582-Torphy, Lis *(b)(6)* @va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen *(b)(6)* @va.gov>
Sent Date:	2019/06/17 15:44:32
Delivered Date:	2019/06/17 15:44:33

AMERICAN OVERSIGHT

From:	Valentino, Michael (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO, (b)(6) @va.gov>
To:	Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat (b)(6) @va.gov>
Subject:	RE: Dial-in information
Date:	2019/06/17 13:42:36
Priority:	Normal
Type:	Note

Thanks Matthew!

(I sent her the slides already and advised her to consider them pre-decisional deliberative information)

Mike

From: Fuller, Matthew A. (PBM)
Sent: Monday, June 17, 2019 1:39 PM
To: Valentino, Michael (VACO) <(b)(6) @va.gov>
Subject: RE: Dial-in information

Hi Mike,

Will do.

Matthew

From: Valentino, Michael (VACO)
Sent: Monday, June 17, 2019 1:16 PM
To: Fuller, Matthew A. (PBM) (b)(6) @va.gov>; Torphy, Lisa (b)(6) @va.gov>
Cc: Wiechers, Ilse (b)(6) @va.gov>
Subject: Dial-in information

Hi Matt and Lisa,

I invited Ilse to join the esketamine discussion.

Would one of you please send her the dial in information and the time and day of the call?

Ilse, the meeting is in Chicago, so the time is CST.

Mike

Michael A. Valentino, R.Ph., MHSA
Chief Consultant, Pharmact Benefits Management Services

AMERICAN OVERSIGHT

Department of Veterans Affairs
Room 982
810 Vermont Avenue NW
Washington DC

(b)(6)

Sender:	Valentino, Michael (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO, *(b)(6)* @va.gov>
Recipient:	Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat *(b)(6)* @va.gov>
Sent Date:	2019/06/17 13:42:35
Delivered Date:	2019/06/17 13:42:36

AMERICAN OVERSIGHT

From:	Valentino, Michael (VACO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO,>
To:	Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen (b)(6) @va.gov>
Subject:	RE: Call With J&J
Date:	2019/06/26 17:10:37
Priority:	Normal
Type:	Note

Thanks Jenn.

(b5)

Sent with BlackBerry Work
(www.blackberry.com)

From: Zacher, Jennifer L. (PBM) (b)(6) @va.gov>
Date: Wednesday, Jun 26, 2019, 5:03 PM
To: Valentino, Michael (VACO) <(b)(6) @va.gov>
Subject: Call With J&J

Hi Mike,
I had a follow up call with J&J today, because they alluded to me that they were hearing conflicting information from the VISNs, and they wanted to clarify (email attached).

(b5)

AMERICAN OVERSIGHT



They indicated that they may have further questions once they inform their senior leadership, but wanted to make sure you were in the loop as to what the conversation was. Let me know if questions.
JZ

Jennifer L. Zacher, PharmD, BCPP
Associate Chief Consultant – Formulary Management
VA Pharmacy Benefits Management Services
(b)(6)
(b)(6) @va.gov

Sender:	Valentino, Michael (VACO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO,>
Recipient:	Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen (b)(6) @va.gov>
Sent Date:	2019/06/26 17:10:36
Delivered Date:	2019/06/26 17:10:37

AMERICAN OVERSIGHT

VA-19-1109-B-001032

From:	Valentino, Michael (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO, (b)(6) @va.gov>
To:	Smith, Avery /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9471c2d02a8b472b8543e09cb140085f-Smith, Aver (b)(6) @va.gov>; VHA 10P4P Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8dc3dab451414f59b9797e8ed199c1e8-VHA 10P4P A <vha10P4Paction@va.gov>; VHA 10P4 Communication Group /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4ba2ff9b4604547be7834a71415253c-VHA 10P4 Co <vha10p4comm@va.gov>
CC:	VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>
Subject:	RE: APPROVAL NEEDED: Spravato/esketamine approval
Date:	2019/06/25 15:05:09
Priority:	Normal
Type:	Note

I answered almost identical questions yesterday.

Please see the attached e-mail.....

Mike

From: Smith, Avery
Sent: Tuesday, June 25, 2019 2:27 PM
To: VHA 10P4P Action <vha10P4Paction@va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Subject: FW: APPROVAL NEEDED: Spravato/esketamine approval

10P4P,

Please review the request below and provide response to VHA 10P4 Communication Group as soon as possible.

Thanks

Avery

From: Snyder, Jill
Sent: Tuesday, June 25, 2019 2:22 PM
To: Valentino, Michael (VACO) (b)(6) @va.gov>; Wiechers, Ilse <(b)(6) @va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Cc: Snyder, Jill <(b)(6) @va.gov>
Subject: FW: APPROVAL NEEDED: Spravato/esketamine approval

AMERICAN OVERSIGHT

Good afternoon –

The reporter came back with two additional questions – I let OPIA know that they already have the answer to the first and they have sent it to the reporter. Are you able to answer the questions about a contract highlighted below? Hoping for quick response.

Thanks,
Jill

From: Abbie Bennett ·(b)(6)
Sent: Monday, June 24, 2019 3:15 PM
To: Carter, Susan <(b)(6) @va.gov>
Cc: Mojay, Ndidi (b)(6) @va.gov>; Noller, Randal <(b)(6) @va.gov>
Subject: [EXTERNAL] Re: Spravato/esketamine approval

Thanks so much for this, Susan.

Does VA have any idea of how much esketamine will cost per dosage or course?

Is there an existing contract with a particular producer of the drug? If so, what was the amount of that contract?

Thanks again,

Abbie Bennett
Reporter
Connecting Vets
C (b)(6)
(b)(6)

Entercom | Washington D.C.
1015 Half Street, S.E., Suite 200
Washington, D.C. 20003
M: ·(b)(6)
(b)(6)

AMERICAN OVERSIGHT

From: Carter, Susan <(b)(6) @va.gov>
Sent: Monday, June 24, 2019 3:10 PM
To: Abbie Bennett
Cc: Mojay, Ndidi; Noller, Randal
Subject: RE: Spravato/esketamine approval

Hi Abbie,

Please see the answers to your other questions.

Q: What is the estimated cost to the VA for Spravato/esketamine prescription per veteran?

A: The frequency of administration, dosage and duration of therapy will vary from patient to patient, so it is not possible to provide a cost per Veteran.

Q: How will the VA monitor its use nationwide?

A: VA will collect and aggregate effectiveness and safety data on each administration of the product.

This information will be reviewed with VA subject matter experts to continually assess this product's place in therapy for treatment resistant depression.

Regards,

Susan Carter
Director, Office of Media Relations
U.S. Department of Veterans Affairs
(b)(6) @va.gov
Desk.(b)(6)
Cell: (b)(6)



cid:image002.jpg@01D3D61E.49531160

From: Abbie Bennett <(b)(6)
Sent: Monday, June 24, 2019 9:09 AM
To: VA Public Affairs <VAPublicAffairs@va.gov>
Subject: [EXTERNAL] Spravato/esketamine approval

Could I please get a statement ASAP on the VA's decision to approve Spravato/esketamine for use in VA medical centers ASAP?

AMERICAN OVERSIGHT

I would also like the following information:

1. What is the estimated cost to the VA for Spravato/esketamine prescription per veteran?

2. How will the VA monitor its use nationwide?

Abbie Bennett
Reporter
Connecting Vets
C (b)(6)
(b)(6)

Entercom | Washington D.C.
1015 Half Street, S.E., Suite 200
Washington, D.C. 20003
M: (b)(6)
(b)(6)

Sender:	Valentino, Michael (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO, (b)(6) @va.gov>
Recipient:	Smith, Avery /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9471c2d02a8b472b8543e09cb140085f-Smith, Aver (b)(6) @va.gov>; VHA 10P4P Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8dc3dab451414f59b9797e8ed199c1e8-VHA 10P4P A <vha10P4Paction@va.gov>; VHA 10P4 Communication Group /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4ba2ff9b4604547be7834a71415253c-VHA 10P4 Co <vha10p4comm@va.gov>; VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>
Sent Date:	2019/06/25 15:05:02
Delivered Date:	2019/06/25 15:05:09
From:	Valentino, Michael (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO, (b)(6) @va.gov>
To:	VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>
Subject:	RE: Spravato/esketamine approval
Date:	2019/06/24 12:09:00
Priority:	Normal

AMERICAN OVERSIGHT

Type: Note

1. What is the estimated cost to the VA for Spravato/esketamine prescription per veteran?

(b5)

2. How will the VA monitor its use nationwide?

(b5)

Mike

From: Sandifer, Estella (Maria)
Sent: Monday, June 24, 2019 10:35 AM
To: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Cc: VHA 10P Actions <VHA10PActions@va.gov>
Subject: FW: Spravato/esketamine approval

10P4,

Please see the entire email and provide a response no later than 11:30 a.m., today.

Request:
We have received additional questions on Spravato/esketamine. Is it possible to receive responses by noon?

There are two new questions highlighted below. For everyone awareness I am copying the statement that was cleared last week.

V/r,

Maria Sandifer
Office of the Deputy Under Secretary for Health

AMERICAN OVERSIGHT

for Policy and Services (10P)
Work ph: (202) 461-7413
Cell: (b)(6)
Email: (b)(6) @va.gov

From: Snyder, Jill
Sent: Monday, June 24, 2019 10:29 AM
To: VHA 10P Actions <VHA10PActions@va.gov>; Valentino, Michael (VACO) (b)(6) @va.gov>; Wiechers, Ilse (b)(6) @va.gov>
Cc: VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: FW: Spravato/esketamine approval

Good morning,

We have received additional questions on Spravato/esketamine. Is it possible to receive responses by noon?

There are two new questions highlighted below. For everyone awareness I am copying the statement that was cleared last week.

After reviewing the available published evidence regarding the safety and effectiveness of esketamine (Spravato), a team of VA clinicians approved on June 20 the use of esketamine (Spravato) on a non-formulary basis. This process is similar to "prior authorization" formulary designations used in non-VA health care systems, and will enable VA psychiatrists to offer esketamine to patients when clinically indicated.

In addition, VA developed clinical and procedural guidance and other tools to promote thoughtful patient selection and safe administration practices, in keeping with the FDA-approved indications for esketamine use and safety requirements. These evidence-based processes will ensure the medication is prioritized for use in Veterans who have not previously responded to adequate trials of other available treatments for major depression.

VA will closely monitor the use of esketamine in Veterans to more fully understand its relative safety and effectiveness as compared to other available treatments. Based on this information, VA may revise its clinical guidance and formulary status if warranted.

This decision reflects VA's commitment to seek new ways to provide the best health care available for our nation's Veterans.

Thanks,
Jill

From: Abbie Bennett (b)(6)
Sent: Monday, June 24, 2019 9:09 AM

AMERICAN OVERSIGHT

To: VA Public Affairs <VAPublicAffairs@va.gov>
Subject: [EXTERNAL] Spravato/esketamine approval

Could I please get a statement ASAP on the VA's decision to approve Spravato/esketamine for use in VA medical centers ASAP?

I would also like the following information:

1. What is the estimated cost to the VA for Spravato/esketamine prescription per veteran?

2. How will the VA monitor its use nationwide?

Abbie Bennett
Reporter
Connecting Vets
C (b)(6)
(b)(6)

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1015 Half Street, S.E., Suite 200
Washington, D.C. 20003
M: -(b)(6)
(b)(6)

Sender:	Valentino, Michael (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO, (b)(6) @va.gov>
Recipient:	VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>
Sent Date:	2019/06/24 12:09:20
Delivered Date:	2019/06/24 12:09:00

AMERICAN OVERSIGHT

From:	Snyder, Jill /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0B6E91EF72EE4A05ACC63873C64570E1-SNYDER, JIL (b)(6) @va.gov>
To:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b)(6) @va.gov>; VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>; VHA 10P Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5098b521b1f34f8a97f74be24709d62f-VHA 10P Act <VHA10PActions@va.gov>
Subject:	RE: APPROVAL NEEDED: Spravato/esketamine approval
Date:	2019/06/25 15:28:16
Priority:	Normal
Type:	Note

Thank you!

From: Valentino, Michael (VACO)
Sent: Tuesday, June 25, 2019 3:09 PM
To: Snyder, Jill (b)(6) @va.gov>; Wiechers, Ilse <(b)(6) @va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Subject: RE: APPROVAL NEEDED: Spravato/esketamine approval

I provided the contract price but if they want more detail about the contract, that question should be referred to the Office of Acquisition and Logistics…specifically to the National Acquisition Center

---

From: Snyder, Jill
Sent: Tuesday, June 25, 2019 2:22 PM
To: Valentino, Michael (VACO) (b)(6) @va.gov>; Wiechers, Ilse (b)(6) @va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Cc: Snyder, Jill (b)(6) @va.gov>
Subject: FW: APPROVAL NEEDED: Spravato/esketamine approval

Good afternoon –

The reporter came back with two additional questions – I let OPIA know that they already have the answer to the first and they have sent it to the reporter. Are you able to answer the questions about a contract highlighted below? Hoping for quick response.

Thanks,
Jill

From: Abbie Bennett <(b)(6)
Sent: Monday, June 24, 2019 3:15 PM

AMERICAN OVERSIGHT

To: Carter, Susan <(b)(6) @va.gov>
Cc: Mojay, Ndidi <(b)(6) @va.gov>; Noller, Randal <(b)(6) @va.gov>
Subject: [EXTERNAL] Re: Spravato/esketamine approval

Thanks so much for this, Susan.

Does VA have any idea of how much esketamine will cost per dosage or course?

Is there an existing contract with a particular producer of the drug? If so, what was the amount of that contract?

Thanks again,

Abbie Bennett
Reporter
Connecting Vets
C (b)(6)
(b)(6)

Entercom | Washington D.C.
1015 Half Street, S.E., Suite 200
Washington, D.C. 20003
M: (b)(6)
(b)(6)

From: Carter, Susan <(b)(6) @va.gov>
Sent: Monday, June 24, 2019 3:10 PM
To: Abbie Bennett
Cc: Mojay, Ndidi; Noller, Randal
Subject: RE: Spravato/esketamine approval

Hi Abbie,

Please see the answers to your other questions.

Q: What is the estimated cost to the VA for Spravato/esketamine prescription per veteran?

AMERICAN OVERSIGHT

A: The frequency of administration, dosage and duration of therapy will vary from patient to patient, so it is not possible to provide a cost per Veteran.

Q: How will the VA monitor its use nationwide?

A: VA will collect and aggregate effectiveness and safety data on each administration of the product.

This information will be reviewed with VA subject matter experts to continually assess this product's place in therapy for treatment resistant depression.

Regards,

Susan Carter
Director, Office of Media Relations
U.S. Department of Veterans Affairs
(b)(6) *@va.gov*
Desk: (b)(6)
Cell: (b)(6)



cid:image002.jpg@01D3D61E.49531160

From: Abbie Bennett *(b)(6)*
Sent: Monday, June 24, 2019 9:09 AM
To: VA Public Affairs <VAPublicAffairs@va.gov>
Subject: [EXTERNAL] Spravato/esketamine approval

Could I please get a statement ASAP on the VA's decision to approve Spravato/esketamine for use in VA medical centers ASAP?

I would also like the following information:

1. What is the estimated cost to the VA for Spravato/esketamine prescription per veteran?

2. How will the VA monitor its use nationwide?

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Abbie Bennett
Reporter
Connecting Vets
C (b)(6)
(b)(6)

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Sent Date:	2019/06/25 15:28:13
Delivered Date:	2019/06/25 15:28:16
Message Flags:	Unread

AMERICAN OVERSIGHT

From:	Stone, Richard A., MD </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BD16619615D64ADEA22E45E63FF6462A-STONE, RICH>
To:	Cashour, Curtis /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dba510634baa46a085e28c62c254093f-Cashour, Cu (b)(6) va.gov>; Tucker, Brooks /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=24ae47cff629405aa8557cc2cc792903-Tucker, Bro (b)(6) va.gov>; Lieberman, Steven /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=25138f5d2e734afa81397f0b357cbcc1-Lieberman, (b)(6) @va.gov>
CC:	Hutton, James /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7da07a304d245cca9fca81fbc0da800-Hutton, Jam (b)(6) @va.gov>; Eason, William J. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90c9ec8badb4538afbfe0b7a69f4422-Eason, Will (b)(6) va.gov>
Subject:	RE: Anti-Depression Drug
Date:	2019/06/23 08:14:18
Priority:	Normal
Type:	Note

Excellent!
Rich

Sent with BlackBerry Work
(www.blackberry.com)

From: Cashour, Curtis <(b)(6) @va.gov>
Date: Saturday, Jun 22, 2019, 7:36 AM
To: Tucker, Brooks (b)(6) @va.gov>, Stone, Richard A., MD <(b)(6) @va.gov>, Lieberman, Steven <(b)(6) @va.gov>
Cc: Hutton, James <(b)(6) @va.gov>, Eason, William J. <(b)(6) @va.gov>
Subject: RE: Anti-Depression Drug

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After reviewing the available published evidence regarding the safety and effectiveness of esketamine (Spravato), a team of VA clinicians approved on June 20 the use of esketamine (Spravato) on a non-formulary basis. This process is similar to "prior authorization" formulary designations used in non-VA health care systems, and will enable VA psychiatrists to offer esketamine to patients when clinically indicated.

In addition, VA developed clinical and procedural guidance and other tools to promote thoughtful patient selection and safe administration practices, in keeping with the FDA-approved indications for esketamine use and safety requirements. These evidence-based processes will ensure the medication is prioritized for use in Veterans who have not previously responded to adequate trials of other available treatments for major depression.

AMERICAN OVERSIGHT

VA will closely monitor the use of esketamine in Veterans to more fully understand its relative safety and effectiveness as compared to other available treatments. Based on this information, VA may revise its clinical guidance and formulary status if warranted.

This decision reflects VA's commitment to seek new ways to provide the best health care available for our nation's Veterans.

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Adding OPIA for any input. (b) (6)
(b) (6)

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Subject: RE: Anti-Depression Drug

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To: Stone, Richard A., MD <(b)(6) @va.gov>, Lieberman, Steven (b)(6) @va.gov>
Subject: RE: Anti-Depression Drug

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(b) (6)

Brooks

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From: Stone, Richard A., MD <(b)(6) @va.gov>
Date: Saturday, Jun 22, 2019, 6:56 AM
To: RLW (b)(6) @va.gov>, Lieberman, Steven <(b)(6) @va.gov>
Cc: Powers, Pamela <(b)(6) @va.gov>, Tucker, Brooks (b)(6) @va.gov>
Subject: RE: Anti-Depression Drug

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Subject: Anti-Depression Drug

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Robert

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Recipient:	Cashour, Curtis /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dba510634baa46a085e28c62c254093f-Cashour, Cu (b)(6) @va.gov>; Tucker, Brooks /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=24ae47cff629405aa8557cc2cc792903-Tucker, Bro (b)(6) @va.gov>; Lieberman, Steven /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=25138f5d2e734afa81397f0b357cbcc1-Lieberman, (b)(6) @va.gov>; Hutton, James /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7da07a304d245cca9fca81fbc0da800-Hutton, Jam (b)(6) @va.gov>;

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	Eason, William J. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90c9ec8badb4538afbfe0b7a69f4422-Eason, Will (b)(6) @va.gov>
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Subject:	RE: Anti-Depression Drug
Date:	2019/06/22 07:34:57
Priority:	Normal
Type:	Note

(b) (6)

(b) (6) It's use and monitoring has a level of complexity well beyond the retail pharmacy dispensing system.
Rich

Sent with BlackBerry Work
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Date: Saturday, Jun 22, 2019, 7:11 AM
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Sent Date:	2019/06/22 07:34:56
Delivered Date:	2019/06/22 07:34:57

AMERICAN OVERSIGHT

From:	Boyd, Teresa D. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F6886A7D555A43E0BEE23C1E40E1C234-BOYD, TERES (b)(6) @va.gov>
To:	Lieberman, Steven /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=25138f5d2e734afa81397f0b357cbcc1-Lieberman, (b)(6) @va.gov>
Subject:	RE: Anti-Depression Drug
Date:	2019/06/22 13:37:22
Priority:	Normal
Type:	Note

You are correct

Sent with BlackBerry Work
(www.blackberry.com)

From: Lieberman, Steven <(b)(6) @va.gov>
Date: Saturday, Jun 22, 2019, 12:17 PM
To: Boyd, Teresa D. (b)(6) @va.gov>
Subject: FW: Anti-Depression Drug

(b) (6) To your knowledge, we never had a committee deny using this? Correct?

Sent with BlackBerry Work
(www.blackberry.com)

From: Cashour, Curtis (b)(6) @va.gov>
Date: Saturday, Jun 22, 2019, 7:36 AM
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Recipient:	Lieberman, Steven /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=25138f5d2e734afa81397f0b357cbcc1-Lieberman, (b)(6) va.gov>
Sent Date:	2019/06/22 13:37:20
Delivered Date:	2019/06/22 13:37:22

AMERICAN OVERSIGHT

From:	Llorente, Maria D. </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F5C91F577D894BD9A0F09305DB34DD4F-LLORENTE, M>
To:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>; Bartch, Chantelle /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b9ba056376bd41a49c4ebae378e14ffe-Bartch, Cha (b)(6) @va.gov>
CC:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>
Subject:	RE: Agenda for Chief Consultants Meeting- 3-11-19
Date:	2019/03/08 17:36:00
Priority:	Normal
Type:	Note

Thank you!!!

From: Emmendorfer, Thomas (PBM)
Sent: Friday, March 8, 2019 5:26 PM
To: Llorente, Maria D. (b)(6) @va.gov>; Bartch, Chantelle (b)(6) @va.gov>
Cc: Valentino, Michael (VACO) (b)(6) @va.gov>
Subject: RE: Agenda for Chief Consultants Meeting- 3-11-19

Will do

Sent with BlackBerry Work
(www.blackberry.com)

From: Llorente, Maria D (b)(6) @va.gov>
Date: Friday, Mar 08, 2019, 5:09 PM
To: Bartch, Chantelle <(b)(6) @va.gov>
Cc: Valentino, Michael (VACO) (b)(6) @va.gov>, Emmendorfer, Thomas (PBM) (b)(6) @va.gov>
Subject: RE: Agenda for Chief Consultants Meeting- 3-11-19

Mike and Tom, will you be also to provide a brief presentation to the Chief Consultants meeting on Monday on Spravato (esketamine – intranasal)? Thank you.
Maria

From: Bartch, Chantelle
Sent: Friday, March 8, 2019 3:41 PM
To: VHA 10P4 Chief Consultants &Execs <vha10P4cce@va.gov>; Utech, Anne E. (HOU) (b)(6) @va.gov>; Smith, Amy W. (V16) (b)(6) @va.gov>; Carroll, David (VACO) (b)(6) @va.gov>; Hartronft, Scotte R. (b)(6) @va.gov>
Subject: Agenda for Chief Consultants Meeting- 3-11-19

AMERICAN OVERSIGHT

Good Afternoon,

Attached is our Chief Consultants meeting agenda for March 11, 2019. We will be discussing EHRM efforts and have a great weekend.

Chantelle

Sender:	Llorente, Maria D. </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F5C91F577D894BD9A0F09305DB34DD4F-LLORENTE, M>
Recipient:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <*(b)(6)* @va.gov>; Bartch, Chantelle /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b9ba056376bd41a49c4ebae378e14ffe-Bartch, Cha *(b)(6)* @va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, *(b)(6)* @va.gov>
Sent Date:	2019/03/08 17:36:07
Delivered Date:	2019/03/08 17:36:00

AMERICAN OVERSIGHT

To:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b)(6) @va.gov>
Subject:	RE: ACTION - FW: Memorandum: Certification with SPRAVATO™ Risk Evaluation and Mitigation Strategy (REMS)
Date:	2019/03/21 20:10:27
Priority:	Normal
Type:	Note

I think you are right on. I also think that it may be valuable to remind people that gearing up for implementation will take time. There are many steps, many people involved – i.e., so although it may seem somewhat premature now, by the time the medication is available everything will be in place. Thanks.

From: Wiechers, Ilse
Sent: Thursday, March 21, 2019 11:42 AM
To: Carroll, David (VACO) (b)(6) @va.gov>
Subject: FW: ACTION - FW: Memorandum: Certification with SPRAVATO™ Risk Evaluation and Mitigation Strategy (REMS)

FYSA – some additional questions from the field, and my response. Please advise if my messaging is off target here, my main emphasis moving forward is on the highlighted sentence.

From: Wiechers, Ilse
Sent: Thursday, March 21, 2019 8:39 AM
To: Leinbach, Jonathan E DURVAMC (b)(6) @va.gov>
Cc: Mankad, Mehul V. DURVAMC (b)(6) @va.gov>; Durkee, Melissa DURVAMC (b)(6) @va.gov>; Goldberg, Kenneth (b)(6) @va.gov>
Subject: RE: ACTION - FW: Memorandum: Certification with SPRAVATO™ Risk Evaluation and Mitigation Strategy (REMS)

Dear Jonathan –

Thanks for being in touch with your questions. Our efforts here are to ensure that access to this medication, when clinically appropriate for use, is available to Veterans regardless of location. My aim is to ensure we have processes and procedures in place that are consistent across the VHA system to ensure safe use of this medication.

This memo to ensure REMS certification is step 1 of a multistep process. I am working now with SMEs on developing national guidance for clinical procedures for administration of the medication, including safety monitoring. By asking all facilities to certify with the FDA REMS, we are hoping to minimize the barriers to access for when clinical use is possible.

AMERICAN OVERSIGHT

The Spravato® formulary review will be on the May 2019 National Formulary Committee agenda. Prior to the National Formulary Committee review, VA providers will be able to prescribe Spravato® based on their clinical assessment and the individual medical needs of the Veteran.

Please let me know if you have any additional questions.

Best,
Ilse

From: Leinbach, Jonathan E DURVAMC
Sent: Thursday, March 21, 2019 5:56 AM
To: Wiechers, Ilse <(b)(6) @va.gov>
Cc: Mankad, Mehul V. DURVAMC <(b)(6) @va.gov>; Durkee, Melissa DURVAMC (b)(6) @va.gov>; Goldberg, Kenneth (b)(6) @va.gov>
Subject: FW: ACTION - FW: Memorandum: Certification with SPRAVATO™ Risk Evaluation and Mitigation Strategy (REMS)

Good morning,

Are you able to provide any context here? It appears that we are being required to register as a provider of a drug that is not yet on our formulary. As a service chief, I am being asked to certify that I have procedures in place to administer this medication, when I am not even sure we are ready to prescribe it.

(b6)

Any information is helpful. Thank you. Jonathan

Jonathan E. Leinbach, MD
ACOS for Mental and Behavioral Health Services
Assistant Professor, Duke Department of Psychiatry and Behavioral Sciences
Durham VA Health Care System
508 Fulton Street
Durham, NC 27705
(b)(6)



cid:image006.png@01D32BE2.86684520

Suicide Prevention is Everyone's Business. *#BeThere.*

From: Kale, Matthew A VISN 6 HQ
Sent: Monday, March 18, 2019 2:34 PM
To: VISN 6 Administration <VISN6ADMIN@med.va.gov>; VISN 6 MHSL Admin <VISN6MHSLAdmin@va.gov>
Cc: Coombs, Stephen J. VISN 6 (b)(6) @va.gov>; VHA VISN 6 Action Group

AMERICAN OVERSIGHT

<VHAVISN6ActionGroup@va.gov>
Subject: ACTION - FW: Memorandum: Certification with SPRAVATO™ Risk Evaluation and Mitigation Strategy (REMS)

Good afternoon,

Please see the message below regarding Certification with SPRAVATO™ Risk Evaluation and Mitigation Strategy (REMS). Each Medical Center must become a Spravato® REMS certified Healthcare Setting and certified Pharmacy. **Attachment #3** provides certification guidance, please follow the instructions and report completion of REMS Healthcare Setting certification to the **VISN 6 MHSL Admin** group by **Noon April 10, 2019.**

Once all facilities have reported completion, the VISN 6 Chief Mental Health Officer will then report VISN-wide REMS certification by email to Dr. Ilse Wiechers at Ilse.Wiechers@va.gov by **April 17, 2019.**

Thank you,

Matthew Kale
Management Analyst
VISN 6 – VA Mid-Atlantic Health Care Network
3518 Westgate Drive, Suite 200
Durham, NC 27707
(b)(6) @va.gov | (b)(6)

From: Office of the DUSHOM Communications
Sent: Monday, March 18, 2019 2:15 PM
To: VHA VISN Directors <VHAVISNDirectors@va.gov>; VHACLE BVAC Group <VHACLEBVACGroup@va.gov>
Cc: VHA VISN Admin Reps <VHAVISNAdminReps@va.gov>; VHA 10NC Action <vha10ncaction@va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>; Wiechers, Ilse (b)(6) @va.gov>; VHA CO 10N Support Staff <VHACO10NSS@va.gov>; McCarthy, Brian (b)(6) @va.gov>
Subject: Memorandum: Certification with SPRAVATO™ Risk Evaluation and Mitigation Strategy (REMS)

Good Afternoon,

Please see the attached memorandum "Certification with SPRAVATO™ Risk Evaluation and Mitigation Strategy (REMS)."

1. The purpose of this memorandum and its attachments is to outline the procedures for the use of Spravato® (eskatamine) nasal spray which was approved by the Food and Drug Administration (FDA) on March 5, 2019, to be used in conjunction with an oral antidepressant, for the treatment of depression in adults who have tried other antidepressant medicines but have not benefited from them (see Attachment A for Esketamine Frequently Asked Questions).

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2. Because of the risk of serious adverse outcomes resulting from sedation and dissociation caused by Spravato® administration, and the potential for abuse and misuse of the drug, it is only available through a restricted distribution system, under an FDA approved Risk Evaluation and Mitigation Strategy (REMS). Please see and follow instructions in Attachment B for REMS Healthcare Setting Certification Guidance.

3. All medical centers must become a Spravato® REMS certified Healthcare Setting and certified Pharmacy. *Within 30 days of this memorandum*, facilities should report completion of REMS Healthcare Setting certification to their VISN Chief Mental Health Officer, who should then report VISN-wide REMS certification by email to Dr. Ilse Wiechers at *(b)(6)* @va.gov.

4. There are resource requirements that facilities must plan to accommodate. Spravato® is intended for patient self-administration under the direct observation of a healthcare provider, and patients are required to be monitored by a healthcare provider for at least 2 hours after Spravato® administration. Spravato® must never be dispensed directly to a patient for home use.

5. • No special privileges are required to prescribe Spravato®.

6. Once educational materials from the manufacturer of Spravato® are made available to VA to review, the review and use of those materials will be consistent with VHA Directive, 1108.10, Promotion of Drugs and Drug-Related Supplies By Pharmaceutical Company Representatives (PCR) located at: https://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=6435.

7. Please contact Ilse Wiechers, MD, Office of Mental Health and Suicide Prevention at *(b)(6)* @va.gov with any questions related to this request.

Renee Oshinski

Attachments

Recipient:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I *(b)(6)* @va.gov>
Sent Date:	2019/03/21 20:10:31
Delivered Date:	2019/03/21 20:10:27
Message Flags:	Unread Unsent

AMERICAN OVERSIGHT

From:	Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd.DIBOHF23SPDLT)/CN=RECIPIENTS/CN=9027C425646E4DE8A7D196908016331B-ZACHER, JEN (b)(6) @va.gov>
To:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>
Subject:	RE: a request for our collaboration with the VA
Date:	2019/06/25 14:27:35
Priority:	Normal
Type:	Note

(b6) I have it for tomorrow too

From: Valentino, Michael (VACO)
Sent: Tuesday, June 25, 2019 1:26 PM
To: (b6))(6) Zacher, Jennifer L. (PBM) (b)(6) @va.gov>; Glassman, Peter A. (b)(6) @va.gov>; (b6) (b)(6)
Subject: RE: a request for our collaboration with the VA

Hi (b6)

I have the call on my calendar for tomorrow……do I have that wrong?

From: (b6))(6)
Sent: Tuesday, June 25, 2019 2:07 PM
To: Valentino, Michael (VACO) (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) <(b)(6) @va.gov>; Glassman, Peter A (b)(6) @va.gov>; (b6) (b)(6)
Subject: [EXTERNAL] Fw: a request for our collaboration with the VA

FYI to discuss as part of our call later today.

Steve

(b6)
(b6)
Institute for Clinical and Economic Review
Two Liberty Square, 9th floor
Boston, MA 02109
(b)(6)
www.icer-review.org

AMERICAN OVERSIGHT

Executive Assistant(b6)
(b)(6)
(b)(6)

From:(b6)
Sent: Wednesday, June 19, 2019 9:21 AM
To:(b6)
Subject: RE: a request for our collaboration with the VA

Hi(b6)
Attached is the updated VA data request document with changes made based on our discussion on this a few days ago. When we spoke, we had discussed using "price paid" instead of "cost", for anti-depressant use. I have stuck to using costs here since these are essentially costs to the VA that would come from reimbursed claims, and can be different therapies for different patients. Please let me know if you think otherwise.

The attached document now specifies a suggested time-duration for the VA to use to look up TRD patient population and associated health care resource use, and specifies resource use to be depression management-related. Mortality and utility-specific requests have now been removed since we believe the VA will not have any data on these estimates.

Thank You.

(b6)

From:(b6) b)(6)
Sent: Thursday, May 30, 2019 11:41 AM
To:(b6) b)(6)
Subject: Re: a request for our collaboration with the VA

Thanks,(b6) please bring a printed out copy of the template to our meeting on Friday so we can go over it together.

Thanks,

(b6)
Institute for Clinical and Economic Review

AMERICAN OVERSIGHT

Two Liberty Square, 9th floor
Boston, MA 02109
(b)(6)
www.icer-review.org

Executive Assistant: (b6)
(b)(6)
(b)(6)

From: (b6)
Sent: Wednesday, May 29, 2019 7:47 PM
To: (b6)
Cc: (b6)
Subject: Re: a request for our collaboration with the VA

Hi (b6)
Sure, will work wit (b6) o find some time in your calendar when you are here.
Thanks.

(b6)

On May 29, 2019, at 6:59 PM (b6) (b)(6) wrote:

(b6)

Thanks for sending this through. I was going to share with the VA today but realized that I don't understand some elements of this and need to talk with you to understand better what we are asking for and what role that data point plays in our model. I will need to talk with you about this later next week, perhaps when I'm up at ICER on June 6-7. Could you please work with (b6) to find a good time, and very glad if (b6) wants to join as well but not required.

Thanks,

(b6)

(b6)

Institute for Clinical and Economic Review
Two Liberty Square, 9th floor
Boston, MA 02109
(b)(6)
www.icer-review.org

AMERICAN OVERSIGHT

Executive Assistant: (b6)
(b)(6)
(b)(6)

From: (b6)
Sent: Tuesday, May 21, 2019 3:48 PM
To:
Cc: (b6)
Subject: RE: a request for our collaboration with the VA

Hi (b6)
Attached is the data request list for esketamine that was prepared in collaboration with (b6)
(b6) from UIC.
Will check on Xarelto's data request and revert.

Please let me know if you have any questions.
Thanks.

(b6)

From (b6))(6)
Sent: Tuesday, May 21, 2019 2:56 PM
To: (b6))(6) (b6) (b)(6)
Subject: Fw: a request for our collaboration with the VA

Hi,

I'm hoping that now that Valuing a Cure analyses won't be as intensive that we can get back to the VA request below. Soon it will be two months since I told them we would be getting them information as per below so it's important we get back to them as soon as we can. If we need to talk again about the overall goal of this just let me know. Otherwise, when you get back from ISPOR please let me know a new timeline for this that fits in with other responsibilities.

Thanks,

(b6)

AMERICAN OVERSIGHT

(b6)
Institute for Clinical and Economic Review
Two Liberty Square, 9th floor
Boston, MA 02109
(b)(6)
www.icer-review.org

Executive Assistant: (b6)
(b)(6)
(b)(6)

From: (b6)
Sent: Monday, April 1, 2019 7:49 PM
To:
Cc: (b6)
Subject: Re: a request for our collaboration with the VA

Perfect, thanks (b6)

(b6)
President
Institute for Clinical and Economic Review
Two Liberty Square, 9th floor
Boston, MA 02109
(b)(6)
www.icer-review.org

Executive Assistant: (b6)
(b)(6)
(b)(6)

From: (b6)
Sent: Monday, April 1, 2019 7:00 PM
To
Cc: (b6)
Subject: Re: a request for our collaboration with the VA

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Hi (b6)

I believe this can be done. It is still early days for Xarelto, which can be a good thing actually since we can model this scenario alongside our main analysis. For esketamine, as you mentioned, population characteristics such as age and gender mix, comorbidities, and cost parameters would be the ones we can change to fit a VA setting. Will speak to the modeling group about this and revert by the end of this week.

(b6)

On Apr 1, 2019, at 6:06 PM, (b6) (b)(6) wrote:

Hi guys,

In a recent conversation with the VA we decided to try a pilot effort in "customizing" one of our reports to their population and their costs. This pilot is intended to serve as a proof of concept, so it doesn't have to be perfect, but here's what we were thinking: for esketamine or Xarelto/Vascepa, which parameter inputs would we want the VA to provide in order to give them model results that reflected their system/population -- but they would have to be data points that they can find easily in their medical records/utilization records. What comes to my mind are things like level of comorbidities/severity; age; cost and mix of comparators; cost of events like hospitalization, ER visit, etc.

Can you let me know whether you think it would be possible to get an Excel chart or something similar with a list of these data elements so we could give it to the VA, have them fill it out, and then use it to run a "VA" scenario analysis? There is no specific timeline for this so it's not like we have to squeeze it in during a busy phase for the modelers or us, but let me know what you think about how big an ask this would be. Thanks!

(b6)
Institute for Clinical and Economic Review
Two Liberty Square, 9th floor
Boston, MA 02109
(b)(6)
www.icer-review.org

Executive Assistant: (b6)
(b)(6)
(b)(6)

Sender:	Zacher, Jennifer L. (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9027C425646E4DE8A7D196908016331B-ZACHER, JEN

AMERICAN OVERSIGHT

	(b)(6) @va.gov>
Recipient:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>
Sent Date:	2019/06/25 14:27:34
Delivered Date:	2019/06/25 14:27:35
Message Flags:	Unread

AMERICAN OVERSIGHT

From:	Brooks, Aja /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5C59E6730234420DA11251416B699F1C-BROOKS, AJA (b)(6) @va.gov>
To:	Copeland, Brittany R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0f1ebffbc694bb09b048ce0f296763e-Copeland, B (b)(6) @va.gov>
CC:	VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>; VHA 10B /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e8da02703bf40af822fcc49b8463979-VHA 10B <vha10b@va.gov>; Law, Cassandra M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f888d507d6c54eb5a92fc44199eb5838-Law, Cassan (b)(6) @va.gov>; VHA 10P Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5098b521b1f34f8a97f74be24709d62f-VHA 10P Act <VHA10PActions@va.gov>
Subject:	RE: 4- Corners Briefing on VA Formulary Process
Date:	2019/06/26 12:35:46
Priority:	Normal
Type:	Note

Thank you.

From: Copeland, Brittany R.
Sent: Wednesday, June 26, 2019 12:35 PM
To: Brooks, Aja (b)(6) @va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; VHA 10B <vha10b@va.gov>; Law, Cassandra M. (b)(6) @va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Subject: RE: 4- Corners Briefing on VA Formulary Process

Afternoon AJ,

On behalf of Krystal Toles, both Dr. Llorente and the slides are cleared.

Thanks,

Brittany R. Copeland, MHA
Health System Specialist
Office of the VHA Chief of Staff (10B)
810 Vermont Ave NW | Washington, DC 20420
o: (b)(6) | c: (b)(6)

From: Brooks, Aja
Sent: Wednesday, June 26, 2019 11:43 AM
To: Law, Cassandra M. (b)(6) @va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; VHA 10B <vha10b@va.gov>

AMERICAN OVERSIGHT

Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Subject: FW: 4- Corners Briefing on VA Formulary Process

OCLA acknowledges receipt, adding VHA 10B for clearance.

OCLA also request Dr. Maria Llorente be cleared to attend this briefing.

v/r
AJ

From: Law, Cassandra M.
Sent: Wednesday, June 26, 2019 11:35 AM
To: Brooks, Aja <(b)(6) @va.gov>; VHA 10B3 Legislative Team <VHA10B3LegislativeTeam@va.gov>
Cc: VHA 10P Actions <VHA10PActions@va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>
Subject: FW: 4- Corners Briefing on VA Formulary Process

Good morning Aja.

10P clears the attached PPT to support the 4 corners briefing.

Please Note: Dr. Maria Llorente's (ADUSH for PCS) name has been added to the title slide and she and Mr. Mike Valentino, Pharmacy Benefits Management will both participate in the briefing.

Thank you, Cassie

-----Original Message-----
From: Brooks, Aja
Sent: Monday, June 24, 2019 10:42 AM
To: VHA 10P Actions <VHA10PActions@va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Subject: RE: 4- Corners Briefing on VA Formulary Process

Good morning, VHA 10P

OCLA request Michael Valentino and Thomas Emmendorfer to brief the 4-Corners on VA's formulary process, including an overview of the drug Spravato. Please list availabilities of the above mentioned SME's for the week of:

June 25 -28
July 1 - 3
OR
July 9, - 1 -3pm

v/r
AJ

-----Original Message-----

AMERICAN OVERSIGHT

From: Melendrez, Dahlia (Veterans Affairs) (b)(6) @vetaff.senate.gov>
Sent: Friday, June 21, 2019 8:41 AM
To: Brooks, Aja (b)(6) @va.gov>
Cc: Campbell, Leslie (Veterans Affairs) <(b)(6) @vetaff.senate.gov>; Workman, Jillian (Veterans Affairs) <(b)(6) @vetaff.senate.gov>; Friedl, Sophia (Veterans Affairs) (b)(6) @vetaff.senate.gov>; (b)(6) @mail.house.gov; (b)(6) @mail.house.gov
Subject: [EXTERNAL] Briefing on formulary process

Hi AJ -

We'd appreciate a briefing on VA's process to consider, deliberate and add drugs to its formulary. In particular, we'd like an overview of the drug Spravato - we understand it's under consideration. Sometime in the next two weeks would be great.

Thanks,
Dahlia

Sent from my iPhone

Sender:	Brooks, Aja /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5C59E6730234420DA11251416B699F1C-BROOKS, AJA (b)(6) @va.gov>
Recipient:	Copeland, Brittany R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0f1ebffbc694bb09b048ce0f296763e-Copeland, B (b)(6) @va.gov>; VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>; VHA 10B /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e8da02703bf40af822fcc49b8463979-VHA 10B <vha10b@va.gov>; Law, Cassandra M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f888d507d6c54eb5a92fc44199eb5838-Law, Cassan (b)(6) @va.gov>; VHA 10P Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5098b521b1f34f8a97f74be24709d62f-VHA 10P Act <VHA10PActions@va.gov>
Sent Date:	2019/06/26 12:35:45
Delivered Date:	2019/06/26 12:35:46

AMERICAN OVERSIGHT

From:	Toles, Krystal M. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1156B622F1BA464FA61884615342FF18-TOLES, KRYS (b)(6) @va.gov>
To:	Copeland, Brittany R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0f1ebffbc694bb09b048ce0f296763e-Copeland, B (b)(6) @va.gov>
CC:	VHA 10B /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e8da02703bf40af822fcc49b8463979-VHA 10B <vha10b@va.gov>
Subject:	RE: 4- Corners Briefing on VA Formulary Process
Date:	2019/06/26 12:28:47
Priority:	Normal
Type:	Note

Thanks, Brittany. This is cleared.

From: Copeland, Brittany R.
Sent: Wednesday, June 26, 2019 12:12 PM
To: Toles, Krystal M. <(b6) @va.gov>
Cc: VHA 10B <vha10b@va.gov>
Subject: FW: 4- Corners Briefing on VA Formulary Process

Hi Krystal,

For clearance, please see the attached slides for the upcoming 4 Corners briefing regarding the VA formulary process. SME clearance is also requested for Dr. Maria Llorente to participate, as she has been added as a presenter.

Thank you,

Brittany R. Copeland, MHA
Health System Specialist
Office of the VHA Chief of Staff (10B)
810 Vermont Ave NW | Washington, DC 20420
o: (b)(6) | c(b)(6)

From: Brooks, Aja
Sent: Wednesday, June 26, 2019 11:43 AM
To: Law, Cassandra M. (b)(6) @va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; VHA 10B <vha10b@va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Subject: FW: 4- Corners Briefing on VA Formulary Process

OCLA acknowledges receipt, adding VHA 10B for clearance.

OCLA also request Dr. Maria Llorente be cleared to attend this briefing.

AMERICAN OVERSIGHT

v/r
AJ

From: Law, Cassandra M.
Sent: Wednesday, June 26, 2019 11:35 AM
To: Brooks, Aja <(b)(6) @va.gov>; VHA 10B3 Legislative Team <VHA10B3LegislativeTeam@va.gov>
Cc: VHA 10P Actions <VHA10PActions@va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>
Subject: FW: 4- Corners Briefing on VA Formulary Process

Good morning Aja.

10P clears the attached PPT to support the 4 corners briefing.

Please Note: Dr. Maria Llorente's (ADUSH for PCS) name has been added to the title slide and she and Mr. Mike Valentino, Pharmacy Benefits Management will both participate in the briefing.

Thank you, Cassie

-----Original Message-----
From: Brooks, Aja
Sent: Monday, June 24, 2019 10:42 AM
To: VHA 10P Actions <VHA10PActions@va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Subject: RE: 4- Corners Briefing on VA Formulary Process

Good morning, VHA 10P

OCLA request Michael Valentino and Thomas Emmendorfer to brief the 4-Corners on VA's formulary process, including an overview of the drug Spravato. Please list availabilities of the above mentioned SME's for the week of:

June 25 -28
July 1 - 3
OR
July 9, - 1 -3pm

v/r
AJ

-----Original Message-----
From: Melendrez, Dahlia (Veterans Affairs) <(b)(6) @vetaff.senate.gov>
Sent: Friday, June 21, 2019 8:41 AM
To: Brooks, Aja (b)(6) @va.gov>
Cc: Campbell, Leslie (Veterans Affairs) (b)(6) @vetaff.senate.gov>; Workman, Jillian (Veterans Affairs) (b)(6) @vetaff.senate.gov>; Friedl, Sophia (Veterans Affairs)

AMERICAN OVERSIGHT

(b)(6) @vetaff.senate.gov>; (b)(6) @mail.house.gov;
(b)(6) @mail.house.gov
Subject: [EXTERNAL] Briefing on formulary process

Hi AJ -

We'd appreciate a briefing on VA's process to consider, deliberate and add drugs to its formulary. In particular, we'd like an overview of the drug Spravato - we understand it's under consideration. Sometime in the next two weeks would be great.

Thanks,
Dahlia

Sent from my iPhone

Sender:	Toles, Krystal M. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1156B622F1BA464FA61884615342FF18-TOLES, KRYS (b)(6) @va.gov>
Recipient:	Copeland, Brittany R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0f1ebffbc694bb09b048ce0f296763e-Copeland, B (b)(6) @va.gov>; VHA 10B /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e8da02703bf40af822fcc49b8463979-VHA 10B <vha10b@va.gov>
Sent Date:	2019/06/26 12:28:46
Delivered Date:	2019/06/26 12:28:47
Message Flags:	Unread

AMERICAN OVERSIGHT

From:	Llorente, Maria D. </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F5C91F577D894BD9A0F09305DB34DD4F-LLORENTE, M>
To:	Smith, Avery /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9471c2d02a8b472b8543e09cb140085f-Smith, Aver (b)(6) @va.gov>; Hastings, Patricia R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a504fbfe766048a5a65461c45f28e9de-Hastings, P (b)(6) @va.gov>; VHA 10P4 PCS Clearance /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fff83d687b9d4fa78cd996960409675b-VHA 10P4 PC <VHA10P4PCSClearance@va.gov>
Subject:	RE: 4- Corners Briefing on VA Formulary Process
Date:	2019/06/26 10:01:00
Priority:	Normal
Type:	Note

Yes, cleared to go forward. Mike Valentino incorporated the changes we discussed.

From: Smith, Avery
Sent: Wednesday, June 26, 2019 8:24 AM
To: Hastings, Patricia R. (b)(6) @va.gov>; VHA 10P4 PCS Clearance <VHA10P4PCSClearance@va.gov>; Llorente, Maria D. (b)(6) @va.gov>
Subject: RE: 4- Corners Briefing on VA Formulary Process

Dr. Hastings per your comments from yesterday below and your call, was check to see if Dr Llorente is okay for submission?

From: Hastings, Patricia R.
Sent: Wednesday, June 26, 2019 8:14 AM
To: Smith, Avery (b)(6) @va.gov>; VHA 10P4 PCS Clearance <VHA10P4PCSClearance@va.gov>; Llorente, Maria D. (b)(6) @va.gov>
Subject: RE: 4- Corners Briefing on VA Formulary Process

Yes.
pat

From: Smith, Avery
Sent: Wednesday, June 26, 2019 7:54 AM
To: Hastings, Patricia R. (b)(6) @va.gov>; VHA 10P4 PCS Clearance <VHA10P4PCSClearance@va.gov>; Llorente, Maria D. (b)(6) @va.gov>
Subject: RE: 4- Corners Briefing on VA Formulary Process

Good Morning

Checking status, is this ready for submission?

Thank you

AMERICAN OVERSIGHT

Avery

From: Hastings, Patricia R.
Sent: Tuesday, June 25, 2019 4:29 PM
To: Smith, Avery <(b)(6) @va.gov>; VHA 10P4 PCS Clearance <VHA10P4PCSClearance@va.gov>
Cc: Llorente, Maria D. <(b)(6) @va.gov>
Subject: RE: 4- Corners Briefing on VA Formulary Process

Avery,
I am leaving this for Dr. Llorente to approve as she is attending as a briefer with Mike.
pat

From: Smith, Avery
Sent: Tuesday, June 25, 2019 4:26 PM
To: VHA 10P4 PCS Clearance <VHA10P4PCSClearance@va.gov>
Cc: Hastings, Patricia R. <(b)(6) @va.gov>; Llorente, Maria D. (b)(6) @va.gov>
Subject: FW: 4- Corners Briefing on VA Formulary Process
Importance: High

For clearance forward through 10P to OCLA

Request:
We'd appreciate a briefing on VA's process to consider, deliberate and add drugs to its formulary. In particular, we'd like an overview of the drug Spravato - we understand it's under consideration. Sometime in the next two weeks would be great.)

Response:
Please see the attached PPT to support the 4 corners briefing **(**

NOTE: Dr. Maria Llorente's (ADUSH for PCS) name has been added to the title slide and she and Mr. Mike Valentino, Pharmacy Benefits Management will both participate in the briefing.

10P

Request:
OCLA request Michael Valentino and Thomas Emmendorfer to brief the 4-Corners on VA's formulary process, including an overview of the drug Spravato. Please list availabilities of the above mentioned SME's for the week of:

June 25 -28
July 1 – 3
OR
July 9, - 1 -3pm

AMERICAN OVERSIGHT

Response:
Please see availability below:

June 25 -28 Mike Valentino is available the 27th and 28th but Tom Emmendorfer is on leave this week and not available.
July 1 – 3 Both are available the 1st and 2nd
OR
July 9, - 1 -3pm Both are available

Thank you

From: Sandifer, Estella (Maria)
Sent: Monday, June 24, 2019 10:50 AM
To: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Cc: VHA 10P Actions <VHA10PActions@va.gov>
Subject: FW: 4- Corners Briefing on VA Formulary Process

10P4,

Please see the request below and provide availabilities to 10P no later than 3 p.m., today.

Request:
OCLA request Michael Valentino and Thomas Emmendorfer to brief the 4-Corners on VA's formulary process, including an overview of the drug Spravato. Please list availabilities of the above mentioned SME's for the week of:

June 25 -28 I am available the 27th and 28th but Tom is on leave this week and not available.
July 1 – 3 We are both available the 1st and 2nd
OR
July 9, - 1 -3pm We are both available

V/r,

Maria Sandifer
Office of the Deputy Under Secretary for Health
for Policy and Services (10P)
Work ph: (202) 461-7413
Cell: (b)(6)
Email: (b)(6) @va.gov

AMERICAN OVERSIGHT

-----Original Message-----
From: Brooks, Aja
Sent: Monday, June 24, 2019 10:42 AM
To: VHA 10P Actions <VHA10PActions@va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Subject: RE: 4- Corners Briefing on VA Formulary Process

Good morning, VHA 10P

OCLA request Michael Valentino and Thomas Emmendorfer to brief the 4-Corners on VA's formulary process, including an overview of the drug Spravato. Please list availabilities of the above mentioned SME's for the week of:

June 25 -28
July 1 - 3
OR
July 9, - 1 -3pm

v/r
AJ

-----Original Message-----
From: Melendrez, Dahlia (Veterans Affairs) <(b)(6) @vetaff.senate.gov>
Sent: Friday, June 21, 2019 8:41 AM
To: Brooks, Aja (b)(6) @va.gov>
Cc: Campbell, Leslie (Veterans Affairs) (b)(6) @vetaff.senate.gov>; Workman, Jillian (Veterans Affairs) <(b)(6) @vetaff.senate.gov>; Friedl, Sophia (Veterans Affairs) (b)(6) @vetaff.senate.gov>;(b)(6) @mail.house.gov; (b)(6) @mail.house.gov
Subject: [EXTERNAL] Briefing on formulary process

Hi AJ -

We'd appreciate a briefing on VA's process to consider, deliberate and add drugs to its formulary. In particular, we'd like an overview of the drug Spravato - we understand it's under consideration. Sometime in the next two weeks would be great.

Thanks,
Dahlia

Sent from my iPhone

Sender:	Llorente, Maria D. </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F5C91F577D894BD9A0F09305DB34DD4F-LLORENTE, M>
Recipient:	Smith, Avery /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9471c2d02a8b472b8543e09cb140085f-Smith, Aver

AMERICAN OVERSIGHT

	(b)(6) @va.gov>; Hastings, Patricia R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a504fbfe766048a5a65461c45f28e9de-Hastings, P (b)(6) @va.gov>; VHA 10P4 PCS Clearance /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fff83d687b9d4fa78cd996960409675b-VHA 10P4 PC <VHA10P4PCSClearance@va.gov>
Sent Date:	2019/06/26 10:01:54
Delivered Date:	2019/06/26 10:01:00

AMERICAN OVERSIGHT

From:	Hastings, Patricia R. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A504FBFE766048A5A65461C45F28E9DE-HASTINGS, P (b)(6) @va.gov>
To:	Smith, Avery /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9471c2d02a8b472b8543e09cb140085f-Smith, Aver <(b)(6) @va.gov>; VHA 10P4 PCS Clearance /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fff83d687b9d4fa78cd996960409675b-VHA 10P4 PC <VHA10P4PCSClearance@va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M (b)(6) @va.gov>
Subject:	RE: 4- Corners Briefing on VA Formulary Process
Date:	2019/06/26 08:28:02
Priority:	Normal
Type:	Note

Yes, Dr. Llorente will review before it is final final as she is a briefer with Mike Valentino.
pat

From: Smith, Avery
Sent: Wednesday, June 26, 2019 8:24 AM
To: Hastings, Patricia R. (b)(6) @va.gov>; VHA 10P4 PCS Clearance <VHA10P4PCSClearance@va.gov>; Llorente, Maria D. (b)(6) @va.gov>
Subject: RE: 4- Corners Briefing on VA Formulary Process

Dr. Hastings per your comments from yesterday below and your call, was check to see if Dr Llorente is okay for submission?

From: Hastings, Patricia R.
Sent: Wednesday, June 26, 2019 8:14 AM
To: Smith, Avery <(b)(6) @va.gov>; VHA 10P4 PCS Clearance <VHA10P4PCSClearance@va.gov>; Llorente, Maria D. <(b)(6) @va.gov>
Subject: RE: 4- Corners Briefing on VA Formulary Process

Yes.
pat

From: Smith, Avery
Sent: Wednesday, June 26, 2019 7:54 AM
To: Hastings, Patricia R. <(b)(6) @va.gov>; VHA 10P4 PCS Clearance <VHA10P4PCSClearance@va.gov>; Llorente, Maria D. (b)(6) @va.gov>
Subject: RE: 4- Corners Briefing on VA Formulary Process

Good Morning

Checking status, is this ready for submission?

AMERICAN OVERSIGHT

Thank you

Avery

From: Hastings, Patricia R.
Sent: Tuesday, June 25, 2019 4:29 PM
To: Smith, Avery <(b)(6) @va.gov>; VHA 10P4 PCS Clearance <VHA10P4PCSClearance@va.gov>
Cc: Llorente, Maria D. (b)(6) @va.gov>
Subject: RE: 4- Corners Briefing on VA Formulary Process

Avery,
I am leaving this for Dr. Llorente to approve as she is attending as a briefer with Mike.
pat

From: Smith, Avery
Sent: Tuesday, June 25, 2019 4:26 PM
To: VHA 10P4 PCS Clearance <VHA10P4PCSClearance@va.gov>
Cc: Hastings, Patricia R.(b)(6) @va.gov>; Llorente, Maria D. (b)(6) @va.gov>
Subject: FW: 4- Corners Briefing on VA Formulary Process
Importance: High

For clearance forward through 10P to OCLA

Request:
We'd appreciate a briefing on VA's process to consider, deliberate and add drugs to its formulary. In particular, we'd like an overview of the drug Spravato - we understand it's under consideration. Sometime in the next two weeks would be great.)

Response:
Please see the attached PPT to support the 4 corners briefing **(**

NOTE: Dr. Maria Llorente's (ADUSH for PCS) name has been added to the title slide and she and Mr. Mike Valentino, Pharmacy Benefits Management will both participate in the briefing.

10P

Request:
OCLA request Michael Valentino and Thomas Emmendorfer to brief the 4-Corners on VA's formulary process, including an overview of the drug Spravato. Please list availabilities of the above mentioned SME's for the week of:

June 25 -28
July 1 – 3

AMERICAN OVERSIGHT

OR
July 9, - 1 -3pm

Response:
Please see availability below:

June 25 -28 Mike Valentino is available the 27th and 28th but Tom Emmendorfer is on leave this week and not available.
July 1 – 3 Both are available the 1st and 2nd
OR
July 9, - 1 -3pm Both are available

Thank you

From: Sandifer, Estella (Maria)
Sent: Monday, June 24, 2019 10:50 AM
To: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Cc: VHA 10P Actions <VHA10PActions@va.gov>
Subject: FW: 4- Corners Briefing on VA Formulary Process

10P4,

Please see the request below and provide availabilities to 10P no later than 3 p.m., today.

Request:
OCLA request Michael Valentino and Thomas Emmendorfer to brief the 4-Corners on VA's formulary process, including an overview of the drug Spravato. Please list availabilities of the above mentioned SME's for the week of:

June 25 -28 I am available the 27th and 28th but Tom is on leave this week and not available.
July 1 – 3 We are both available the 1st and 2nd
OR
July 9, - 1 -3pm We are both available

V/r,

Maria Sandifer
Office of the Deputy Under Secretary for Health
for Policy and Services (10P)
Work ph: (b)(6)
Cell: (b)(6)

AMERICAN OVERSIGHT

Email: (b)(6) @va.gov

-----Original Message-----
From: Brooks, Aja
Sent: Monday, June 24, 2019 10:42 AM
To: VHA 10P Actions <VHA10PActions@va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Subject: RE: 4- Corners Briefing on VA Formulary Process

Good morning, VHA 10P

OCLA request Michael Valentino and Thomas Emmendorfer to brief the 4-Corners on VA's formulary process, including an overview of the drug Spravato. Please list availabilities of the above mentioned SME's for the week of:

June 25 -28
July 1 - 3
OR
July 9, - 1 -3pm

v/r
AJ

-----Original Message-----
From: Melendrez, Dahlia (Veterans Affairs) (b)(6) @vetaff.senate.gov>
Sent: Friday, June 21, 2019 8:41 AM
To: Brooks, Aja (b)(6) @va.gov>
Cc: Campbell, Leslie (Veterans Affairs)(b)(6) @vetaff.senate.gov>; Workman, Jillian (Veterans Affairs) (b)(6) @vetaff.senate.gov>; Friedl, Sophia (Veterans Affairs) (b)(6) @vetaff.senate.gov>;(b)(6) @mail.house.gov; (b)(6) @mail.house.gov
Subject: [EXTERNAL] Briefing on formulary process

Hi AJ -

We'd appreciate a briefing on VA's process to consider, deliberate and add drugs to its formulary. In particular, we'd like an overview of the drug Spravato - we understand it's under consideration. Sometime in the next two weeks would be great.

Thanks,
Dahlia

Sent from my iPhone

Sender:	Hastings, Patricia R. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A504FBFE766048A5A65461C45F28E9DE-HASTINGS, P

AMERICAN OVERSIGHT

	(b)(6) @va.gov>
Recipient:	Smith, Avery /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9471c2d02a8b472b8543e09cb140085f-Smith, Aver (b)(6) @va.gov>; VHA 10P4 PCS Clearance /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fff83d687b9d4fa78cd996960409675b-VHA 10P4 PC <VHA10P4PCSClearance@va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M (b)(6) @va.gov>
Sent Date:	2019/06/26 08:28:01
Delivered Date:	2019/06/26 08:28:02

AMERICAN OVERSIGHT

From:	Valentino, Michael (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO, (b)(6) @va.gov>
To:	Hastings, Patricia R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a504fbfe766048a5a65461c45f28e9de-Hastings, P (b)(6) @va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M (b)(6) @va.gov>
Subject:	RE: 4- Corners Briefing on VA Formulary Process
Date:	2019/06/25 08:00:23
Priority:	Normal
Type:	Note

Thanks Pat.....what I sent is not the current format....will make the changes

Sent with BlackBerry Work
(www.blackberry.com)

From: Hastings, Patricia R. (b)(6) @va.gov>
Date: Tuesday, Jun 25, 2019, 7:50 AM
To: Valentino, Michael (VACO) (b)(6) @va.gov>, Llorente, Maria D. (b)(6) @va.gov>
Subject: RE: 4- Corners Briefing on VA Formulary Process

Mike,

(b) (5)

pat

From: Valentino, Michael (VACO)
Sent: Monday, June 24, 2019 6:16 PM
To: Llorente, Maria D. (b)(6) @va.gov>
Cc: Hastings, Patricia R. (b)(6) @va.gov>
Subject: FW: 4- Corners Briefing on VA Formulary Process

(b) (5)

I took Tom's PPT and added the most recent milestones.

This is a rough draft.....happy to make any and all revisions suggested (I also need to update some of the info....took it from an old slide deck)

AMERICAN OVERSIGHT

Mike

<<File: VA PBM Formulary OverviewV2.pptx >>

From: Valentino, Michael (VACO)
Sent: Monday, June 24, 2019 11:39 AM
To: Smith, Avery *(b)(6)* @va.gov>; VHA 10P4P Action <vha10P4Paction@va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Subject: RE: 4- Corners Briefing on VA Formulary Process

Please see below.....

Mike

From: Smith, Avery
Sent: Monday, June 24, 2019 11:26 AM
To: VHA 10P4P Action <vha10P4Paction@va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Subject: FW: 4- Corners Briefing on VA Formulary Process

10P4P,

Please review the request below and provide response to **VHA 10P4 Actions before 1:30pm today June 24th.**

Thanks

Avery

From: Sandifer, Estella (Maria)
Sent: Monday, June 24, 2019 10:50 AM
To: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Cc: VHA 10P Actions <VHA10PActions@va.gov>
Subject: FW: 4- Corners Briefing on VA Formulary Process

10P4,

Please see the request below and provide availabilities to 10P no later than 3 p.m., today.

Request:

AMERICAN OVERSIGHT

OCLA request Michael Valentino and Thomas Emmendorfer to brief the 4-Corners on VA's formulary process, including an overview of the drug Spravato. Please list availabilities of the above mentioned SME's for the week of:

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July 1 – 3 We are both available the 1st and 2nd
OR
July 9, - 1 -3pm We are both available

V/r,

Maria Sandifer
Office of the Deputy Under Secretary for Health
for Policy and Services (10P)
Work ph: (b)(6)
Cell: (b)(6)
Email: (b)(6) @va.gov

-----Original Message-----
From: Brooks, Aja
Sent: Monday, June 24, 2019 10:42 AM
To: VHA 10P Actions <VHA10PActions@va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Subject: RE: 4- Corners Briefing on VA Formulary Process

Good morning, VHA 10P

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July 1 - 3
OR
July 9, - 1 -3pm

v/r
AJ

-----Original Message-----
From: Melendrez, Dahlia (Veterans Affairs) <(b)(6) @vetaff.senate.gov>
Sent: Friday, June 21, 2019 8:41 AM
To: Brooks, Aja <(b)(6) @va.gov>
Cc: Campbell, Leslie (Veterans Affairs) <(b)(6) @vetaff.senate.gov>; Workman, Jillian (Veterans Affairs) <(b)(6) @vetaff.senate.gov>; Friedl, Sophia (Veterans Affairs)

AMERICAN OVERSIGHT

(b)(6) @vetaff.senate.gov>; (b)(6) @mail.house.gov;
(b)(6) @mail.house.gov
Subject: [EXTERNAL] Briefing on formulary process

Hi AJ -

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Thanks,
Dahlia

Sent from my iPhone

Sender:	Valentino, Michael (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO, (b)(6) @va.gov>
Recipient:	Hastings, Patricia R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a504fbfe766048a5a65461c45f28e9de-Hastings, P (b)(6) @va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M (b)(6) @va.gov>
Sent Date:	2019/06/25 08:00:15
Delivered Date:	2019/06/25 08:00:23

AMERICAN OVERSIGHT

From:	Hastings, Patricia R. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A504FBFE766048A5A65461C45F28E9DE-HASTINGS, P (b)(6) @va.gov>
To:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>; VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>
CC:	Law, Cassandra M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f888d507d6c54eb5a92fc44199eb5838-Law, Cassan (b)(6) @va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M (b)(6) @va.gov>
Subject:	RE: 4- Corners Briefing on VA Formulary Process
Date:	2019/06/25 16:26:31
Priority:	Normal
Type:	Note

Mike,
It looks good.

(b) (5)

pat

From: Valentino, Michael (VACO)
Sent: Tuesday, June 25, 2019 4:14 PM
To: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Cc: Hastings, Patricia R. (b)(6) @va.gov>; Law, Cassandra M. (b)(6) @va.gov>; Llorente, Maria D. (b)(6) @va.gov>
Subject: RE: 4- Corners Briefing on VA Formulary Process

Please see the attached PPT to support the 4 corners briefing **(specific request: We'd appreciate a briefing on VA's process to consider, deliberate and add drugs to its formulary. In particular, we'd like an overview of the drug Spravato - we understand it's under consideration. Sometime in the next two weeks would be great.)**

NOTE: Dr. Llorente's name has been added to the title slide and she and I will both participate in the briefing.

Once reviewed and cleared by Dr. Llorente, it should be sent forward through channels to OCLA.

Thanks

Mike

AMERICAN OVERSIGHT

From: Valentino, Michael (VACO)
Sent: Monday, June 24, 2019 11:39 AM
To: Smith, Avery (b)(6) @va.gov>; VHA 10P4P Action <vha10P4Paction@va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Subject: RE: 4- Corners Briefing on VA Formulary Process

Please see below.....

Mike

From: Smith, Avery
Sent: Monday, June 24, 2019 11:26 AM
To: VHA 10P4P Action <vha10P4Paction@va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Subject: FW: 4- Corners Briefing on VA Formulary Process

10P4P,

Please review the request below and provide response to **VHA 10P4 Actions before 1:30pm today June 24th.**

Thanks

Avery

From: Sandifer, Estella (Maria)
Sent: Monday, June 24, 2019 10:50 AM
To: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Cc: VHA 10P Actions <VHA10PActions@va.gov>
Subject: FW: 4- Corners Briefing on VA Formulary Process

10P4,

Please see the request below and provide availabilities to 10P no later than 3 p.m., today.

Request:
OCLA request Michael Valentino and Thomas Emmendorfer to brief the 4-Corners on VA's formulary process, including an overview of the drug Spravato. Please list availabilities of the above mentioned SME's for the week of:

AMERICAN OVERSIGHT

June 25 -28 I am available the 27th and 28th but Tom is on leave this week and not available.
July 1 – 3 We are both available the 1st and 2nd
OR
July 9, - 1 -3pm We are both available

V/r,

Maria Sandifer
Office of the Deputy Under Secretary for Health
for Policy and Services (10P)
Work ph: (b)(6)
Cell: (b)(6)
Email: (b)(6) @va.gov

-----Original Message-----
From: Brooks, Aja
Sent: Monday, June 24, 2019 10:42 AM
To: VHA 10P Actions <VHA10PActions@va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Subject: RE: 4- Corners Briefing on VA Formulary Process

Good morning, VHA 10P

OCLA request Michael Valentino and Thomas Emmendorfer to brief the 4-Corners on VA's formulary process, including an overview of the drug Spravato. Please list availabilities of the above mentioned SME's for the week of:

June 25 -28
July 1 - 3
OR
July 9, - 1 -3pm

v/r
AJ

-----Original Message-----
From: Melendrez, Dahlia (Veterans Affairs) <(b)(6) @vetaff.senate.gov>
Sent: Friday, June 21, 2019 8:41 AM
To: Brooks, Aja (b)(6) @va.gov>
Cc: Campbell, Leslie (Veterans Affairs) <(b)(6) @vetaff.senate.gov>; Workman, Jillian (Veterans Affairs) <(b)(6) @vetaff.senate.gov>; Friedl, Sophia (Veterans Affairs) <(b)(6) @vetaff.senate.gov>; (b)(6) @mail.house.gov; (b)(6) @mail.house.gov
Subject: [EXTERNAL] Briefing on formulary process

AMERICAN OVERSIGHT

Hi AJ -

We'd appreciate a briefing on VA's process to consider, deliberate and add drugs to its formulary. In particular, we'd like an overview of the drug Spravato - we understand it's under consideration. Sometime in the next two weeks would be great.

Thanks,
Dahlia

Sent from my iPhone

Sender:	Hastings, Patricia R. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A504FBFE766048A5A65461C45F28E9DE-HASTINGS, P (b)(6) @va.gov>
Recipient:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>; VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>; Law, Cassandra M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f888d507d6c54eb5a92fc44199eb5838-Law, Cassan (b)(6) @va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M (b)(6) @va.gov>
Sent Date:	2019/06/25 16:26:29
Delivered Date:	2019/06/25 16:26:31
Message Flags:	Unread

AMERICAN OVERSIGHT

From:	Glassman, Peter A. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90608D43EF14423DB308FB6C71ED750B-GLASSMAN, P (b)(6) @va.gov>
To:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b)(6) @va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen (b)(6) @va.gov>
Subject:	RE: 4 Corners Briefing
Date:	2019/06/25 12:43:33
Priority:	Normal
Type:	Note

Got it. Actually I like what you just said below because it illustrates the thought process at the extremes How about something like:

(b) (5)

From: Valentino, Michael (VACO)
Sent: Tuesday, June 25, 2019 9:34 AM
To: Glassman, Peter A. (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) <(b)(6) @va.gov>
Subject: RE: 4 Corners Briefing

Thanks Pete.

(b) (5)

Maybe there is a better way to say it?

AMERICAN OVERSIGHT

From: Glassman, Peter A.
Sent: Tuesday, June 25, 2019 12:27 PM
To: Valentino, Michael (VACO) (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) (b)(6) @va.gov>
Subject: RE: 4 Corners Briefing

Also I might suggest that (b) (5)

(b) (5)

From: Valentino, Michael (VACO)
Sent: Tuesday, June 25, 2019 8:40 AM
To: Zacher, Jennifer L. (PBM) (b)(6) @va.gov>; Glassman, Peter A. (b)(6) @va.gov>
Subject: 4 Corners Briefing

Hi Jenn and Pete,

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I've drafted some slides and hope you can review them, correct any inaccuracies (especially about the composition of the MAP and VPE committees), add anything you think would he helpful (considering that they want me to use as FEW slides as possible) and send back to me?

Thanks in advance

Mike

Michael A. Valentino, R.Ph., MHSA
Chief Consultant, Pharmact Benefits Management Services
Department of Veterans Affairs
Room 982
810 Vermont Avenue NW
Washington DC

(b)(6)

Sender:	Glassman, Peter A. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90608D43EF14423DB308FB6C71ED750B-GLASSMAN, P (b)(6) @va.gov>
Recipient:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino,

AMERICAN OVERSIGHT

	(b)(6) @va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen (b)(6) @va.gov>
Sent Date:	2019/06/25 12:43:32
Delivered Date:	2019/06/25 12:43:33

AMERICAN OVERSIGHT

From:	Glassman, Peter A. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90608D43EF14423DB308FB6C71ED750B-GLASSMAN, P (b)(6) @va.gov>
To:	Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen (b)(6) @va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>
Subject:	RE: 4 Corners Briefing
Date:	2019/06/25 12:33:18
Priority:	Normal
Type:	Note

(b5)

From: Zacher, Jennifer L. (PBM)
Sent: Tuesday, June 25, 2019 9:20 AM
To: Valentino, Michael (VACO) (b)(6) @va.gov>; Glassman, Peter A. (b)(6) @va.gov>
Subject: RE: 4 Corners Briefing

Hi Mike,

(b5) Updated version is attached.

JZ

From: Valentino, Michael (VACO)
Sent: Tuesday, June 25, 2019 10:40 AM
To: Zacher, Jennifer L. (PBM) (b)(6) @va.gov>; Glassman, Peter A. (b)(6) @va.gov>
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Mike

Michael A. Valentino, R.Ph., MHSA

AMERICAN OVERSIGHT

Chief Consultant, Pharmact Benefits Management Services
Department of Veterans Affairs
Room 982
810 Vermont Avenue NW
Washington DC

(b)(6)

Sender:	Glassman, Peter A. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90608D43EF14423DB308FB6C71ED750B-GLASSMAN, P *(b)(6)* @va.gov>
Recipient:	Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen *(b)(6)* @va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, *(b)(6)* @va.gov>
Sent Date:	2019/06/25 12:33:17
Delivered Date:	2019/06/25 12:33:18

AMERICAN OVERSIGHT

From:	Valentino, Michael (VACO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO,>
To:	Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen (b)(6) @va.gov>; Glassman, Peter A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90608d43ef14423db308fb6c71ed750b-Glassman, P (b)(6) @va.gov>
Subject:	RE: 4 Corners Briefing
Date:	2019/06/25 12:23:00
Priority:	Normal
Type:	Note

Thanks jenn

From: Zacher, Jennifer L. (PBM)
Sent: Tuesday, June 25, 2019 12:20 PM
To: Valentino, Michael (VACO) (b)(6) @va.gov>; Glassman, Peter A. (b)(6) @va.gov>
Subject: RE: 4 Corners Briefing

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(b5) Updated version is attached.
JZ

From: Valentino, Michael (VACO)
Sent: Tuesday, June 25, 2019 10:40 AM
To: Zacher, Jennifer L. (PBM) (b)(6) @va.gov>; Glassman, Peter A. (b)(6) @va.gov>
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Mike

Michael A. Valentino, R.Ph., MHSA
Chief Consultant, Pharmact Benefits Management Services

AMERICAN OVERSIGHT

Department of Veterans Affairs
Room 982
810 Vermont Avenue NW
Washington DC

(b)(6)

Sender:	Valentino, Michael (VACO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO,>
Recipient:	Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen *(b)(6)* @va.gov>; Glassman, Peter A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90608d43ef14423db308fb6c71ed750b-Glassman, P *(b)(6)* @va.gov>
Sent Date:	2019/06/25 12:23:17
Delivered Date:	2019/06/25 12:23:00

AMERICAN OVERSIGHT

From:	Glassman, Peter A. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90608D43EF14423DB308FB6C71ED750B-GLASSMAN, P (b)(6) @va.gov>
To:	Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen (b)(6) @va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>
Subject:	RE: 4 Corners Briefing
Date:	2019/06/25 12:25:24
Priority:	Normal
Type:	Note

Was just completing the review—my comments attached.

(b5) [redacted]

From: Zacher, Jennifer L. (PBM)
Sent: Tuesday, June 25, 2019 9:20 AM
To: Valentino, Michael (VACO) (b)(6) @va.gov>; Glassman, Peter A. (b)(6) @va.gov>
Subject: RE: 4 Corners Briefing

Hi Mike,
(b5) [redacted] Updated version is attached.
JZ

From: Valentino, Michael (VACO)
Sent: Tuesday, June 25, 2019 10:40 AM
To: Zacher, Jennifer L. (PBM) (b)(6) @va.gov>; Glassman, Peter A. (b)(6) @va.gov>
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Thanks in advance

Mike

AMERICAN OVERSIGHT

Michael A. Valentino, R.Ph., MHSA
Chief Consultant, Pharmact Benefits Management Services
Department of Veterans Affairs
Room 982
810 Vermont Avenue NW
Washington DC

(b)(6)

Sender:	Glassman, Peter A. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90608D43EF14423DB308FB6C71ED750B-GLASSMAN, P *(b)(6)* @va.gov>
Recipient:	Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen *(b)(6)* @va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, *(b)(6)* @va.gov>
Sent Date:	2019/06/25 12:25:18
Delivered Date:	2019/06/25 12:25:24

AMERICAN OVERSIGHT

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AMERICAN OVERSIGHT

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AMERICAN OVERSIGHT

(b5)

AMERICAN OVERSIGHT

(b5)

AMERICAN OVERSIGHT

From:	Cassanova, Wendy C. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FBCEDADEA2FF414A9185F75239063865-CASSANOVA, (b)(6) @va.gov>
To:	Brooks, Aja /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5c59e6730234420da11251416b699f1c-Brooks, Aja (b)(6) @va.gov>
CC:	VHA 10B /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e8da02703bf40af822fcc49b8463979-VHA 10B <vha10b@va.gov>
Subject:	RE: 4 Corner Briefing Request - VA Formulary/ Spravato
Date:	2019/06/24 11:38:18
Priority:	Normal
Type:	Note

Hi Aja,

On behalf of Krystal Toles, 10B clears the SMEs below.

Michael Valentino, Chief Consultant, Pharmacy Benefits Management (PBM)
Thomas Emmendorfer, Deputy Chief Consultant, PBM

Thank you,

Wendy C. Cassanova
Office of the VHA Chief of Staff (10B)
Office: (b)(6)

From: Brooks, Aja
Sent: Monday, June 24, 2019 11:02 AM
To: VHA 10B <vha10b@va.gov>
Subject: 4 Corner Briefing Request - VA Formulary/ Spravato

VHA 10B –

OCLA request VHA 10B clear Michael Valentino and Thomas Emmendorfer to brief the 4-Corners on VA's formulary process, including an overview on the drug Spravato. OCLA will confirm a date within the next 2 weeks w/the SMEs.

June 26-28
July 1-3
Or
July 9, 1-3pm

v/r

AMERICAN OVERSIGHT

AJ

-----Original Message-----
From: Melendrez, Dahlia (Veterans Affairs) (b)(6) @vetaff.senate.gov>
Sent: Friday, June 21, 2019 8:41 AM
To: Brooks, Aja (b)(6) @va.gov>
Cc: Campbell, Leslie (Veterans Affairs) (b)(6) @vetaff.senate.gov>; Workman, Jillian (Veterans Affairs) (b)(6) @vetaff.senate.gov>; Friedl, Sophia (Veterans Affairs) (b)(6) @vetaff.senate.gov>; (b)(6) @mail.house.gov; (b)(6) @mail.house.gov
Subject: [EXTERNAL] Briefing on formulary process

Hi AJ -

We'd appreciate a briefing on VA's process to consider, deliberate and add drugs to its formulary. In particular, we'd like an overview of the drug Spravato - we understand it's under consideration. Sometime in the next two weeks would be great.

Thanks,
Dahlia

Sent from my iPhone

AJ Brooks, JD, HCISPP
Congressional Relations Officer
Office of Congressional &Legislative Affairs
Department of Veterans Affairs
(b)(6) @va.gov
Office (b)(6)
Cell: (b)(6)

Sender:	Cassanova, Wendy C. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FBCEDADEA2FF414A9185F75239063865-CASSANOVA, (b)(6) @va.gov>
Recipient:	Brooks, Aja /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5c59e6730234420da11251416b699f1c-Brooks, Aja (b)(6) @va.gov>; VHA 10B /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e8da02703bf40af822fcc49b8463979-VHA 10B <vha10b@va.gov>
Sent Date:	2019/06/24 11:38:17
Delivered Date:	2019/06/24 11:38:18
Message Flags:	Unread

AMERICAN OVERSIGHT

AMERICAN OVERSIGHT

From:	Toles, Krystal M. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1156B622F1BA464FA61884615342FF18-TOLES, KRYS (b)(6) @va.gov>
To:	Cassanova, Wendy C. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbcedadea2ff414a9185f75239063865-Cassanova, (b)(6) @va.gov>
CC:	VHA 10B /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e8da02703bf40af822fcc49b8463979-VHA 10B <vha10b@va.gov>
Subject:	RE: 4 Corner Briefing Request - VA Formulary/ Spravato
Date:	2019/06/24 11:34:52
Priority:	Normal
Type:	Note

Thanks, Wendy. SMEs are cleared.

From: Cassanova, Wendy C.
Sent: Monday, June 24, 2019 11:15 AM
To: Toles, Krystal M. (b)(6) @va.gov>
Cc: VHA 10B <vha10b@va.gov>
Subject: FW: 4 Corner Briefing Request - VA Formulary/ Spravato

Hi Krystal,

For clearance, Michael Valentino, Chief Consultant, Pharmacy Benefits Management (PBM), and Thomas Emmendorfer, Deputy Chief Consultant, PBM, to brief the 4-Corners on VA's formulary process, including an overview on the drug Spravato. OCLA will confirm a date within the next 2 weeks w/the SMEs.

Thank you,

Wendy C. Cassanova
Office of the VHA Chief of Staff (10B)
Office: (b)(6)

From: Brooks, Aja
Sent: Monday, June 24, 2019 11:02 AM
To: VHA 10B <vha10b@va.gov>
Subject: 4 Corner Briefing Request - VA Formulary/ Spravato

VHA 10B –

OCLA request VHA 10B clear Michael Valentino and Thomas Emmendorfer to brief the 4-Corners on VA's formulary process, including an overview on the drug Spravato. OCLA will confirm a date within the next 2 weeks w/the SMEs.

June 26-28

AMERICAN OVERSIGHT

July 1-3
Or
July 9, 1-3pm

v/r
AJ

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Sent: Friday, June 21, 2019 8:41 AM
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Sent from my iPhone

AJ Brooks, JD, HCISPP
Congressional Relations Officer
Office of Congressional &Legislative Affairs
Department of Veterans Affairs
(b)(6) @va.gov
Office: (b)(6)
Cell: (b)(6)

Sender:	Toles, Krystal M. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1156B622F1BA464FA61884615342FF18-TOLES, KRYS (b)(6) @va.gov>
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AMERICAN OVERSIGHT

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Sent Date:	2019/06/24 11:34:52
Message Flags:	Unread

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From:	Lahl, Dennis /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=39FBA8EA7CD941B3A0A4F79CA3C6EE87-LAHL, DENNI (b)(6) va.gov>
To:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>
CC:	Law, Cassandra M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f888d507d6c54eb5a92fc44199eb5838-Law, Cassan (b)(6) @va.gov>; VHA 10P4 Chief Consultants /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a87c5f11e8414617ac89553ec0973f08-VHA 10P4 Ch <VHA10P4ChiefConsultants@va.gov>; VHA 10P4 Communication Group /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4ba2ff9b4604547be7834a71415253c-VHA 10P4 Co <vha10p4comm@va.gov>; Costa, Francis R. (Frank) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce3e48b6fbcf4b40b30be399fb389ed4-Costa, Fran (b)(6) @va.gov>; Utech, Anne E. (HOU) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=da5fd2ae604b4384b33d451c137c3bae-Utech, Anne (b)(6) @va.gov>; Morgan, Mark (NOLA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e93d04bca2648b78a574942c6412a4f-Morgan, Mar (b)(6) @va.gov>
Subject:	RE: 26 August Veterans Affairs Media Summary and News Clips
Date:	2019/08/26 07:25:02
Priority:	Normal
Type:	Note

My apologies forgot the other 2 attachments.

Dennis

Dennis Lahl FAC-P/PM
Office of the Assistant Deputy Under Secretary for Health for Patient Care Services (10P4)
VACO PCS IT/BCAG/ISO Liaison
TMS OPCS DM
ph: (b)(6)
fax: 202-273-5483
Dennis Lahl

From: Lahl, Dennis
Sent: Monday, August 26, 2019 7:23 AM
To: Valentino, Michael (VACO) (b)(6) @va.gov>
Cc: Law, Cassandra M. (b)(6) @va.gov>; VHA 10P4 Chief Consultants <VHA10P4ChiefConsultants@va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>; Costa, Francis R. (Frank) (b)(6) @va.gov>; Utech, Anne E. (HOU) (b)(6) @va.gov>;

AMERICAN OVERSIGHT

Morgan, Mark (NOLA) (b)(6) @va.gov>
Subject: FW: 26 August Veterans Affairs Media Summary and News Clips

Morning,

The below are submitted FYSA:

August 24th:

- • President orders VA to purchase new drug – esketamine (1.4, 1.7), VA opens research center for Burn Pit related illness, Veterans have to ravel to cochlear implants, Physician Assistants fight for right to follow patients care in hospice facilities,

August 25th:

- • Exoskeleton helps Veteran walk again, local VAMC agrotherapy program, foundation raise funds for therapy golf course for Veterans, local VAMC honors women Veterans, local VAMC garden helps address food instability

August 26th:

- • Article highlighting "My Life My Story"

Dennis

August 24th

1.4 - The Atlantic: Trump Orders 'a Lot' of Ketamine for Depressed Veterans (23 August, James Hamblin, 22.4M uvm; Washington, DC)
President Donald Trump said on Wednesday that the government will purchase "a lot" of the drug esketamine, a derivative of ketamine. Though ketamine is known as a recreational hallucinogen, Trump asserted that a new nasal-spray derivative would be of great benefit to veterans with depression. As he left the White House for a veterans' conference in Kentucky, he told reporters that he had instructed the Department of Veterans Affairs to make a large purchase—overriding a recent decision by the doctors who manage the hospitals' formulary of which drugs are to be prescribed.

Hyperlink to Above

1.7 - Government Executive: Trump Told the VA to Order 'a Lot' of Ketamine for Vets (23 August, James Hamblin, 250k uvm; Washington, DC)
President Donald Trump said on Wednesday that the government will purchase "a lot" of the drug esketamine, a derivative of ketamine. Though ketamine is known as a recreational hallucinogen, Trump asserted that a new nasal-spray derivative would be of great benefit to veterans with depression.

Hyperlink to Above

1.5 - Military.com: After Mandate from Congress, VA Opens Research Center for Burn Pit-Related Illnesses (23 August, Patricia Kime, 4.3M uvm; San Francisco, CA)
The Department of Veterans Affairs is increasing its focus on health conditions linked to burn pits and other airborne pollution in combat zones, establishing a "center of excellence" to better understand the extent of related illnesses and treatments for affected veterans.

AMERICAN OVERSIGHT

Hyperlink to Above

2.1 - Reuters: VA facilities offering cochlear implants to vets are few and far between (23 August, Lisa Rapaport, 24.6M uvm; New York, NY)
Even though American veterans are at high risk for the type of hearing loss that may be improved with cochlear implants, many of them live hours from a VA facility that provides cochlear implant services, a U.S. study suggests.

Hyperlink to Above

2.3 - Medscape: PAs Fight for Right to Follow Patients Into Hospice (23 August, Ingrid Hein, 8.9M uvm; New York, NY)
"Every day I see someone we should have seen sooner," said Judy Knudson, PA-C, MPAS, Hospice and Palliative Medicine, University of Colorado Hospital, Aurora. She recalls a Veterans Affairs (VA) patient she saw briefly after treatment. His cancer therapy was ending, and he was preparing to die.

Hyperlink to Above

August 25th

2.6 - Kearney Hub: Device helps Lawter, a paraplegic, take first steps in 25 years (24 August, Mary Jane Skala, 71k uvm; Kearney, NE)
Tammy Lawter struggled to hold back tears. Paralyzed from the chest down 25 years ago, she slowly took her first steps this summer with the assistance of a device called an Indego Exoskeleton. “I couldn’t feel my legs, so it was kind of weird, but it felt really good,” she said. “It was tempting to stare at my feet to see if they were moving. I was trying hard not to cry, but if I cried, I knew I wouldn’t be able to see.”

Hyperlink to Above

6.1 - U.S. News &World Report (AP): Veterans Program Yields More Than Just Honey (24 August, Michelle James, 23.3M uvm; Washington, DC)
For 10 days, Ed Forney chatted with each visitor who passed by his table at the West Virginia Grown Country Store at the State Fair of West Virginia. Forney's display attracted a lot of attention, too. Turns out, fairgoers have quite the sweet tooth and there isn't much sweeter — even at the state fair, where food lurks around every corner — than a bottle of honey.

Hyperlink to Above

6.3 - WSAW (CBS-7, Video): Simcakoski Foundation raises money for therapy golf course for veterans (24 August, Stella Porter, 212k uvm; Wausau, WI)
About 150 golfers hit the links at the Glacier Wood Golf Club in Iola on Saturday, playing a round to raise money for the Simcakoski Foundation as a part of their second annual golf outing. The foundation works to help veterans receive proper mental healthcare.

Hyperlink to Above

6.5 - WYOU (CBS-22, Video): Female veterans honored for their service (24 August, Morgan Parrish, 117k uvm; Wilkes Barre, PA)

AMERICAN OVERSIGHT

Pennsylvania is home to the fourth-largest veteran population in the country. Female veterans, who account for roughly eight percent of that population, were honored Saturday morning for their service. Dozens of community members gathered at the Wilkes-Barre VA Center Saturday morning for a women veterans town hall and expo.

Hyperlink to Above

6.11 - The Sheridan Press: Feeding communities: Program helps bridge gap for affordable food (24 August, Claire Schnatterbeck, 18k uvm; Sheridan, WY)
When looking for food on a slim budget, people don't usually turn to the fruit and vegetable section of a grocery store or seek organic produce. Sometimes, when food instability is affecting families, healthy food and cheap food seem mutually exclusive. However, the Cent$able Nutrition program through University of Wyoming Extension at Sheridan College is looking...

Hyperlink to Above

August 26

1.4 - Forbes: A Novel Program at VA Hospitals Uses An Old-World Tradition To Advance Patient Care (25 August, Carmine Gallo, 59.9M uvm; New York, NY)
Humans are hardwired for narrative. We think in story, talk in story and connect with others through the power of story. Storytelling is at the heart of a novel program that's expanding across VA medical facilities across the country.

Hyperlink to Above

Dennis Lahl FAC-P/PM

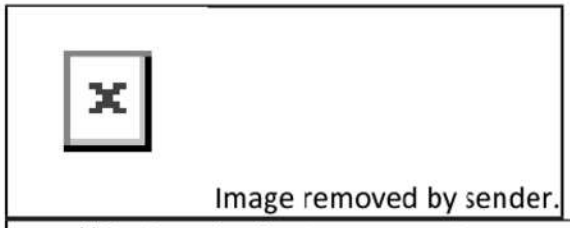
Office of the Assistant Deputy Under Secretary for Health for Patient Care Services (10P4)
VACO PCS IT/BCAG/ISO Liaison
TMS OPCS DM
ph: *(b)(6)*
fax: 202-273-5483
Dennis Lahl

From: VA Media Analysis <VAMediaAnalysis@barbaricum.com>
Sent: Monday, August 26, 2019 5:17 AM
To: Barbaricum VA Media Analysis <VAMediaAnalysis@barbaricum.com>
Subject: [EXTERNAL] 26 August Veterans Affairs Media Summary and News Clips

Good morning,

AMERICAN OVERSIGHT

Please find the attached Veterans Affairs Media Summary and News Clips.



Sender:	Lahl, Dennis /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=39FBA8EA7CD941B3A0A4F79CA3C6EE87-LAHL, DENNI (b)(6) @va.gov>
Recipient:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>; Law, Cassandra M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f888d507d6c54eb5a92fc44199eb5838-Law, Cassan (b)(6) @va.gov>; VHA 10P4 Chief Consultants /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a87c5f11e8414617ac89553ec0973f08-VHA 10P4 Ch <VHA10P4ChiefConsultants@va.gov>; VHA 10P4 Communication Group /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4ba2ff9b4604547be7834a71415253c-VHA 10P4 Co <vha10p4comm@va.gov>; Costa, Francis R. (Frank) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce3e48b6fbcf4b40b30be399fb389ed4-Costa, Fran (b)(6) @va.gov>; Utech, Anne E. (HOU) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=da5fd2ae604b4384b33d451c137c3bae-Utech, Anne (b)(6) @va.gov>; Morgan, Mark (NOLA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e93d04bca2648b78a574942c6412a4f-Morgan, Mar (b)(6) @va.gov>
Sent Date:	2019/08/26 07:24:59
Delivered Date:	2019/08/26 07:25:02
Message Flags:	Unread

AMERICAN OVERSIGHT

1. Top Stories

1.1 - The New York Times (AP): AP Fact Check: Trump's Swerves on Economy, Guns and Migrants (24 August, 98.3M uvm; New York, NY)
President Donald Trump can't seem to get his facts straight when it comes to Barack Obama. From the economy to veterans and immigration, Trump routinely claims achievements of the former president as fully his own or distorts the truth to undermine the Democrat's legacy. On problems uniquely his own, Trump deflects.

Hyperlink to Above

1.2 - WPEC (CBS-12, Video): Report finds local VA leaders 'lacked awareness' ahead of veteran's suicide (25 August, Jay O'Brien, 442k uvm; West Palm Beach, FL)
A recent report from government investigators found leaders at the West Palm Beach Veteran's Administration Hospital "lacked awareness" about aspects of patient safety, in the wake of a soldier's suicide in March 2019. Additionally, the report found several lapses in protocol by hospital staff, including security cameras that were out of work "for years."

Hyperlink to Above

1.3 - Charleston Gazette-Mail: Veteran's death ruled homicide amid investigation into deaths at VA hospital (24 August, Lacie Pierson, 202k uvm; Charleston, WV)
A Ritchie County woman says her father was one of about 10 patients who died at the Veterans Affairs medical center in Clarksburg after they were wrongfully injected with insulin by a person who is known to federal administrators through an investigation into the deaths. A deputy medical examiner with the U.S. Department of Defense ruled the death of Felix "Kirk" McDermott a homicide…

Hyperlink to Above

2. Improving Customer Service

2.1 - KDKA (CBS-2, Video): Westmoreland County Man's Death Ruled A Homicide After VA Hospital Treatment In West Virginia (24 August, Bob Allen, 1.2M uvm; Pittsburgh, PA)
The death of a military veteran from Ruffs Dale in Westmoreland County is the subject of a wrongful death lawsuit following treatment at a veterans hospital. Retired Sergeant Felix McDermott died April 8, 2018, at the Loius A. Johnson VA Medical Center in Clarksburg, West Virginia after he was injected with a fatal dose of insulin while at the center, the complaint said.

Hyperlink to Above

2.2 - Daily Press: Aug. 24 Letters: Unions, ship building and the electoral college (23 August, 370k uvm; Newport News, VA)
VA union fight: It is often said that those who do not know their history, are doomed to repeat it. This is a dangerous time in our country for many groups of people. One group that should not be overlooked is labor unions. Unions help level the playing field. Labor unions are the reason we have child labor laws, health benefits, livable wages, weekends off, eight-hour work days, and safe working conditions.

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Hyperlink to Above

2.3 - The Columbian: **Seeking care for mental health a top frustration for vets** (24 August, Tatiana Parafiniuk-Talesnick, 309k uvm; Vancouver, WA)
Oregon veterans may be at lower risk for depression or sadness, but they are more likely to die from suicide and opioid overdose than nonveterans, according to a recent state study on veteran health. “We’re just so focused on the mission,” Laura Follett, a Springfield resident and a 15-year Navy veteran, said. “We’re not necessarily focused on ourselves, you know?”

Hyperlink to Above

2.4 - MetroNews: **Manchin, Capito call for investigations after claims of suspicious deaths at Clarksburg VA hospital** (23 August, Jeff Jenkins, 242k uvm; Charleston, WV)
Both U.S. Senators Joe Manchin and Shelley Moore Capito are calling for full investigations after learning of a claim that a patient at the VA Medical Center in Clarksburg was the victim of homicide while in the care of the hospital while also learning there may have been a number of other deaths with similar circumstances.

Hyperlink to Above

2.5 - KTVQ (CBS-2): **Montana VA announces new Chief of Staff** (24 August, 169k uvm; Billings, MT)
The Montana VA Health Care System welcomed Dr. JP Maganito as the new Chief of Staff on July 21, 2019. Dr. Maganito originally joined the Montana VA Health Care System, Fort Harrison in 2012, serving as the Staff Gynecologist and Occupational Health Medical Officer where he became the Women’s Health Medical Director until 2015.

Hyperlink to Above

2.6 - Kearney Hub: **Device helps Lawter, a paraplegic, take first steps in 25 years** (24 August, Mary Jane Skala, 71k uvm; Kearney, NE)
Tammy Lawter struggled to hold back tears. Paralyzed from the chest down 25 years ago, she slowly took her first steps this summer with the assistance of a device called an Indego Exoskeleton. “I couldn’t feel my legs, so it was kind of weird, but it felt really good,” she said. “It was tempting to stare at my feet to see if they were moving. I was trying hard not to cry, but if I cried, I knew I wouldn’t be able to see.”

Hyperlink to Above

2.7 - The Daily Sentinel: **Opioid Epidemic** (25 August, Joe Vaccarelli, 53k uvm; Grand Junction, CO)
Two years ago, Dr. Bill Hilty could count the opioid overdoses he'd see in a year on one hand. But as local hospitals, health care providers and dentists have reduced the number of opioids prescribed to patients, Hilty, the emergency department medical director for St. Mary's Medical Center, now sees an average of three overdoses per week coming into the hospital.

Hyperlink to Above

2.8 - The News-Review: **DeFazio discusses local healthcare challenges at town hall** (24 August, Carisa Cegavske, 50k uvm; Roseburg, OR)

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The federal government needs to do more to help the Roseburg Veterans Affairs Medical Center recruit and retain health care professionals, U.S. Rep. Peter DeFazio, D-Springfield, said Friday at a town hall meeting at Umpqua Community College. DeFazio spoke about a range of healthcare topics including the Affordable Care Act, Medicare for All and the problems that led to the closure of the VA's emergency department.

Hyperlink to Above

2.9 - WBOY (NBC-12): Filing against VA Medical Center in Clarksburg claims patient was the victim of homicide (23 August, Clarksburg, WV)
A lawyer representing the estate of a U.S. Army veteran who died from low blood sugar while at the Louis A. Johnson VA Medical Center in Clarksburg has filed a notice of claim with the U.S. Department of Veterans Affairs, alleging that the veteran died as a result of homicide. The claim also alleges that nine to 10 other patients died at the VA under similar circumstances.

Hyperlink to Above

3. Business Transformation

3.1 - Times & Democrat: New veterans' clinic coming (24 August, Dionne Gleaton, 158k uvm; Orangeburg, SC)
Dorn Veterans Affairs Medical Center is planning to build a new outpatient clinic in Orangeburg, just one of several construction projects for which the center has $160 million in funding. "A lessor has been selected for the Orangeburg CBOC (Community-Based Outpatient Clinic). This selection is undergoing legal review before award. The Orangeburg CBOC was approved for 24,000 square feet.

Hyperlink to Above

3.2 - The Exponent Telegram: Saturday Salutes (24 August, 133k uvm; Clarksburg, WV)
Editor's Note: The Exponent Telegram presents Saturday's Salutes in an effort to recognize the positive efforts of many throughout North Central West Virginia and the Mountain State… Those who made a new Community Living Center a reality at the Louis A. Johnson VA Medical Center.

Hyperlink to Above

4. DOD Cooperation / Electronic Health Records / MISSION Act Implementation

5. Suicide Prevention

5.1 - The Community Voice: Sept. is suicide prevention month (23 August, Irene Hilsendager, 2k uvm; Rohnert Park, CA)
Is suicide contagious? Suicide is the tenth leading cause of death in the United States for all ages. However, it seems suicide deaths for teenagers has increased as of late even though suicide has taken the lives of over 44,000 in the United States. Every year the highest suicide rate is in the United States and among them are Caucasian, American Indians and Alaska Natives.

Hyperlink to Above

AMERICAN OVERSIGHT

6. Women Veterans / Homelessness / Benefits / Cemeteries

6.1 - U.S. News & World Report (AP): Veterans Program Yields More Than Just Honey (24 August, Michelle James, 23.3M uvm; Washington, DC)
For 10 days, Ed Forney chatted with each visitor who passed by his table at the West Virginia Grown Country Store at the State Fair of West Virginia. Forney's display attracted a lot of attention, too. Turns out, fairgoers have quite the sweet tooth and there isn't much sweeter — even at the state fair, where food lurks around every corner — than a bottle of honey.

Hyperlink to Above

6.2 - Connecting Vets: New platform creates digital memorials for all veterans in national cemeteries (23 August, Abbie Bennett, 5.8M uvm; Washington, DC)
A new searchable online tool from the Department of Veterans Affairs and National Cemetery Administration allows creates digital memorials for fallen service members buried in national cemeteries across the United States. The Veterans Legacy Memorial is an online memorial space managed by the National Cemetery Administration, which oversees the 136 national cemeteries where 3.7 million veterans are interred.

Hyperlink to Above

6.3 - WSAW (CBS-7, Video): Simcakoski Foundation raises money for therapy golf course for veterans (24 August, Stella Porter, 212k uvm; Wausau, WI)
About 150 golfers hit the links at the Glacier Wood Golf Club in Iola on Saturday, playing a round to raise money for the Simcakoski Foundation as a part of their second annual golf outing. The foundation works to help veterans receive proper mental healthcare.

Hyperlink to Above

6.4 - The Herald-Dispatch: VA to host event on overdose awareness (24 August, 135k uvm; Huntington, WV)
International Overdose Awareness Day, a global event held each year to raise awareness of overdoses and reduce the stigma of a drug-related death, acknowledges the impact of drug use and the risk of opioid overdose, including individuals directly impacted, family and friends.

Hyperlink to Above

6.5 - WYOU (CBS-22, Video): Female veterans honored for their service (24 August, Morgan Parrish, 117k uvm; Wilkes Barre, PA)
Pennsylvania is home to the fourth-largest veteran population in the country. Female veterans, who account for roughly eight percent of that population, were honored Saturday morning for their service. Dozens of community members gathered at the Wilkes-Barre VA Center Saturday morning for a women veterans town hall and expo.

Hyperlink to Above

6.6 - KBAK (CBS-29): VA launches online memorial to honor deceased veterans of Bakersfield National Cemetery (24 August, 104k uvm; Bakersfield, CA)

AMERICAN OVERSIGHT

The VA has launched a new online program to honored deceased veterans. This week, the Bakersfield National Cemetery launched the Veterans Legacy Memorial. The memorial is the country first digital platform dedicated to the preservation of the memory of the 7,000 veterans buried at the cemetery.

Hyperlink to Above

6.7 - WCBD (NBC-2): Vietnam veteran evicted from apartment; people seen rummaging through belongings (23 August, 83k uvm; Mount Pleasant, SC)
A Carolina Forest veteran is headed to New York after an eviction. Veterans Outreach Program Specialist Chris Aranda, with the Department of Veterans Affairs, told WBTW the veteran, identified as Tom, was released from the hospital around 3 p.m. on Wednesday and was dropped off at a homeless shelter.

Hyperlink to Above

6.8 - Chillicothe Gazette: Local veteran awarded degree after leaving university 40 years ago (24 August, Toria Barnhart, 49k uvm; Chillicothe, OH)
One local veteran has dedicated his time to learning through audited classes and his children's textbooks after he was forced to leave university behind. But earlier this month, he finally received his degree after waiting for more than 40 years. Larry McKillip, a 74-year-old U.S. Navy veteran, was surprised by his family and faculty at the University of Louisville with his associates degree earlier this month.

Hyperlink to Above

6.9 - Palm Beach Daily News: Handyman spent 50 years working in Palm Beach; now he's living in a group home (23 August, Wendy Rhodes, 48k uvm; Palm Beach, FL)
Roger Colvard, recently diagnosed with terminal bone cancer, says he feels 'abandoned' One day, Roger Colvard lived in a $17 million mansion. The next, he was homeless. Colvard didn't exactly live inside the mansion — he lived in a two-room apartment above the garage until July 28. The house, named Southways, had been owned by the Gallant family for 50 years — the same amount of time Colvard said he worked as a handyman in Palm Beach.

Hyperlink to Above

6.10 - NorthCentralPA.com: Student Loan Debt for Totally and Permanently Disabled Veterans to be Forgiven (25 August, 32k uvm; Williamsport, PA)
Today, President Donald J. Trump signed a Presidential Memorandum that will significantly streamline the process to erase federal student loan debt for totally and permanently disabled veterans. Through a process called Total and Permanent Disability (TPD) Discharge, veterans will now have their student loan debt discharged unless they decide to opt-out of the process.

Hyperlink to Above

6.11 - The Sheridan Press: Feeding communities: Program helps bridge gap for affordable food (24 August, Claire Schnatterbeck, 18k uvm; Sheridan, WY)
When looking for food on a slim budget, people don't usually turn to the fruit and vegetable section of a grocery store or seek organic produce. Sometimes, when food instability is affecting families, healthy food and cheap food seem mutually exclusive. However, the Cent$able Nutrition program through University of Wyoming Extension at Sheridan College is looking…

AMERICAN OVERSIGHT

Hyperlink to Above

6.12 - My Buckhannon: **'This would mean everything to my mom': Vietnam veteran receives diploma 60 years after high school graduation** (24 August, Beth Christian Broschart, Buckhannon, WV)
Some people wait their entire lives to have their deepest wishes come true with no luck. Fortunately, the dream of a U.S. Army Vietnam Veteran and Purple Heart recipient with ties to Buckhannon was recently granted in July when he was 78 years old. Floyd Nimrod Covey lived in Upshur County and was enrolled in high school when he was drafted to serve his country in the Vietnam War; in fact, while serving his country, he missed his high school graduation.

Hyperlink to Above

6.13 - Cherokee Tribune & Ledger News: **Veteran-focused community eyed near national cemetery** (23 August, Donald Campbell, Canton, GA)
Dozens turned out this week to learn more about a proposed community geared toward veterans that would sit on 500 acres next to Georgia National Cemetery. The community room at Fire Station No. 22 in the BridgeMill community was packed with members of the public Wednesday evening to hear from developer Peter Sanders. For two hours, Sanders presented his proposed plans and answered questions from those attending the meeting.

Hyperlink to Above

6.14 - KOAM (CBS-7, Video): **"Wreath Ride" spurs patriotic convoy** (24 August, Kate Kelley, Pittsburg, KS)
Hundreds of bikers line Main Street, gearing up for a ride to support Wreaths Across America, but this year is particularly special because they're joined by all eight military wrapped CFI trucks, all driven by veterans themselves.

Hyperlink to Above

7. Other

7.1 - U.S. News & World Report (AP): **Veterans Band Together to Give Vietnam Vet a Proper Burial** (24 August, Mark Rice, 23.3M uvm; Washington, DC)
Billy Harold Watts was a decorated and disabled Vietnam War veteran. He had six children, 14 grandchildren and six great-grandchildren. After collapsing in early June while home alone in Marion County, the 70-year-old lost his battle with lung cancer on Father's Day in a Columbus hospice.

Hyperlink to Above

AMERICAN OVERSIGHT

Back to Top

1. Top Stories

1.1 - The New York Times (AP): AP Fact Check: Trump's Swerves on Economy, Guns and Migrants (24 August, 98.3M uvm; New York, NY)

WASHINGTON — President Donald Trump can't seem to get his facts straight when it comes to Barack Obama.

From the economy to veterans and immigration, Trump routinely claims achievements of the former president as fully his own or distorts the truth to undermine the Democrat's legacy. On problems uniquely his own, Trump deflects.

This past week was no different.

Fresh off vacation in Bedminster, New Jersey, and mindful of the 2020 campaign, Trump insisted that economists don't believe his trade disputes with China could spur recession even though most analysts believe a downturn could start in the next two years. He also claimed progress on veterans' health care under his watch that didn't happen and blamed Obama for a policy of separating migrant children from their parents that he himself started.

Trump repeatedly pointed to mental illness, not access to guns, as a main culprit behind the recent mass shootings in Texas and Ohio. That's oversimplifying the issue.

A recap, also covering fuel economy standards and judges:

[…]

TRUMP: "My administration has worked aggressively to boost veterans employment, and we're setting records. ... Veterans unemployment has reached the lowest level ever recorded." — remarks Wednesday at AMVETS convention in Louisville, Kentucky.

THE FACTS: It's true that the unemployment rate for veterans fell to 2.3% in April, matching the low set in May 2000 under President Bill Clinton. But this figure is volatile on a monthly basis, not adjusted for seasonal changes, and has since risen. The figure stood at 3.4% in July, according to the Labor Department.

Veterans' unemployment has fallen mostly for the same reasons that joblessness has dropped generally: strong hiring and steady economic growth over the past decade dating to the Obama administration.

[…]

VETERANS

TRUMP: "We are modernizing your medical records to begin a seamless transition from the Department of Defense into the VA — something that they just said they couldn't do. You know that, right? They said, 'We can't do it. It's just too complicated.' We did it." — AMVETS convention.

AMERICAN OVERSIGHT

THE FACTS: No, it's not done. The Department of Veterans Affairs last year signed a $10 billion contract with Cerner Corp., the same company that is overhauling the Pentagon's electronic health records; some $6 billion more will be needed for IT upgrades and program staff. But a full rollout of the new VA health records is expected to take 10 years.

The aim of the new system is to provide veterans easy access to their health records upon leaving active-duty service and when they receive medical treatment at a VA facility or a private doctor referred under the VA's Choice private-sector program.

The contract, one of the largest in VA's history, has drawn concern from lawmakers that it could be plagued with problems and ultimately prove ineffective.

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TRUMP: "The VA is now providing same-day emergency mental health care and mental health screenings to every patient that walks through the door." — AMVETS convention.

THE FACTS: Same-day mental health service started at VA before Trump took office in January 2017.

VA's effort to provide same-day primary and mental-health care when medically necessary at every VA medical center was publicized in April 2016, during the Obama administration. By late 2016, the department's blog announced that goal would be achieved by year's end.

A Dec. 23, 2016, article in the Harvard Business Review cites new same-day services at all VA hospitals as evidence of notable progress at the department. Former VA Secretary David Shulkin told Congress in late January 2017 the services already were fully in place.

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TRUMP: "Veterans Choice, as you've been trying to get that for 44 years, they say — 44 years. I guess it's longer than that; probably earlier than that. But for 44 years, at least, that we know of. And you got it." — AMVETS convention.

THE FACTS: You wouldn't know from Trump's boasting that it was Obama who won passage of the Veterans Choice program, which gives veterans the option to see private doctors outside the VA medical system at government expense. Congress approved the program in 2014, and Obama signed it into law. Trump expanded it. Its ultimate scope remains uncertain, in part because of questions of money.

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1.2 - WPEC (CBS-12, Video): Report finds local VA leaders 'lacked awareness' ahead of veteran's suicide (25 August, Jay O'Brien, 442k uvm; West Palm Beach, FL)

A recent report from government investigators found leaders at the West Palm Beach Veteran's Administration Hospital "lacked awareness" about aspects of patient safety, in the wake of a

soldier's suicide in March 2019. Additionally, the report found several lapses in protocol by hospital staff, including security cameras that were out of work "for years."

In a statement to CBS 12 News, the West Palm Beach VA said that "since the time of the review, the West Palm Beach VA Medical Center has taken action on all of the OIG's recommendations."

U.S. Army Sergeant Brieux Dash took his own life inside the West Palm Beach VA Hospital on March 14, 2019. After his death, Sgt. Dash's family told CBS 12 News they believe he was suffering from PTSD. Sgt. Dash served two tours in Iraq.

An investigation into the hospital by the VA's Office of the Inspector General (OIG) began five days later, naming an undisclosed patient's suicide as the purpose of the inquiry. The report was released August 22, 2019.

Investigators found that the unnamed patient received appropriate mental health care, after he was admitted to the hospital under Florida's Baker Act. Dash was admitted to the VA hospital under the Baker Act in the same time frame as the unnamed patient, after family contacted authorities saying they were concerned for his safety, according to his family.

However, the 48 page report also details that hospital staff lacked appropriate mental health training at the time they were treating Dash. Federal investigators found that less than half of hospital staff who required certain mental health training underwent the training.

"Only 44 percent of employees required to have [Mental Health Environment Care Checklist] training were in compliance," says the report.

Additionally, investigators found that security and patient safety cameras in one of the hospital's mental health units were not operational. The cameras, intended to monitor all patients, had not worked "for at least three years" due to a network crash in 2016, according to the OIG report.

"Had the cameras been functional and monitored as required by policy, an employee may have seen the patient preparing for the event,"
the report adds.

"You guys are supposed to be taking care of him," said Sherron Permashwar, Sgt. Dash's Aunt. "What happened?"

"We appreciate the Office of Inspector General's (OIG) oversight, which focuses on an event that occurred in March 2019. Any time an unexpected death occurs at a VA facility, a comprehensive review is conducted to see if changes in policies and procedures are warranted. OIG reviews are opportunities to strengthen our processes and the way we deliver care to America's Veterans," said a spokesperson for the West Palm Beach VA in a statement to CBS 12 News.

"We encourage any Veteran, family member or friend concerned about a Veteran's mental health to contact the Veterans Crisis Line at 1-800-273-8255 and press 1 or text 838255. Trained professionals are also available to chat at www.veteranscrisisline.net. The lines are available 24 hours a day, 7 days a week a week," added the VA spokesperson.

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1.3 - Charleston Gazette-Mail: **Veteran's death ruled homicide amid investigation into deaths at VA hospital** (24 August, Lacie Pierson, 202k uvm; Charleston, WV)

A Ritchie County woman says her father was one of about 10 patients who died at the Veterans Affairs medical center in Clarksburg after they were wrongfully injected with insulin by a person who is known to federal administrators through an investigation into the deaths.

A deputy medical examiner with the U.S. Department of Defense ruled the death of Felix "Kirk" McDermott a homicide during an investigation by the VA Inspector General's Office into the suspicious deaths of patients at the Louis A. Johnson VA Hospital, according to a statement of claim submitted to the U.S. Department of Veterans Affairs.

Investigators for Veterans Affairs have identified a person of interest in the case, but they have not disclosed the identity of that person to McDermott's family, and no criminal charges have been filed in the case, according to the claim.

The claim doesn't indicate whether the person of interest was an employee at the hospital.

The Gazette-Mail obtained a copy of the claim, filed by McDermott's daughter, Melanie Proctor. The claim addresses only the circumstances surrounding McDermott's death, but it refers to the investigation into his and other deaths.

According to the claim, medical staff did not tell McDermott's family how he died on April 9, 2018, when he was a patient being treated for pneumonia.

McDermott was a Vietnam veteran, and he retired as a sergeant to end a 20-year career in the U.S. Army. He subsequently served in the Pennsylvania National Guard.

"If the medical examiner's conclusion is correct, Felix 'Kirk' McDermott was murdered while he was in the care and custody of the Louis A. Johnson VA Medical Center despite the VAMC being on notice of the previous wrongful injections," said Proctor's attorney, Tony O'Dell, with Tiano O'Dell PLLC in Charleston.

O'Dell said on Friday that he was not aware of any claims filed on behalf of the other potential victims in the case.

The Gazette-Mail reached out to the Veterans Affairs Office of the Inspector General for comment, but an office representative declined to comment as to whether there was an investigation, citing office policy.

Sen. Joe Manchin, D-W.Va., issued a statement Friday, after news reports about the investigation were released, saying the reports were "shocking if accurate."

"I am appalled that these crimes were not only committed, but that our Veterans who have sacrificed so much for our country, were the victims," Manchin wrote. "As a member of the Senate Veterans Affairs Committee I will do everything in my power to investigate these accusations and get to the bottom of what happened. These families and loved ones deserve answers as soon as possible and I will make sure they get them."

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Proctor, who is the executor of McDermott's estate, is seeking monetary damages, including $7,500 for funeral expenses.

If McDermott's family and the government can't resolve the claim within six months, the family will have the ability to file a lawsuit in federal court.

McDermott died after he was injected with insulin while he was a patient at the hospital in April 2018, O'Dell said in the claim.

At the time of McDermott's death, employees at the hospital were aware of the "unexpected and suspicious" deaths from unexplained severe hypoglycemia.

"Each of these nine or ten patients had received a large and wrongful injection of insulin in the abdomen that was neither ordered by a doctor or medically necessary," the claim states.

McDermott did not suffer from diabetes, nor had he ever been diagnosed or taken medication for the condition, O'Dell said.

The other patients whose deaths are subject to the investigation also died as a result of being wrongfully injected with insulin in their abdomens, O'Dell said in the claim.

McDermott was admitted to the Clarksburg VA medical center on April 6, 2018, for pneumonia. At the time of his admission, he had been diagnosed with dementia and experienced a physical disability as a result of a stroke.

During his initial stay at the facility, McDermott's health condition improved, but he unexpectedly developed shortness of breath during the morning of April 9, 2018, O'Dell said.

A blood test showed McDermott was suffering from hypoglycemia, meaning his blood sugar was "critically and profoundly" low, and medical efforts to raise it were unsuccessful.

"His condition continued to worsen, and he died from severe hypoglycemia at roughly 9:00 a.m. on the morning of April 9, 2018," O'Dell said. "Employees of the VAMC never explained to Ret. Army Sgt. McDermott's family the unexplained diagnosis of hypoglycemia."

McDermott's family arranged funeral services for him, and he was buried on April 13, 2018.

On Oct. 23, 2018, McDermott's remains were disinterred and taken to Dover Air Force Base, Delaware, for an autopsy as part of the investigation into the suspicious deaths at the Clarksburg VA hospital. The deputy medical examiner who performed the autopsy determined that his cause of death was the insulin administration and said McDermott's manner of death was a homicide.

It was during the process of this investigation that Proctor and the rest of McDermott's family learned there was evidence that her father might have died as a result of the insulin injection and that her father was one of the last known victims to have died in that manner.

"It was not until months later [after McDermott died] that government investigators contacted Ret. Army Sgt. McDermott's daughter Melanie Proctor and advised her of the earlier deaths and their belief that her father's death was not a result of natural causes," O'Dell said.

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2. Improving Customer Service

2.1 - KDKA (CBS-2, Video): Westmoreland County Man's Death Ruled A Homicide After VA Hospital Treatment In West Virginia (24 August, Bob Allen, 1.2M uvm; Pittsburgh, PA)

CLARKSBURG, W. Va. (KDKA) — The death of a military veteran from Ruffs Dale in Westmoreland County is the subject of a wrongful death lawsuit following treatment at a veterans hospital.

Retired Sergeant Felix McDermott died April 8, 2018, at the Loius A. Johnson VA Medical Center in Clarksburg, West Virginia after he was injected with a fatal dose of insulin while at the center, the complaint said.

He was admitted three days before his death because developed aspiration pneumonia.

McDermott was one of nine or 10 patients at the center that died as a result of unexplained low blood sugar, the complaint reads.

The complaint said each person received a large and wrongful injection of insulin in the abdomen that wasn't ordered by a doctor or medically necessary.

"It's all very disturbing that people can serve their country that are being killed either extremely negligently, grossly negligently or intentionally," the McDermott family attorney Tony O'Dell said.

The complaint said McDermott did not have diabetes, though he suffered from dementia and was physically disable because of a previous stroke.

McDermott's family was not told about how low blood sugar caused his death. They learned months later after government investigators contacted McDermott's daughter, telling her about the early deaths and a belief how her father's death was not from natural causes.

The inspector general ordered McDermott's remains exhumed in October 2018, and they were flown to Dover Air Force Base for an autopsy.

The complaint says an autopsy revealed there were no hospital orders for the administration of insulin, and McDermott was wrongfully, negligently or intentionally injected.

The autopsy also revealed McDermott received an insulin shot in the left side of his abdomen, was not diabetic and had no history of insulin use.

The report indicated that the retired sergeant's medical condition was clearly improving when he was injected with insulin.

His death was ruled a homicide, and the VA investigators have a person of interest in the death.

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“Each time one of these deaths happened, they had an obligation,” O’Dell said. “They had an obligation to run it to ground to find out what happened, why it happened, how it can be prevented.”

McDermott was a Vietnam veteran and was a member of the U.S. Army and Pennsylvania National Guard.

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2.2 - Daily Press: **Aug. 24 Letters: Unions, ship building and the electoral college** (23 August, 370k uvm; Newport News, VA)

VA union fight
It is often said that those who do not know their history, are doomed to repeat it.

This is a dangerous time in our country for many groups of people. One group that should not be overlooked is labor unions.

Unions help level the playing field. Labor unions are the reason we have child labor laws, health benefits, livable wages, weekends off, eight-hour work days, and safe working conditions. Unions are the reason that when we go to work, the doors are not locked from the outside to keep us from leaving during a shift - which happened during the Triangle Shirtwaist factory fire.

Currently, Veteran Affairs Secretary Robert Wilkie is plotting to cripple the union for VA workers by attacking workers’ collective bargaining agreement - the document that safeguards whistleblowers and protects them from retaliation, that guarantees employees are adequately trained, and that protects workplace safety.

A third of VA workers are veterans. An attack on VA workers is an attack on veterans. An attack on AFGE (American Federation of Government Employees) is an attack on VA workers. If you believe that all workers deserve to be treated with dignity, fairness, and respect, please join us in this fight.

Contact your lawmakers, wear Red every Wednesday in a show of solidarity (#RedforFeds), and stand up to #SaveOurVA before it is too late.

Stacy Shorter

Vice President, AFGE Local 2328

Hampton

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2.3 - The Columbian: **Seeking care for mental health a top frustration for vets** (24 August, Tatiana Parafiniuk-Talesnick, 309k uvm; Vancouver, WA)

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EUGENE, Ore. — Oregon veterans may be at lower risk for depression or sadness, but they are more likely to die from suicide and opioid overdose than nonveterans, according to a recent state study on veteran health.

“We’re just so focused on the mission,” Laura Follett, a Springfield resident and a 15-year Navy veteran, said. “We’re not necessarily focused on ourselves, you know?”

Follett is one of about 310,000 veterans in Oregon — a group that makes up 10 percent of the adult population. Navigating the medical system is far from the only obstacle for veterans in need of health care. One in four Oregon veterans experience frustration in seeking care for mental health or substance use issues, according to the 200-page health study funded by the Oregon Health Authority and the Oregon Department of Veterans Affairs.

The study is made up of 3,915 veterans from across the state who completed an online questionnaire and 63 veterans who participated in focus groups. The project set out to describe the type and availability of behavioral health services for veterans in Oregon, provide findings regarding facilitators of and barriers to the use of behavioral health services for veterans, and to make recommendations that may result in improved accessibility of behavioral health services by veterans in Oregon.

Some of the notable findings include:

• 1 out of 3 veterans surveyed who felt they needed behavioral health care didn’t seek services because they felt uncomfortable or unsafe.

• Specific needs and expectations of veteran subgroups vary in ways that affect how those veterans seek care. Tribal representatives report a need for services that meet cultural needs with an emphasis on a preference for traditional healing methods and peer support as the most important factors in care-seeking behavior for tribal veterans.

• Sexual harassment and assault impacts service members of all genders, including at least 50 percent of female veterans. Interviewees reported a need for more community-based, gender-specific options in Oregon, particularly for military sexual trauma.

• Oregon veterans ages 18-34 are at the highest risk for suicide. Lane County has the second-highest rate of veteran suicide of all Oregon counties. In 2016, 79 people died by suicide in Lane County — around a fourth of those who died were veterans.

Out of the study’s key findings it offered 19 recommendations to help improve veteran care.

Following one of the study’s recommendations that OHA, ODVA, and the VA Health Care Systems in Oregon should collaborate to develop a cohesive, well-researched, and targeted education and outreach effort to destigmatize behavioral health issues and treatment, OHA and ODVA are taking a statewide tour to learn more from particular communities over the next several months.

As part of the statewide tour, in Eugene the first hour of a community forum will be reserved for LGBTQI-identifying people. This relates to the recommendation that VHA and Vet Centers make plans to build capacity for cultural competency practices with measurable objectives that address the unique needs of groups of veterans, such as tribal, LGBTQI and women.

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2.4 - MetroNews: Manchin, Capito call for investigations after claims of suspicious deaths at Clarksburg VA hospital (23 August, Jeff Jenkins, 242k uvm; Charleston, WV)

CLARKSBURG, W.Va. — Both U.S. Senators Joe Manchin and Shelley Moore Capito are calling for full investigations after learning of a claim that a patient at the VA Medical Center in Clarksburg was the victim of homicide while in the care of the hospital while also learning there may have been a number of other deaths with similar circumstances.

The Clarksburg Exponent first reported the claim, which is a six-month notice of a pending lawsuit against the federal government, Friday. Charleston attorney Tony O'Dell filed a notice of claim with the U.S. Department of Veterans Affairs on behalf of the family of Retired Army Sgt. Felix Kirk McDermott.

McDermott was 82 when he died at the Louis A. Johnson VA Medical Center in April 2018. Federal investigators ordered his body exhumed later that year. The Armed Forces Medical Examiner later ruled the death a homicide, according to the report.

Manchin and Capito both responded Friday.

"This report is shocking and if accurate, I am appalled that these crimes were not only committed but that our Veterans, who have sacrificed so much for our country, were the victims," Manchin said in a released statement. "As a member of the Senate Veterans Affairs Committee I will do everything in my power to investigate these accusations and get to the bottom of what happened. These families and loved ones deserve answers as soon as possible and I will make sure they get them."

Capito told the Exponent the report was "sickening and troubling."

"My office has reached out to the VA to learn more details, and I will do everything I can to make sure this is fully investigated," Capito said.

O'Dell, who represents McDermott's sister Melanie Proctor, wrote in his recently filed claim that his client was told her brother's death was not the only suspicious death at the medical center in Clarksburg.

"During its investigation, VA investigators advised Melanie Proctor … that there was evidence that nine or ten other patients of the Louis A. Johnson VA Medical Center had been wrongfully injected with insulin in their abdomen, thereby causing their deaths. Ms. Proctor was further advised that her father was one of the last known victims," O'Dell wrote reported in the Exponent.

There's been no comment from the Department of Veterans Affairs or the Clarksburg VA Medical Center.

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2.5 - KTVQ (CBS-2): **Montana VA announces new Chief of Staff** (24 August, 169k uvm; Billings, MT)

HELENA — The Montana VA Health Care System welcomed Dr. JP Maganito as the new Chief of Staff on July 21, 2019.

Dr. Maganito originally joined the Montana VA Health Care System, Fort Harrison in 2012, serving as the Staff Gynecologist and Occupational Health Medical Officer where he became the Women's Health Medical Director until 2015.

During his time at the VA, he was involved in multiple process improvement and women's health committees helping increase access to care for our Veterans.

After finishing his internship and residency at Botsford Hospital in Farmington Hills, Michigan in 2009, he became and has maintained his board certification with the American Osteopathic Board of Obstetrics and Gynecologists.

He earned his Doctor of Osteopathic Medicine degree from Des Moines University College of Osteopathic Medicine and Surgery. While earning his doctorate, he simultaneously finished his Masters in Public Health and Masters in Healthcare Administration at Des Moines University College of Health Sciences – Division of Health Management. He's also certified as a health education specialist and computer information specialist.

He had left the VA in 2015 in pursuit of subspecialty training as a Female Pelvic Medicine and Reconstructive Surgery fellow with plans to return to the VA to apply this training in serving the Women Veterans.

He has spent the past few years as a lead Medical Director and became the Chief Medical Officer of Blue Cross Blue Shield of Montana whereby he was responsible for providing executive medical leadership as a spokesperson on medical affairs, management, policy, and procedure.

He is a graduate of the Montana Medical Association Physician Leadership Effectiveness Program in 2016 and was recently accepted as a fellow for the American Hospital Insurance Plan Physician Executive Leadership Program for 2020.

With his involvement in our local community and the State of Montana, Dr. Maganito is honored and looks forward to returning to the VA to apply all the experience he has learned both clinically, surgically, and administratively to represent and serve, not only those who have worked tirelessly within the VA system, but more importantly those who so nobly serve this country, our Veterans.

The Montana VA Health Care System serves over 47,000 enrolled Veterans across Montana—an area roughly 147,000 square miles in size. Veterans are cared for by a staff of nearly 1,200 at 17 sites of care across the state.

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2.6 - Kearney Hub: **Device helps Lawter, a paraplegic, take first steps in 25 years** (24 August, Mary Jane Skala, 71k uvm; Kearney, NE)

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Tammy Lawter struggled to hold back tears.

Paralyzed from the chest down 25 years ago, she slowly took her first steps this summer with the assistance of a device called an Indego Exoskeleton.

“I couldn’t feel my legs, so it was kind of weird, but it felt really good,” she said. “It was tempting to stare at my feet to see if they were moving. I was trying hard not to cry, but if I cried, I knew I wouldn’t be able to see.”

It was a life-changing moment for Lawter, director of Kearney’s Friends Program and a U.S. Army veteran. When she brings home her own Indego Exoskeleton later this year, it will allow her to do ordinary things like stand at the stove to cook, stand at the sink to wash dishes, and walk in the winter at Hilltop Mall.

“It gets old and tiring sitting in a chair all day,” she said. “This is an opportunity to stand up and walk and improve my health while doing it.”

It all began at the National Veterans Wheelchair Games in 2018 when, at an expo, Lawter saw a man who had been paralyzed for 28 years walking with the assistance of a ReWalk device. The ReWalk provides battery-powered hip and knee motion that allows a person to stand up and walk.

Instantly, she knew it was something she had to try.

‘A death grip’

With permission from the VA hospital in Grand Island, Lawter tried the ReWalk at the Veterans Administration Hospital last year in Minneapolis, where she is treated for her spinal cord injuries. She did not have enough bone density to use the 78-pound ReWalk, but she qualified to try the Indego Exoskeleton, an alternative, which weighs just 28 pounds.

She returned to Minneapolis in July for the three-to-five week training session on the Indego Exoskeleton. She spent the first day learning how to put on its five pieces. “Everything in the military is made for men, so they had to do a lot of adjustment because I had hips. The company had to redo some of the pieces,” she said.

Then, assisted by two physical therapists, she practiced standing up and sitting down. “The robot has a vibration, so when I stand up, I have to lean forward and wait three seconds as it vibrates. Then the machine will stand you straight up,” she said. “But there are different vibrations. If I lean too far forward, I fall forward.”

Because she was injured so badly in 1994, her balance is off-kilter, and she had not walked in so long that walking was new to her. “I had a death grip on the walker. I thought I’d fall forward. I had to learn that I could actually hold onto the walker and move,” she said.

A setback

The next day, she relaxed a bit and was able to walk 193 steps from the physical therapy room down the hallway and back to the room. She fought back tears. “It was a wonderful feeling to take those steps,” she said.

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The next day, more adjustments were necessary, so she took just 53 steps, but she was mastering the machine quickly and hoped to take it home. Then came a setback. After lunch, she noticed a lump the size of a goose egg on her ankle. Doctors discovered an old fracture. They put her foot in a boot that she will wear for four weeks, so the Indego device is on hold for now. She returned to Kearney last week.

“When it heals, I’m going back up there,” she said. “By the end of the year, I’m going to do the training and bring that device home. I feel really blessed that I can do this.”

She eagerly anticipates its benefits. “It will be nice to be a little higher. It’ll be nice to do a few dishes and reach all the dusty places that nobody wants to reach,” she said. “I want to be able to go to the grocery store and reach up. All the items that were at chest level before my accident are way up high now. I will be able to reach up and grab them.”

The device’s battery has a span of between eight and 10 hours. It is recharged by plugging it into a socket. The VA will pay its $60,000 cost.

A military career

Born in Fort Morgan, Colo., Lawter grew up in Kearney and graduated from Kearney High School in 1984. She went to Kearney State College on a swimming scholarship, but after two years, she joined the U.S. Army and spent two years on active duty at Fort Stewart, Ga.

The day she was discharged, she joined the South Carolina Army National Guard for four years. At the University of South Carolina at Spartanburg, she earned a bachelor’s degree in interdisciplinary studies with a focus on math, political science, sociology and business administration.

Upon graduation, she was also commissioned as a second lieutenant in the Army’s Medical Service Corps and expected to make the military her career. “I like helping people, and I thought if I ever left the service, there would always be jobs available in medicine,” she said.

Life-changing accident

Those plans were shattered in February 1994 when she was severely injured in a traffic accident in Florence, S.C. She was ejected from the vehicle, landed on her back and severed her spinal cord. Instantly, she became a paraplegic. She spent the next eight months in the hospital.

“It was hard to accept that I would never walk again. I had dedicated eight years to the military, and now I had to figure out what else I could do. I have a great support system with my family and friends, so I did not dwell on the negative. I just focused on finding something else I really liked doing,” she said.

Two therapists recommended that she participate in sports activity despite her injury. For Lawter, who played volleyball and softball and ran track in high school, this was good news.

NVWG games

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After being released from the hospital in late 1994, Lawter was headed home to Nebraska when she stopped to watch the National Veterans Wheelchair Games in Kansas City. Each year, 700 veterans from the U.S., England, Puerto Rico and Guam compete in 21 events.

“Everyone was having a good time,” she said. She had heard about the games’ basketball and wheelchair races, but not the 19 other events.

The following summer, Lawter began competing at the NVWG and does so every year. She now focuses on 9-ball pool, shot put, discus, javelin and power lifting. In 1995, just 15 women competed among 400 men, but 150 women participate now, she said. Since 2013, the Challenge Athlete Foundation/Operation Rebound has sponsored her participation.

She also attends the National Disabled Veterans Winter Sports Clinic every year. At home, she stays fit by lifting weights and using a stationery hand cycle.

Lawter, mother of two grown sons, will bring home her Indego Exoskeleton from Minneapolis later this year. “Whether it’s me or a robot walking or standing, I don’t care,” she said. “When I stand up and I can talk to people face to face, it feels normal. Being able to do something without the wheelchair makes me feel like everyone else again.”

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2.7 - The Daily Sentinel: **Opioid Epidemic** (25 August, Joe Vaccarelli, 53k uvm; Grand Junction, CO)

Two years ago, Dr. Bill Hilty could count the opioid overdoses he'd see in a year on one hand.

But as local hospitals, health care providers and dentists have reduced the number of opioids prescribed to patients, Hilty, the emergency department medical director for St. Mary's Medical Center, now sees an average of three overdoses per week coming into the hospital.

Many patients are saved. Some are already dead when they arrive, while a few, Hilty said, go without oxygen for such a length of time that they will have brain damage if they can be saved.

"These are young kids from a variety of socio-economic groups," Hilty said. "It's sad."

The opioid epidemic has swung like a pendulum in the past decade, starting with the medical field overprescribing pain pills to the point where many were prosecuted, including some professionals with ties to Mesa County.

Upon recognizing the problem, a reduction of pills led some patients to seek alternative narcotics on the street. Today, local law enforcement says people are leaping straight to opiates such as heroin -without ever getting hooked on pain pills.

Meanwhile, area health care providers are still looking for ways to reduce the number of pills prescribed by searching for pain management alternatives, joining state programs and obtaining grants to improve the situation close to home.

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CURBING ABUSE

The Grand Junction Veterans Affairs Medical Center often deals with veterans who have long-term chronic pain, including some who have taken opioids for several years. The hospital opened a wellness center on campus in early 2018 focused on working with veterans to improve their physical issues through therapy.

Dr. Ben Atwater, the director of the wellness center, said many veterans are receptive to staying away from opioids.

"It does not mean all patients are off opioids, but we try to identify patients who are at high risk for opioid abuse," Atwater said.

Aside from overdoses, Atwater noted that overuse can result in slowed breathing, a buildup of tolerance, reduction of testosterone in men and, in some cases, increased pain.

In the dental field, Dr. John Poovey, a dentist with JP Dental and Implant Center in Grand Junction, said he used to see patients come in with addictions to the point that he had to press charges against one who tried to falsify a prescription for Vicodin.

While dentists don't prescribe as many opioids across Colorado as doctors, physician assistants and nurse practitioners, 90% of prescriptions dispensed by dentists over a one-year period from August 2017-18 were opioids.

For physicians, that number was less than 50%, according to the Colorado Prescription Drug Monitoring Program.

Poovey said after reading studies in the British Journal of Medicine and through the American Medical Association, he started using ibuprofen and Tylenol to treat pain after oral surgeries instead of opiates.

"I'm trying to minimize their exposure to opioids as much as possible with protocols and taking a heavy hand with suspicion for addiction," he said.

Jackman feels scrutiny over opioids began when physicians were dissatisfied with their work and were noticing overdoses and deaths related to the issue. In the past five years, that scrutiny has advanced to the political and public level.

"I think the epidemic has increased scrutiny. I think physicians have been decrying the situation of how pain is being treated," Jackman said.

He traces the start of opioid issues to when doctors were trained on pain as a vital sign that needed to be treated. Physicians were also rated by patients on how they helped them manage their pain, which gave doctors incentive to prescribe pain medicine, Jackman said.

Now, he said it can be difficult for those who are not addicted to opioids to get drugs for chronic pain. He said continuing education will help level things out in the future.

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"I think we're all at fault, but there is a lot of education that needs to take place so patients understand they don't need these pills long term," he said. "These are all new frontiers that people weren't getting trained on in med school until recently."

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2.8 - The News-Review: **DeFazio discusses local healthcare challenges at town hall** (24 August, Carisa Cegavske, 50k uvm; Roseburg, OR)

The federal government needs to do more to help the Roseburg Veterans Affairs Medical Center recruit and retain health care professionals, U.S. Rep. Peter DeFazio, D-Springfield, said Friday at a town hall meeting at Umpqua Community College.

DeFazio spoke about a range of healthcare topics including the Affordable Care Act, Medicare for All and the problems that led to the closure of the VA's emergency department. He was joined onstage by the directors of the Roseburg VA and Mercy Medical Center, along with other local healthcare leaders.

Prior to the town hall, DeFazio visited The News-Review, where he spoke about the recent entrance of Republican candidate Alek Skarlatos to the race for the congressional seat he holds.

"I recognize his heroism in the terrorist incident on the train. I applaud his third-place finish in Dancing with the Stars. I'm not very good at that. But representing the Fourth District of Oregon in the United States Congress, those aren't exactly stellar qualifications," he said. "It's a very complicated job."

He said he's in a senior position and that means he can do a lot for his district.

"For someone to come along whose experience is not at all relevant and think that they could better represent the Fourth District I think is a very big leap," he said.

DeFazio has held the seat for more than 30 years. He serves a divided district, one of few purple districts in the country. Democratic presidential candidate Hillary Clinton won the district by just 554 votes over President Trump in the 2016 election, while DeFazio held onto his seat with 62,000 more votes than his Republican challenger Art Robinson.

At Friday's town hall, DeFazio said Americans need to improve on the Affordable Care Act and have a serious debate about Medicare for All. He said Republicans have attempted to repeal the Affordable Care Act but haven't proposed a replacement.

"The day that the health care act is repealed, 21 million Americans would lose their insurance, 450,000 here in Oregon," he said. And the insurance of 133 million Americans with pre-existing conditions would be at risk, he said.

"We're really at a very critical point regarding health care here in the United States of America. It's going to be an ongoing and major issue and it's really important down here in Douglas County," DeFazio said.

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Asked by an audience member if he supports Medicare for All, DeFazio noted he co-sponsored the Medicare for All bill. Medicare has issues, but its overhead costs are 3% compared with 26% for private insurance, he said.

“We could do away with an awful lot of bureaucracy. Next time you go see your personal physician, ask ‘em how many people they have on staff to deal with billing,” he said.

The directors of Mercy and the Roseburg VA said a key struggle is the recruitment and retention of healthcare professionals.

DeFazio said the VA Central Office should do more to help the local VA provide incentives that could bring medical staff here and convince them to stay.

“There are tools that we should and could be able to access to help the VA recruit here locally,” DeFazio said.

During his meeting with The News-Review, DeFazio said the Trump administration is pushing very hard for privatizing the VA.

“I have yet to find a veterans group that supports that idea,” he said. “We need targeted care at our veterans facilities and most veterans or many veterans want to seek care in an environment where they understand the unique needs of the veterans and where they’re with other veterans.”

Roseburg VA Director Keith Allen said at the town hall that the hospital had to shut down its emergency room this month, several months ahead of a predicted December closure, because some lab technicians quit in July.

It’s been downsized to a daytime, five-day-a-week urgent care.

“It wasn’t something that we just did on a whim. It was something we did because we could not provide safe care,” he said.

Under the newly implemented Mission Act, veterans can access urgent care in the community, but it has to be in-network. Currently, the only in-network urgent care in Douglas County is in Canyonville, and it doesn’t offer weekend hours.

Allen said he’s working to hire replacements so he can open the urgent care seven days a week.

Mercy Director Kelly Morgan said the key to recruiting and retaining medical personnel is to offer training to local people who want to stay here. He said a proposed Allied Health College, which has already received two-thirds of the necessary funding from the state and city governments, would provide the needed workers for both hospitals.

“We think this is one of the best things we could possibly do, not only to help the economy but also really solve our issue for access for the residents of Douglas County as well as for rural Oregon,” he said.

Morgan also said the Affordable Care Act ensured coverage for many local people who didn’t have it before.

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“From the hospital’s perspective and from the doctor’s perspective, the Affordable Care Act was the best thing that ever happened to us,” he said.

Without it, a lot of people came to the emergency department, couldn’t pay for it and the hospital wrote off millions of dollars in bills each year. That doesn’t happen anymore, he said.

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2.9 - WBOY (NBC-12): Filing against VA Medical Center in Clarksburg claims patient was the victim of homicide (23 August, Clarksburg, WV)

A lawyer representing the estate of a U.S. Army veteran who died from low blood sugar while at the Louis A. Johnson VA Medical Center in Clarksburg has filed a notice of claim with the U.S. Department of Veterans Affairs, alleging that the veteran died as a result of homicide. The claim also alleges that nine to 10 other patients died at the VA under similar circumstances.

Tony O’Dell, an attorney with Tiano O’Dell in Charleston, filed the claim this week on behalf of Melanie Proctor, who is the daughter of Ret. Sgt. Felix Kirk McDermott and the administratrix of his estate.

The following information comes from the claim filed this week, which you can read in its entirety here.

McDermott, 82, of Ellenboro, was admitted to the VA on April 6, 2018 after developing pneumonia, and his condition improved. McDermott was not diagnosed with diabetes and did not have a history of ever taking any medication for the treatment of diabetes. During his stay at the VA, McDermott’s blood glucose levels were monitored by a daily fingerstick test. His levels were all shown to be in the normal range. During his stay at the VA, there were no doctor’s orders for McDermott to receive insulin.

On April 9, while still at the VA, McDermott unexpectedly developed shortness of breath. VA staff found that McDermott’s blood sugar level was very low, a condition known as hypoglycemia. Medical efforts to raise his blood sugar level were unsuccessful, and McDermott died later that morning.

McDermott’s family was told only that he died, but his cause of death was not explained to them. His body was sent to a funeral home, and he was buried on April 13.

In October 2018, inspectors with the VA Office of the Inspector General contacted Proctor and told her there was evidence that the deaths of her father and nine or 10 other patients of the Clarksburg VA were the result of being wrongfully injected with insulin in their abdomens, with her father being one of the last known victims. At that time, McDermott’s body was disinterred and sent to Dover Air Force Base for an autopsy.

The autopsy showed that McDermott had been injected with insulin in his left abdomen and that there were no hospital orders for the injection. Following the autopsy and investigation, the Armed Forces Medical Examiner ruled McDermott’s death a homicide. Investigators told McDermott’s family that they do have a person of interest in the deaths of multiple VA patients.

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The claim lists a series of ways the VA was negligent in relation to McDermott's death:

- Knowing that nine to 10 other patients died under similar circumstances prior to McDermott being admitted, he and his family should have been alerted so that they could make informed decisions about his care
- By failing to adequately staff the hospital
- By failing to investigate the causes of the previous deaths
- By failing to properly reconcile medications
- By failing to properly train staff

The claim, which is the precursor to a lawsuit, asks for $1 million for personal injury and $5 million for wrongful death, along with funeral costs and loss of income.

When asked for comment, officials at the Louis A. Johnson VA Medical Center referred us to the Department of Veterans Affairs Office of the Inspector General, which we have not heard back from yet.

West Virginia's U.S. Senators each issued statements on the situation.

"This report is shocking and if accurate, I am appalled that these crimes were not only committed but that our Veterans, who have sacrificed so much for our country, were the victims. As a member of the Senate Veterans Affairs Committee I will do everything in my power to investigate these accusations and get to the bottom of what happened. These families and loved ones deserve answers as soon as possible and I will make sure they get them."

SEN. JOE MANCHIN-D

"This news is sickening and troubling. My office has reached out to the VA to learn more details, and I will do everything I can to make sure this is fully investigated."

SEN. SHELLEY MOORE CAPITO-R

"Congressman McKinley is aware of an ongoing investigation at Clarksburg by the Veterans Administration Office of the Inspector General. We hope to get more answers about this situation as that investigation progresses," said Amanda Hyman, Communications Director for U.S. Rep. David McKinley-R.

The investigation was opened in July 2018 after the leadership of the Clarksburg VA alerted investigators to "unexplained diagnosis of severe low blood sugar in several patients," government sources said.

McDermott retired from the U.S. Army as a sergeant after 20 years of active duty, during which time he served in Vietnam. Following his retirement, he spent time in the Pennsylvania National Guard.

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3. Business Transformation

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3.1 - Times & Democrat: New veterans' clinic coming (24 August, Dionne Gleaton, 158k uvm; Orangeburg, SC)

Dorn Veterans Affairs Medical Center is planning to build a new outpatient clinic in Orangeburg, just one of several construction projects for which the center has $160 million in funding.

“A lessor has been selected for the Orangeburg CBOC (Community-Based Outpatient Clinic). This selection is undergoing legal review before award. The Orangeburg CBOC was approved for 24,000 square feet. The Columbia VA Health Care System currently has $160 million in funding for projects that are in design or construction,” said Christopher Zell, chief of engineering at the Dorn VA Medical Center.

Synethia Taylor, facilities planner at the Dorn VA Medical Center, said the clinic is being built for a reason.

“The impetus for development in this community rests on the Columbia VA Health Care System’s commitment to veterans in the South Carolina market. The VHA (Veterans Health Administration) continues to transform and, in doing so, provide additional options for veterans to receive care in their communities close to their homes and by individuals that honor their service,” Taylor said.

She said that the percentage of VHA enrollees is expected to increase.

“Population growth in the Orangeburg submarket has been projected to decrease in the next 10 years. However, the percentage of enrollees in VHA is projected to steadily grow. Projections from 2013 suggested an overall 49 percent growth in enrollees. This projection means there are approximately 3,410 new enrollees projected in this market.

“There is currently a clinic located in Orangeburg and with the projected growth in veterans utilizing the VHA system for their needs, we have designed a replacement CBOC that will house state-of-the-art equipment and utilize new modalities to provide the veterans with the care they deserve,” Taylor said.

The Columbia VA Health Care System hosted a town hall meeting in Orangeburg in July.

It was during a February 2018 forum that the Dorn VA Medical Center announced it was adding an $8.9 million, three-and-a-half deck parking garage with 280 parking spaces, along with two full-time, 15-passenger handicapped-accessible shuttles to move veterans across the center’s 93-acre campus as needed.

Zell said, “The parking garage is 90 percent complete and is scheduled to open mid-September. There are currently two shuttles in operation.”

The center had also been awarded a 16-suite Fisher House through the Rockville, Maryland-based Fisher House Foundation, or FHF.

Zell said the Columbia VA Health Care System and FHF are currently crafting the site development plan for the project.

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“The Fisher House Foundation has notified the Columbia VA Health Care System that it has been approved for development of the Fisher House site on the northwest corner of the campus in calendar year 2020,” he said.

The center’s remodeling effort also includes the renovation of Building 10, a 20,000-square-foot facility built in 1930, which will be turned into a primary campus.

“The primary care design for Building 10 is complete. Construction advisement is scheduled by the end of September,” Zell said, noting that a 7,000-square-foot police headquarters is currently under construction and is anticipated to be complete between October and December of this year.

A Red Coat Ambassador program, which includes employees who are throughout the lobby answering veterans’ questions and escorting them to appointments, is also underway.

Jill Bonkowske, program supervisor, said, “The program was implemented in December 2018. Initially we were approved for 10 positions but have since been approved for 20. We have 19 on board and are in the process of hiring for the last position.”

She added, “The ambassadors are the first impression of the VA and enhance the veterans’ experience in our facility. In the first six months, our ambassadors have walked 5,891,953 steps, or 2,790 miles, while helping 48,239 veterans and visitors.”

The center is also providing cardiac intervention services as part of its medical care.

Tanya Henry, acute medicine nurse manager at Dorn VA Medical Center, said the Columbia VA Health Care system was approved for initiation of the Percutaneous Coronary Intervention (PCI) program in August 2018.

“We had our first PCA in December 2018. To date, we have successfully completed 37 PCIs, which has saved the facility a significant amount of money by not sending these cases out into the community. We have one interventional cardiologist and there is currently a part-time Department of Defense vascular surgeon on board through the Surgical Service Line,” Henry said.

No additional operating rooms have been added to any floors to complete any PCIs because the center currently has two functioning cardiac catheterization laboratories, she said.

Dr. Bernard DeKoning, chief of staff at the center, said that mental health care is also among the services provided at the center.

“Mental health continues to comprise a significant portion of our telehealth services,” he said.

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3.2 - The Exponent Telegram: Saturday Salutes (24 August, 133k uvm; Clarksburg, WV)

Editor’s Note: The Exponent Telegram presents Saturday’s Salutes in an effort to recognize the positive efforts of many throughout North Central West Virginia and the Mountain State. To

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nominate a person or group for recognition, send submissions to “Saturday Salutes” at jmiller@theet.com or call 304-626-1473.

— Jerry “The Logo” West and wife Karen. The WVU and NBA legend and his spouse made a leadership-level donation to the Grow Children’s Campaign to pay for the new tower of WVU Medicine Children’s.

— Those who made a new Community Living Center a reality at the Louis A. Johnson VA Medical Center.

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4. DOD Cooperation / Electronic Health Records / MISSION Act Implementation

5. Suicide Prevention

5.1 - The Community Voice: Sept. is suicide prevention month (23 August, Irene Hilsendager, 2k uvm; Rohnert Park, CA)

Is suicide contagious? Suicide is the tenth leading cause of death in the United States for all ages.

However, it seems suicide deaths for teenagers has increased as of late even though suicide has taken the lives of over 44,000 in the United States. Every year the highest suicide rate is in the United States and among them are Caucasian, American Indians and Alaska Natives.

Around 32 percent of high school students have feelings of sadness and hopelessness. 17 percent said they considered attempting suicide, 14 percent made a suicide plan and seven percent tried to kill themselves.

There is one suicide for every 25 suicide attempts and one suicide for every four suicide attempts in the elderly. Alaska is the largest state in the United States for having the highest suicide rate with Montana having the highest suicide among the US states. California had a 10.5 suicide rate per 100,000 people individually.

Researching suicide rates by countries, it seems the Eastern European countries are on top. The lowest rates are in the Caribbean Islands.

Now according to the WHO, the suicide rate in South Korea is the tenth highest in the world. Many are among the elderly. In Japan the leading cause of death in men are the ages of 24-44 and in women 15-34. With a high culture tolerance for suicide Japanese families think suicide is honorable and many elders end their lives after retirement as a way out so as to not burden their children with financial problems.

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A new report shows a troubling trend of veterans committing suicides on VA hospital campuses, especially after receiving inadequate care from VA facilities.

Is the Department of Veterans' Affairs offering enough services in the mental health department?

While rates of suicide were among the highest for younger veterans-18-34 and lower and vets ages 55-and older, vets ages 55 and older accounted for 58.1 percent of all veteran suicide deaths a few years back.

Veteran suicide presents a challenge to the Pentagon and the military services claims they have instituted programs to save lives and promote prevention.

In many cases, family and friends are affected by a suicide loss and feelings of shame and stigma prevent them from talking freely. A fact that gets thrown around is suicide is often the result of untreated mental health conditions. Suicidal thoughts should not be considered normal and should get looked at as a more serious issue.

There are warning signs, but sometimes family and close friends think it's just a phase especially for teenagers. Do you ever hear someone say, "I wish I wasn't here?" Is the increased use of drugs and alcohol, has the behavior become more aggressive, have they withdrawn from friends, etc. Are there severe mood swings and do they draw things about death?

If there is immediate danger such as giving away possessions, saying good bye to friends, the mood shifts become very calm as they already have their plan in action and make sure there are no weapons around.

If you are not sure about the sign you are seeing, get in touch with a mental health professional immediately.

Other risk factors can be access to fire arms, a chronic medical illness, prolonged stress, a recent tragedy or loss and even agitation and sleep deprivation will trigger things.

Teens are willing to try anything, or peer pressure is a factor. In Broward County in southern Florida, a huge epidemic has arisen in the past two years. There is a new designer drug on the market called "flakka" It is found to have the same class of chemicals as in bath salts. It is a synthetic drug that can be snorted, smoked, injected and even ingested.

"Flakka" comes in a crystalline rock form and is sold online, manufactured in drug labs in China and can be ordered to be delivered to your home. This drug is highly addictive both physically and psychologically. It is as potent as crystal meth, bath salts and cocaine. User become very aggressive, hallucinate, loss of memory and acting impulsive.

Affects may include hypertension with an elevated heart rate and a hypermetabolic state that can lead to hyperthermia. In some parts of the country flakka is called gravel because of its white crystal chunks. Flakka can be much more dangerous than cocaine. Probably what has brought flakka the most attention is it gives the user the strength and fury of someone with extreme strength. A dose of flakka can go for only $3 to $5 which makes it a cheap alternative to cocaine.

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Flakka resembles white or pink gravel or grains of sand. It is foul smelling and also comes as a powder. Those who use it can sweat profusely, are disoriented, paranoia, extreme agitations, panic attacks and feel everyone is after them, slurred speech and these effects can occur five to fifteen minutes after ingesting.

If someone exhibits bizarre or harmful behaviors after taking flakka, call 911 immediately. Do not engage with the person because they will most likely become violent.

Flakka is made from synthetic version of an amphetamine-like stimulant in the cathinone class called alpha-PVP. Cathinone's are chemicals gotten from khet plants originating in the Middle East and Somalia where the leaves are chewed for a buzz.

Is the medical community prepared for this epidemic? After being addicted, will suicides increase among the young set of people? Parents beware of crystals in your homes. The CDC says suicide rates are increasing.

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6. Women Veterans / Homelessness / Benefits / Cemeteries

6.1 - U.S. News & World Report (AP): Veterans Program Yields More Than Just Honey (24 August, Michelle James, 23.3M uvm; Washington, DC)

BECKLEY, W.Va. (AP) — For 10 days, Ed Forney chatted with each visitor who passed by his table at the West Virginia Grown Country Store at the State Fair of West Virginia.

Forney's display attracted a lot of attention, too.

Turns out, fairgoers have quite the sweet tooth and there isn't much sweeter — even at the state fair, where food lurks around every corner — than a bottle of honey.

But it wasn't just the honey, or the samples Forney offered, that drew the crowd.

The signs around his display helped quite a bit, as people stopped by to learn more about, and purchase, "West Virginia Veteran Produced Honey."

Although Forney is the face fairgoers and many others might associate with veteran-produced honey, he is actually one of more than 300 veterans in the West Virginia Veterans & Warriors to Agriculture Program.

Forney, a U.S. Army veteran who resides in Hedgesville in Berkeley County, explains his wife Cheryl retired from the WVU Medical Center where she spent a lot of her time working in the trauma center.

"After she retired she got into beekeeping for relaxation," he said.

As the two built an apiary on their farm, he said they began to look into establishing a veteran's beekeeping program in the eastern panhandle.

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That was 2012, which coincided with the establishment of the state's Veterans & Warriors Program.

Instead of creating a program, Forney joined one as a participant.

"I was one of the very first folks to sign up for it," he said.

A few days later, representatives from the Department of Agriculture visited his farm to view his apiary and asked if he would train other veterans.

"We had no idea what we were getting into, but we said we would volunteer," he said.

Although the program was up and running for several years before West Virginia Department of Agriculture Commissioner Kent Leonhardt took office in 2017, Forney said it was after the change of guard that things began to take off.

"We saw major changes," he said. "He (Leonhardt) is a veteran and is the driving force behind the program. So it's been much better communication and a much better partnership. Now that he's at the helm, there's more structure."

There are several reasons for the beekeeping program. One is that it provides a form of therapy for veterans who might be suffering from PTSD.

Leonhardt, a retired Marine lieutenant colonel, actually brings beekeeping experience to the job and said he knows first-hand how calming it can be.

He said those beehives were especially useful when he was on active duty, serving as a liaison to the National Security Agency in the early 1990s.

"I had beehives in my backyard and if I had a very stressful day, I'd get one of those 5-gallon buckets, turn it upside down and I'd watch the bees come and go," he said. "You wouldn't believe the calming effect watching how those bees would struggle, laden with pollen, just to get back to the hive and distribute it into the combs."

That's what Forney said drew him and his wife to beekeeping, and now other veterans to the program.

"If you've ever had a garden, you may go out working for 'an hour,' and then four hours later you realize, 'My goodness, it's been four hours,' because you relax so much," he said. "That's the thing."

The men say they hear stories like that often. Stories about how the program has helped people forget their troubles. How it has saved their lives.

"We have people like Eric (Grandon) who say they owe their lives to the program," Leonhardt said of a Clay County veteran who served in recent Middle East wars. "He found this has become a business for him. He now has a hive at the Culture Center in Charleston and he says he owes it to the program that he didn't put a gun to his head."

Forney added, "I've been his mentor since the beginning and it's life-changing. Not just a little bit, but completely life-changing for his family."

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Through beekeepers like Forney, the WVDA offers training to the veterans in the program, and also purchases and provides extraction equipment so that participants can make a go of a business at home.

That's another part of the program.

"What we're doing is setting up a structure that allows a veteran to start a business in West Virginia," Leonhardt said. "Some people do it as a part-time business. Some people do it as a full-time business like Ed does. But the idea is to grow West Virginia agriculture at the same time we're helping people who need some help."

Forney explains veterans purchase their own bees, labels and bottles, and their new business often becomes a family affair as they work together to produce and sell honey.

In some cases, Forney sells it for them if a veteran, for example, struggles with crowds or simply doesn't want to set up and sell.

But in all cases, veterans keep 100 percent of the profits from the honey they produce.

And beekeeping isn't the only program that falls under the Veterans & Warriors umbrella as, since the legislature funded it for $250,000 in 2018, agrotherapy has been introduced at the Huntington VA.

That program trains veterans in various areas of agriculture.

Also, Leonhardt said the department hopes to set up a mentoring program that places veterans with farms that don't have an heir. He said the goal is that farm might continue when an owner passes away or retires.

Leonhardt and Forney both said they're excited about the direction of Veterans & Warriors and of the beekeeping program itself, which has received attention throughout the country and as far away as Angola.

They encourage other veterans who might be struggling or who might be interested in learning more, to reach out for more information.

"This veterans program is one of those tools we use to bring everybody together," Leonhardt said. "It's a common goal that people feel passionate about. For me it's very important, being a veteran.

"We want people to talk to us," he continued, adding the program is not treatment for PTSD and offers no medical advice, but can provide a connection to help. "Sometimes all they (someone in crisis) need to hear is just a voice on the other end of the phone."

For more information on the West Virginia Veterans & Warriors to Agriculture program call 304-558-2210 or visit www.agriculture.wv.gov.

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6.2 - Connecting Vets: **New platform creates digital memorials for all veterans in national cemeteries** (23 August, Abbie Bennett, 5.8M uvm; Washington, DC)

A new searchable online tool from the Department of Veterans Affairs and National Cemetery Administration allows creates digital memorials for fallen service members buried in national cemeteries across the United States.

The Veterans Legacy Memorial is an online memorial space managed by the National Cemetery Administration, which oversees the 136 national cemeteries where 3.7 million veterans are interred.

The VLM creates a profile page for each service member.

To find a memorial profile, go to vlm.cem.va.gov and search the name of your veteran, using their first and last name.

You can narrow your search by providing the veteran's branch of service and the cemetery name, along with other information.

Each veteran's page includes their name, dates of birth and death, last rank held, service branch, cemetery, address and contact information for the cemetery, section of the cemetery they are interred in and the date of their internment.

Upcoming features will include the ability to leave tribute messages, photographs and more to individual profiles.

"Veterans Legacy Memorial ensures 'no veteran ever dies' by honoring the legacy of our nation's veterans, not just in our cemeteries, but in a new and innovative digital setting," VA Secretary Robert Wilkie said in a statement announcing the new tool. "It enhances the onsite national cemetery experience and extends the experience to those who otherwise are unable to physically visit the cemetery."

For more information, go to va.gov/remember. For assistance using the VLM, click here.

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6.3 - WSAW (CBS-7, Video): **Simcakoski Foundation raises money for therapy golf course for veterans** (24 August, Stella Porter, 212k uvm; Wausau, WI)

IOLA, Wis. (WSAW)-- About 150 golfers hit the links at the Glacier Wood Golf Club in Iola on Saturday, playing a round to raise money for the Simcakoski Foundation as a part of their second annual golf outing.

The foundation works to help veterans receive proper mental healthcare.

"Our hope is, I guess, is to help veterans with PTSD and mental health issues, help them not just take the opiates and pills, but have alternative methods for them," said Linda Simcakoski.

Founded by the family of u-s marine Jason Simcakoski-- who died after being over prescribed opioids at the Tomah VA Hospital.

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The foundation has worked with lawmakers to create Jason's Law-- which reduces the number of opioids prescribed to veterans.

"We're hoping to raise 30,000 dollars, and I think we're going to be able to hit the goal," said Jason's father and President of the foundation, Marv Simcakoski.

Jason's buddies from the marines came from all over to support the cause in memory of their friend.

"We have one coming from Louisiana, we have one from Oklahoma, one from Ohio, and then one from Wisconsin here," said Jason's mother Linda.

The money raised today will go towards helping other veterans heal through golf, just as Jason did.

"We took over the V.A. 9-hole golf course in Tomah, which is going to be a therapy course, and we're re-doing the greens, and we're sticking money into that golf course," said Jason's father.

Closed for years, the group hopes to bring the golf course back as an outlet for veterans going through a tough time.

"We want something for veterans when they are patients at the VA.clinic and other places in Wisconsin that they can go and golf for free, and it gives them alternative therapy, besides medicine," he said.

Because golf is something that helped Jason when he was a patient.

"It gave him a chance to get out with me, just to get out and get some sunlight and talk and relax instead of being in a building," Simcakoski said.

The foundation plans to have the therapy golf course ready by spring 2020.

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6.4 - The Herald-Dispatch: **VA to host event on overdose awareness** (24 August, 135k uvm; Huntington, WV)

International Overdose Awareness Day, a global event held each year to raise awareness of overdoses and reduce the stigma of a drug-related death, acknowledges the impact of drug use and the risk of opioid overdose, including individuals directly impacted, family and friends.

The Hershel "Woody" Williams Veterans Affairs Medical Center will host an Overdose Awareness Information Fair from 9 to 11 a.m. and 1 to 3 p.m. Wednesday, Aug. 28, in the main lobby of the medical center. Educational materials will be available regarding local VA resources and programs to assist veterans in need.

VA initiatives are in place to prevent drug overdose through education, proper disposal of unused medication and access to naloxone (Narcan), a lifesaving medication that is an antidote to opioids that can prevent fatal opioid overdose. Staff will be available to discuss risk reduction strategies as well as treatment options for at-risk veterans.

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Aug. 28 also has been designated "Wear Purple" day for all U.S. Department of Veterans Affairs staff to bring more awareness of overdoses and reduce the stigma of a drug-related death.

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6.5 - WYOU (CBS-22, Video): Female veterans honored for their service (24 August, Morgan Parrish, 117k uvm; Wilkes Barre, PA)

Pennsylvania is home to the fourth-largest veteran population in the country.

Female veterans, who account for roughly eight percent of that population, were honored Saturday morning for their service.

Dozens of community members gathered at the Wilkes-Barre VA Center Saturday morning for a women veterans town hall and expo. The goal? To honor women veterans for their service as well as update them on programs and services they may have earned.

“2016 we actually opened our women’s clinic here which is a self-contained clinic. It gives them the privacy that they want. We have children coming in with their moms,” Patricia Conroy, women veterans program manager for the center said.

In terms of healthcare, the Wilkes-Barre VA provides primary care, behavioral healthcare, as well as all of the pharmacy services throughout the facility.

“Anything a woman veteran may need in her care,” Sumit Ghosh, medical director of women’s health at the center said.

Veterans tell Eyewitness News it’s also important to remind people that women veterans’ needs are equally as important as men’s.

“Historically if you thought of a veteran, you thought of maybe the WW2, you thought of a male veteran. You thought of a male Vietnam veteran. Females are veterans as well. They have served this country throughout our entire history. This is nothing new,” Conroy said.

“It is stereotypical to a degree. A lot of generational gender gaps but ultimately, it’s just speaking out beyond that and saying ‘no I did serve. I am also a soldier and I have served in the military’,” Lisa Kaye, director of the Monroe County Veterans Affairs said.

Kaye is a U.S. Army veteran who served three years active duty and one year in the National Guard. She says she experiences first-hand what it’s like to not be taken seriously as a veteran.

“You see an Army veteran license plate or sticker on the back of a vehicle, they automatically assume you must be a male driver,” Kaye said.

Leaders say they hope the expo will raise awareness in the area on how important it is to help our female veterans in need and also to make sure they always feel appreciated.

“We may think that we know what our veterans’ needs are, but there is nothing like having the veterans speak to what her needs may be,” Ghosh said.

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This event is the third in a series of town hall and expos put on by the governor's advisory council for veterans services and the Department of Military and Veterans Affairs.

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6.6 - KBAK (CBS-29): VA launches online memorial to honor deceased veterans of Bakersfield National Cemetery (24 August, 104k uvm; Bakersfield, CA)

The VA has launched a new online program to honored deceased veterans.

This week, the Bakersfield National Cemetery launched the Veterans Legacy Memorial.

The memorial is the country first digital platform dedicated to the preservation of the memory of the 7,000 veterans buried at the cemetery.

Each veteran will have a memorial page on the site.

The public will be able to search the site for where veterans are buried, as well as read about the basic details of their lives and service.

For more information check out their website.

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6.7 - WCBD (NBC-2): Vietnam veteran evicted from apartment; people seen rummaging through belongings (23 August, 83k uvm; Mount Pleasant, SC)

MYRTLE BEACH, S.C. (WBTW) – A Carolina Forest veteran is headed to New York after an eviction.

Veterans Outreach Program Specialist Chris Aranda, with the Department of Veterans Affairs, told WBTW the veteran, identified as Tom, was released from the hospital around 3 p.m. on Wednesday and was dropped off at a homeless shelter.

When VA members went to the shelter, the veteran wasn't there, Aranda said. The members went looking for the veteran and found him on Oak Street.

The veteran stayed in a hotel overnight, where he was able to shower and sleep in a bed, Aranda added. On Thursday, volunteers from various vet organizations helped the veteran load the rest of his things before he heads to New York to stay with family and friends.

"Very unfortunate event that he came home to this, but veteran community stepped up once again and ensured we leave no veteran behind," Aranda said.

WBTW is not using the veteran's last name for his protection.

Sterling Management, which runs Canterbury Appartments said to us in a partial statement "Due to the nature and sensitivity of the matter, it is taking us time to ensure we're delivering

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facts in a thoughtful manner. It is the customary practice of Sterling Management to respect the privacy of its tenants and not to comment on specific situations involving its tenants."

News13's Elisia Alonso spoke to the veteran and volunteers.

"I will never leave a veteran behind. If there's a veteran in need, if there's a veteran in the street, if a veteran just needs a meal – I'm there," said Chase McCarthy.

Some volunteers stayed overnight to protect Tom's property.

"We basically just stayed here to make sure that what was left of his property was, that nobody else looted or messed with anything else. A lot of his stuff had already been taken. To my understanding it had been here a few days already," said Chuck Hooks.

On Wednesday, WBTW reported that pictures on social media have people talking after the veteran was evicted from his apartment.

Christopher Trinemeyer, who is the Assistant Director for Operation Veteran Reintegration, has been looking after the 72-year-old Vietnam veteran.

Images show the veteran's belongings sitting out after the former marine was apparently evicted from his apartment at the Canterbury Apartments.

Trinemeyer said the veteran suffered a heart attack at around the same time he got the eviction notice and only recently got out of the hospital.

Several neighbors told WBTW that some people are stealing items that belong to the veteran.

"To see somebody's whole life just, you know, sitting there in the rain — I mean, it's a huge amount of empathy that I have for another human being to — especially talking to him," Trinemeyer said. "He was like, I don't want to go see it today, I don't want to do it tonight. he was like, I will do it in the morning. we're like, okay."

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6.8 - Chillicothe Gazette: **Local veteran awarded degree after leaving university 40 years ago** (24 August, Toria Barnhart, 49k uvm; Chillicothe, OH)

One local veteran has dedicated his time to learning through audited classes and his children's textbooks after he was forced to leave university behind. But earlier this month, he finally received his degree after waiting for more than 40 years.

Larry McKillip, a 74-year-old U.S. Navy veteran, was surprised by his family and faculty at the University of Louisville with his associates degree earlier this month. McKillip left the university in 1977 after his mother, who cared for his father, was diagnosed with cancer.

"I am so grateful to the university for what they have done," McKillip said. "This is something that I've wanted for so long."

Choosing a path

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While McKillip's family describes him as a lifelong learner, he says that it wasn't always the case. In high school, McKillip never applied himself to his coursework. So after graduating in 1966, he enlisted in the Navy.

For five years, McKillip served as an active duty medic. He worked in Vietnam providing care to civilians and soldiers. Through the military, McKillip became disciplined and developed a plan for his future.

Once discharged, McKillip used the GI Bill to attend the University of Louisville where he was pursuing a bachelor's degree in educational recreation. With his degree, McKillip aspired to work in a Veterans Affairs medical center directly with his peers.

As he progressed through the first semester of his senior year, McKillip learned that his mother had been diagnosed with cancer. At the time, his mom was also the primary caretaker for his father who had a form of muscular dystrophy.

McKillip decided to leave college and return home to Ohio to help care for his ailing parents. But because McKillip left the university before the semester finished, the stipulations of the GI Bill required he pay the tuition back. More than five years passed before he was ready to return to the University of Louisville. And once the time came, McKillip was considered an out-of-state resident and couldn't afford the increased fees.

"Sometimes life happens and it just doesn't work out," he said.

Instead, McKillip began to work at the Chillicothe VA Medical Center. For more than 36 years he worked at the center starting in acute nursing and eventually moved into recreation. Although McKillip didn't have an official degree in recreation, he was still able to take what he had learned from his time at college and apply it to his career.

He worked with residents at the center on therapy for issues related to dependency on drugs and alcohol. McKillip also spent time with the veterans in different workshops or groups to reminisce or socialize.

While working at the VA, McKillip also spent time auditing classes online or at local colleges. In some ways, it was to show his family that although he didn't have a degree, he was still committed to higher education.

And when McKillip's children were of age he ensured that all four of them attended university - and graduated. When they came home after finishing each semester, he asked that they also bring their textbooks. Then, McKillip read about abnormal psychology, statistics and more just as his children did in the classroom.

"I've always enjoyed learning new things," he said. "But part of it was that I wanted to be fulfilled."

McKillip retired from the VA in 2006 and stopped auditing classes before that. But he still continues to read about topics that fascinate him. McKillip's son-in-law Jason Beavers believes that McKillip partook in these courses to keep his mind engaged.

But McKillip's love for learning was halted three years ago when he was diagnosed with stage four esophageal cancer. During that time, he was completely focused on taking his medication

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and staying healthy. And by 2019, McKillip recalls giving up any hope of receiving his degree or pursuing any other education.

Amending the past
When Beavers learned of McKillip's diagnosis, he wanted to do something to honor the man who had given so much to others. Beavers reached out to the University of Louisville to see if they would be able to grant McKillip an honorary bachelor's degree for the time he spent at the college.

Staff at the university informed Beavers that they did not issue honorary degrees. Beavers gave up hope. But he soon learned that McKillip had earned enough credits to receive an associate degree in his own right.

"It wasn't something that was awarded as an honorary thing, but as something he had done on his own initiative and gumption," Beavers said. "We knew that would help make that missing piece from his past feel filled in."

After the announcement, Beavers and his wife, his mother-in-law, Linda McKillip, and staff at the university worked to surprise McKillip. The family told McKillip that they were taking a vacation to Louisville with a pit stop at the university. Once there, the University of Louisville Alumni Office, President Neeli Bendapudi and provost Beth Boehm held a special ceremony to declare McKillip an adopted alumnus and present him his degree.

“Some lives are exemplified by service,” Bendapudi said at the ceremony. “Service to others, service above self, service selflessly. And that, I think, truly exemplifies this man.”

Through his experience, McKillip wants nontraditional students, and others who may have given up on their degrees, to continue working towards their academic goals and learn of other programs designed to help them be successful.

After decades of waiting, McKillip is finally able to feel closure in his academic accomplishments with the newfound confidence that the label of college graduate brings. And although he now has his degree, McKillip plans to continue his passion for learning.

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6.9 - Palm Beach Daily News: **Handyman spent 50 years working in Palm Beach; now he’s living in a group home** (23 August, Wendy Rhodes, 48k uvm; Palm Beach, FL)

Roger Colvard, recently diagnosed with terminal bone cancer, says he feels ‘abandoned’

One day, Roger Colvard lived in a $17 million mansion. The next, he was homeless.

Colvard didn’t exactly live inside the mansion — he lived in a two-room apartment above the garage until July 28. The house, named Southways, had been owned by the Gallant family for 50 years — the same amount of time Colvard said he worked as a handyman in Palm Beach.

Colvard’s boss and friend, Antoinette “Toni” Gallant died last summer, at which time her son Steven Gallant took over care of the estate. The 14,000-square-foot historic mansion was then sold, and Colvard was told he had to leave.

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The apartment was simple, and the 75-year-old Army veteran had to climb a steep set of narrow stairs to get to it, but it was home. There was no kitchenette and no air conditioning. It was bright, but the walls were grimy and the bathroom fixtures corroded. A 10-inch box television was perched next to a small table with 11 bottles of pain pills that Colvard refused to take.

The pills were prescribed to ease the pain of terminal bone cancer — a diagnosis he received after riding his blue bicycle to see his doctor at the VA Medical Center in Riviera Beach. Two to five years, they told him.

Not long after receiving that news is when Colvard found out he had two weeks to vacate his apartment.

Gallant said he allowed Colvard to remain living in the apartment after his mother died for $250 a month rent. The agreement, Gallant said, was that Colvard would make $12 an hour as a handyman for the property, but would not get paid until his bill exceeded the $250 rent. “It’s kind of an off-and-on part-time job,” Gallant said. “We let him live here. There are many weeks we didn’t ask him to do anything.”

Colvard said he feels like he is “being kicked to the curb” after being a dedicated worker and friend to Toni Gallant, who he loved with all his heart.

“I used to play piano for her,” he said, adding that she even bought him an electric piano because she loved to hear him play. “I gave her the best Hoffman’s chocolates and flowers. She made me happy. She made me feel good, and I really loved her for that.”

Colvard said he would hold Toni Gallant’s hand when she took walks around the courtyard, because he couldn’t stand the thought that she might slip and fall.

Chasing love

It was for the love of a woman that Colvard first came Florida in 1969, after serving in the Army since 1964. Originally from California, he moved between Florida, New York and Massachusetts, working for families like the Kennedys, Mr. and Mrs. Benjamin Goodale, the Pulitzers and the Gallants, he said. He survived melanoma and three surgeries that left his nose disfigured, but said he always had friends to help him.

Ruth Yaeger Lane, who was Colvard’s boss when he worked at the mansion that Estée Lauder subsequently purchased, once bought him a $27,500 piano just to hear him play, he said.

Lane died in 1985, Colvard said, and he was devastated until he developed a special relationship with Lilly Pulitzer, who he said became his “closest friend in Palm Beach.”

For 30 years he did odds jobs for Pulitzer. “She’d call me up when a rat got in the house,” he said. “Once there were two, and she said, ‘I want you to catch them for me, but I don’t want you to hurt them and I don’t want you to kill them. Give them some food, give them some water, and leave them.’”

Eventually, “time caught up with her” Colvard said of Pulitzer, who died in 2013. “I’ve said more prayers for her than anybody,” he said, his voice dropping.

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Liza Pulitzer, Lilly's Pulitzer's daughter, said she doesn't remember a time when Colvard wasn't around. "They really had a special relationship, those guys," she said of Colvard and her mother. "Mom cared so much about him. She would have never, ever fired him in his lifetime."

Pulitzer said that Colvard and her mom used to run errands together: the hardware store, Kentucky Fried Chicken, anywhere they could just take off on a mini adventure. She said she is heartbroken to see Colvard feeling so scared and alone.

"When you age out, it's frightening," she said. "You want to know that you mean something to someone. Any of us getting kicked out to the curbside has got to be a terrifying thing."

Tough luck

Colvard said his monthly VA benefit of $1,100 doesn't go far, and he is not eligible for Social Security because his income was largely under the table. He gets $16 a month in food stamps.

"I'm not really happy," he said the day after he left his Palm Beach apartment. "I'm going to have to sleep outside tonight. I hope I have a heart attack. If I could push a button, I wish I could just go away. I feel abandoned."

A week later, Colvard moved into a five-bedroom house in West Palm Beach with four other men, thanks to the the assistance of a Palm Springs charity called Faith, Hope Love and Charity, Inc. The organization paid $650 for the first month's rent, but Colvard said he will not be able to afford to stay after this month.

He subsists on big pots of spaghetti and pasta sauce that he said he can make last for days.

"I've looked for work in Palm Beach," he said, frustrated that he can't earn enough to get himself back to the town he loves. "Forget it. The only work I can get is walking the dog."

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6.10 - NorthCentralPA.com: Student Loan Debt for Totally and Permanently Disabled Veterans to be Forgiven (25 August, 32k uvm; Williamsport, PA)

LOUISVILLE, KY— Today, President Donald J. Trump signed a Presidential Memorandum that will significantly streamline the process to erase federal student loan debt for totally and permanently disabled veterans. Through a process called Total and Permanent Disability (TPD) Discharge, veterans will now have their student loan debt discharged unless they decide to opt-out of the process. The Department anticipates notifying more than 25,000 eligible veterans and continuing the discharge process on a quarterly basis.

The memorandum issued today builds on improvements to the TPD discharge process implemented by U.S. Secretary of Education Betsy DeVos and U.S. Secretary of Veterans Affairs Robert Wilkie. In April 2018, the Department established a data matching process with the VA to identify totally and permanently disabled veterans who are eligible for student loan relief. Since April 2018, this process has resulted in Secretary DeVos providing more than $650 million in student loan relief to more than 22,000 eligible veterans.

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"Supporting and caring for those who have sacrificed much in service to our country is a priority for President Trump and the entire Administration," said Secretary DeVos. "I appreciate the President's strong leadership on this issue and his willingness to provide much-needed student loan relief. We will continue to prioritize the needs of our nation's veterans and provide them the help and support they have earned and deserve."

Veterans will still have the right to weigh their options and to decline loan discharge within 60 days of notification of their eligibility. Veterans may elect to decline loan relief either because of potential tax liability in some states, or because receiving loan relief could make it more difficult to take future student loans. Eligible veterans who do not opt out of the program will have their remaining student loan balance discharged and will be reimbursed for payments made following the date of their disability discharge.

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6.11 - The Sheridan Press: Feeding communities: Program helps bridge gap for affordable food (24 August, Claire Schnatterbeck, 18k uvm; Sheridan, WY)

When looking for food on a slim budget, people don't usually turn to the fruit and vegetable section of a grocery store or seek organic produce. Sometimes, when food instability is affecting families, healthy food and cheap food seem mutually exclusive.

However, the Cent$able Nutrition program through University of Wyoming Extension at Sheridan College is looking to bridge the gap between money-savvy and health-savvy nutrition with educational programs and a new community garden.

The garden is the brainchild of Lori Dickinson, a community educator for the Cent$able Nutrition program.

The program works with people dealing with food insecurity and offers interactive class on cooking, healthy eating and saving money.

As part of the education arm of the Supplemental Nutrition Assistance Program, the nutrition program receives federal funding. SNAP supports better nutrition for low-income households.

While Dickinson mostly does direct education, the new community garden is branching off by incorporating community involvement.

"We tried to reach demographics that could utilize it," Dickinson said.

The garden is divided into two sections, one half gardened by youth community members and the other half by veterans in the recreation therapy program at the Sheridan Veterans Affairs Health Care System. All of the produce is donated to the soup kitchen, food pantry, SNAP table at the Sheridan Farmers Market on Thursdays or veterans in the community.

Dickinson has a social work background so, for her, partnering with different groups in the community has been very important for the project. Volunteers come from many groups, including Girl Scouts, Boy Scouts, Volunteers of America Northern Rockies Milestones Youth Home, 4-H, youth that require community service and veterans. The extension program is also in the agriculture building at Sheridan College, so being able to connect with ag experts for the

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garden has been fruitful. So far, volunteers have put in more than 90 hours of time in the garden.

“It’s really important to instill in youth the concept of altruism and giving back,” Dickinson said. “They can learn in the process and have fun and still give back to the community and people who can really use it.”

Reed Novak is involved in 4-H and has been working in the garden since the beginning. He enjoys “digging through the soil and smelling the fresh plant life,” volunteering and the satisfaction of watching plants grow to share with others.

“I would encourage people to get into gardening too because it’s fun and it’s also rewarding,” Novak said.

The volunteers have worked to grow a variety of produce, ranging from many different types of squash to corn to jalapeños to Brussels sprouts, just to name a few. So far, the garden has yielded almost 100 pounds of produce that has been donated.

Hesid Brandow is the temporary local food and agriculture organizer and operates the SNAP booth at the farmers market where some of the produce is donated. The booth allows people to swipe their SNAP card and purchase SNAP bucks to use at the farmers market. Brandow understands the importance of promoting healthy food to people with food insecurity and coming together with community partners.

“Whenever we can come together to provide good, wholesome food for our community, everyone wins,” Brandow said. “Food is becoming increasingly important…and for people who are just trying to survive month to month and get the healthiest, best food for their family with their benefits programs…SNAP at the farmers market really increase the chances that what people are getting are going the be healthy foods that are going to increase the nutritional value of their household, and so put in that context it’s pretty obvious why this is a good thing for our community and why we should all care.”

In addition, the involvement of the SVAHCS recreation therapy program with the garden has proved beneficial for community building and recreation. The therapy program finds things that veterans have an interest in, or might have an interest in, and allows those interests to help further the therapy they may need. Veterans — particularly those in the inpatient program who have had a brain injury or post-traumatic stress disorder — are involved with the program to find things that help heal them in a different way than traditional therapy.

Kristina Miller, the public affairs officer at the VA, said community partnerships are important for veterans, including involvement with the garden.

“There was a veteran who hadn’t gardened since he was a kid…this was reconnecting with those positive memories. Allowing them to remember that there are things they can do that aren’t meditation or traditional therapy may be what they need to be accepted in the community,” Miller said. “Anyone who has touched a plant or pulled a weed can appreciate the value in planting something and seeing it grow and being a part of its development.”

Veterans have also participated with the direct education aspect of Cent$able nutrition through classes on eating healthy on a budget, food safety and receiving cookbooks.

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Brian Mealor is the director of the Sheridan Research and Extension Center, which houses the agricultural experiment station, offices for UW distance education and the UW extension programs like Cent$able nutrition. He feels that the garden could serve as a model for community engagement with encouraging healthy eating among demographics with food instability.

“I think hands-on, truly engaged programs like what Lori [Dickinson] is doing is the best way to do that extension and for people to learn about the importance of good nutrition and healthy eating habits and then tie that in with the ability to grow your own food and know the origin of where that food came from. It’s really a win-win on both sides. It’s taking the traditional model of extension and doing it a little bit differently.”

For Dickinson, the process of putting together the garden and growing it together with community partners is just as important as the product.

“There is a great need in this community to help people who have food insecurity,” Dickinson said. “It’s important to not only help them in the moment but to help them learn healthy life skills that can help them in the long run.”

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6.12 - My Buckhannon: ‘This would mean everything to my mom’: Vietnam veteran receives diploma 60 years after high school graduation (24 August, Beth Christian Broschart, Buckhannon, WV)

MARTINSBURG – Some people wait their entire lives to have their deepest wishes come true with no luck.

Fortunately, the dream of a U.S. Army Vietnam Veteran and Purple Heart recipient with ties to Buckhannon was recently granted in July when he was 78 years old.

Floyd Nimrod Covey lived in Upshur County and was enrolled in high school when he was drafted to serve his country in the Vietnam War; in fact, while serving his country, he missed his high school graduation.

Covey, who now resides in the Martinsburg VA Medical Center, told some of the staff members he really wished he had graduated high school, saying his mother was disappointed that he never finished high school and received his diploma.

Upshur County Schools Superintendent Dr. Sara Stankus and assistant superintendent Dr. Debra Harrison packed up and traveled to Martinsburg on July 8 to present Covey with his high school diploma and celebrate with those gathered at the VA Center.

“During a time in his life while others were graduating, he was unable to,” Stankus told My Buckhannon when she had returned from the special trip to Martinsburg.

The ceremony was orchestrated by cooperation between VA staff members and Upshur County Schools.

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When staff members heard Covey's story, they stepped in to help him achieve that goal. The West Virginia Department of Veterans Assistance has a two-page form to help veterans who served in World War II, the Korean War or the Vietnam Conflict earn their high school diploma.

The application lists three requirements: the applicant must have served in the U.S. Armed Forces between Sept. 16, 1940 and Dec. 31, 1946, June 27, 1950 and Jan. 31, 1955 or between Feb. 28, 1961 and May 7, 1975; they must have been discharged from the Armed Forces under honorable conditions; and they must not have previously received a high school diploma.

West Virginia State Code 18-2-34 provides that veterans who left school prior to their graduation and served in the referenced wars will be awarded their high school diploma in either the county where they currently reside or in the county where the veteran would have originally received his diploma.

So, Covey completed his paperwork and was approved to receive his diploma. Members of the Upshur County School system called Covey and invited him to attend graduation and walk in the May 24 ceremony held at West Virginia Wesleyan College. Covey initially planned to attend the ceremony; however, he had a medical issue that prevented him from attending.

Since Covey could not travel to Buckhannon, Upshur County School personnel traveled to Covey.

Harrison said it was a pleasure to share this milestone with Covey.

"We drove four hours to meet with Covey," she said. "To see the tears in his eyes and to hear him talk about how he would give anything if his mother could have been there – her dream was that her son would be a high school graduate," she said.

"This was the best feeling that meant so much for him – finally achieving this milestone," Harrison added. "He was there in his cap and gown and he was so proud."

Stankus said the tears just flowed from Covey's eyes.

The superintendent said she and Harrison felt so blessed to be a part of sharing that moment with Covey.

"When we drove down, we didn't know how it would be, but the staff made him a cake to celebrate," Stankus said. "All of the residents on his floor came out to celebrate with him and see him graduate and see him be presented with his diploma. Even the administrator came to share the event."

Stankus said Covey was presented with a quilt, adding that they are usually patriotic-themed but said his had birds since they're one of his favorite things.

Harrison said going to Martinsburg and presenting Covey with his high school diploma was "some of the most rewarding time she has spent since taking on her current position."

Stankus said following the ceremony, U.S. Senator Joe Manchin presented Covey with a Letter of Commendation on his graduation.

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"Covey's story was also on the Today Show," she said. "I'm so excited he received his diploma. His social worker printed off all on the comments on his accomplishment from Facebook and shared them with Covey. There were more than 1,000 reactions. It was amazing."

Covey said he was pleased with finally receiving his diploma and added he kept thinking about his mother. He said he told everyone, "This would mean everything to my mom."

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6.13 - Cherokee Tribune & Ledger News: Veteran-focused community eyed near national cemetery (23 August, Donald Campbell, Canton, GA)

Dozens turned out this week to learn more about a proposed community geared toward veterans that would sit on 500 acres next to Georgia National Cemetery.

The community room at Fire Station No. 22 in the BridgeMill community was packed with members of the public Wednesday evening to hear from developer Peter Sanders. For two hours, Sanders presented his proposed plans and answered questions from those attending the meeting.

According to Sanders, the Freedom development, as the project is being called, would include:

♦ A museum/living history center;

♦ A lodge and convention center;

♦ An 18-hole golf course with military monuments at each hole, along with an additional nine holes that that are handicap accessible;

♦ A section of low-cost housing catering to veterans; and,

♦ A more traditional residential development that would also be veteran-centric.

Being roughly halfway between Interstates 75 and 575, the conference center would be attractive for companies and organizations to hold meetings, Sanders said.

A major goal of the development is to give back to charities helping veterans, with revenue coming in to be donated out to organizations serving veterans, Sanders said.

Sanders said there would be two access points, to Freedome one on Scott Hudgens Drive and the other on Ga. Highway 20 with a traffic light approximately halfway up the incline and a roundabout on Scott Hudgens Drive to control traffic at the entrances.

The golf course would be a combination of public and private, as there would be times when companies holding conferences at the lodge could take to the course while paying a higher rate. The course would also be open to residents of the development and members of the public much of the time, with veterans paying the lowest rates to play, Sanders said.

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Freedom would be built in several phases, according to Sanders, with the golf course and lodge being the first focus of construction. He did not present a timeline for construction and said the project is in early planning stages.

James Mitchum, director of the Georgia National Cemetery had a prepared statement for the meeting. He explained that the Department of Veterans Affairs and the National Cemetery Administration are neither in support of or opposed to the development.

Mitchum did list a handful of concerns the cemetery and the VA had, including increased traffic in the area, the amount of noise generated during construction, errant golf balls making their way onto the cemetery grounds and that Freedom's main theme of recognizing and remembering America's veterans might create an implied relationship between the development and the VA.

A number of area veterans, including Robert Judd who is a member of the Marine Corps League spoke in favor of the development.

Judd said he and a number of other veterans in the Marine Corps League like what the plan involves, particularly the museum and living history center.

Several residents said a traffic light at the suggested location on Highway 20, would be a mistake because tractor-trailers coming down the incline from the west would have a hard time stopping, while westbound trucks going up the incline would lose their momentum and make it virtually impossible for them to climb the rest of the way up.

Some residents at the meeting questioned the non-profit status of the project, while others said there is inadequate water service in the area.

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6.14 - KOAM (CBS-7, Video): "Wreath Ride" spurs patriotic convoy (24 August, Kate Kelley, Pittsburg, KS)

FORT SCOTT, Kan. - Hundreds of bikers line Main Street, gearing up for a ride to support Wreaths Across America, but this year is particularly special because they're joined by all eight military wrapped CFI trucks, all driven by veterans themselves.

"That's why I volunteer to drive this truck, because of what the truck represents, not only for the company, for myself, but for our country, what stands behind it. It's something that doesn't go away," expressed Scott Bell, an army veteran and CFI driver.

"I've lost a lot of shipmates over the years through accidents. We had a couple KIA's, so it's a big deal," explained Mike Slack, a navy veteran and CFI driver.

Each driver's registration fee goes towards purchasing a wreath, to honor more than 6,000 veterans on their graves at Fort Scott National Cemetery.

"There's so many graves out there that don't ever get anything put on them. Some of them have never seen anything on them in years, and knowing that we helped get a wreath put on that

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person's grave, it's a pretty good feeling," said Kevin Wagner, Volunteer Coordinator with Fort Scott National Cemetery Wreath's Across America project.

"It's just a great honor to be able to show support for the veterans that have paid that ultimate sacrifice and bring a little bit back to them," said Jeff Thurlow, a driver advocate for CFI.

Whether they're driving on 18 wheels or two, all of these drivers are committed to the same thing: preserving the memory of veterans.

"My step dad passed away in 2012, and we wanted a wreath for his grave, so it's just a good way to pay tribute," said Rich Murray, a biker from Nevada, Missouri.

"In the end, we're all a family. We're all brothers, and that's what brings everybody together," said Bell.

At 11 a.m. on December 14, all the wreaths purchased with funds from this event will be placed on veteran graves at Fort Scott Cemetery.

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7. Other

7.1 - U.S. News & World Report (AP): Veterans Band Together to Give Vietnam Vet a Proper Burial (24 August, Mark Rice, 23.3M uvm; Washington, DC)

COLUMBUS, Ga. (AP) — Billy Harold Watts was a decorated and disabled Vietnam War veteran. He had six children, 14 grandchildren and six great-grandchildren.

After collapsing in early June while home alone in Marion County, the 70-year-old lost his battle with lung cancer on Father's Day in a Columbus hospice.

Estranged from his family, no next-of-kin was found before he was buried in a pauper's grave.

But through a remarkable series of events, his family was eventually reached and local veterans were alerted. They, along with other caring folks in the community, rallied together to have his body exhumed for a proper burial: a funeral with military honors in his hometown of Oxford, Mississippi.

"It was just a blessing after a blessing at the end of all of this," said daughter-in-law Carla Watts of Jackson, Tennessee.

Billy served for three years active-duty in the U.S. Marines Corps. He earned two Purple Hearts, a National Defense Service Medal, a Vietnamese Service Medal, a Vietnamese Campaign Medal and a Combat Action Ribbon. He was a private when he was honorably discharged in 1970 at age 21.

Although he wasn't diagnosed, Billy had symptoms associated with post-traumatic stress disorder and was "highly medicated by the VA," Carla said. "When we cleaned Billy's house out, we took 26 bottles of narcotics to the sheriff's department and turned them in."

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From:	Capehart, Bruce P. DURVAMC /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6866EFF4E9DF4A48846D056A02044C38-CAPEHART, B (b)(6) @va.gov>
To:	Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat (b)(6) @va.gov>; Glassman, Peter A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90608d43ef14423db308fb6c71ed750b-Glassman, P (b)(6) @va.gov>; Schreiber, Matthew A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=db4d0324bf0945f183f33816c7fd1db0-Schreiber, (b)(6) @va.gov>
CC:	Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen (b)(6) @va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b)(6) @va.gov>; Cunningham, Fran /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=613f0d8e535d46af95fed310f100dcbc-Cunningham, <(b)(6) @va.gov>
Subject:	RE: [MARKETING] [EXTERNAL] U.S. Medicine Direct - August Issue
Date:	2019/08/16 13:52:56
Priority:	Normal
Type:	Note

From the article Matthew sent:
"Already, many concerns have been raised about the drug's safety and efficacy, its suspicious fast-track approval through FDA review, and VA's contracting process," House VA Committee Chair Mark Takano said in a statement the day the Guardian article was released. "Today's reporting raises additional concerns that VA's own process for objective review is being undercut by undue influences. Questions remain about the ultimate impact on the health and safety of veterans, who should not be made into a 'test case' while the clinical community continues to gather data about this treatment.

Have any media outlets reported the esketamine do not promote decision? Seems to me that our do not promote decision addresses the possibility of 'undue influence' regarding esketamine.

The article Pete sent doesn't mention Dr. Thase receiving research support from Janssen. It should have.

You all have a great weekend.

From: Fuller, Matthew A. (PBM)
Sent: Friday, August 16, 2019 1:30 PM
To: Glassman, Peter A. (b)(6) @va.gov>; Capehart, Bruce P. DURVAMC <(b)(6) @va.gov>; Schreiber, Matthew A. (b)(6) @va.gov>
Cc: Zacher, Jennifer L. (PBM) (b)(6) @va.gov>; Valentino, Michael (VACO) (b)(6) @va.gov>; Cunningham, Fran (b)(6) @va.gov>
Subject: RE: [MARKETING] [EXTERNAL] U.S. Medicine Direct - August Issue

AMERICAN OVERSIGHT

Thanks Pete.

I found the accompanying article more interesting.

Matthew

Political Issues Related to VA's Limited Approval of Esketamine for Depression
by Stephen Spotswood

August 16, 2019
WASHINGTON—A VA panel this summer opted not to add the new depression medication esketamine, Spravato, to the department's formulary in the usual way. This came despite strong support from President Donald Trump and an effort by VA officials to fast-track the drug for approved use at VA facilities.
Instead, the panel voted to allow VA physicians to prescribe the ketamine derivative on a pre-approved, case-by-case basis and also required physicians adhere to the Food and Drug Administration's limited distribution requirements. According to those requirements, Spravato can only be prescribed following failure by at least two other medications.
The drug will need to be administered by a physician who will be required to observe the patient after dosing. The patient also will need to be on another antidepressant medication while taking Spravato.
In the week prior to the VA panel's vote, Trump met with VA Secretary Robert Wilkie and others to discuss the ongoing opioid abuse crisis, during which he brought up Spravato and its reported success in treating depression.
Trump told those present that that he had previously spoken with Wilkie about the drug and told him to "Corner the market on it and give it to anybody that has the problem. You have people calling—and our folks do a great job on the phone, but it's a telephone. You have people calling, looking for help. And if those people had that, I'm hearing like instantaneously they're in much better shape," according to a transcript of the meeting released by the White House.
Asked for an update on VA's progress with Spravato, Wilkie told the president, "We are working with Johnson &Johnson to distribute it. We should have it in all our VA hospitals by the end of the year. But it's in the purchasing process right now."
Trump told Wilkie that he expected Johnson &Johnson, to be "very generous to you. And if you'd like, I'll help you negotiate. Because, seriously, I just said 'Corner the market.'"

Under Scrutiny

This support by the president and the fast-tracking of the drug through FDA approval is now coming under scrutiny by legislators and the press, with questions being asked about possible unethical influence being asserted on VA by the Mar-a-Lago Trio—a group of unofficial advisers to Trump who are at the center of a number of lawsuits.
The three men—Ike Perlmutter, CEO of Marvel Entertainment; Dr. Bruce Moskowitz, an internal medicine specialist; and Marc Sherman, a private attorney—reportedly had a hand in using their relationship to the president to direct policy and personnel decisions at VA. Questions have been raised about possible financial benefit to them.
Among their several contacts with VA officials, they reportedly pushed for the department to partner with Johnson &Johnson in 2017 on a campaign around veteran suicide awareness. This resulted in the #BeThere campaign in 2017, according to media reports.
This connection between Spravato's manufacturer and the ongoing Mar-a-Lago controversy was cited in an article in *The Guardian* in June. That article, along with questions raised by physicians and

AMERICAN OVERSIGHT

researchers about the trials FDA considered in approving Spravato has legislators demanding answers from VA.

"Already, many concerns have been raised about the drug's safety and efficacy, its suspicious fast-track approval through FDA review, and VA's contracting process," House VA Committee Chair Mark Takano said in a statement the day the *Guardian* article was released. "Today's reporting raises additional concerns that VA's own process for objective review is being undercut by undue influences. Questions remain about the ultimate impact on the health and safety of veterans, who should not be made into a 'test case' while the clinical community continues to gather data about this treatment.

"We demand that VA provide documents and information about its review and contracting process to adequately address critical questions—including whether VA officials were pressured by the White House or the Mar-a-Lago 'three' to prescribe this drug to veterans. Spravato should not be added to VA's formulary until we have more answers about what this means for our nation's veterans."

Representatives from Janssen Pharmaceuticals—the subsidiary of Johnson &Johnson that developed Spravato—released a statement conveying their deep disappointment with "recent misleading media coverage" around the drug.

"Treatment-resistant depression is a critical unmet health need that carries significant economic, emotional and functional burden. ... Spravato offers significant and sustained improvement in symptoms of depression, bringing hope to patients who have cycled through multiple medicines without relief," the company said in their statement. "We firmly believe that people suffering from TRD, including our nation's veterans, deserve the opportunity to benefit from this breakthrough medicine."

VA has estimated that 10-15% of the 20 million veterans has major depression requiring psychotherapy or antidepressants. About one-third of those are considered treatment-resistant, having tried multiple antidepressants without success.

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From:	Glassman, Peter A. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90608D43EF14423DB308FB6C71ED750B-GLASSMAN, P (b)(6) @va.gov>
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Subject:	RE: [MARKETING] [EXTERNAL] U.S. Medicine Direct - August Issue
Date:	2019/08/16 13:51:41
Priority:	Normal
Type:	Note

Very interesting, indeed. Thanks

From: Fuller, Matthew A. (PBM)
Sent: Friday, August 16, 2019 10:30 AM
To: Glassman, Peter A. (b)(6) @va.gov>; Capehart, Bruce P. DURVAMC (b)(6) @va.gov>; Schreiber, Matthew A. (b)(6) @va.gov>
Cc: Zacher, Jennifer L. (PBM) (b)(6) @va.gov>; Valentino, Michael (VACO) (b)(6) @va.gov>; Cunningham, Fran (b)(6) @va.gov>
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AMERICAN OVERSIGHT

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To:	Glassman, Peter A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90608d43ef14423db308fb6c71ed750b-Glassman, P (b)(6) @va.gov>
Subject:	RE: [MARKETING] [EXTERNAL] U.S. Medicine Direct - August Issue
Date:	2019/08/16 14:56:00
Priority:	Normal
Type:	Note

Thanks Pete…safe travels

From: Glassman, Peter A.
Sent: Friday, August 16, 2019 2:51 PM
To: Valentino, Michael (VACO) (b)(6) @va.gov>
Subject: RE: [MARKETING] [EXTERNAL] U.S. Medicine Direct - August Issue

(b) (6)

As a FYI, I will be in Atlanta at Anthony's group next week

I think all is set for Scotland—just waiting to get the official passport…..

P

From: Valentino, Michael (VACO)
Sent: Friday, August 16, 2019 11:49 AM
To: Glassman, Peter A. (b)(6) @va.gov>
Subject: RE: [MARKETING] [EXTERNAL] U.S. Medicine Direct - August Issue

(b) (6)

Were making it available to appropriately selected patients, have put safeguards in place for safe administration and are collecting safety and effectiveness data (b) (6)

From: Glassman, Peter A.
Sent: Friday, August 16, 2019 2:43 PM
To: Valentino, Michael (VACO) (b)(6) @va.gov>
Subject: RE: [MARKETING] [EXTERNAL] U.S. Medicine Direct - August Issue

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(b) (6) Glad they are supportive and that HVAC understands that we are trying to balance all these factors for efficacy and safety.

From: Valentino, Michael (VACO)
Sent: Friday, August 16, 2019 11:40 AM
To: Glassman, Peter A. (b)(6) @va.gov>
Subject: RE: [MARKETING] [EXTERNAL] U.S. Medicine Direct - August Issue

Not a peep.

I did have to go brief the HVAC majority staff. They had no problem with our approach.

From: Glassman, Peter A.
Sent: Friday, August 16, 2019 2:39 PM
To: Valentino, Michael (VACO) (b)(6) @va.gov>
Subject: RE: [MARKETING] [EXTERNAL] U.S. Medicine Direct - August Issue

(b) (6)

Have we received any feedback/push back on our decision of placement in therapy? I had anticipated that but haven't heard anything negative....

p

From: Valentino, Michael (VACO)
Sent: Friday, August 16, 2019 11:30 AM
To: Glassman, Peter A. (b)(6) @va.gov>
Subject: RE: [MARKETING] [EXTERNAL] U.S. Medicine Direct - August Issue

(b) (6)

"The effect of esketamine isn't as large or quite as fast as IV ketamine, but a form of treatment that doesn't require an IV is a good thing when you have to gauge and marshal cost and efficacy," he said. Ketamine does not have FDA approval for treatment of depression, but is increasingly used off-label for that purpose

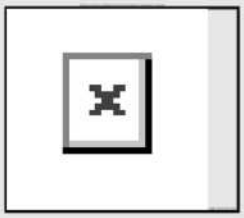
Annette Boyle and U.S. medicine should be ashamed of themselves

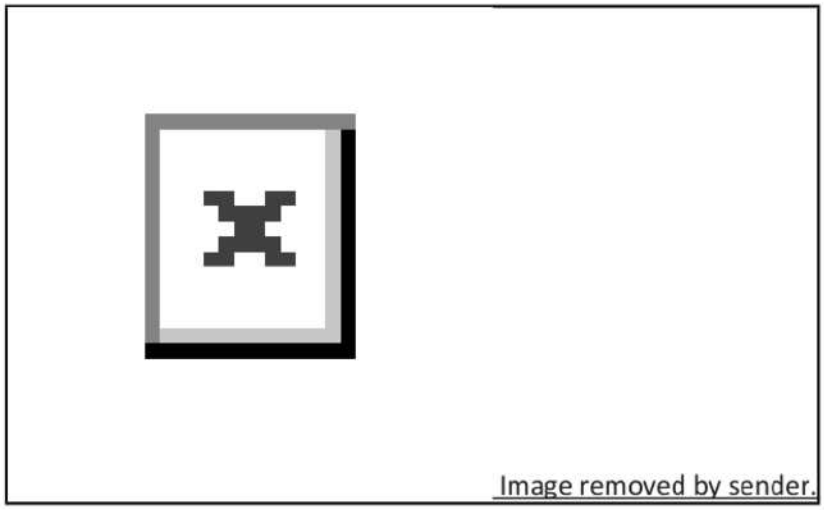
AMERICAN OVERSIGHT

From: Glassman, Peter A.
Sent: Friday, August 16, 2019 12:54 PM
To: Fuller, Matthew A. (PBM) (b)(6) @va.gov>; Capehart, Bruce P. DURVAMC (b)(6) @va.gov>; Schreiber, Matthew A. <(b)(6) @va.gov>
Cc: Zacher, Jennifer L. (PBM) (b)(6) @va.gov>; Valentino, Michael (VACO) (b)(6) @va.gov>; Cunningham, Fran <(b)(6) @va.gov>
Subject: FW: [MARKETING] [EXTERNAL] U.S. Medicine Direct - August Issue

FYI—first article is of interest

From: U.S. Medicine <usmdirect@usmedicine.com>
Sent: Friday, August 16, 2019 9:44 AM
To: Glassman, Peter A. (b)(6) @va.gov>
Subject: [MARKETING] [EXTERNAL] U.S. Medicine Direct - August Issue





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U.S. MEDICINE NEWS UPDATE

Debate Continues on Esketamine Efficacy and Safety for Depression Treatment

PHILADELPHIA - Is esketamine a revolutionary treatment for depression or just another moderately effective adjunctive medication with some potentially serious risks? The VA's Medical Advisory Panel leaned toward the latter position when it decided in June to approve the use of esketamine on a non-formulary basis for individuals who have previously failed at least two trials of other anti-depressants. The formulary committee's decision has done little to tamp down debate about the drug, however.

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HIGHLIGHTS FROM THE AUGUST ISSUE OF U.S. MEDICINE

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Guidelines Reduced Morality in Veterans at High Risk of Recurrent Stroke

INDIANAPOLIS - Meticulously following clinical guidelines in VA patients who suffered transient ischemic attack or nonsevere ischemic stroke reduced by nearly one-third their risk of death within a year, according to a new study. Yet, in the cohort study led by researchers at Richard L. Roudebush VAMC, of 8,076 patients with those cardiovascular events from October 2010 until September 2011, only 15.3% were recipients of so-called without-fail care.

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Ensuring Community Providers Meet Veteran Suicide Prevention Standards

WASHINGTON - As leaders from across multiple federal agencies begin work on a roadmap to combat veteran suicide, they are searching for ways to turn existing efforts in towns, cities, counties and neighborhoods across the country into a net that can help catch struggling veterans. What remains unclear is if those local organizations, especially non-VA healthcare providers, are fully trained and ready to provide the level of care these veterans need.

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VA Study Shows Benefit of PCSK9 Inhibitors After Maximizing Other Therapies

HOUSTON - Veterans who have experienced acute coronary syndrome within the past year face a substantial risk of a repeat event. Proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitors significantly reduce that risk, but determining who would benefit most and when they should be initiated has been challenging. Researchers determined that the inhibitors clearly have a role in reducing mortality in high-risk veterans with acute coronary syndrome.

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From the Editor in Chief

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Chester Buckenmaier

13. The delivery of good medical care is to do as much nothing as possible.

"Laws of the House of God" ~Samuel Shem

An editorial idea that was rattling around in my skull had to do with my concern that medicine has become too focused on "doing things" to patients in support of a warped (in my opinion) economic profit model of medicine. Physicians are incentivized and encouraged to favor profitable prescriptions and procedures with little regard to the outcomes that result in their patients from these therapeutic activities that we inflict upon them. As I perused the internet with this dark and rather cumbersome idea in mind, I stumbled upon an old friend from my formative years as a medical student,

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III, MD COL (ret), MC, USA

intern and resident. That friend was a book I had read multiple times to help me cope with the stresses that are inherent to becoming a physician.

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Brenda L. Mooney, Editorial Director | U.S. Medicine | www.usmedicine.com

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Sent Date:	2019/08/16 14:56:20
Delivered Date:	2019/08/16 14:56:00

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Subject:	RE: [MARKETING] [EXTERNAL] U.S. Medicine Direct - August Issue
Date:	2019/08/16 14:51:05
Priority:	Normal
Type:	Note

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(b) (6) . Glad they are supportive and that HVAC understands that we are trying to balance all these factors for efficacy and safety.

From: Valentino, Michael (VACO)
Sent: Friday, August 16, 2019 11:40 AM
To: Glassman, Peter A. (b)(6) @va.gov>
Subject: RE: [MARKETING] [EXTERNAL] U.S. Medicine Direct - August Issue

Not a peep.

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I did have to go brief the HVAC majority staff. They had no problem with our approach.

From: Glassman, Peter A.
Sent: Friday, August 16, 2019 2:39 PM
To: Valentino, Michael (VACO) <(b)(6) @va.gov>
Subject: RE: [MARKETING] [EXTERNAL] U.S. Medicine Direct - August Issue

(b) (6)

Have we received any feedback/push back on our decision of placement in therapy? I had anticipated that but haven't heard anything negative....

p

From: Valentino, Michael (VACO)
Sent: Friday, August 16, 2019 11:30 AM
To: Glassman, Peter A. (b)(6) @va.gov>
Subject: RE: [MARKETING] [EXTERNAL] U.S. Medicine Direct - August Issue

(b) (6)

"The effect of esketamine isn't as large or quite as fast as IV ketamine, but a form of treatment that doesn't require an IV is a good thing when you have to gauge and marshal cost and efficacy," he said. Ketamine does not have FDA approval for treatment of depression, but is increasingly used off-label for that purpose

Annette Boyle and U.S. medicine should be ashamed of themselves

From: Glassman, Peter A.
Sent: Friday, August 16, 2019 12:54 PM
To: Fuller, Matthew A. (PBM) (b)(6) @va.gov>; Capehart, Bruce P. DURVAMC (b)(6) @va.gov>; Schreiber, Matthew A. (b)(6) @va.gov>
Cc: Zacher, Jennifer L. (PBM) (b)(6) @va.gov>; Valentino, Michael (VACO) (b)(6) @va.gov>; Cunningham, Fran <(b)(6) @va.gov>
Subject: FW: [MARKETING] [EXTERNAL] U.S. Medicine Direct - August Issue

FYI—first article is of interest

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From: U.S. Medicine <usmdirect@usmedicine.com>
Sent: Friday, August 16, 2019 9:44 AM
To: Glassman, Peter A. (b)(6) @va.gov>
Subject: [MARKETING] [EXTERNAL] U.S. Medicine Direct - August Issue

USM - August 2019 Direct **usmedicine.com**

U.S. MEDICINE NEWS UPDATE

Debate Continues on Esketamine Efficacy and Safety for Depression Treatment

PHILADELPHIA - Is esketamine a revolutionary treatment for depression or just another moderately effective adjunctive medication with some potentially serious risks? The VA's Medical Advisory Panel leaned toward the latter position when it decided in June to approve the use of esketamine on a non-formulary basis for individuals who have previously failed at least two trials of other anti-depressants. The formulary committee's decision has done little to tamp down debate

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about the drug, however.

Read More

HIGHLIGHTS FROM THE AUGUST ISSUE OF U.S. MEDICINE

Guidelines Reduced Morality in Veterans at High Risk of Recurrent Stroke

INDIANAPOLIS - Meticulously following clinical guidelines in VA patients who suffered transient ischemic attack or nonsevere ischemic stroke reduced by nearly one-third their risk of death within a year, according to a new study. Yet, in the cohort study led by researchers at Richard L. Roudebush VAMC, of 8,076 patients with those cardiovascular events from October 2010 until September 2011, only 15.3% were recipients of so-called without-fail care.

Read More

Ensuring Community Providers Meet Veteran Suicide Prevention Standards

WASHINGTON - As leaders from across multiple federal agencies begin work on a roadmap to combat veteran suicide, they are searching for ways to turn existing efforts in towns, cities, counties and neighborhoods across the country into a net that can help catch struggling veterans. What remains unclear is if those local organizations, especially non-VA healthcare providers, are fully trained and ready to provide the level of care these veterans need.

Read More

VA Study Shows Benefit of PCSK9 Inhibitors After Maximizing Other Therapies

HOUSTON - Veterans who have experienced acute coronary syndrome within the past year face

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a substantial risk of a repeat event. Proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitors significantly reduce that risk, but determining who would benefit most and when they should be initiated has been challenging. Researchers determined that the inhibitors clearly have a role in reducing mortality in high-risk veterans with acute coronary syndrome.

Read More

From the Editor in Chief



Chester Buckenmaier III, MD COL (ret), MC, USA

13. The delivery of good medical care is to do as much nothing as possible. "Laws of the House of God" ~Samuel Shem

An editorial idea that was rattling around in my skull had to do with my concern that medicine has become too focused on "doing things" to patients in support of a warped (in my opinion) economic profit model of medicine. Physicians are incentivized and encouraged to favor profitable prescriptions and procedures with little regard to the outcomes that result in their patients from these therapeutic activities that we inflict upon them. As I perused the internet with this dark and rather cumbersome idea in mind, I stumbled upon an old friend from my formative years as a medical student, intern and resident. That friend was a book I had read multiple times to help me cope with the stresses that are inherent to becoming a physician.

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Sender:	Glassman, Peter A. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90608D43EF14423DB308FB6C71ED750B-GLASSMAN, P (b)(6) @va.gov>
Recipient:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>
Sent Date:	2019/08/16 14:51:04
Delivered Date:	2019/08/16 14:51:05

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From:	Mackenzie, Elizabeth (b)(6) @mail.house.gov>
To:	Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd.DIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>
Subject:	Re: [EXTERNAL] Thoughts on Spravato?
Date:	2019/06/18 19:59:16
Priority:	Normal
Type:	Note

Sorry I missed your call. Was in Member meetings this evening.
Are you free tomorrow morning or Thursday afternoon?

Sent from my iPhone

On Jun 18, 2019, at 5:04 PM, Valentino, Michael (VACO) <(b)(6) @va.gov>wrote:

Hi Elizabeth,
Tried your office but missed you.
I'm on VA travel but am available by phone if you need to chat.
(b)(6)

Sent with BlackBerry Work
(www.blackberry.com)

From: Mackenzie, Elizabeth (b)(6) @mail.house.gov>
Date: Tuesday, Jun 18, 2019, 1:52 PM
To: Valentino, Michael (VACO) <(b)(6) @va.gov>
Subject: [EXTERNAL] Thoughts on Spravato?

https://www.theguardian.com/us-news/2019/jun/17/spravato-ketamine-like-drug-that-experts-doubt-and-trump-is-pushing-on-veterans
https://publicintegrity.org/federal-politics/trumps-raves-put-drug-for-vets-on-fast-track-but-experts-arent-sure-it-works/

Happy to chat via phone if you prefer, and doesn't need to be today.

Elizabeth Mackenzie, PhD
Democratic Staff Director
Subcommittee on Health
House Committee on Veterans' Affairs
3470 O'Neill House Office Building
Washington, D.C. 20515
(b)(6)

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Sender:	Mackenzie, Elizabeth (b)(6) @mail.house.gov>
Recipient:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>
Sent Date:	2019/06/18 19:57:54
Delivered Date:	2019/06/18 19:59:16

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From:	Carroll, David (VACO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=95E14EBD3B6745C8952A823B04DABFF5-CARROLL, DA>
To:	Strmiska, Jon G. (Jon.Strmiska@va.gov) /o=VA/ou=VISN 22/cn=RECIPIENTS/cn=VHASDCSTRMIJ *(b)(6)* @va.gov>
Subject:	RE: [EXTERNAL] Task & Purpose media query: President Trump says the VA is buying a product from Johnson and Johnson to combat veterans suicide
Date:	2019/08/21 13:36:00
Priority:	Normal
Type:	Note

Ilse – for all things Spravato.

From: Hammonds, Michele
Sent: Wednesday, August 21, 2019 1:33 PM
To: VHA 10P Actions <VHA10PActions@va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>; VHA 10NC Action <vha10ncaction@va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>
Cc: VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: FW: [EXTERNAL] Task &Purpose media query: President Trump says the VA is buying a product from Johnson and Johnson to combat veterans suicide
Importance: High

Dennis /10P – Hot -This is another Spravato/esketamine query from the president's recent comment earlier today.
Seeking written responses to the following questions

Deadline is today

Q1: What is the product?
A1:

Q2: How exactly does it work to reduce veterans suicides? Mental Health 10NC5
A1:

Q3: Has it been approved by the FDA?
A3: Yes (please insert date)

Q4: How can veterans get this product?
A4:

Q5: What results has this product shown in reducing veterans suicides?
A5:

Michele Hammonds

AMERICAN OVERSIGHT

Office of Communications (10b2B)
(b)(6)

From: Carter, Susan
Sent: Wednesday, August 21, 2019 1:17 PM
To: Hammonds, Michele (b)(6) @va.gov>; Greilsamer, Alan (b)(6) @va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Cc: Noller, Randal (b)(6) @va.gov>; Mandreucci, Christina M. (b)(6) @va.gov>
Subject: FW: [EXTERNAL] Task &Purpose media query: President Trump says the VA is buying a product from Johnson and Johnson to combat veterans suicide

This is another Spravato/esketamine query from the president's recent comment earlier today. Deadline is today. Thanks – Susan

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A4:

Q5: What results has this product shown in reducing veterans suicides?
A5:

Susan Carter
Director, Office of Media Relations
U.S. Department of Veterans Affairs
(b)(6) @va.gov
Desk: (b)(6)
Cell: (b)(6)



cid:image002.jpg@01D3D61E.49531160

From: Jeff Schogol (b)(6) @taskandpurpose.com>
Sent: Wednesday, August 21, 2019 12:49 PM
To: Carter, Susan (b)(6) @va.gov>
Subject: [EXTERNAL] Task &Purpose media query: President Trump says the VA is buying a product from Johnson and Johnson to combat veterans suicide

AMERICAN OVERSIGHT

Good afternoon Ms. Carter,

Thank you for taking my call!

President Trump told reporters today that the VA is buying a new product from Johnson and Johnson that has proven to be effective in combating veterans suicide:

"There's a product that's made right now that just came out by Johnson and Johnson, which has a tremendously positive – pretty short-term – but nevertheless a positive effect.

"I've instructed the head of the VA to go out and buy a lot of it, and we are buying a lot of it. Hopefully, we're getting it at a very good cost. And this is a – I guess it's a form of a stimulant, where if somebody is really in trouble, from the standpoint of suicide, it can do something.

"It's pretty well know, just came out. It's made, I believe, by Johnson and Johnson, and we have calls in now to Johnson and Johnson. Those calls – we've been dealing with them for two months and buying a lot of it."

Can the VA say:

1. What is the product?
2. How exactly does it work to reduce veterans suicides?
3. Has it been approved by the FDA?
4. How can veterans get this product?
5. What results has this product shown in reducing veterans suicides?

My deadline is today. Please feel free to email or call me at 703-697-6623.

Thank you.

Jeff Schogol

Sender:	Carroll, David (VACO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=95E14EBD3B6745C8952A823B04DABFF5-CARROLL, DA>
Recipient:	Strmiska, Jon G. (Jon.Strmiska@va.gov) /o=VA/ou=VISN 22/cn=RECIPIENTS/cn=VHASDCSTRMIJ *(b)(6)* @va.gov>
Sent Date:	2019/08/21 13:36:18
Delivered Date:	2019/08/21 13:36:00

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To:	Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b)(6) @va.gov>
Subject:	RE: [EXTERNAL] Task & Purpose media query: President Trump says the VA is buying a product from Johnson and Johnson to combat veterans suicide
Date:	2019/08/21 15:56:33
Priority:	Normal
Type:	Note

(b) (6)

Sent with BlackBerry Work
(www.blackberry.com)

From: Carroll, David (VACO) (b)(6) @va.gov>
Date: Wednesday, Aug 21, 2019, 3:53 PM
To: VHA CO 10NC5 EXEC <VHACO10NC5EXEC@va.gov>
Subject: FW: [EXTERNAL] Task &Purpose media query: President Trump says the VA is buying a product from Johnson and Johnson to combat veterans suicide

Just for your awareness. This has had a lot of swirl today. Ilse and PBM collaborated on the responses. We just sent this to 10NC for routing back to Comms.

From: Carroll, David (VACO)
Sent: Wednesday, August 21, 2019 3:51 PM
To: Strmiska, Jon G. (b)(6) @va.gov>
Cc: Daniels, Lindsay (b)(6) @va.gov>
Subject: RE: [EXTERNAL] Task &Purpose media query: President Trump says the VA is buying a product from Johnson and Johnson to combat veterans suicide

Cleared. Please note collaboration with PBM and 10P4M. Thanks.

Q1: What is the product?
A1: Esketamine (Spravato)

Q2: How exactly does it work to reduce veterans suicides? Mental Health 10NC5
A2: Spravato was approved by the Food and Drug Administration (FDA) to be used in conjunction with an oral antidepressant for the treatment of treatment resistant depression (TRD). If Spravato treatment of Veterans with TRD is successful, it is expected to have a

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positive impact on death by suicide. Spravato has not been FDA approved for treatment of acute suicidality.

Q3: Has it been approved by the FDA?
A3: Yes. It was approved on March 5, 2019

Q4: How can veterans get this product?
A4: Spravato is available to Veterans enrolled for VA care based on an individualized treatment plan developed by their provider in collaboration with the Veteran.

Q5: What results has this product shown in reducing veterans suicides?
A5: Spravato has not been in use long enough to assess it's effectiveness and safety. VA will closely monitor the use of Spravato in Veterans to more fully understand its relative safety and effectiveness as compared to other available treatments.

From: Hammonds, Michele
Sent: Wednesday, August 21, 2019 1:33 PM
To: VHA 10P Actions <VHA10PActions@va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>; VHA 10NC Action <vha10ncaction@va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>
Cc: VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: FW: [EXTERNAL] Task &Purpose media query: President Trump says the VA is buying a product from Johnson and Johnson to combat veterans suicide
Importance: High

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A1: Spravato was approved by the Food and Drug Administration (FDA) to be used in conjunction with an oral antidepressant for the treatment of treatment resistant depression (TRD). If Spravato treatment of Veterans with TRD is successful, it is expected to have a positive impact on death by suicide. Spravato has not been FDA approved for treatment of acute suicidality.

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Q3: Has it been approved by the FDA?
A3: Yes (please insert date). It was approved on March 5, 2019

Q4: How can veterans get this product?
A4: Spravato is available to Veterans enrolled for VA care based on an individualized treatment plan developed by their provider in collaboration with the Veteran.

Q5: What results has this product shown in reducing veterans suicides?
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Michele Hammonds
Office of Communications (10b2B)
(b)(6)

From: Carter, Susan
Sent: Wednesday, August 21, 2019 1:17 PM
To: Hammonds, Michele (b)(6) @va.gov>; Greilsamer, Alan (b)(6) @va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Cc: Noller, Randal (b)(6) @va.gov>; Mandreucci, Christina M. (b)(6) @va.gov>
Subject: FW: [EXTERNAL] Task &Purpose media query: President Trump says the VA is buying a product from Johnson and Johnson to combat veterans suicide

This is another Spravato/esketamine query from the president's recent comment earlier today. Deadline is today. Thanks – Susan

Q1: What is the product?
A1:

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Susan Carter
Director, Office of Media Relations
U.S. Department of Veterans Affairs
(b)(6) *@va.gov*
Desk: (b)(6)
Cell: .(b)(6)



cid:image002.jpg@01D3D61E.49531160

From: Jeff Schogol *(b)(6)* @taskandpurpose.com>
Sent: Wednesday, August 21, 2019 12:49 PM
To: Carter, Susan *(b)(6)* @va.gov>
Subject: [EXTERNAL] Task &Purpose media query: President Trump says the VA is buying a product from Johnson and Johnson to combat veterans suicide

Good afternoon Ms. Carter,

Thank you for taking my call!

President Trump told reporters today that the VA is buying a new product from Johnson and Johnson that has proven to be effective in combating veterans suicide:

"There's a product that's made right now that just came out by Johnson and Johnson, which has a tremendously positive – pretty short-term – but nevertheless a positive effect.

"I've instructed the head of the VA to go out and buy a lot of it, and we are buying a lot of it. Hopefully, we're getting it at a very good cost. And this is a – I guess it's a form of a stimulant, where if somebody is really in trouble, from the standpoint of suicide, it can do something.

"It's pretty well know, just came out. It's made, I believe, by Johnson and Johnson, and we have calls in now to Johnson and Johnson. Those calls – we've been dealing with them for two months and buying a lot of it."

Can the VA say:

1. What is the product?
2. How exactly does it work to reduce veterans suicides?
3. Has it been approved by the FDA?
4. How can veterans get this product?
5. What results has this product shown in reducing veterans suicides?

My deadline is today. Please feel free to email or call me at *(b)(6)*

Thank you.

Jeff Schogol

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Sender:	Smith, Clifford A. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B729882079394F37AF66F66722F99400-SMITH, CLIF *(b)(6)* @va.gov>
Recipient:	Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da *(b)(6)* @va.gov>
Sent Date:	2019/08/21 15:56:32
Delivered Date:	2019/08/21 15:56:33

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From:	Strmiska, Jon G. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9872F41BF2844C8085D371E21482B635-STRMISKA, J (b)(6) @va.gov>
To:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b)(6) @va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>
CC:	Daniels, Lindsay /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ed253196fb6b4f32aa922c90dbd05f29-Daniels, Li (b)(6) @va.gov>; Lahl, Dennis /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=39fba8ea7cd941b3a0a4f79ca3c6ee87-Lahl, Denni (b)(6) @va.gov>
Subject:	RE: [EXTERNAL] Task & Purpose media query: President Trump says the VA is buying a product from Johnson and Johnson to combat veterans suicide
Date:	2019/08/21 14:25:49
Priority:	Normal
Type:	Note

Dennis in 10P4 is assigning this out as well. We'll clear 2 and 5 once responses are developed.

Jon G. Strmiska
Business Operations Manager (10NC5)
Phone: (b)(6) **FAX: 202.495.5933**

From: Wiechers, Ilse
Sent: Wednesday, August 21, 2019 2:15 PM
To: Strmiska, Jon G. <(b)(6) @va.gov>; Valentino, Michael (VACO) (b)(6) @va.gov>; Emmendorfer, Thomas (PBM) (b)(6) @va.gov>
Cc: Daniels, Lindsay (b)(6) @va.gov>
Subject: RE: [EXTERNAL] Task &Purpose media query: President Trump says the VA is buying a product from Johnson and Johnson to combat veterans suicide

Jon – I should work directly with Mike Valentino and the PBM team on response to all of these.

I'm cc'ing Mike and Tom (looks like Jen is OOO) and will work with them on this now.

Ilse

From: Strmiska, Jon G.
Sent: Wednesday, August 21, 2019 10:58 AM
To: Wiechers, Ilse (b)(6) @va.gov>
Cc: Daniels, Lindsay (b)(6) @va.gov>
Subject: FW: [EXTERNAL] Task &Purpose media query: President Trump says the VA is buying a product

AMERICAN OVERSIGHT

from Johnson and Johnson to combat veterans suicide
Importance: High

Ilse,

Looks like 2 and 5 are assigned to 10NC5.

Please review and provide response as soon as reasonably possible.

Thanks!

Jon G. Strmiska
Business Operations Manager (10NC5)
Phone: (b)(6) **FAX: 202.495.5933**

From: Hammonds, Michele
Sent: Wednesday, August 21, 2019 1:33 PM
To: VHA 10P Actions <VHA10PActions@va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>; VHA 10NC Action <vha10ncaction@va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>
Cc: VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
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Q4: How can veterans get this product?
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A5:

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Michele Hammonds
Office of Communications (10b2B)
(b)(6)

From: Carter, Susan
Sent: Wednesday, August 21, 2019 1:17 PM
To: Hammonds, Michele <(b)(6) @va.gov>; Greilsamer, Alan <(b)(6) @va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Cc: Noller, Randal <(b)(6) @va.gov>; Mandreucci, Christina M. <(b)(6) @va.gov>
Subject: FW: [EXTERNAL] Task &Purpose media query: President Trump says the VA is buying a product from Johnson and Johnson to combat veterans suicide

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Susan Carter
Director, Office of Media Relations
U.S. Department of Veterans Affairs
(b)(6) @va.gov
Desk: (b)(6)
Cell: (b)(6)



cid:image002.jpg@01D3D61E.49531160

From: Jeff Schogol (b)(6) @taskandpurpose.com>
Sent: Wednesday, August 21, 2019 12:49 PM
To: Carter, Susar (b)(6) @va.gov>

AMERICAN OVERSIGHT

Subject: [EXTERNAL] Task &Purpose media query: President Trump says the VA is buying a product from Johnson and Johnson to combat veterans suicide

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2. How exactly does it work to reduce veterans suicides?
3. Has it been approved by the FDA?
4. How can veterans get this product?
5. What results has this product shown in reducing veterans suicides?

My deadline is today. Please feel free to email or call me at (b)(6)

Thank you.

Jeff Schogol

Sender:	Strmiska, Jon G. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9872F41BF2844C8085D371E21482B635-STRMISKA, J (b)(6) @va.gov>
Recipient:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b)(6) @va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>; Daniels, Lindsay /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ed253196fb6b4f32aa922c90dbd05f29-Daniels, Li (b)(6) @va.gov>; Lahl, Dennis /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=39fba8ea7cd941b3a0a4f79ca3c6ee87-Lahl, Denni (b)(6) @va.gov>

AMERICAN OVERSIGHT

Sent Date:	2019/08/21 14:25:47
Delivered Date:	2019/08/21 14:25:49
From:	Lahl, Dennis /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=39FBA8EA7CD941B3A0A4F79CA3C6EE87-LAHL, DENNI (b)(6) @va.gov>
To:	Hammonds, Michele /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c03c261b4add4a6a9923f5c5335acb42-Hammonds, M (b)(6) @va.gov>; VHA 10P Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5098b521b1f34f8a97f74be24709d62f-VHA 10P Act <VHA10PActions@va.gov>; VHA 10P4 Communication Group /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4ba2ff9b4604547be7834a71415253c-VHA 10P4 Co <vha10p4comm@va.gov>; VHA 10NC Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aeebc70340b3476a87b15fbe600f1888-VHA 10NC Ac <vha10ncaction@va.gov>; VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>
CC:	VHA CO 10B2B Media /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12e0caca48054b8da1e793651a89d81c-VHA CO 10B2 <VHACO10B2BMedia@va.gov>
Subject:	RE: [EXTERNAL] Task & Purpose media query: President Trump says the VA is buying a product from Johnson and Johnson to combat veterans suicide
Date:	2019/08/21 13:38:34
Priority:	Normal
Type:	Note

Michele,

Moving this along, however I think 2 and 5 will be to 10NC5.

Dennis

Dennis Lahl FAC-P/PM
Office of the Assistant Deputy Under Secretary for Health for Patient Care Services (10P4)
VACO PCS IT/BCAG/ISO Liaison
TMS OPCS DM
ph: (b)(6)
fax: 202-273-5483
Dennis Lahl

From: Hammonds, Michele
Sent: Wednesday, August 21, 2019 1:33 PM
To: VHA 10P Actions <VHA10PActions@va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>; VHA 10NC Action <vha10ncaction@va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>

AMERICAN OVERSIGHT

Cc: VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: FW: [EXTERNAL] Task & Purpose media query: President Trump says the VA is buying a product from Johnson and Johnson to combat veterans suicide
Importance: High

Dennis /10P – Hot -This is another Spravato/esketamine query from the president's recent comment earlier today.
Seeking written responses to the following questions

Deadline is today

Q1: What is the product?
A1:

Q2: How exactly does it work to reduce veterans suicides? Mental Health 10NC5
A1:

Q3: Has it been approved by the FDA?
A3: Yes (please insert date)

Q4: How can veterans get this product?
A4:

Q5: What results has this product shown in reducing veterans suicides?
A5:

Michele Hammonds
Office of Communications (10b2B)
(b)(6)

From: Carter, Susan
Sent: Wednesday, August 21, 2019 1:17 PM
To: Hammonds, Michele (b)(6) @va.gov>; Greilsamer, Alan <(b)(6) @va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Cc: Noller, Randal (b)(6) @va.gov>; Mandreucci, Christina M. (b)(6) @va.gov>
Subject: FW: [EXTERNAL] Task & Purpose media query: President Trump says the VA is buying a product from Johnson and Johnson to combat veterans suicide

This is another Spravato/esketamine query from the president's recent comment earlier today. Deadline is today. Thanks – Susan

Q1: What is the product?
A1:

AMERICAN OVERSIGHT

Q2: How exactly does it work to reduce veterans suicides?
A1:

Q3: Has it been approved by the FDA?
A3: Yes (please insert date)

Q4: How can veterans get this product?
A4:

Q5: What results has this product shown in reducing veterans suicides?
A5:

Susan Carter
Director, Office of Media Relations
U.S. Department of Veterans Affairs
(b)(6) @va.gov
Desk:(b)(6)
Cell: (b)(6)



cid:image002.jpg@01D3D61E.49531160

From: Jeff Schogol <(b)(6)@taskandpurpose.com>
Sent: Wednesday, August 21, 2019 12:49 PM
To: Carter, Susan (b)(6) @va.gov>
Subject: [EXTERNAL] Task & Purpose media query: President Trump says the VA is buying a product from Johnson and Johnson to combat veterans suicide

Good afternoon Ms. Carter,

Thank you for taking my call!

President Trump told reporters today that the VA is buying a new product from Johnson and Johnson that has proven to be effective in combating veterans suicide:

"There's a product that's made right now that just came out by Johnson and Johnson, which has a tremendously positive – pretty short-term – but nevertheless a positive effect.

"I've instructed the head of the VA to go out and buy a lot of it, and we are buying a lot of it. Hopefully, we're getting it at a very good cost. And this is a – I guess it's a form of a stimulant, where if somebody is really in trouble, from the standpoint of suicide, it can do something.

"It's pretty well know, just came out. It's made, I believe, by Johnson and Johnson, and we have calls in now to Johnson and Johnson. Those calls – we've been dealing with them for two months and buying a lot of it."

AMERICAN OVERSIGHT

Can the VA say:

1. What is the product?
2. How exactly does it work to reduce veterans suicides?
3. Has it been approved by the FDA?
4. How can veterans get this product?
5. What results has this product shown in reducing veterans suicides?

My deadline is today. Please feel free to email or call me at (b)(6)

Thank you.

Jeff Schogol

Sender:	Lahl, Dennis /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=39FBA8EA7CD941B3A0A4F79CA3C6EE87-LAHL, DENNI (b)(6) @va.gov>
Recipient:	Hammonds, Michele /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c03c261b4add4a6a9923f5c5335acb42-Hammonds, M (b)(6) @va.gov>; VHA 10P Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5098b521b1f34f8a97f74be24709d62f-VHA 10P Act <VHA10PActions@va.gov>; VHA 10P4 Communication Group /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4ba2ff9b4604547be7834a71415253c-VHA 10P4 Co <vha10p4comm@va.gov>; VHA 10NC Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aeebc70340b3476a87b15fbe600f1888-VHA 10NC Ac <vha10ncaction@va.gov>; VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>; VHA CO 10B2B Media /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12e0caca48054b8da1e793651a89d81c-VHA CO 10B2 <VHACO10B2BMedia@va.gov>
Sent Date:	2019/08/21 13:38:33
Delivered Date:	2019/08/21 13:38:34

AMERICAN OVERSIGHT

To:	Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd.LT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <Ilse.Wiechers@va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>
Subject:	RE: [EXTERNAL] Task & Purpose media query: President Trump says the VA is buying a product from Johnson and Johnson to combat veterans suicide
Date:	2019/08/21 14:27:50
Priority:	Normal
Type:	Note

My thoughts below:

Sent with BlackBerry Work
(www.blackberry.com)

From: Wiechers, Ilse (b)(6) @va.gov>
Date: Wednesday, Aug 21, 2019, 2:15 PM
To: Strmiska, Jon G. (b)(6) @va.gov>, Valentino, Michael (VACO) (b)(6) @va.gov>, Emmendorfer, Thomas (PBM) (b)(6) @va.gov>
Cc: Daniels, Lindsay (b)(6) @va.gov>
Subject: RE: [EXTERNAL] Task &Purpose media query: President Trump says the VA is buying a product from Johnson and Johnson to combat veterans suicide
Jon – I should work directly with Mike Valentino and the PBM team on response to all of these.

I'm cc'ing Mike and Tom (looks like Jen is OOO) and will work with them on this now.

Ilse

From: Strmiska, Jon G.
Sent: Wednesday, August 21, 2019 10:58 AM
To: Wiechers, Ilse (b)(6) @va.gov>
Cc: Daniels, Lindsay (b)(6) @va.gov>
Subject: FW: [EXTERNAL] Task &Purpose media query: President Trump says the VA is buying a product from Johnson and Johnson to combat veterans suicide
Importance: High

Ilse,

Looks like 2 and 5 are assigned to 10NC5.

Please review and provide response as soon as reasonably possible.

Thanks!

Jon G. Strmiska

AMERICAN OVERSIGHT

Business Operations Manager (10NC5)
Phone: (b)(6) **FAX: 202.495.5933**

From: Hammonds, Michele
Sent: Wednesday, August 21, 2019 1:33 PM
To: VHA 10P Actions <VHA10PActions@va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>; VHA 10NC Action <vha10ncaction@va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>
Cc: VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: FW: [EXTERNAL] Task &Purpose media query: President Trump says the VA is buying a product from Johnson and Johnson to combat veterans suicide
Importance: High

Dennis /10P – Hot -This is another Spravato/esketamine query from the president's recent comment earlier today.
Seeking written responses to the following questions

Deadline is today

Q1: What is the product?
A1: Esketamine (Spravato)

Q2: How exactly does it work to reduce veterans suicides? Mental Health 10NC5
A1: Spravato was approved by the FDA for Treatment Resistant Depression (TRD). If Spravato treatment of Veterans with TRD is successful, it is expected to have a positive impact on death by suicide.

Q3: Has it been approved by the FDA?
A3: Yes (please insert date). It was approved on March 5, 2019

Q4: How can veterans get this product?
A4: Spravato is available to Veterans enrolled for VA care based on an individualized treatment plan developed by their provider in collaboration with the Veteran

Q5: What results has this product shown in reducing veterans suicides?
A5: Spravato has not been in use long enough to assess it's effectiveness and safety

Michele Hammonds
Office of Communications (10b2B)
(b)(6)

From: Carter, Susan
Sent: Wednesday, August 21, 2019 1:17 PM

AMERICAN OVERSIGHT

To: Hammonds, Michele <(b)(6) @va.gov>; Greilsamer, Alan (b)(6) @va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Cc: Noller, Randal <(b)(6) @va.gov>; Mandreucci, Christina M. <(b)(6) @va.gov>
Subject: FW: [EXTERNAL] Task &Purpose media query: President Trump says the VA is buying a product from Johnson and Johnson to combat veterans suicide

This is another Spravato/esketamine query from the president's recent comment earlier today. Deadline is today. Thanks – Susan

Q1: What is the product?
A1:

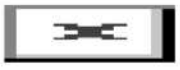
Q2: How exactly does it work to reduce veterans suicides?
A1:

Q3: Has it been approved by the FDA?
A3: Yes (please insert date)

Q4: How can veterans get this product?
A4:

Q5: What results has this product shown in reducing veterans suicides?
A5:

Susan Carter
Director, Office of Media Relations
U.S. Department of Veterans Affairs
(b)(6) @va.gov
Desk: (b)(6)
Cell (b)(6)



cid:image002.jpg@01D3D61E.49531160

From: Jeff Schogol <(b)(6) @taskandpurpose.com>
Sent: Wednesday, August 21, 2019 12:49 PM
To: Carter, Susan <(b)(6) @va.gov>
Subject: [EXTERNAL] Task &Purpose media query: President Trump says the VA is buying a product from Johnson and Johnson to combat veterans suicide

Good afternoon Ms. Carter,

Thank you for taking my call!

President Trump told reporters today that the VA is buying a new product from Johnson and Johnson that has proven to be effective in combating veterans suicide:

AMERICAN OVERSIGHT

"There's a product that's made right now that just came out by Johnson and Johnson, which has a tremendously positive – pretty short-term – but nevertheless a positive effect.

"I've instructed the head of the VA to go out and buy a lot of it, and we are buying a lot of it. Hopefully, we're getting it at a very good cost. And this is a – I guess it's a form of a stimulant, where if somebody is really in trouble, from the standpoint of suicide, it can do something.

"It's pretty well know, just came out. It's made, I believe, by Johnson and Johnson, and we have calls in now to Johnson and Johnson. Those calls – we've been dealing with them for two months and buying a lot of it."

Can the VA say:

1. What is the product?
2. How exactly does it work to reduce veterans suicides?
3. Has it been approved by the FDA?
4. How can veterans get this product?
5. What results has this product shown in reducing veterans suicides?

My deadline is today. Please feel free to email or call me at (b)(6)

Thank you.

Jeff Schogol

Recipient:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b)(6) va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>
Sent Date:	2019/08/21 14:27:50
Message Flags:	Unsent

AMERICAN OVERSIGHT

From:	Zacher, Jennifer L. (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9027C425646E4DE8A7D196908016331B-ZACHER, JEN (b)(6) @va.gov>
To:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>; Slagle, Mark (V9) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b618b365e2e41509ee26c5586e88679-Slagle, Mar (b)(6) @va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>
Subject:	RE: [EXTERNAL] SPRAVATO (esketamine hydrochloride) CIII REMS - Know Your Customer Questionnaire Required
Date:	2019/03/19 14:14:18
Priority:	Normal
Type:	Note

On it

From: Valentino, Michael (VACO)
Sent: Tuesday, March 19, 2019 1:14 PM
To: Zacher, Jennifer L. (PBM) (b)(6) @va.gov>; Slagle, Mark (V9) (b)(6) @va.gov>; Emmendorfer, Thomas (PBM) (b)(6) @va.gov>
Subject: RE: [EXTERNAL] SPRAVATO (esketamine hydrochloride) CIII REMS - Know Your Customer Questionnaire Required

I see no mention of REMS on the questionnaire, so I consider completing and sending it 100% OPTIONAL.

Jen,

Can you confirm with J&J that there is no requirement for customers to send them this information and if that is the case, let them know we are going to advise sites NOT to complete and send in the form?

Mike

From: Zacher, Jennifer L. (PBM)
Sent: Tuesday, March 19, 2019 2:09 PM
To: Slagle, Mark (V9) (b)(6) @va.gov>; Emmendorfer, Thomas (PBM) (b)(6) @va.gov>; Valentino, Michael (VACO) (b)(6) @va.gov>
Subject: RE: [EXTERNAL] SPRAVATO (esketamine hydrochloride) CIII REMS - Know Your Customer Questionnaire Required

I happen to have a call with J&J this afternoon, so I will ask. They have NEVER mentioned to me that there is any additional information needed....More to come

AMERICAN OVERSIGHT

From: Slagle, Mark (V9)
Sent: Tuesday, March 19, 2019 1:06 PM
To: Zacher, Jennifer L. (PBM) (b)(6) @va.gov>; Emmendorfer, Thomas (PBM) (b)(6) @va.gov>; Valentino, Michael (VACO) (b)(6) @va.gov>
Subject: FW: [EXTERNAL] SPRAVATO (esketamine hydrochloride) CIII REMS - Know Your Customer Questionnaire Required

One of my sites has now registered for the SPRAVATO REMS program. Apparently, they received another questionnaire after they received their confirmation. I really don't see how some of this is relevant, especially Question 32. I'm assuming you guys may be working on additional specific guidance, but I see no need to disclose our prescription information.

Thanks,

Mark A. Slagle, PharmD, BCPS
VISN 9 Pharmacist Executive
1801 West End Ave., Suite 600
Nashville, TN 37203
(b)(6)

From: Kuehl, Brian J.
Sent: Tuesday, March 19, 2019 1:01 PM
To: Slagle, Mark (V9) (b)(6) @va.gov>
Subject: FW: [EXTERNAL] SPRAVATO (esketamine hydrochloride) CIII REMS - Know Your Customer Questionnaire Required

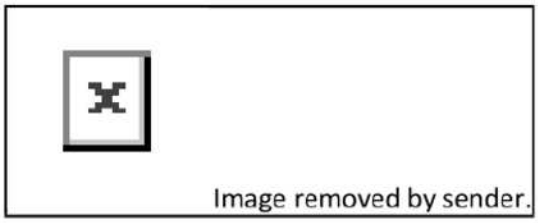
Mark,
Is there another path for the VA here? I registered the facility and the pharmacy this morning, they sent me confirmation of both. Now this arrived, looking at the questionnaire, it doesn't seem to be tailored to the VA clinic where this would be coordinated and procedures followed. This doesn't seem like things we answer as a facility or pharmacy to order, and question 32 wouldn't be something I'd report to anyone outside the VA.
Appreciate any help.
Brian

Brian Kuehl, Pharm.D.,MBA, BCPS, VHA-CM
Chief, Pharmacy Service
Lexington VA Health Care System

From: SPRAVATO REMS (b)(6) @ubc.com>
Sent: Tuesday, March 19, 2019 1:48 PM
To: Kuehl, Brian J. (b)(6) @va.gov>
Subject: [EXTERNAL] SPRAVATO (esketamine hydrochloride) CIII REMS - Know Your Customer Questionnaire Required

AMERICAN OVERSIGHT

Dear Brian Kuehl,



Welcome to the SPRAVATO REMS.

Attached is the Janssen "Know Your Customer Questionnaire" which needs to be completed prior to ordering SPRAVATO.

Please fax the completed form to 1-877-778-0091

Thank you for your participation in the program. If you have any questions, please contact the SPRAVATO REMS Monday through Friday, 8:00 AM to 8:00 PM ET at 1-855-382-6022 to speak with a REMS team member.

Please retain a copy of this notification for your records.

Please see full Prescribing Information, including Boxed WARNING, and Medication Guide for SPRAVATO

Sincerely,

The SPRAVATO REMS
Phone: (b)(6)
Fax: 1-877-778-0091
www.SPRAVATOREMS.com

This is a system-generated e-mail. Please do not respond to this message.

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This e-mail message and any attachments contain confidential information. If you are not the intended recipient, you are hereby notified that disclosure, printing, copying, distribution, or the taking of any action in reliance on the contents of this electronic information is strictly prohibited. If you have received this e-mail message in error, please immediately notify the sender by reply message and then delete the electronic message and any attachments. Exclaimer Version 4.82

Sender:	Zacher, Jennifer L. (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9027C425646E4DE8A7D196908016331B-ZACHER, JEN <(b)(6) @va.gov>
Recipient:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>; Slagle, Mark (V9) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b618b365e2e41509ee26c5586e88679-Slagle, Mar (b)(6) @va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group

AMERICAN OVERSIGHT

	(FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer ·(b)(6) @va.gov>
Sent Date:	2019/03/19 14:14:16
Delivered Date:	2019/03/19 14:14:18

AMERICAN OVERSIGHT

From:	Valentino, Michael (VACO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO,>
To:	(b) (6) (b)(6) @trea.org>
CC:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>
Subject:	RE: [EXTERNAL] RE: VA Pharmacy Benefits Management Group
Date:	2019/06/18 09:28:54
Priority:	Normal
Type:	Note

On my way to the formulary meeting now Ken.
No idea what the decision will be....

Sent with BlackBerry Work
(www.blackberry.com)

From (b6) (b)(6) @trea.org>
Date: Tuesday, Jun 18, 2019, 9:21 AM
To: Valentino, Michael (VACO) <(b)(6) @va.gov>
Cc: Emmendorfer, Thomas (PBM) (b)(6) @va.gov>
Subject: [EXTERNAL] RE: VA Pharmacy Benefits Management Group

Good Morning Mike –

I am following up and asking about the status of Spravato and if it will be added to VA's Formulary? The media is reporting the following.

This week a VA committee will meet to decide whether to add the drug to its formulary – the list of drugs that must be available to VA pharmacies. If Spravato is placed on the formulary, it could be a real boon for marketing.

If the drug is not put on the formulary, doctors can still prescribe it "off-formulary" but the drug will lack the VA's imprimatur. For veterans whose ranks are plagued by depression and suicides, much is at stake too. A drug that offers fast and lasting answer for treatment-resistant depression would be a godsend.

Thanks for your review of this issue.

V/R
(b6)
(b6)
TREA: The Enlisted Association
1800 Diagonal Road, Suite 600
Alexandria. VA 22314
(b)(6) @trea.org

AMERICAN OVERSIGHT

(b)(6)

From: Valentino, Michael (VACO) [mailto (b)(6) @va.gov]
Sent: Thursday, June 06, 2019 1:38 PM
To: (b6))(6) @trea.org>
Cc: Emmendorfer, Thomas (PBM) <(b)(6) @va.gov>
Subject: RE: VA Pharmacy Benefits Management Group

H(b6)

Nothing has changed about the VA National Formulary process....it is exactly the same as it has been for the past decade or so.

In regard to the MISSION act, VA beneficiaries have the option of having urgent and emergent prescriptions written by authorized non-VA community providers filed in non-VA community pharmacies. All non-emergent, non-urgent prescriptions are sent to VA for fulfillment. Non-VA providers are required to follow the VA National Formulary process just like VA providers are required to do.

If you want to talk about any of this in more depth, I'd be happy to participate on a phone call or meeting. I should point out that the Office of Community Care has the lead on all non-VA care, so anything specific about that should be referred to them.

Mike

From: (b6) (6) @trea.org>
Sent: Wednesday, June 5, 2019 1:04 PM
To: Valentino, Michael (VACO) (b)(6) @va.gov>
Cc: (b6))(6) @trea.org>
Subject: [EXTERNAL] VA Pharmacy Benefits Management Group

Good Afternoon Michael:
I wanted to reintroduce myself as I am now working for TREA:(b6) Veterans and Military Policy. You may remember me when I worked as the Executive Secretary in the Office of the Secretary and I retired in January 2013. A short bio is attached for your review.

I am looking to reconnect with officials in the PBMG as TREA reviews pharmacy benefits under the MISSION Act as well as looks at the VA Formulary. Please let me know if you can provide me with information on both of these topics. I would be pleased to schedule a phone call or set up a meeting with you or any member of PBMG to exchange information on these matters.

My contact information is below and my cell # is (b)(6) I look forward to talking with you or meeting you in the near future.

Best Regards,
(b6)

AMERICAN OVERSIGHT

(b6)
TREA: The Enlisted Association
1800 Diagonal Road, Suite 600
Alexandria, VA 22314
(b)(6) @trea.org
(b)(6)

Sender:	Valentino, Michael (VACO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO,>
Recipient:	(b6) b)(6) trea.org>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) va.gov>
Sent Date:	2019/06/18 09:28:53
Delivered Date:	2019/06/18 09:28:54

AMERICAN OVERSIGHT

From:	Torrise, Virginia (VHACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=519204DF507344AC8FA3045B2B4FC762-TORRISE, VI (b)(6) @va.gov>
To:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b)(6) @va.gov>; Boyd, Teresa D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6886a7d555a43e0bee23c1e40e1c234-Boyd, Teres (b)(6) @va.gov>; Wiechers, Ilse (b)(6)
CC:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da (b)(6) @va.gov>
Subject:	RE: [EXTERNAL] Re: Plan
Date:	2019/06/18 14:31:22
Priority:	Normal
Type:	Note

PBM concurs.

From: Wiechers, Ilse
Sent: Tuesday, June 18, 2019 2:11 PM
To: Boyd, Teresa D. (b)(6) @va.gov>; Wiechers, Ilse (b)(6)
Cc: Emmendorfer, Thomas (PBM)(b)(6) @va.gov>; Valentino, Michael (VACO) (b)(6) @va.gov>; Carroll, David (VACO) (b)(6) @va.gov>
Subject: RE: [EXTERNAL] Re: Plan

Dr. Boyd –

Below is content that can be used for briefing Dr. Leiberman and that can also be used as the starting point of some copy for the comms team. I've highlighted one statement that needs approval by the PBM before sending forward. Let me know what you think.

Also as a personal FYI – (b) (6)

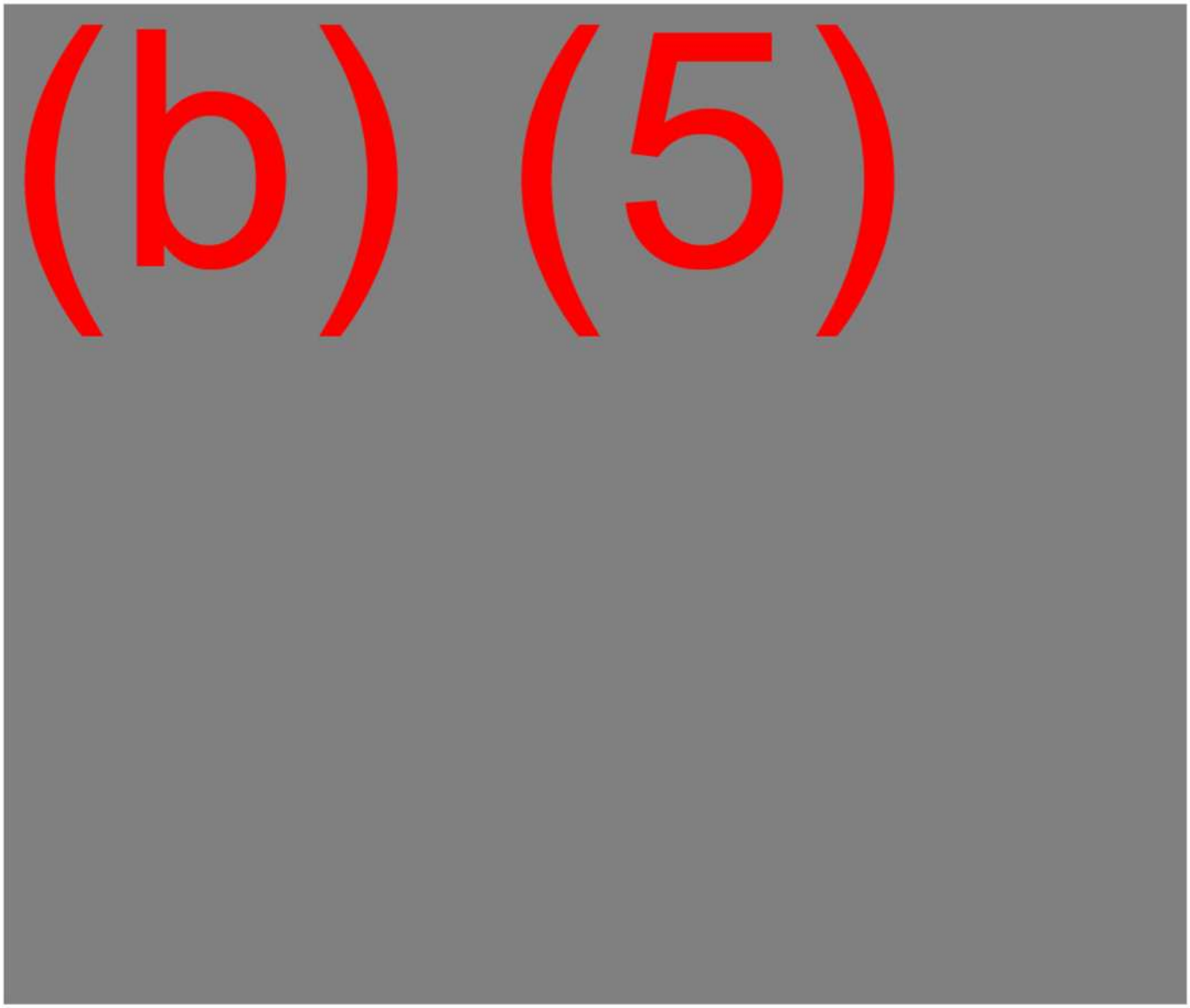
(b) (6)

Best, Ilse

***

(b) (5)

AMERICAN OVERSIGHT



From: Boyd, Teresa D.
Sent: Tuesday, June 18, 2019 10:19 AM
To: Wiechers, Ilse <(b)(6)
Cc: Emmendorfer, Thomas (PBM) <(b)(6) @va.gov>; Valentino, Michael (VACO) (b)(6) @va.gov>; Carroll, David (VACO) (b)(6) @va.gov>; Wiechers, Ilse (b)(6) @va.gov>
Subject: RE: [EXTERNAL] Re: Plan

Thank you!

Sent with BlackBerry Work
(www.blackberry.com)

AMERICAN OVERSIGHT

From: Wiechers, Ilse <(b)(6)
Date: Tuesday, Jun 18, 2019, 1:16 PM
To: Boyd, Teresa D. (b)(6) @va.gov>
Cc: Emmendorfer, Thomas (PBM) <(b)(6) va.gov>, Valentino, Michael (VACO) (b)(6) @va.gov>, Carroll, David (VACO) <(b)(6) @va.gov>, Wiechers, Ilse (b)(6) @va.gov>
Subject: [EXTERNAL] Re: Plan

Adding my VA email. I'll get you some bullet points before COB today, if not sooner. On a couple calls where I need to participate, but then will get this out.

>On Jun 18, 2019, at 9:22 AM, Boyd, Teresa D. <(b)(6) @va.gov>wrote:
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>Teresa
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>Sent with BlackBerry Work
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Recipient:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b)(6) @va.gov>; Boyd, Teresa D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6886a7d555a43e0bee23c1e40e1c234-Boyd, Teres (b)(6) @va.gov>; Wiechers, Ilse <(b)(6) Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da (b)(6) @va.gov>
Sent Date:	2019/06/18 14:31:21
Delivered Date:	2019/06/18 14:31:22

AMERICAN OVERSIGHT

From:	Boyd, Teresa D. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F6886A7D555A43E0BEE23C1E40E1C234-BOYD, TERES (b)(6) @va.gov>
To:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b)(6) @va.gov>; Wiechers, Ilse (b)(6)
CC:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da (b)(6) @va.gov>
Subject:	RE: [EXTERNAL] Re: Plan
Date:	2019/06/18 14:28:04
Priority:	Normal
Type:	Note

Thank you!
Also, will be good to hear further updates from Boston re patient outcome.
Teresa

Sent with BlackBerry Work
(www.blackberry.com)

From: Wiechers, Ilse (b)(6) @va.gov>
Date: Tuesday, Jun 18, 2019, 2:10 PM
To: Boyd, Teresa D. <(b)(6) @va.gov>, Wiechers, Ilse (b)(6)
Cc: Emmendorfer, Thomas (PBM) <(b)(6) @va.gov>, Valentino, Michael (VACO) (b)(6) @va.gov>, Carroll, David (VACO) <(b)(6) @va.gov>
Subject: RE: [EXTERNAL] Re: Plan

Dr. Boyd –

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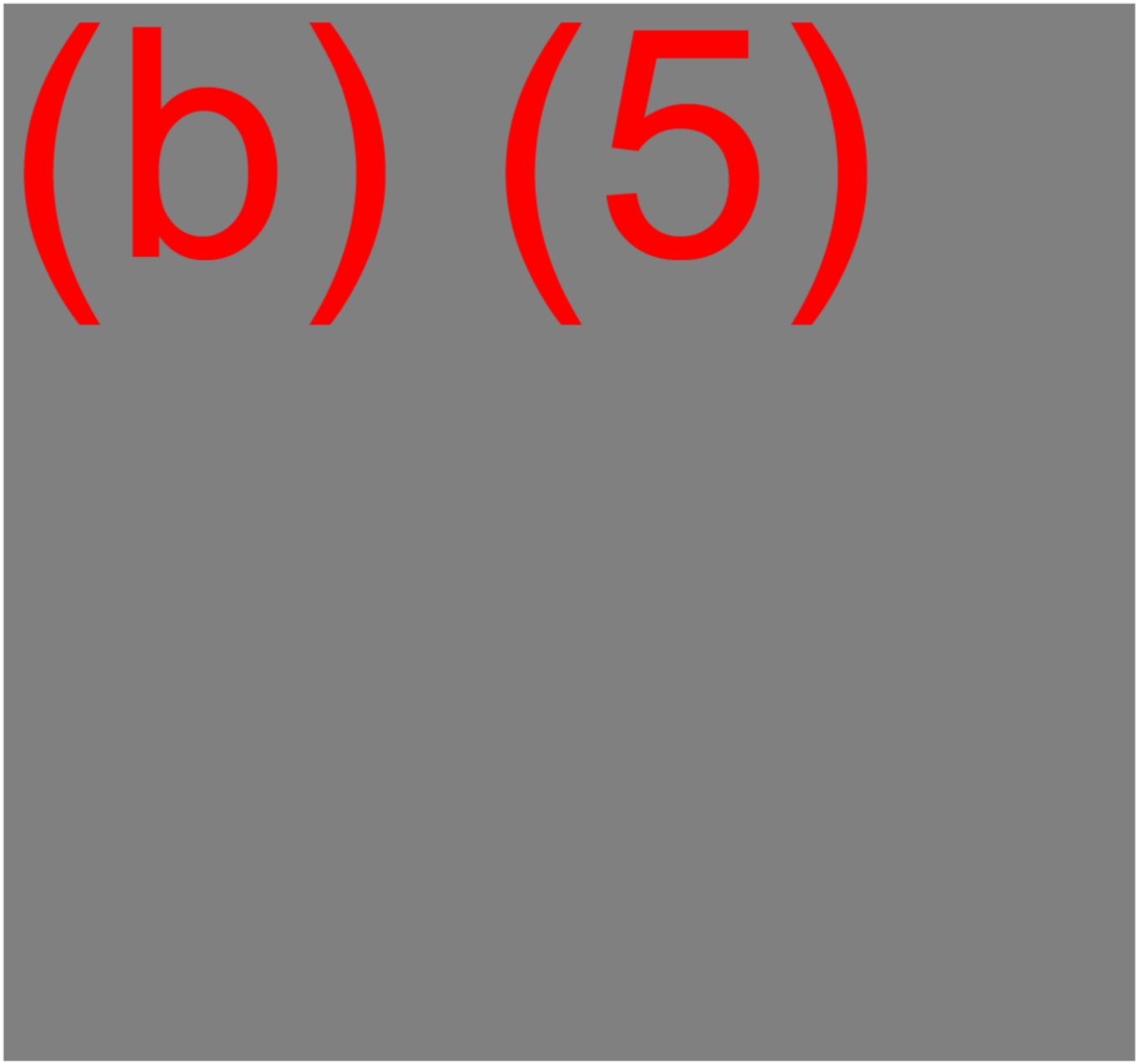
Also as a personal FYI – (b6)

(b6)

Best, Ilse

***

AMERICAN OVERSIGHT



From: Boyd, Teresa D.
Sent: Tuesday, June 18, 2019 10:19 AM
To: Wiechers, Ilse (b)(6)
Cc: Emmendorfer, Thomas (PBM) <(b)(6) @va.gov>; Valentino, Michael (VACO) <(b)(6) @va.gov>; Carroll, David (VACO) <(b)(6) @va.gov>; Wiechers, Ilse <(b)(6) @va.gov>
Subject: RE: [EXTERNAL] Re: Plan

Thank you!

AMERICAN OVERSIGHT

Sent with BlackBerry Work
(www.blackberry.com)

From: Wiechers, Ilse (b)(6) @yale.edu>
Date: Tuesday, Jun 18, 2019, 1:16 PM
To: Boyd, Teresa D. (b)(6) @va.gov>
Cc: Emmendorfer, Thomas (PBM) (b)(6) @va.gov>, Valentino, Michael (VACO) (b)(6) @va.gov>, Carroll, David (VACO) (b)(6) @va.gov>, Wiechers, Ilse (b)(6) @va.gov>
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>On Jun 18, 2019, at 9:22 AM, Boyd, Teresa D. (b)(6) @va.gov>wrote:
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>Sent with BlackBerry Work
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Sender:	Boyd, Teresa D. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F6886A7D555A43E0BEE23C1E40E1C234-BOYD, TERES (b)(6) @va.gov>
Recipient:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b)(6) @va.gov>; Wiechers, Ilse (b)(6) Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da (b)(6) @va.gov>
Sent Date:	2019/06/18 14:28:01
Delivered Date:	2019/06/18 14:28:04

AMERICAN OVERSIGHT

From:	Boyd, Teresa D. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F6886A7D555A43E0BEE23C1E40E1C234-BOYD, TERES (b)(6) @va.gov>
To:	Lieberman, Steven /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=25138f5d2e734afa81397f0b357cbcc1-Lieberman, (b)(6) @va.gov>
Subject:	RE: [EXTERNAL] Re: Plan
Date:	2019/06/18 20:40:28
Priority:	Normal
Type:	Note

You are welcome - anything for our Veterans and staff.

Sent with BlackBerry Work
(www.blackberry.com)

From: Lieberman, Steven (b)(6) @va.gov>
Date: Tuesday, Jun 18, 2019, 6:41 PM
To: Boyd, Teresa D. <(b)(6) @va.gov>
Subject: RE: [EXTERNAL] Re: Plan

What a terrific endeavor. Thank you very much for your leadership with this! No simple task to get us to this point.

From: Boyd, Teresa D.
Sent: Tuesday, June 18, 2019 2:29 PM
To: Lieberman, Steven (b)(6) @va.gov>
Subject: FW: [EXTERNAL] Re: Plan

I have asked for f/u on patient as time goes on...

Info below is for you. I could not cut/paste on mobile...

Teresa

Sent with BlackBerry Work
(www.blackberry.com)

From: Wiechers, Ilse <(b)(6) @va.gov>
Date: Tuesday, Jun 18, 2019, 2:10 PM
To: Boyd, Teresa D. <(b)(6) @va.gov>, Wiechers, Ilse (b)(6)
Cc: Emmendorfer, Thomas (PBM) (b)(6) @va.gov>, Valentino, Michael (VACO) (b)(6) @va.gov>, Carroll, David (VACO) (b)(6) va.gov>
Subject: RE: [EXTERNAL] Re: Plan

Dr. Boyd –

AMERICAN OVERSIGHT

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(b6)

Best, Ilse

***

(b) (5)

AMERICAN OVERSIGHT

From: Boyd, Teresa D.
Sent: Tuesday, June 18, 2019 10:19 AM
To: Wiechers, Ilse (b)(6)
Cc: Emmendorfer, Thomas (PBM) (b)(6) va.gov>; Valentino, Michael (VACO) (b)(6) @va.gov>; Carroll, David (VACO) (b)(6) @va.gov>; Wiechers, Ilse (b)(6) @va.gov>
Subject: RE: [EXTERNAL] Re: Plan

Thank you!

Sent with BlackBerry Work
(www.blackberry.com)

From: Wiechers, Ilse (b)(6)
Date: Tuesday, Jun 18, 2019, 1:16 PM
To: Boyd, Teresa D. (b)(6) @va.gov>
Cc: Emmendorfer, Thomas (PBM) (b)(6) @va.gov>, Valentino, Michael (VACO) (b)(6) @va.gov>, Carroll, David (VACO) <(b)(6) @va.gov>, Wiechers, Ilse (b)(6) @va.gov>
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Recipient:	Lieberman, Steven /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=25138f5d2e734afa81397f0b357cbcc1-Lieberman, (b)(6) @va.gov>
Sent Date:	2019/06/18 20:40:27
Delivered Date:	2019/06/18 20:40:28

AMERICAN OVERSIGHT

From:	Zacher, Jennifer L. (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9027C425646E4DE8A7D196908016331B-ZACHER, JEN (b)(6) @va.gov>
To:	Torrise, Virginia (VHACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=519204df507344ac8fa3045b2b4fc762-Torrise, Vi (b)(6) @va.gov>
Subject:	RE: [EXTERNAL] Re: Plan
Date:	2019/06/19 09:46:02
Priority:	Normal
Type:	Note

Agree!

From: Torrise, Virginia (VHACO)
Sent: Tuesday, June 18, 2019 1:31 PM
To: Zacher, Jennifer L. (PBM)(b)(6) @va.gov>
Subject: FW: [EXTERNAL] Re: Plan

MUE statement looks fine to me.

From: Wiechers, Ilse
Sent: Tuesday, June 18, 2019 2:11 PM
To: Boyd, Teresa D. (b)(6) @va.gov>; Wiechers, Ilse (b)(6)
Cc: Emmendorfer. Thomas (PBM) <(b)(6) @va.gov>; Valentino, Michael (VACO) (b)(6) @va.gov>; Carroll, David (VACO) (b)(6) @va.gov>
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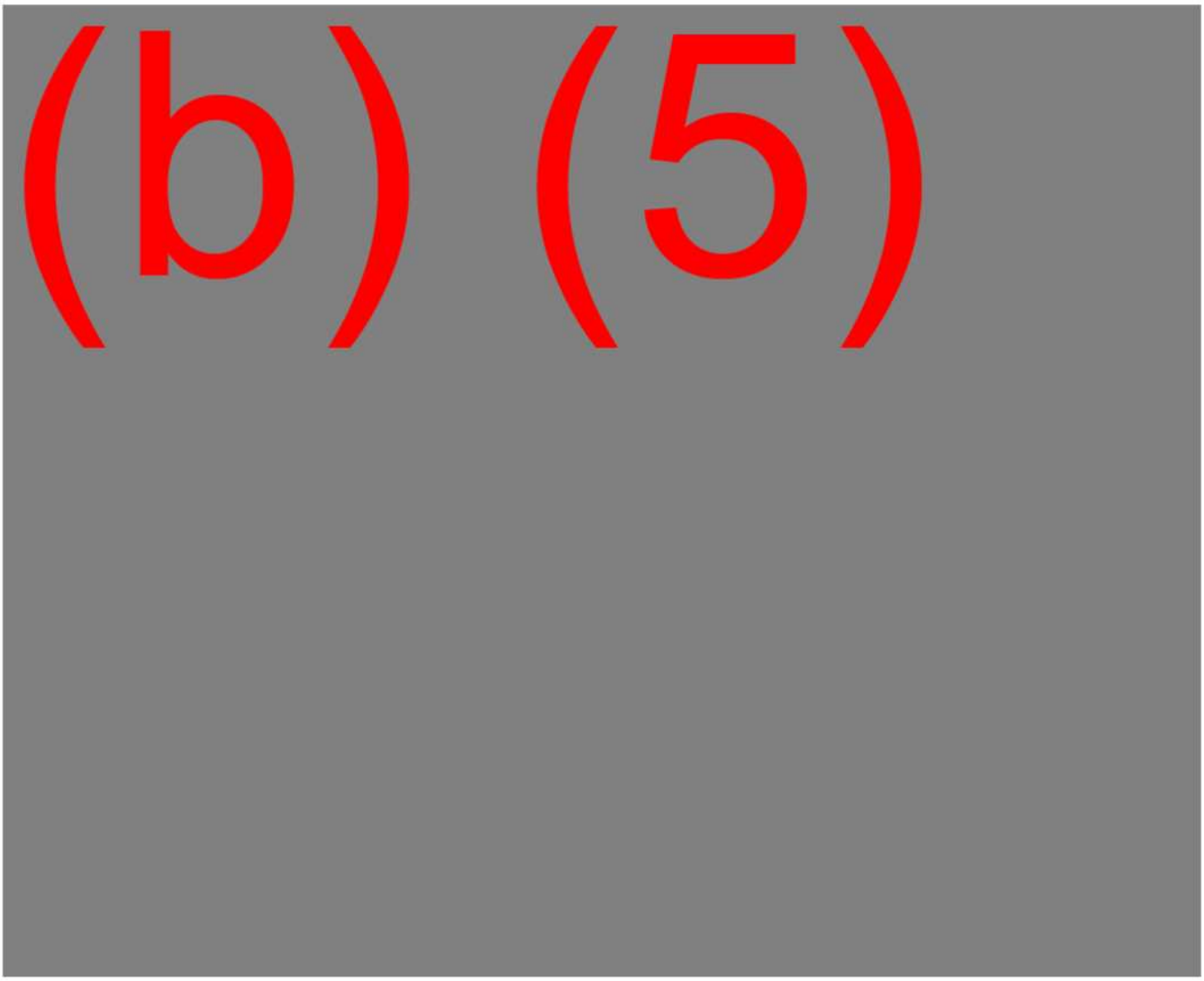
(b) (5)

AMERICAN OVERSIGHT



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Subject: RE: [EXTERNAL] Re: Plan

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From: Wiechers, Ilse (b)(6)
Date: Tuesday, Jun 18, 2019, 1:16 PM
To: Boyd, Teresa D. (b)(6) @va.gov>

AMERICAN OVERSIGHT

Cc: Emmendorfer, Thomas (PBM)(b)(6) @va.gov>, Valentino, Michael (VACO) <(b)(6) @va.gov>, Carroll, David (VACO) <(b)(6) @va.gov>, Wiechers, Ilse <(b)(6) @va.gov>
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Recipient:	Torrise, Virginia (VHACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=519204df507344ac8fa3045b2b4fc762-Torrise, Vi (b)(6) @va.gov>
Sent Date:	2019/06/19 09:46:01
Delivered Date:	2019/06/19 09:46:02

AMERICAN OVERSIGHT

From:	Fuller, Matthew A. (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=62D9CBB23B184CACB98895776E36A471-FULLER, MAT>
To:	Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen (b)(6) @va.gov>
Subject:	RE: [EXTERNAL] RE: Spravato
Date:	2019/03/16 14:11:00
Priority:	Normal
Type:	Note

Hi Jenn,

I looked over the document. I did not see anything blatantly misleading but there are (b) (5)

(b5)

Matthew

From: Zacher, Jennifer L. (PBM)
Sent: Wednesday, March 13, 2019 4:37 PM
To: Fuller, Matthew A. (PBM) <(b)(6) @va.gov>
Subject: FW: [EXTERNAL] RE: Spravato

Can you review this ASAP after you are back in the office next week? Please just see if there is anything blatantly misleading about it.
Thanks,
JZ

From: (b) (6) (b)(6) @ITS.JNJ.com>
Sent: Wednesday, March 13, 2019 1:25 PM
To: Zacher, Jennifer L. (PBM) <(b)(6) @va.gov>
Cc: (b6) <(b)(6) @its.jnj.com>
Subject: [EXTERNAL] RE: Spravato

Jen,

We have all hands on deck to support you and your team. So far we have put together a comprehensive support plan to meet questions like this and others for our call on Monday.

The following websites are all active and inclusive of clinical information and a variety of resources for HCP, treatment center, and REMs:
- www.spravatohcp.com
- www.spravatotreatmentcenter.com
- www.spravatorems.com

AMERICAN OVERSIGHT

We want to be certain that all aspects of the 3 prong REMS are clearly defined and that you feel comfortable with how to build processes around them. Would you like for us to invite our REMS expert to the call?

I have attached the current approved value proposition deck and we are working very hard to get a veteran centric educational tool updated with appropriate legal and FDA language for your use as well. This will not be available by Friday but it is in the top of our queue. We can discuss this on Monday as well.

I have said this many times, but always worth saying! J&J is fully committed to ensuring that VA leadership has an opportunity to review, comment, and approve all branded/unbranded educational materials prior to any exposure to VA stakeholders and patients. We will comply with all policies. We look forward to doing whatever it takes to support you and the patients we collectively serve.

Thanks,

(b6)

National Federal Team - Strategic Customer Group
Johnson &Johnson Health Care Systems
T: (b)(6) *https://www.jnj.com/heroes: Johnson &Johnson Supports Our Troops &Veterans*

Providing services for Janssen Pharmaceutical Companies of Johnson &Johnson

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From: Zacher, Jennifer L. (PBM) (b)(6) @va.gov>
Sent: Wednesday, March 13, 2019 10:14 AM
To: (b6) (b)(6) @ITS.JNJ.com>
Cc: (b6) (b)(6) @its.jnj.com>
Subject: RE: [EXTERNAL] RE: Spravato

Hi,
Thanks for the quick response...that makes me a little uneasy, (b5) (b5) we may just need to make a policy decision (b5) (b5) ..I will think on it, but the information is helpful.
Thanks,
JZ

From (b) (6) (b)(6) @ITS.JNJ.com>
Sent: Wednesday, March 13, 2019 11:54 AM
To: Zacher, Jennifer L. (PBM) (b)(6) @va.gov>
Cc: (b) (6) GUS] (b)(6) @its.jnj.com>
Subject: [EXTERNAL] RE: Spravato

Hi Jen,

This is the response from my risk management leader:

That's a great question and one we had significant discussions with the FDA on.

Will pharmacy be able to query the REMS database to assure that a patient has been registered before they dispense the drug to be administered?
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- • Currently our SPRAVATO REMS does not require pharmacies to verify patient registration and enrollment
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I believe the last bullet speaks to how your team, or the designated treatment site, will capture when this takes place and assure that this has occurred prior to administration of the drug.

Does this answer your question?

(b) (6)
National Federal Team - Strategic Customer Group
Johnson &Johnson Health Care Systems
T: (b)(6) *https://www.jnj.com/heroes: Johnson &Johnson Supports Our Troops &Veterans*
Providing services for Janssen Pharmaceutical Companies of Johnson &Johnson

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From: Zacher, Jennifer L. (PBM) <(b)(6) @va.gov>
Sent: Wednesday, March 13, 2019 9:06 AM
To: (b) (6) (b)(6) @ITS.JNJ.com>
Cc: (b) (6) CGUSJ (b)(6) @its.jnj.com>
Subject: RE: [EXTERNAL] RE: Spravato

Hi,
One quick question that came up today....

Will pharmacy be able to query the REMS database to assure that a patient has been registered before they dispense the drug to be administered?

Thanks,
JZ

From: (b6) (b)(6) @ITS.JNJ.com>
Sent: Tuesday, March 12, 2019 2:48 PM
To: Zacher, Jennifer L. (PBM) <(b)(6) @va.gov>

AMERICAN OVERSIGHT

Cc: (b6) (b)(6) @its.jnj.com>
Subject: [EXTERNAL] RE: Spravato

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I know that we both had several asks with very tight timelines and we want to be sure to meet them. There has been significant work by the entire team and we would like to fill you in on progress.

I suggest we hop on a call to talk through the 4 primary areas we have identified as crucial components to a successful launch for the treatment experience for our veterans.

- • Clinical Needs (Focused on education with HCPs)
- • REMS (3 components: Hospital/ Clinic REMS certification, Pharmacy REMS certification, and Patient Enrollment REMS program)
- • Setting up treatment centers
- • Patient Journey

I know that you are traveling and we can make ourselves available whenever you have some free time. What works best for you?

Thanks,

(b6)

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From: Zacher, Jennifer L. (PBM) (b)(6) @va.gov>
Sent: Friday, March 08, 2019 6:16 AM
To: (b6) (b)(6) @ITS.JNJ.com>
Subject: RE: [EXTERNAL] Re: Spravato
Importance: High

Hi,
Apparently your president talked to Trump yesterday, so I really need to talk to you today.....can you call me as soon as you are available?
Thanks,
JZ

From: (b6))(6) @ITS.JNJ.com]
Sent: Thursday, March 07, 2019 12:05 AM
To: Zacher, Jennifer L. (PBM) (b)(6) @va.gov>
Subject: [EXTERNAL] Re: Spravato

AMERICAN OVERSIGHT

Hi Jen,

I recommend we set up a call next week if you are available to discuss. Product is not yet available at McKesson and we will submit the FSS contract as soon as the dailymed website is updated. I am sure there are a ton of questions as this is a unique product with unique operational considerations. Please let me know if you want to connect live next week.

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Sent from iPad

From: Zacher, Jennifer L. (PBM) (b)(6) @va.gov>
Sent: Wednesday, March 6, 2019 8:57 PM
To: (b6)
Subject: [EXTERNAL] Spravato

Hi,
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Thanks,
JZ

Jennifer L. Zacher, PharmD, BCPP
Associate Chief Consultant
VA Pharmacy Benefits Management Services
(b)(6)
(b)(6) @va.gov

Sender:	Fuller, Matthew A. (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=62D9CBB23B184CACB98895776E36A471-FULLER, MAT>
Recipient:	Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen (b)(6) @va.gov>
Sent Date:	2019/03/16 14:11:45

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Delivered Date:	2019/03/16 14:11:00

AMERICAN OVERSIGHT

From:	Fuller, Matthew A. (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=62D9CBB23B184CACB98895776E36A471-FULLER, MAT>
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Subject:	RE: [EXTERNAL] RE: Spravato
Date:	2019/03/13 16:41:00
Priority:	Normal
Type:	Note

Will do.

From: Zacher, Jennifer L. (PBM)
Sent: Wednesday, March 13, 2019 4:37 PM
To: Fuller, Matthew A. (PBM) (b)(6) @va.gov>
Subject: FW: [EXTERNAL] RE: Spravato

Can you review this ASAP after you are back in the office next week? (b6) (b6)
Thanks,
JZ

From: (b6) (b)(6) @ITS.JNJ.com>
Sent: Wednesday, March 13, 2019 1:25 PM
To: Zacher, Jennifer L. (PBM) (b)(6) @va.gov>
Cc: (b6) (b)(6) @its.jnj.com>
Subject: [EXTERNAL] RE: Spravato

Jen,

We have all hands on deck to support you and your team. So far we have put together a comprehensive support plan to meet questions like this and others for our call on Monday.

The following websites are all active and inclusive of clinical information and a variety of resources for HCP, treatment center, and REMs:
- www.spravatohcp.com
- www.spravatotreatmentcenter.com
- www.spravatorems.com

We want to be certain that all aspects of the 3 prong REMS are clearly defined and that you feel comfortable with how to build processes around them. Would you like for us to invite our REMS expert to the call?

I have attached the current approved value proposition deck and we are working very hard to get a veteran centric educational tool updated with appropriate legal and FDA language for your use as

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well. This will not be available by Friday but it is in the top of our queue. We can discuss this on Monday as well.

I have said this many times, but always worth saying! J&J is fully committed to ensuring that VA leadership has an opportunity to review, comment, and approve all branded/unbranded educational materials prior to any exposure to VA stakeholders and patients. We will comply with all policies. We look forward to doing whatever it takes to support you and the patients we collectively serve.

Thanks,

(b6)

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From: Zacher, Jennifer L. (PBM) (b)(6) @va.gov>
Sent: Wednesday, March 13, 2019 10:14 AM
To: (b6) [JAN] (b)(6) @ITS.JNJ.com>
Cc: (b6) SCGUS] (b)(6) @its.jnj.com>
Subject: RE: [EXTERNAL] RE: Spravato

Hi,
Thanks for the quick response...that makes me a little uneasy, as pharmacy will be the entity actually supplying the drug, but let me see what I can do with that in terms of providing internal direction...We may just need to make a policy decision that the provider has to communicate with pharmacy when the patient is enrolled....I will think on it, but the information is helpful.
Thanks,
JZ

From: (b6) AN] <(b)(6) @ITS.JNJ.com>
Sent: Wednesday, March 13, 2019 11:54 AM
To: Zacher, Jennifer L. (PBM) <(b)(6) @va.gov>
Cc: (b6) [SCGUS] <(b)(6) @its.jnj.com>
Subject: [EXTERNAL] RE: Spravato

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AMERICAN OVERSIGHT

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VA Pharmacy Benefits Management Services
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Sent Date:	2019/03/13 16:41:59
Delivered Date:	2019/03/13 16:41:00

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From:	Boyd, Teresa D. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F6886A7D555A43E0BEE23C1E40E1C234-BOYD, TERES (b)(6) @va.gov>
To:	Connell, Lawrence B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a3e7233376344045980ad214122389f4-Connell, La (b)(6) @va.gov>
Subject:	RE: [EXTERNAL] Re conference call with Pres Trump & VA Sec Robert Wilkie....
Date:	2019/06/25 15:26:58
Priority:	Normal
Type:	Note

Dr. Edward P. Cutolo is theVISN8 CMO. I am glad to connect them if you prefer.

Sent with BlackBerry Work
(www.blackberry.com)

From: Connell, Lawrence B. (b)(6) @va.gov>
Date: Tuesday, Jun 25, 2019, 3:21 PM
To: Boyd, Teresa D. (b)(6) @va.gov>
Subject: RE: [EXTERNAL] Re conference call with Pres Trump &VA Sec Robert Wilkie....

Ok. Good idea. Do you have contact info?

Larry Connell
Chief of Staff
Veterans' Health Administration
(b)(6) @va.gov
(b)(6)
Sent with iPhone. Please forgive the typos.

From: Boyd, Teresa D. (b)(6) @va.gov>
Date: Tuesday, Jun 25, 2019, 3:15 PM
To: Connell, Lawrence B. (b)(6) @va.gov>
Subject: RE: [EXTERNAL] Re conference call with Pres Trump &VA Sec Robert Wilkie....

Suspect reference to intranasal ketamine. What kind of information do you prefer? Could refer her to COS/CMO re PBM decision on this or the local MH lead.
Teresa

Sent with BlackBerry Work

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(www.blackberry.com)

From: Connell, Lawrence B. <(b)(6) @va.gov>
Date: Tuesday, Jun 25, 2019, 2:02 PM
To: Boyd, Teresa D. <(b)(6) @va.gov>
Subject: FW: [EXTERNAL] Re conference call with Pres Trump &VA Sec Robert Wilkie....

T,
Do you have any info on this?

Larry Connell
Chief of Staff
Veterans' Health Administration
(b)(6) @va.gov
(b)(6)

-----Original Message-----
From: Selnick, Darin
Sent: Tuesday, June 25, 2019 1:48 PM
To: Connell, Lawrence B. (b)(6) @va.gov>
Subject: RE: [EXTERNAL] Re conference call with Pres Trump &VA Sec Robert Wilkie....

I think she may be referring to Spravato.

Darin

Darin Selnick
Executive Consultant
Office of the Secretary
(b)(6)

-----Original Message-----
From: Selnick, Darin
Sent: Tuesday, June 25, 2019 1:46 PM
To: Connell, Lawrence B. <(b)(6) @va.gov>
Subject: FW: [EXTERNAL] Re conference call with Pres Trump &VA Sec Robert Wilkie....

Hi Larry

Can you track down an answer to this question?

Thanks

Darin

Darin Selnick
Executive Consultant
Office of the Secretary
(b)(6)

-----Original Message-----

AMERICAN OVERSIGHT

From: (b6) (b)(6) @aol.com>
Sent: Tuesday, June 25, 2019 1:35 PM
To: Selnick, Darin (b)(6) @va.gov>; (b6) (b)(6) @aol.com>
Subject: [EXTERNAL] Re conference call with Pres Trump &VA Sec Robert Wilkie....

Good afternoon Darin,

I was very honored to be on the conference call today with Pres Trump &VA Sec Robert Wilkie, and other Veterans, regarding the VA Mission Act.

As a Veterans Advocate, it is important to me to get as much info as possible when it comes to Veterans issues.

With that being said, I heard something about a spray to help our Depressed &Suicidal Veterans.

Could you please send me more information on that, as being out here in the field, there is always a great delay in getting up-to-date information, and each day that we can save the life of a Veteran....is priceless.

Thanks again....and have a blessed day!

(b6) USMC-USMCR 20 years, Gulf War Veteran &Veterans Advocate.
Florida Gov. Ron DeSantis "Forward March" Initiative / Board Member Orlando-Lake Nona VA Hospital/ Board Member
Email: (b)(6) @aol.com (b)(6)
"I am a Veteran - I am an Asset..NOT a Liability"

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Recipient:	Connell, Lawrence B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a3e7233376344045980ad214122389f4-Connell, La (b)(6) @va.gov>
Sent Date:	2019/06/25 15:26:57
Delivered Date:	2019/06/25 15:26:58

AMERICAN OVERSIGHT

From:	Connell, Lawrence B. </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A3E7233376344045980AD214122389F4-CONNELL, LA>
To:	Selnick, Darin /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b42e3e7200d24bc6aeafc5fd36be8d2b-Selnick, Da (b)(6) @va.gov>
Subject:	RE: [EXTERNAL] Re conference call with Pres Trump & VA Sec Robert Wilkie....
Date:	2019/06/26 09:28:00
Priority:	Normal
Type:	Note

Yeah, you can send the info to her. Not sure exactly what she wants.

There's lots of open source info on the drug e.g. https://www.nytimes.com/2019/03/08/health/depression-drugs-ketamine.html

And this: https://www.statnews.com/2019/06/21/va-declines-broad-coverage-for-new-jj-depression-drug-touted-by-trump/

Any idea what she is looking for other than General Info?

Larry Connell
Chief of Staff
Veterans' Health Administration
(b6) va.gov
(b)(6)

-----Original Message-----
From: Selnick, Darin
Sent: Tuesday, June 25, 2019 5:08 PM
To: Connell, Lawrence B. (b)(6) @va.gov>
Subject: RE: [EXTERNAL] Re conference call with Pres Trump & VA Sec Robert Wilkie....

Do you want her to contact him directly? Or do you want him to send me the information she wants and I will send it to her.

Darin

Darin Selnick
Executive Consultant
Office of the Secretary
(b)(6)

-----Original Message-----
From: Connell, Lawrence B.
Sent: Tuesday, June 25, 2019 4:38 PM
To: Selnick, Darin (b)(6) @va.gov>
Subject: RE: [EXTERNAL] Re conference call with Pres Trump & VA Sec Robert Wilkie....

Darin,
Dr. Edward P. Cutolo is theVISN8 CMO and the Ketamine expert. You need me to link you guys up?

Larry Connell
Chief of Staff
Veterans' Health Administration
(b)(6) @va.gov
(b)(6)

-----Original Message-----
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Sent: Tuesday, June 25, 2019 1:48 PM
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Subject: RE: [EXTERNAL] Re conference call with Pres Trump & VA Sec Robert Wilkie....

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Sent Date:	2019/06/26 09:28:58
Delivered Date:	2019/06/26 09:28:00

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From:	Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd.DIBOHF23SPDLT)/CN=RECIPIENTS/CN=519204DF507344AC8FA3045B2B4FC762-TORRISE, VI (b)(6) @va.gov>
To:	Lahl, Dennis /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=39fba8ea7cd941b3a0a4f79ca3c6ee87-Lahl, Denni (b)(6) @va.gov>; VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>
CC:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen (b)(6) @va.gov>; Strmiska, Jon G. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9872f41bf2844c8085d371e21482b635-Strmiska, J (b)(6) @va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen (b)(6) @va.gov>
Subject:	RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision
Date:	2019/06/18 14:58:47
Priority:	Normal
Type:	Note

(b5)

From: Lahl, Dennis
Sent: Tuesday, June 18, 2019 2:52 PM
To: Torrise, Virginia (VHACO) (b)(6) @va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>
Cc: Valentino. Michael (VACO) (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) (b)(6) @va.gov>; Strmiska, Jon G. (b)(6) @va.gov>; Wiechers, Ilse (b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Sorry, are we sure about the timeline – reported may hold us to it?

Dennis

Dennis Lahl FAC-P/PM
Office of the Assistant Deputy Under Secretary for Health for Patient Care Services (10P4)
VACO PCS IT/BCAG/ISO Liaison
TMS OPCS DM

AMERICAN OVERSIGHT

ph: (b)(6)
fax: 202-273-5483
Dennis Lahl

From: Torrise, Virginia (VHACO)
Sent: Tuesday, June 18, 2019 2:08 PM
To: Lahl, Dennis (b)(6) @va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>
Cc: Valentino, Michael (VACO) (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) (b)(6) @va.gov>; Strmiska, Jon G. (b)(6) @va.gov>; Wiechers, Ilse (b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Medical Advisory Panel (MAP)
VISN Pharmacy Executive (VPE)

From: Lahl, Dennis
Sent: Tuesday, June 18, 2019 2:07 PM
To: Torrise, Virginia (VHACO) (b)(6) @va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>
Cc: Valentino, Michael (VACO) (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) (b)(6) @va.gov>; Strmiska, Jon G. (b)(6) @va.gov>; Wiechers, Ilse (b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Ginny,

What does MAP and VPE stand for please?

Thanks. Have a great day.

Dennis

Dennis Lahl FAC-P/PM
Office of the Assistant Deputy Under Secretary for Health for Patient Care Services (10P4)
VACO PCS IT/BCAG/ISO Liaison
TMS OPCS DM
ph: (b)(6)
fax: 202-273-5483
Dennis Lahl

From: Torrise, Virginia (VHACO)
Sent: Tuesday, June 18, 2019 1:53 PM
To: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Cc: Valentino, Michael (VACO) (b)(6) va.gov>; Zacher, Jennifer L. (PBM) (b)(6) @va.gov>; Strmiska, Jon G. (b)(6) @va.gov>; Wiechers, Ilse

AMERICAN OVERSIGHT

(b)(6) @va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

(b5)

From: Wiechers, Ilse
Sent: Tuesday, June 18, 2019 1:27 PM
To: Carroll, David (VACO) <(b)(6) @va.gov>; Strmiska, Jon G. (b)(6) @va.gov>; Ilse Wiechers (Yale) <(b)(6) Torrise, Virginia (VHACO) (b)(6) @va.gov>
Cc: Daniels, Lindsay <(b)(6) @va.gov>; Pomerantz, Andrew <(b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Hi – I'm in office and online. I'm working on some high-level bullet points summarizing our progress and will have them up and out to folks shortly.

Ginny – you can comment on the formulary decision, but I know that the MAP/VPE is considering esketamine on the agenda of this week's meeting on Thursday morning. I was planning to use language that states (b) (5)
(b5)
(b5) Please edit that statement as you feel most appropriate.

Ilse

From: Carroll, David (VACO)
Sent: Tuesday, June 18, 2019 10:23 AM
To: Strmiska, Jon G. (b)(6) @va.gov>; Ilse Wiechers (Yale) <(b)(6) Wiechers, Ilse <(b)(6) @va.gov>; Torrise, Virginia (VHACO) (b)(6) @va.gov>
Cc: Daniels, Lindsay (b)(6) @va.gov>; Pomerantz, Andrew (b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Actually – Ilse responded on a similar request from Dr. Boyd. Looks like she may have something together later this afternoon.

From: Strmiska, Jon G.
Sent: Tuesday, June 18, 2019 1:17 PM
To: Ilse Wiechers (Yale) <(b)(6) Wiechers, Ilse (b)(6) @va.gov>; Torrise, Virginia (VHACO) (b)(6) @va.gov>

AMERICAN OVERSIGHT

Cc: Daniels, Lindsay <(b)(6) @va.gov>; Pomerantz, Andrew <(b)(6) @va.gov>; VHA 10P4P Action <vha10P4Paction@va.gov>; Carroll, David (VACO) <(b)(6) @va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Ginny,

As discussed, your assistance is greatly appreciated with providing a response on this one. Ilse is out of the office until tomorrow. Please see below and provide your response by **3pm today.**

New York Times is asking when a decision will be made as to when VA will be putting Spravato in its formulary. We recently provide the response below, highlighted yellow.

Is there any more specific information that we can provide about timeline?

FDA has approved the use of intranasal esketamine for adults with treatment-resistant depression (when used in conjunction with an oral antidepressant). VA has not yet administered esketamine to any patients, and is in the process of designing a clinical implementation plan optimized for safety and efficacy.

Thanks!

Jon G. Strmiska
Business Operations Manager (10NC5)
VA Central Office – Washington, DC
Phone: (b)(6)
FAX: 202.495.5933

From: Dudley, Tracy
Sent: Tuesday, June 18, 2019 1:00 PM
To: VHA 10NC5 Action <VHA10NC5Action@va.gov>
Cc: VHA CO 10NC Front Office HSSs <VHACO10NCFOHSSs@va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

GOOD Afternoon

Please see below and provide your response by **3pm today**.

Thank You!
Tracy

Tracy L. Dudley
Health System Specialist
ADUSH for Clinical Operations (10NC)
(b)(6) (Direct)
(b)(6) (iPhone)

AMERICAN OVERSIGHT

From: Greilsamer, Alan
Sent: Tuesday, June 18, 2019 12:46 PM
To: VHA 10N Action <VHA10NAction@va.gov>; VHA 10NC Action <vha10ncaction@va.gov>
Cc: VHA 10NC5 Action <VHA10NC5Action@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Good afternoon,

New York Times is asking when a decision will be made as to when VA will be putting Spravato in its formulary. We recently provide the response below.

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FDA has approved the use of intranasal esketamine for adults with treatment-resistant depression (when used in conjunction with an oral antidepressant). VA has not yet administered esketamine to any patients, and is in the process of designing a clinical implementation plan optimized for safety and efficacy.

Requesting a response by today (June 18) NLT 5 p.m. ET.

Thanks, Alan

From: Cashour, Curtis
Sent: Tuesday, June 18, 2019 12:38 PM
To: Greilsamer, Alan <(b)(6) @va.gov>; Screen, Gina (b)(6) @va.gov>
Cc: Eason, William J. <(b)(6) @va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Please let me know your recommended response to the below.

Thanks,

Curt Cashour
Press Secretary
Department of Veterans Affairs
(b)(6)
(b)(6) @va.gov
(b)(6)

From: Ben Carey <(b)(6) @nytimes.com>
Sent: Tuesday, June 18, 2019 12:35 PM
To: Cashour, Curtis (b)(6) @va.gov>
Subject: Re: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Thanks Curt, please do. Main question for now is when is decision expected..? (i.e. how much time I got?)

AMERICAN OVERSIGHT

Ben

Sent from my iPhone

On Jun 18, 2019, at 12:22 PM, Cashour, Curtis (b)(6) @va.gov>wrote:

Will keep you posted. Thanks, Ben.

Curt Cashour
Press Secretary
Department of Veterans Affairs
(b)(6)
(b)(6) @va.gov
(b)(6)

From: Carey, Ben <(b)(6) @nytimes.com>
Sent: Tuesday, June 18, 2019 11:36 AM
To: Cashour, Curtis <(b)(6) @va.gov>
Subject: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Curt Cashour-

Hello from New York. It's Ben Carey emailing. I am a reporter in science at the NY Times, I cover psych topics. I have your email from Jennifer Steinhauer, NYT reporter in DC.

I would love to hear what/ when on the VA's expected decision this week whether to put Spravato on its formulary. Keep me in the loop on this, kindly, would be good to know when decision will be made, with some notice, and anything else VA puts out on this.

We'll likely cover decision either way.

Sincerely,

Ben Carey

Sender:	Torrise, Virginia (VHACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=519204DF507344AC8FA3045B2B4FC762-TORRISE, VI (b)(6) @va.gov>
Recipient:	Lahl, Dennis /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=39fba8ea7cd941b3a0a4f79ca3c6ee87-Lahl, Denni (b)(6) @va.gov>; VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen (b)(6) @va.gov>; Strmiska, Jon G. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9872f41bf2844c8085d371e21482b635-Strmiska, J

AMERICAN OVERSIGHT

	(b)(6) @va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen (b)(6) @va.gov>
Sent Date:	2019/06/18 14:58:46
Delivered Date:	2019/06/18 14:58:47
Message Flags:	Unread
From:	Wiechers, Ilse /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0C7B1428D9E4233A641F125C5B6FC4F-WIECHERS, I <(b)(6) @va.gov>
To:	Torrise, Virginia (VHACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=519204df507344ac8fa3045b2b4fc762-Torrise, Vi (b)(6) @va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b)(6) @va.gov>; Strmiska, Jon G. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9872f41bf2844c8085d371e21482b635-Strmiska, J (b)(6) @va.gov>; Ilse Wiechers (Yale) (b)(6)
CC:	Daniels, Lindsay /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ed253196fb6b4f32aa922c90dbd05f29-Daniels, Li (b)(6) @va.gov>; Pomerantz, Andrew /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29a9288df9a34e84bddfd00cde79f11b-Pomerantz, (b)(6) @va.gov>
Subject:	RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision
Date:	2019/06/18 14:17:13
Priority:	Normal
Type:	Note

FYSA – here is the update I provided to Dr. Boyd. It included the statement Ginny concurred with, and one additional statement pending PBM approval re the status of the MUE.

Ilse

From: Torrise, Virginia (VHACO)
Sent: Tuesday, June 18, 2019 10:45 AM
To: Wiechers, Ilse (b)(6) @va.gov>; Carroll, David (VACO) (b)(6) @va.gov>; Strmiska, Jon G. <(b)(6) @va.gov>; Ilse Wiechers (Yale) (b)(6)
Cc: Daniels, Lindsay (b)(6) @va.gov>; Pomerantz, Andrew (b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Ilse
This looks good. I will send through my end while you consider any other statements on implementation (original question)

AMERICAN OVERSIGHT

From: Wiechers, Ilse
Sent: Tuesday, June 18, 2019 1:27 PM
To: Carroll, David (VACO) (b)(6) @va.gov>; Strmiska, Jon G. (b)(6) @va.gov>; Ilse Wiechers (Yale) (b)(6) Torrise, Virginia (VHACO) <(b)(6) @va.gov>
Cc: Daniels, Lindsay <(b)(6) @va.gov>; Pomerantz, Andrew <(b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

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Ginny – you can comment on the formulary decision, but I know that the MAP/VPE is considering esketamine on the agenda of this week's meeting on Thursday morning. I was planning to use language that states (b5)
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(b5) Please edit that statement as you feel most appropriate.

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From: Carroll, David (VACO)
Sent: Tuesday, June 18, 2019 10:23 AM
To: Strmiska, Jon G. <(b)(6) @va.gov>; Ilse Wiechers (Yale) (b)(6) Wiechers, Ilse (b)(6) @va.gov>; Torrise, Virginia (VHACO) <(b)(6) @va.gov>
Cc: Daniels, Lindsay <Lindsay.Daniels@va.gov>; Pomerantz, Andrew (b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

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To: Ilse Wiechers (Yale) (b)(6) Wiechers, Ilse (b)(6) @va.gov>; Torrise, Virginia (VHACO) (b)(6) @va.gov>
Cc: Daniels, Lindsay <(b)(6) @va.gov>; Pomerantz, Andrew <(b)(6) @va.gov>; VHA 10P4P Action <vha10P4Paction@va.gov>; Carroll, David (VACO) (b)(6) @va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

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Thanks!

Jon G. Strmiska
Business Operations Manager (10NC5)
VA Central Office – Washington, DC
Phone:*(b)(6)*
FAX: 202.495.5933

From: Dudley, Tracy
Sent: Tuesday, June 18, 2019 1:00 PM
To: VHA 10NC5 Action <VHA10NC5Action@va.gov>
Cc: VHA CO 10NC Front Office HSSs <VHACO10NCFOHSSs@va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

GOOD Afternoon

Please see below and provide your response by **3pm today.**

Thank You!
Tracy

Tracy L. Dudley
Health System Specialist
ADUSH for Clinical Operations (10NC)
(b)(6) (Direct)
(b)(6) iPhone)

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Cc: VHA 10NC5 Action <VHA10NC5Action@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
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From: Cashour, Curtis
Sent: Tuesday, June 18, 2019 12:38 PM
To: Greilsamer, Alan <(b)(6) @va.gov>; Screen, Gina <(b)(6) @va.gov>
Cc: Eason, William J. (b)(6) @va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

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Press Secretary
Department of Veterans Affairs
(b)(6)
(b)(6) @va.gov
(b)(6)

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Sent: Tuesday, June 18, 2019 12:35 PM
To: Cashour, Curtis <(b)(6) @va.gov>
Subject: Re: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

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Press Secretary
Department of Veterans Affairs

AMERICAN OVERSIGHT

(b)(6)
(b)(6) @va.gov
(b)(6)

From: Carey, Ben (b)(6) @nytimes.com>
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Sender:	Wiechers, Ilse /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0C7B1428D9E4233A641F125C5B6FC4F-WIECHERS, I (b)(6) @va.gov>
Recipient:	Torrise, Virginia (VHACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=519204df507344ac8fa3045b2b4fc762-Torrise, Vi (b)(6) @va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b)(6) @va.gov>; Strmiska, Jon G. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9872f41bf2844c8085d371e21482b635-Strmiska, J (b)(6) @va.gov>; Ilse Wiechers (Yale) (b)(6) Daniels, Lindsay /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ed253196fb6b4f32aa922c90dbd05f29-Daniels, Li (b)(6) @va.gov>; Pomerantz, Andrew /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29a9288df9a34e84bddfd00cde79f11b-Pomerantz, (b)(6) @va.gov>
Sent Date:	2019/06/18 14:17:12
Delivered Date:	2019/06/18 14:17:13
From:	Wiechers, Ilse /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0C7B1428D9E4233A641F125C5B6FC4F-WIECHERS, I (b)(6) @va.gov>
To:	Boyd, Teresa D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6886a7d555a43e0bee23c1e40e1c234-Boyd, Teres <(b)(6) @va.gov>; Wiechers, Ilse (b)(6)
CC:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>;

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	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b)(6) @va.gov>
Subject:	RE: [EXTERNAL] Re: Plan
Date:	2019/06/18 14:10:45
Priority:	Normal
Type:	Note

Dr. Boyd –

Below is content that can be used for briefing Dr. Leiberman and that can also be used as the starting point of some copy for the comms team. I've highlighted one statement that needs approval by the PBM before sending forward. Let me know what you think.

Also as a personal FYI –(b) (6)

(b) (6)

Best, Ilse

***

(b5)

AMERICAN OVERSIGHT



From: Boyd, Teresa D.
Sent: Tuesday, June 18, 2019 10:19 AM
To: Wiechers, Ilse (b)(6)
Cc: Emmendorfer, Thomas (PBM) (b)(6) @va.gov>; Valentino, Michael (VACO) (b)(6) @va.gov>; Carroll, David (VACO) (b)(6) @va.gov>; Wiechers, Ilse (b)(6) @va.gov>
Subject: RE: [EXTERNAL] Re: Plan

Thank you!

Sent with BlackBerry Work
(www.blackberry.com)

From: Wiechers, Ilse (b)(6)
Date: Tuesday, Jun 18, 2019, 1:16 PM
To: Boyd, Teresa D. <(b)(6) @va.gov>
Cc: Emmendorfer, Thomas (PBM) (b)(6) @va.gov>, Valentino, Michael (VACO) (b)(6) @va.gov>, Carroll, David (VACO) (b)(6) @va.gov>, Wiechers, Ilse (b)(6) @va.gov>
Subject: [EXTERNAL] Re: Plan

Adding my VA email. I'll get you some bullet points before COB today, if not sooner. On a couple calls where I need to participate, but then will get this out.

>On Jun 18, 2019, at 9:22 AM, Boyd, Teresa D. (b)(6) @va.gov>wrote:
>
>Thank you all again!
>
>In lieu of me trying to cut/paste from multiple emails on my mobile, Ilse, would you be so kind as to give me high level next steps? # early adopter sites currently using IV and have interested Veterans for transition to IN, and forward implementation. I need to share with Dr. Lieberman. Thx!
>
>Teresa

AMERICAN OVERSIGHT

>
>
>Sent with BlackBerry Work
>(www.blackberry.com)

Sender:	Wiechers, Ilse /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0C7B1428D9E4233A641F125C5B6FC4F-WIECHERS, I (b)(6) @va.gov>
Recipient:	Boyd, Teresa D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6886a7d555a43e0bee23c1e40e1c234-Boyd, Teres (b)(6) @va.gov>; Wiechers, Ilse (b)(6) Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da (b)(6) @va.gov>
Sent Date:	2019/06/18 14:10:44
Delivered Date:	2019/06/18 14:10:45

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To:	Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd.DIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>; Hastings, Patricia R. /o=ExchangeLabs/ou=Exchange Administrative Group /EYDIBOHF23SPDLT)/cn=Recipients/cn=a504fbfe766048a5a65461c45f28e9de-Hastings, P (b)(6) @va.gov>
Subject:	RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision
Date:	2019/06/21 10:07:32
Priority:	Normal
Type:	Note

Pat and I briefly discussed this morning. I told her it was my understanding that the decisions were confidential until the minutes were finalized and thru typical procedures.

From: Valentino, Michael (VACO)
Sent: Friday, June 21, 2019 10:04 AM
To: Hastings, Patricia R. <(b)(6) @va.gov>; Llorente, Maria D. (b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

We "normally" don't announce our final formulary decisions until the meeting minutes are finalized, although folks attending the meeting usually share the decisions with their facilities and start implementation).

It isn't a problem to respond to the inquiry and I'm certain it is already common knowledge but interested in your thoughts about sharing with the NYT.

?

Mike

From: Valentino, Michael (VACO)
Sent: Friday, June 21, 2019 9:57 AM
To: Graham, Christopher L. <(b)(6) @va.gov>; Lahl, Dennis (b)(6) @va.gov>; Torrise, Virginia (VHACO) <(b)(6) @va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>; Hastings, Patricia R. <(b)(6) @va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Cc: Zacher, Jennifer L. (PBM) <(b)(6) @va.gov>; Strmiska, Jon G. (b)(6) @va.gov>; Wiechers, Ilse (b)(6) @va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

We'll discuss in 10P4 later this AM and get back to you.

Mike

From: Graham, Christopher L.
Sent: Friday, June 21, 2019 9:54 AM
To: Lahl, Dennis (b)(6) @va.gov>; Torrise, Virginia (VHACO) <(b)(6) @va.gov>; VHA 10P4

AMERICAN OVERSIGHT

Actions <VHA10P4Actions@va.gov>; Hastings, Patricia R. (b)(6) @va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Cc: Valentino, Michael (VACO) (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) (b)(6) @va.gov>; Strmiska, Jon G. (b)(6) @va.gov>; Wiechers, Ilse (b)(6) @va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Good morning,

Do these items still seem likely for today?

Thanks,
Chris Graham, MHA
Health Systems Specialist
Department of Veterans Affairs
Office of the Deputy Under Secretary for Health for Policy and Services (10P)
Office: (b)(6)

From: Lahl, Dennis
Sent: Tuesday, June 18, 2019 3:28 PM
To: Torrise, Virginia (VHACO) (b)(6) @va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>; Hastings, Patricia R. (b)(6) @va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Cc: Valentino, Michael (VACO) (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) (b)(6) @va.gov>; Strmiska, Jon G. (b)(6) @va.gov>; Wiechers, Ilse (b)(6) @va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

All the below is cleared:

10P4P Response: We anticipate having final decisions about Pharmacy Benefits Management policies, including criteria for use, national protocol guidance, and formulary status by end of next week, pending ongoing deliberations of the Medical Advisory Panel (MAP) and VISN Pharmacy Executive (VPE) Committees.

Thanks. Have a great day.

Dennis

Dennis Lahl FAC-P/PM
Office of the Assistant Deputy Under Secretary for Health for Patient Care Services (10P4)
VACO PCS IT/BCAG/ISO Liaison
TMS OPCS DM
ph: (b)(6)
fax: 202-273-5483
Dennis Lahl

AMERICAN OVERSIGHT

From: Lahl, Dennis
Sent: Tuesday, June 18, 2019 3:05 PM
To: Torrise, Virginia (VHACO) <(b)(6) @va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>; Hastings, Patricia R. <(b)(6) @va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Cc: Valentino, Michael (VACO) <(b)(6) @va.gov>; Zacher, Jennifer L. (PBM) <(b)(6) @va.gov>; Strmiska, Jon G. <(b)(6) @va.gov>; Wiechers, Ilse <(b)(6) @va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Dr. Hastings,

10NC5 received the below request for input, 10P4P submitted the noted response. Submitting this for clearance to 10NC5. I've cc'd 10P Actions and 10P4 Actions for tracking purposes. Let me know if you have any questions or concerns.

Feeder Response to OMHS: PBM provides this response to support OMHS statements (Dr Wiechers) regarding implementation timeline.

(b5)

Thanks. Have a great day.

Dennis

Dennis Lahl FAC-P/PM
Office of the Assistant Deputy Under Secretary for Health for Patient Care Services (10P4)
VACO PCS IT/BCAG/ISO Liaison
TMS OPCS DM
ph: (b)(6)
fax: 202-273-5483
Dennis Lahl

From: Torrise, Virginia (VHACO)
Sent: Tuesday, June 18, 2019 2:08 PM
To: Lahl, Dennis <(b)(6) @va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>
Cc: Valentino, Michael (VACO) <(b)(6) @va.gov>; Zacher, Jennifer L. (PBM) <(b)(6) @va.gov>; Strmiska, Jon G. <(b)(6) @va.gov>; Wiechers, Ilse <(b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

AMERICAN OVERSIGHT

Medical Advisory Panel (MAP)
VISN Pharmacy Executive (VPE)

From: Lahl, Dennis
Sent: Tuesday, June 18, 2019 2:07 PM
To: Torrise, Virginia (VHACO) <(b)(6) @va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>
Cc: Valentino, Michael (VACO) <(b)(6) @va.gov>; Zacher, Jennifer L. (PBM) (b)(6) @va.gov>; Strmiska, Jon G. <(b)(6) @va.gov>; Wiechers, Ilse (b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Ginny,

What does MAP and VPE stand for please?

Thanks. Have a great day.

Dennis

Dennis Lahl FAC-P/PM
Office of the Assistant Deputy Under Secretary for Health for Patient Care Services (10P4)
VACO PCS IT/BCAG/ISO Liaison
TMS OPCS DM
ph: (b)(6)
fax: 202-273-5483
Dennis Lahl

From: Torrise, Virginia (VHACO)
Sent: Tuesday, June 18, 2019 1:53 PM
To: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Cc: Valentino, Michael (VACO) <(b)(6) @va.gov>; Zacher, Jennifer L. (PBM) (b)(6) @va.gov>; Strmiska, Jon G. <(b)(6) @va.gov>; Wiechers, Ilse (b)(6) @va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Feeder Response to OMHS: PBM provides this response to support OMHS statements (Dr Wiechers) regarding implementation timeline.

(b5)

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From: Wiechers, Ilse
Sent: Tuesday, June 18, 2019 1:27 PM
To: Carroll, David (VACO) (b)(6) @va.gov>; Strmiska, Jon G. (b)(6) @va.gov>; Ilse Wiechers (Yale) (b)(6) Torrise, Virginia (VHACO) (b)(6) @va.gov>
Cc: Daniels, Lindsay <(b)(6) @va.gov>; Pomerantz, Andrew <(b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Hi – I'm in office and online. I'm working on some high-level bullet points summarizing our progress and will have them up and out to folks shortly.

Ginny – you can comment on the formulary decision, but I know that the MAP/VPE is considering esketamine on the agenda of this week's meeting on Thursday morning. I was planning to use language that states (b5)

(b5)

appropriate.

Ilse

From: Carroll, David (VACO)
Sent: Tuesday, June 18, 2019 10:23 AM
To: Strmiska, Jon G. (b)(6) @va.gov>; Ilse Wiechers (Yale) (b)(6) Wiechers, Ilse (b)(6) @va.gov>; Torrise, Virginia (VHACO) <(b)(6) @va.gov>
Cc: Daniels, Lindsay <(b)(6) @va.gov>; Pomerantz, Andrew <(b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Actually – Ilse responded on a similar request from Dr. Boyd. Looks like she may have something together later this afternoon.

From: Strmiska, Jon G.
Sent: Tuesday, June 18, 2019 1:17 PM
To: Ilse Wiechers (Yale) (b)(6) Wiechers, Ilse <(b)(6) @va.gov>; Torrise, Virginia (VHACO) (b)(6) @va.gov>
Cc: Daniels, Lindsay <(b)(6) @va.gov>; Pomerantz, Andrew <(b)(6) @va.gov>; VHA 10P4P Action <vha10P4Paction@va.gov>; Carroll, David (VACO) <(b)(6) @va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Ginny,

As discussed, your assistance is greatly appreciated with providing a response on this one. Ilse is out of the office until tomorrow. Please see below and provide your response by **3pm today.**

New York Times is asking when a decision will be made as to when VA will be putting Spravato in its formulary. We recently provide the response below, highlighted yellow.

AMERICAN OVERSIGHT

Is there any more specific information that we can provide about timeline?

FDA has approved the use of intranasal esketamine for adults with treatment-resistant depression (when used in conjunction with an oral antidepressant). VA has not yet administered esketamine to any patients, and is in the process of designing a clinical implementation plan optimized for safety and efficacy.

Thanks!

Jon G. Strmiska
Business Operations Manager (10NC5)
VA Central Office – Washington, DC
Phone: *(b)(6)*
FAX: 202.495.5933

From: Dudley, Tracy
Sent: Tuesday, June 18, 2019 1:00 PM
To: VHA 10NC5 Action <VHA10NC5Action@va.gov>
Cc: VHA CO 10NC Front Office HSSs <VHACO10NCFOHSSs@va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

GOOD Afternoon

Please see below and provide your response by **3pm today.**

Thank You!
Tracy

Tracy L. Dudley
Health System Specialist
ADUSH for Clinical Operations (10NC)
(b)(6) (Direct)
(b)(6) (iPhone)

From: Greilsamer, Alan
Sent: Tuesday, June 18, 2019 12:46 PM
To: VHA 10N Action <VHA10NAction@va.gov>; VHA 10NC Action <vha10ncaction@va.gov>
Cc: VHA 10NC5 Action <VHA10NC5Action@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

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FDA has approved the use of intranasal esketamine for adults with treatment-resistant depression (when used in conjunction with an oral antidepressant). VA has not yet administered esketamine to any patients, and is in the process of designing a clinical implementation plan optimized for safety and efficacy.

Requesting a response by today (June 18) NLT 5 p.m. ET.

Thanks, Alan

From: Cashour, Curtis
Sent: Tuesday, June 18, 2019 12:38 PM
To: Greilsamer, Alan <(b)(6) @va.gov>; Screen, Gina <(b)(6) @va.gov>
Cc: Eason, William J. <(b)(6) @va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Please let me know your recommended response to the below.

Thanks,

Curt Cashour
Press Secretary
Department of Veterans Affairs
(b)(6)
(b)(6) @va.gov
(b)(6)

From: Ben Carey (b)(6) @nytimes.com>
Sent: Tuesday, June 18, 2019 12:35 PM
To: Cashour, Curtis <(b)(6) @va.gov>
Subject: Re: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Thanks Curt, please do. Main question for now is when is decision expected..? (i.e. how much time I got?)

Ben

Sent from my iPhone

On Jun 18, 2019, at 12:22 PM, Cashour, Curtis (b)(6) @va.gov>wrote:

Will keep you posted. Thanks, Ben.

Curt Cashour
Press Secretary
Department of Veterans Affairs

AMERICAN OVERSIGHT

(b)(6)
(b)(6) @va.gov
(b)(6)

From: Carey, Ben <(b)(6) @nytimes.com>
Sent: Tuesday, June 18, 2019 11:36 AM
To: Cashour, Curtis <(b)(6) @va.gov>
Subject: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Curt Cashour-

Hello from New York. It's Ben Carey emailing. I am a reporter in science at the NY Times, I cover psych topics. I have your email from Jennifer Steinhauer, NYT reporter in DC.

I would love to hear what/ when on the VA's expected decision this week whether to put Spravato on its formulary. Keep me in the loop on this, kindly, would be good to know when decision will be made, with some notice, and anything else VA puts out on this.

We'll likely cover decision either way.

Sincerely,

Ben Carey

Recipient:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>; Hastings, Patricia R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a504fbfe766048a5a65461c45f28e9de-Hastings, P (b)(6) @va.gov>
Sent Date:	2019/06/21 10:07:41
Delivered Date:	2019/06/21 10:07:32
Message Flags:	Unread Unsent

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From:	Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd. (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=519204DF507344AC8FA3045B2B4FC762-TORRISE, VI>
To:	Christopher, Melissa L (VHASDC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a542daad1277489fb77c0b3d08454521-Christopher <(b)(6) @va.gov>
CC:	Kay, Chad L. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8ecac5c30012472fa21179ae6016add6-Kay, Chad L (b)(6) @va.gov>
Subject:	RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision
Date:	2019/06/18 17:37:33
Priority:	Normal
Type:	Note

Already taken care of

Sent with BlackBerry Work
(www.blackberry.com)

From: Christopher, Melissa L (VHASDC) <(b)(6) @va.gov>
Date: Tuesday, Jun 18, 2019, 4:46 PM
To: Torrise, Virginia (VHACO) (b)(6) @va.gov>
Cc: Kay, Chad L. (b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

I recalled Ilse indicated as of 6/15 one site she has in a facilitation call as part of Esketamine Collaborative will administer to patient. (location Boston) Chad confirmed he found an orderable item record when he ran a query on this. No drug released... but there is some potential information that our first patient has already received this as of last Friday.

From: Strmiska, Jon G.
Sent: Tuesday, June 18, 2019 10:17 AM
To: Ilse Wiechers (Yale) (b)(6) ; Wiechers, Ilse (b)(6) @va.gov>; Torrise, Virginia (VHACO) (b)(6) @va.gov>
Cc: Daniels, Lindsay <(b)(6) @va.gov>; Pomerantz, Andrew (b)(6) @va.gov>; VHA 10P4P Action <vha10P4Paction@va.gov>; Carroll, David (VACO) (b)(6) @va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Ginny,

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New York Times is asking when a decision will be made as to when VA will be putting Spravato in its formulary. We recently provide the response below, highlighted yellow.

Is there any more specific information that we can provide about timeline?

AMERICAN OVERSIGHT

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Thanks!

Jon G. Strmiska
Business Operations Manager (10NC5)
VA Central Office – Washington, DC
Phone:*(b)(6)*
FAX: 202.495.5933

From: Dudley, Tracy
Sent: Tuesday, June 18, 2019 1:00 PM
To: VHA 10NC5 Action <VHA10NC5Action@va.gov>
Cc: VHA CO 10NC Front Office HSSs <VHACO10NCFOHSSs@va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

GOOD Afternoon

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Thank You!
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Tracy L. Dudley
Health System Specialist
ADUSH for Clinical Operations (10NC)
(b)(6) (Direct)
(b)(6) (iPhone)

From: Greilsamer, Alan
Sent: Tuesday, June 18, 2019 12:46 PM
To: VHA 10N Action <VHA10NAction@va.gov>; VHA 10NC Action <vha10ncaction@va.gov>
Cc: VHA 10NC5 Action <VHA10NC5Action@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

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Thanks, Alan

From: Cashour, Curtis
Sent: Tuesday, June 18, 2019 12:38 PM
To: Greilsamer, Alan <(b)(6) @va.gov>; Screen, Gina <(b)(6) @va.gov>
Cc: Eason, William J. (b)(6) @va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Please let me know your recommended response to the below.

Thanks,

Curt Cashour
Press Secretary
Department of Veterans Affairs
(b)(6)
(b)(6) @va.gov
(b)(6)

From: Ben Carey <(b)(6) @nytimes.com>
Sent: Tuesday, June 18, 2019 12:35 PM
To: Cashour, Curtis <(b)(6) @va.gov>
Subject: Re: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Thanks Curt, please do. Main question for now is when is decision expected..? (i.e. how much time I got?)

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Sent from my iPhone

On Jun 18, 2019, at 12:22 PM, Cashour, Curtis (b)(6) @va.gov>wrote:

Will keep you posted. Thanks, Ben.

Curt Cashour
Press Secretary
Department of Veterans Affairs
(b)(6)

AMERICAN OVERSIGHT

(b)(6) @va.gov
(b)(6)

From: Carey, Ben (b)(6) @nytimes.com>
Sent: Tuesday, June 18, 2019 11:36 AM
To: Cashour, Curtis <(b)(6) @va.gov>
Subject: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Curt Cashour-

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I would love to hear what/ when on the VA's expected decision this week whether to put Spravato on its formulary. Keep me in the loop on this, kindly, would be good to know when decision will be made, with some notice, and anything else VA puts out on this.

We'll likely cover decision either way.

Sincerely,

Ben Carey

Sender:	Torrise, Virginia (VHACO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=519204DF507344AC8FA3045B2B4FC762-TORRISE, VI>
Recipient:	Christopher, Melissa L (VHASDC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a542daad1277489fb77c0b3d08454521-Christopher (b)(6) @va.gov>; Kay, Chad L. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8ecac5c30012472fa21179ae6016add6-Kay, Chad L (b)(6) @va.gov>
Sent Date:	2019/06/18 17:37:33

AMERICAN OVERSIGHT

From:	Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd. (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=519204DF507344AC8FA3045B2B4FC762-TORRISE, VI>
To:	Lahl, Dennis /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=39fba8ea7cd941b3a0a4f79ca3c6ee87-Lahl, Denni (b)(6) va.gov>
Subject:	RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision
Date:	2019/06/18 15:28:00
Priority:	Normal
Type:	Note

No problem

From: Lahl, Dennis
Sent: Tuesday, June 18, 2019 3:28 PM
To: Torrise, Virginia (VHACO) (b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

I was asked to change it to next week – just in case

Thanks. Have a great day.

Dennis

Dennis Lahl FAC-P/PM
Office of the Assistant Deputy Under Secretary for Health for Patient Care Services (10P4)
VACO PCS IT/BCAG/ISO Liaison
TMS OPCS DM
ph: (b)(6)
fax: 202-273-5483
Dennis Lahl

From: Torrise, Virginia (VHACO)
Sent: Tuesday, June 18, 2019 3:03 PM
To: Lahl, Dennis (b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

That's what I figured you meant to say. No changes to the statement.

From: Lahl, Dennis
Sent: Tuesday, June 18, 2019 3:01 PM
To: Torrise, Virginia (VHACO) (b)(6) @va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>
Cc: Valentino, Michael (VACO) <(b)(6) @va.gov>; Zacher, Jennifer L. (PBM) (b)(6) @va.gov>; Strmiska, Jon G. <(b)(6) @va.gov>; Wiechers, Ilse

AMERICAN OVERSIGHT

(b)(6) @va.gov>; Zacher, Jennifer L. (PBM) <(b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

My apologies – multitasking too much and spell check correcting my error – I meant reporter.

Thanks. Have a great day.

Dennis

Dennis Lahl FAC-P/PM
Office of the Assistant Deputy Under Secretary for Health for Patient Care Services (10P4)
VACO PCS IT/BCAG/ISO Liaison
TMS OPCS DM
ph:(b)(6)
fax: 202-273-5483
Dennis Lahl

From: Torrise, Virginia (VHACO)
Sent: Tuesday, June 18, 2019 2:59 PM
To: Lahl, Dennis (b)(6) @va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>
Cc: Valentino, Michael (VACO) (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) (b)(6) @va.gov>; Strmiska, Jon G. <(b)(6) @va.gov>; Wiechers, Ilse (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) (b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

The complete report submitted to Dr. Boyd is attached, with PBM concurrence. We are confident the MAP and VPE committee are meeting to determine formulary status and discuss criteria for use this week. It is fair to say we "anticipate" a decision. Dr. Wiechers is the POC for the implementation plan.

From: Lahl, Dennis
Sent: Tuesday, June 18, 2019 2:52 PM
To: Torrise, Virginia (VHACO) (b)(6) @va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>
Cc: Valentino, Michael (VACO) (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) (b)(6) @va.gov>; Strmiska, Jon G. <(b)(6) @va.gov>; Wiechers, Ilse (b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Sorry, are we sure about the timeline – reported may hold us to it?

Dennis

Dennis Lahl FAC-P/PM
Office of the Assistant Deputy Under Secretary for Health for Patient Care Services (10P4)

AMERICAN OVERSIGHT

VA-19-1109-B-001273

VACO PCS IT/BCAG/ISO Liaison
TMS OPCS DM
ph: (b)(6)
fax: 202-273-5483
Dennis Lahl

From: Torrise, Virginia (VHACO)
Sent: Tuesday, June 18, 2019 2:08 PM
To: Lahl, Dennis (b)(6) @va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>
Cc: Valentino, Michael (VACO) (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) (b)(6) @va.gov>; Strmiska, Jon G. (b)(6) @va.gov>; Wiechers, Ilse (b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Medical Advisory Panel (MAP)
VISN Pharmacy Executive (VPE)

From: Lahl, Dennis
Sent: Tuesday, June 18, 2019 2:07 PM
To: Torrise, Virginia (VHACO) (b)(6) @va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>
Cc: Valentino, Michael (VACO) (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) (b)(6) @va.gov>; Strmiska, Jon G. <(b)(6) @va.gov>; Wiechers, Ilse (b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Ginny,

What does MAP and VPE stand for please?

Thanks. Have a great day.

Dennis

Dennis Lahl FAC-P/PM
Office of the Assistant Deputy Under Secretary for Health for Patient Care Services (10P4)
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Cc: Valentino, Michael (VACO) (b)(6) @va.gov>; Zacher, Jennifer L. (PBM)

AMERICAN OVERSIGHT

(b)(6) @va.gov>; Strmiska, Jon G. <(b)(6) @va.gov>; Wiechers, Ilse (b)(6) @va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Feeder Response to OMHS: PBM provides this response to support OMHS statements (Dr Wiechers) regarding implementation timeline.

(b5)

From: Wiechers, Ilse
Sent: Tuesday, June 18, 2019 1:27 PM
To: Carroll, David (VACO) <(b)(6) @va.gov>; Strmiska, Jon G. (b)(6) @va.gov>; Ilse Wiechers (Yale) <(b)(6) Torrise, Virginia (VHACO) <(b)(6) @va.gov>
Cc: Daniels, Lindsay <(b)(6) @va.gov>; Pomerantz, Andrew <(b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Hi – I'm in office and online. I'm working on some high-level bullet points summarizing our progress and will have them up and out to folks shortly.

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Ilse

From: Carroll, David (VACO)
Sent: Tuesday, June 18, 2019 10:23 AM
To: Strmiska, Jon G. <(b)(6) @va.gov>; Ilse Wiechers (Yale) <(b)(6) @yale.edu>; Wiechers, Ilse <(b)(6) @va.gov>; Torrise, Virginia (VHACO) <(b)(6) @va.gov>
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Sent: Tuesday, June 18, 2019 1:17 PM
To: Ilse Wiechers (Yale) (b)(6) Wiechers, Ilse <(b)(6) @va.gov>; Torrise,

AMERICAN OVERSIGHT

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Cc: Daniels, Lindsay (b)(6) @va.gov>; Pomerantz, Andrew (b)(6) @va.gov>; VHA 10P4P Action <vha10P4Paction@va.gov>; Carroll, David (VACO) (b)(6) @va.gov>
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Ginny,

As discussed, your assistance is greatly appreciated with providing a response on this one. Ilse is out of the office until tomorrow. Please see below and provide your response by **3pm today.**

New York Times is asking when a decision will be made as to when VA will be putting Spravato in its formulary. We recently provide the response below, highlighted yellow.

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Thanks!

Jon G. Strmiska
Business Operations Manager (10NC5)
VA Central Office – Washington, DC
Phone: (b)(6)
FAX: 202.495.5933

From: Dudley, Tracy
Sent: Tuesday, June 18, 2019 1:00 PM
To: VHA 10NC5 Action <VHA10NC5Action@va.gov>
Cc: VHA CO 10NC Front Office HSSs <VHACO10NCFOHSSs@va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

GOOD Afternoon

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Thank You!
Tracy

Tracy L. Dudley
Health System Specialist
ADUSH for Clinical Operations (10NC)
(b)(6) (Direct)
(b)(6) Phone)

AMERICAN OVERSIGHT

From: Greilsamer, Alan
Sent: Tuesday, June 18, 2019 12:46 PM
To: VHA 10N Action <VHA10NAction@va.gov>; VHA 10NC Action <vha10ncaction@va.gov>
Cc: VHA 10NC5 Action <VHA10NC5Action@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
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Thanks, Alan

From: Cashour, Curtis
Sent: Tuesday, June 18, 2019 12:38 PM
To: Greilsamer, Alan <(b)(6) @va.gov>; Screen, Gin (b)(6) @va.gov>
Cc: Eason, William J. <(b) (6) @va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Please let me know your recommended response to the below.

Thanks,

Curt Cashour
Press Secretary
Department of Veterans Affairs
(b)(6)
(b)(6) @va.gov
(b)(6)

From: Ben Carey <(b)(6) @nytimes.com>
Sent: Tuesday, June 18, 2019 12:35 PM
To: Cashour, Curtis (b)(6) @va.gov>
Subject: Re: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

AMERICAN OVERSIGHT

Thanks Curt, please do. Main question for now is when is decision expected..? (i.e. how much time I got?)

Ben

Sent from my iPhone

On Jun 18, 2019, at 12:22 PM, Cashour, Curtis (b)(6) @va.gov>wrote:

Will keep you posted. Thanks, Ben.

Curt Cashour
Press Secretary
Department of Veterans Affairs
(b)(6)
(b)(6) @va.gov
(b)(6)

From: Carey, Ben (b)(6) @nytimes.com>
Sent: Tuesday, June 18, 2019 11:36 AM
To: Cashour, Curtis (b)(6) @va.gov>
Subject: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Curt Cashour-

Hello from New York. It's Ben Carey emailing. I am a reporter in science at the NY Times, I cover psych topics. I have your email from Jennifer Steinhauer, NYT reporter in DC.

I would love to hear what/ when on the VA's expected decision this week whether to put Spravato on its formulary. Keep me in the loop on this, kindly, would be good to know when decision will be made, with some notice, and anything else VA puts out on this.

We'll likely cover decision either way.

Sincerely,

Ben Carey

Sender:	Torrise, Virginia (VHACO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=519204DF507344AC8FA3045B2B4FC762-TORRISE, VI>
Recipient:	Lahl, Dennis /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=39fba8ea7cd941b3a0a4f79ca3c6ee87-Lahl, Denni (b)(6) @va.gov>
Sent Date:	2019/06/18 15:28:40
Delivered Date:	2019/06/18 15:28:00

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From:	Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd. (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=519204DF507344AC8FA3045B2B4FC762-TORRISE, VI>
To:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b)(6) @va.gov>
Subject:	RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision
Date:	2019/06/18 13:35:00
Priority:	Normal
Type:	Note

Jenn is at lunch but will look at the statement when she returns. You have the timeline correct.

From: Wiechers, Ilse
Sent: Tuesday, June 18, 2019 1:27 PM
To: Carroll, David (VACO) <(b)(6) @va.gov>; Strmiska, Jon G. (b)(6) @va.gov>; Ilse Wiechers (Yale) (b)(6) Torrise, Virginia (VHACO) <(b)(6) @va.gov>
Cc: Daniels, Lindsay <(b)(6) @va.gov>; Pomerantz, Andrew (b)(6) @va.gov>
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To: Strmiska, Jon G. <(b)(6) @va.gov>; Ilse Wiechers (Yale) <(b)(6) Wiechers, Ilse <(b)(6) @va.gov>; Torrise, Virginia (VHACO) <(b)(6) @va.gov>
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AMERICAN OVERSIGHT

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Cc: Daniels, Lindsay (b)(6) @va.gov>; Pomerantz, Andrew <(b)(6) @va.gov>; VHA 10P4P Action <vha10P4Paction@va.gov>; Carroll, David (VACO) (b)(6) @va.gov>
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Thanks!

Jon G. Strmiska
Business Operations Manager (10NC5)
VA Central Office – Washington, DC
Phone: *(b)(6)*
FAX: 202.495.5933

From: Dudley, Tracy
Sent: Tuesday, June 18, 2019 1:00 PM
To: VHA 10NC5 Action <VHA10NC5Action@va.gov>
Cc: VHA CO 10NC Front Office HSSs <VHACO10NCFOHSSs@va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

GOOD Afternoon

Please see below and provide your response by **3pm today.**

Thank You!
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Tracy L. Dudley
Health System Specialist
ADUSH for Clinical Operations (10NC)
(b)(6) Direct)

AMERICAN OVERSIGHT

(b)(6) (iPhone)

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Cc: Eason, William J. <(b)(6) @va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

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Press Secretary
Department of Veterans Affairs
(b)(6)
(b)(6) @va.gov
(b)(6)

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To: Cashour, Curtis <(b)(6) @va.gov>
Subject: Re: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

AMERICAN OVERSIGHT

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Sincerely,

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Recipient:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b)(6) @va.gov>
Sent Date:	2019/06/18 13:35:20
Delivered Date:	2019/06/18 13:35:00

AMERICAN OVERSIGHT

From:	Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd. (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO,>
To:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b)(6) @va.gov>
Subject:	RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision
Date:	2019/06/20 09:06:33
Priority:	Normal
Type:	Note

Are you able to join the call Ilse?

Sent with BlackBerry Work
(www.blackberry.com)

From: Wiechers, Ilse <(b)(6) @va.gov>
Date: Tuesday, Jun 18, 2019, 2:32 PM
To: Torrise, Virginia (VHACO) <(b)(6) @va.gov>, Carroll, David (VACO) <(b)(6) @va.gov>, Pomerantz, Andrew <(b)(6) @va.gov>
Cc: Valentino, Michael (VACO) <(b)(6) @va.gov>, Zacher, Jennifer L. (PBM) <(b)(6) @va.gov>, Strmiska, Jon G. <(b)(6) @va.gov>, Daniels, Lindsay <(b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Looks like Dennis just sent forward the formulary statement. Do we want to ensure Comms sees the longer statement with the full set of updates on esketamine progress? I saw you tried to do that, Ginny (thanks). I don't think it is needed for the immediate response to the explicit reporter question, but more questions will come. I also want to make sure Comms know we dosed the first Veteran today. Just want to make sure we get the right content in front of people when they need it.

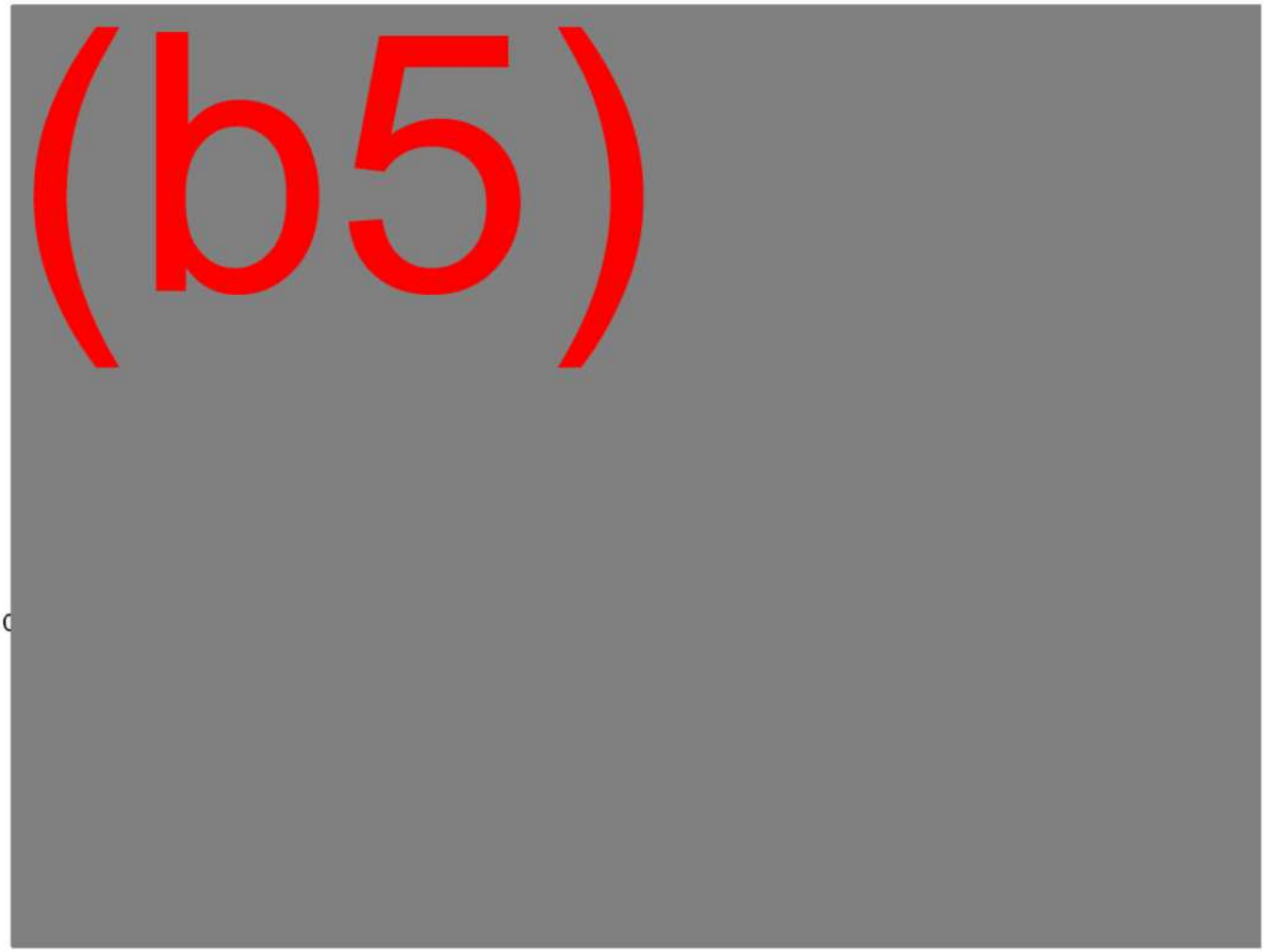
Copy of my comments (sent to Dr. Boyd for internal briefings) below.

Thanks,
Ilse

***



AMERICAN OVERSIGHT



From: Lahl, Dennis
Sent: Tuesday, June 18, 2019 12:05 PM
To: Torrise, Virginia (VHACO) (b)(6) @va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>; Hastings, Patricia R. (b)(6) @va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Cc: Valentino, Michael (VACO) (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) (b)(6) @va.gov>; Strmiska, Jon G. < (b)(6) @va.gov>; Wiechers, Ilse (b)(6) @va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Dr. Hastings,

10NC5 received the below request for input, 10P4P submitted the noted response. Submitting this for clearance to 10NC5. I've cc'd 10P Actions and 10P4 Actions for tracking purposes. Let me know if you have any questions or concerns.

Feeder Response to OMHS: PBM provides this response to support OMHS statements (Dr Wiechers) regarding implementation timeline.

Question: Is there any more specific information that we can provide about timeline?

AMERICAN OVERSIGHT

(b5)

Thanks. Have a great day.

Dennis

Dennis Lahl FAC-P/PM
Office of the Assistant Deputy Under Secretary for Health for Patient Care Services (10P4)
VACO PCS IT/BCAG/ISO Liaison
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AMERICAN OVERSIGHT

Office of the Assistant Deputy Under Secretary for Health for Patient Care Services (10P4)
VACO PCS IT/BCAG/ISO Liaison
TMS OPCS DM
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Dennis Lahl

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AMERICAN OVERSIGHT

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Thanks!

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VA Central Office – Washington, DC
Phone: (b)(6)
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From: Dudley, Tracy
Sent: Tuesday, June 18, 2019 1:00 PM
To: VHA 10NC5 Action <VHA10NC5Action@va.gov>
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GOOD Afternoon

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(b)(6) Direct)
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Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

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New York Times is asking when a decision will be made as to when VA will be putting Spravato in its formulary. We recently provide the response below.

Is there any more specific information that we can provide about timeline?

FDA has approved the use of intranasal esketamine for adults with treatment-resistant depression (when used in conjunction with an oral antidepressant). VA has not yet administered esketamine to any patients, and is in the process of designing a clinical implementation plan optimized for safety and efficacy.

Requesting a response by today (June 18) NLT 5 p.m. ET.

Thanks, Alan

From: Cashour, Curtis
Sent: Tuesday, June 18, 2019 12:38 PM
To: Greilsamer, Alan <(b)(6) @va.gov>; Screen, Gina <(b)(6) @va.gov>
Cc: Eason, William J. <(b)(6) @va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Please let me know your recommended response to the below.

Thanks,

AMERICAN OVERSIGHT

Curt Cashour
Press Secretary
Department of Veterans Affairs
(b)(6)
(b)(6) @va.gov
(b)(6)

From: Ben Carey <(b)(6) @nytimes.com>
Sent: Tuesday, June 18, 2019 12:35 PM
To: Cashour, Curtis <(b)(6) @va.gov>
Subject: Re: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Thanks Curt, please do. Main question for now is when is decision expected..? (i.e. how much time I got?)

Ben

Sent from my iPhone

On Jun 18, 2019, at 12:22 PM, Cashour, Curtis <(b)(6) @va.gov>wrote:

Will keep you posted. Thanks, Ben.

Curt Cashour
Press Secretary
Department of Veterans Affairs
(b)(6)
(b)(6) @va.gov
(b)(6)

From: Carey, Ben (b)(6) @nytimes.com>
Sent: Tuesday, June 18, 2019 11:36 AM
To: Cashour, Curtis <(b)(6) @va.gov>
Subject: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Curt Cashour-

Hello from New York. It's Ben Carey emailing. I am a reporter in science at the NY Times, I cover psych topics. I have your email from Jennifer Steinhauer, NYT reporter in DC.

I would love to hear what/ when on the VA's expected decision this week whether to put Spravato on its formulary. Keep me in the loop on this, kindly, would be good to know when decision will be made, with some notice, and anything else VA puts out on this.

We'll likely cover decision either way.

Sincerely,

AMERICAN OVERSIGHT

Ben Carey

Sender:	Valentino, Michael (VACO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO,>
Recipient:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b)(6) @va.gov>
Sent Date:	2019/06/20 09:06:32
Delivered Date:	2019/06/20 09:06:33

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To:	Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd.HF23SPDLT)/cn=Recipients/cn=a504fbfe766048a5a65461c45f28e9de-Hastings, P (b)(6) @va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M (b)(6) @va.gov>
Subject:	RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision
Date:	2019/06/21 10:57:02
Priority:	Normal
Type:	Note

Some thoughts for a possible response

Question:

Curt Cashour-

Hello from New York. It's Ben Carey emailing. I am a reporter in science at the NY Times, I cover psych topics. I have your email from Jennifer Steinhauer, NYT reporter in DC.

I would love to hear what/ when on the VA's expected decision this week whether to put Spravato on its formulary. Keep me in the loop on this, kindly, would be good to know when decision will be made, with some notice, and anything else VA puts out on this.

We'll likely cover decision either way.

Sincerely,

Ben Carey

Response:

(b5)

From: Valentino, Michael (VACO)
Sent: Friday, June 21, 2019 10:04 AM
To: Hastings, Patricia R. (b)(6) @va.gov>; Llorente, Maria D. <(b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

AMERICAN OVERSIGHT

We "normally" don't announce our final formulary decisions until the meeting minutes are finalized, although folks attending the meeting usually share the decisions with their facilities and start implementation).

It isn't a problem to respond to the inquiry and I'm certain it is already common knowledge but interested in your thoughts about sharing with the NYT.

?

Mike

From: Valentino, Michael (VACO)
Sent: Friday, June 21, 2019 9:57 AM
To: Graham, Christopher L. (b)(6) @va.gov>; Lahl, Dennis <(b)(6) @va.gov>; Torrise, Virginia (VHACO) (b)(6) @va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>; Hastings, Patricia R. (b)(6) @va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Cc: Zacher, Jennifer L. (PBM) (b)(6) @va.gov>; Strmiska, Jon G. (b)(6) @va.gov>; Wiechers, Ilse <(b)(6) @va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

We'll discuss in 10P4 later this AM and get back to you.

Mike

From: Graham, Christopher L.
Sent: Friday, June 21, 2019 9:54 AM
To: Lahl, Dennis <(b)(6) @va.gov>; Torrise, Virginia (VHACO) <(b)(6) @va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>; Hastings, Patricia R. <(b)(6) @va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Cc: Valentino, Michael (VACO) <(b)(6) @va.gov>; Zacher, Jennifer L. (PBM) (b)(6) @va.gov>; Strmiska, Jon G. <(b)(6) @va.gov>; Wiechers, Ilse (b)(6) @va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Good morning,

Do these items still seem likely for today?

Thanks,
Chris Graham, MHA
Health Systems Specialist
Department of Veterans Affairs
Office of the Deputy Under Secretary for Health for Policy and Services (10P)
Office: (b)(6)

From: Lahl, Dennis
Sent: Tuesday, June 18, 2019 3:28 PM

AMERICAN OVERSIGHT

To: Torrise, Virginia (VHACO) (b)(6) @va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>; Hastings, Patricia R. (b)(6) @va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Cc: Valentino, Michael (VACO) (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) (b)(6) @va.gov>; Strmiska, Jon G. (b)(6) @va.gov>; Wiechers, Ilse (b)(6) @va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

All the below is cleared:

(b5)

Thanks. Have a great day.

Dennis

Dennis Lahl FAC-P/PM
Office of the Assistant Deputy Under Secretary for Health for Patient Care Services (10P4)
VACO PCS IT/BCAG/ISO Liaison
TMS OPCS DM
ph: (b)(6)
fax: 202-273-5483
Dennis Lahl

From: Lahl, Dennis
Sent: Tuesday, June 18, 2019 3:05 PM
To: Torrise, Virginia (VHACO) (b)(6) @va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>; Hastings, Patricia R. (b)(6) @va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Cc: Valentino, Michael (VACO) (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) (b)(6) @va.gov>; Strmiska, Jon G. (b)(6) @va.gov>; Wiechers, Ilse (b)(6) @va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Dr. Hastings,

10NC5 received the below request for input, 10P4P submitted the noted response. Submitting this for clearance to 10NC5. I've cc'd 10P Actions and 10P4 Actions for tracking purposes. Let me know if you have any questions or concerns.

Feeder Response to OMHS: PBM provides this response to support OMHS statements (Dr Wiechers) regarding implementation timeline.

Question: Is there any more specific information that we can provide about timeline?

AMERICAN OVERSIGHT

(b5)

Thanks. Have a great day.

Dennis

Dennis Lahl FAC-P/PM
Office of the Assistant Deputy Under Secretary for Health for Patient Care Services (10P4)
VACO PCS IT/BCAG/ISO Liaison
TMS OPCS DM
ph: (b)(6)
fax: 202-273-5483
Dennis Lahl

From: Torrise, Virginia (VHACO)
Sent: Tuesday, June 18, 2019 2:08 PM
To: Lahl, Dennis <(b)(6) @va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>
Cc: Valentino, Michael (VACO) <(b)(6) @va.gov>; Zacher, Jennifer L. (PBM) (b)(6) @va.gov>; Strmiska, Jon G. <(b)(6) @va.gov>; Wiechers, Ilse (b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Medical Advisory Panel (MAP)
VISN Pharmacy Executive (VPE)

From: Lahl, Dennis
Sent: Tuesday, June 18, 2019 2:07 PM
To: Torrise, Virginia (VHACO) (b)(6) @va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>
Cc: Valentino, Michael (VACO) (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) (b)(6) @va.gov>; Strmiska, Jon G. <(b)(6) @va.gov>; Wiechers, Ilse (b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Ginny,

What does MAP and VPE stand for please?

Thanks. Have a great day.

Dennis

Dennis Lahl FAC-P/PM

AMERICAN OVERSIGHT

Office of the Assistant Deputy Under Secretary for Health for Patient Care Services (10P4)
VACO PCS IT/BCAG/ISO Liaison
TMS OPCS DM
ph: (b)(6)
fax: 202-273-5483
Dennis Lahl

From: Torrise, Virginia (VHACO)
Sent: Tuesday, June 18, 2019 1:53 PM
To: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Cc: Valentino, Michael (VACO) <(b)(6) @va.gov>; Zacher, Jennifer L. (PBM) (b)(6) @va.gov>; Strmiska, Jon G. <(b)(6) @va.gov>; Wiechers, Ilse (b)(6) @va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Feeder Response to OMHS: PBM provides this response to support OMHS statements (Dr Wiechers) regarding implementation timeline.

(b5) [redacted]

From: Wiechers, Ilse
Sent: Tuesday, June 18, 2019 1:27 PM
To: Carroll, David (VACO) (b)(6) @va.gov>; Strmiska, Jon G. <(b)(6) @va.gov>; Ilse Wiechers (Yale) <(b)(6) ; Torrise, Virginia (VHACO) (b)(6) @va.gov>
Cc: Daniels, Lindsay <(b)(6) @va.gov>; Pomerantz, Andrew (b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Hi – I'm in office and online. I'm working on some high-level bullet points summarizing our progress and will have them up and out to folks shortly.

Ginny – you can comment on the formulary decision, but I know that the MAP/VPE is considering esketamine on the agenda of this week's meeting on Thursday morning. I was planning to use language that states (b5) [redacted] Please edit that statement as you feel most appropriate.

Ilse

From: Carroll, David (VACO)
Sent: Tuesday, June 18, 2019 10:23 AM
To: Strmiska, Jon G. (b)(6) @va.gov>; Ilse Wiechers (Yale) (b)(6) Wiechers,

AMERICAN OVERSIGHT

Ilse <(b)(6) @va.gov>; Torrise, Virginia (VHACO) (b)(6) @va.gov>
Cc: Daniels, Lindsay <(b)(6) @va.gov>; Pomerantz, Andrew <(b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Actually – Ilse responded on a similar request from Dr. Boyd. Looks like she may have something together later this afternoon.

From: Strmiska, Jon G.
Sent: Tuesday, June 18, 2019 1:17 PM
To: Ilse Wiechers (Yale) (b)(6) ; Wiechers, Ilse (b)(6) @va.gov>; Torrise, Virginia (VHACO)(b)(6) @va.gov>
Cc: Daniels, Lindsay <(b)(6) @va.gov>; Pomerantz, Andrew (b)(6) @va.gov>; VHA 10P4P Action <vha10P4Paction@va.gov>; Carroll, David (VACO) (b)(6) @va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Ginny,

As discussed, your assistance is greatly appreciated with providing a response on this one. Ilse is out of the office until tomorrow. Please see below and provide your response by **3pm today.**

New York Times is asking when a decision will be made as to when VA will be putting Spravato in its formulary. We recently provide the response below, highlighted yellow.

Is there any more specific information that we can provide about timeline?

FDA has approved the use of intranasal esketamine for adults with treatment-resistant depression (when used in conjunction with an oral antidepressant). VA has not yet administered esketamine to any patients, and is in the process of designing a clinical implementation plan optimized for safety and efficacy.

Thanks!

Jon G. Strmiska
Business Operations Manager (10NC5)
VA Central Office – Washington, DC
Phone: (b)(6)
FAX: 202.495.5933

From: Dudley, Tracy
Sent: Tuesday, June 18, 2019 1:00 PM
To: VHA 10NC5 Action <VHA10NC5Action@va.gov>
Cc: VHA CO 10NC Front Office HSSs <VHACO10NCFOHSSs@va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

GOOD Afternoon

AMERICAN OVERSIGHT

Please see below and provide your response by **3pm today.**

Thank You!
Tracy

Tracy L. Dudley

Health System Specialist
ADUSH for Clinical Operations (10NC)
(b)(6) (Direct)
(b)(6) (iPhone)

From: Greilsamer, Alan
Sent: Tuesday, June 18, 2019 12:46 PM
To: VHA 10N Action <VHA10NAction@va.gov>; VHA 10NC Action <vha10ncaction@va.gov>
Cc: VHA 10NC5 Action <VHA10NC5Action@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

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From: Cashour, Curtis
Sent: Tuesday, June 18, 2019 12:38 PM
To: Greilsamer, Alan <(b)(6) @va.gov>; Screen, Gina (b)(6) @va.gov>
Cc: Eason, William J. <(b)(6) @va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Please let me know your recommended response to the below.

Thanks,

AMERICAN OVERSIGHT

Curt Cashour
Press Secretary
Department of Veterans Affairs
(b)(6)
(b)(6) @va.gov
(b)(6)

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Sent: Tuesday, June 18, 2019 12:35 PM
To: Cashour, Curtis <(b)(6) @va.gov>
Subject: Re: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

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Sent from my iPhone

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Curt Cashour
Press Secretary
Department of Veterans Affairs
(b)(6)
(b)(6) @va.gov
(b)(6)

From: Carey, Ben <(b)(6) @nytimes.com>
Sent: Tuesday, June 18, 2019 11:36 AM
To: Cashour, Curtis (b)(6) @va.gov>
Subject: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Curt Cashour-

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Sincerely,

AMERICAN OVERSIGHT

Ben Carey

Recipient:	Hastings, Patricia R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a504fbfe766048a5a65461c45f28e9de-Hastings, P (b)(6) @va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M (b)(6) @va.gov>
Sent Date:	2019/06/21 10:51:59
Delivered Date:	2019/06/21 10:57:02
Message Flags:	Unread Unsent

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From:	Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd.3SPDLT)/CN=RECIPIENTS/CN=C3E1067978634FBF96A382BDCD5C1115-OUTLAW, WIL (b)(6) @va.gov>
To:	Snyder, Jill /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6e91ef72ee4a05acc63873c64570e1-Snyder, Jil (b)(6) @va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b)(6) @va.gov>; Cashour, Curtis /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dba510634baa46a085e28c62c254093f-Cashour, Cu (b)(6) @va.gov>
CC:	Greilsamer, Alan /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fc02807af08443fbb5c68c590d58fa4b-Greilsamer, <(b)(6) @va.gov>
Subject:	RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision
Date:	2019/06/21 12:13:55
Priority:	Normal
Type:	Note

Hi Jill – just saw this

From: Snyder, Jill
Sent: Friday, June 21, 2019 12:02 PM
To: Valentino, Michael (VACO) <(b)(6) @va.gov>; Wiechers, Ilse <(b)(6) @va.gov>; Cashour, Curtis (b)(6) @va.gov>
Cc: Outlaw, William N. <(b)(6) @va.gov>; Greilsamer, Alan <(b)(6) @va.gov>; Snyder, Jill <(b)(6) @va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Good afternoon Mike and Ilse,

I know you all are working on media responses regarding Ketamine, however we just received an email from the Boston Globe that the decision was made NOT to include it in the formulary. Please see email below and I am including Curt Cashour, VA Press Secretary, on this message to streamline responses.

Thank you,
Jill

From: Silverman, Ed (b)(6) @statnews.com>
Sent: Friday, June 21, 2019 11:24 AM
To: VA Public Affairs <VAPublicAffairs@va.gov>
Subject: [EXTERNAL] question from a journalist

AMERICAN OVERSIGHT

Hi ,

My name is Ed Silverman and I work for The Boston Globe's STAT News health site, where I track the pharmaceutical industry.

I understand a VA committee voted not to include a new Johnson&Johnson antidepressant spray drug called Spravato on its pharmacy list.

Can you please confirm and explain why the committee voted not to include it?

Thanks
ed silverman
(b)(6)
www.statnews.com/pharmalot/

From: Snyder, Jill
Sent: Friday, June 21, 2019 9:59 AM
To: Cashour, Curtis <(b)(6) @va.gov>; Greilsamer, Alan (b)(6) @va.gov>
Cc: Eason, William J.(b)(6) @va.gov>; Screen, Gina <(b)(6) @va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Hi Curt –

I am following this in Alan's absence, program office is still working on the response, I will continue to follow up.

Thanks,
Jill

From: Cashour, Curtis
Sent: Friday, June 21, 2019 9:57 AM
To: Greilsamer, Alan <(b)(6) @va.gov>; Snyder, Jill <(b)(6) @va.gov>
Cc: Eason, William J. (b)(6) @va.gov>; Screen, Gina <(b)(6) @va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Just following up here. Thanks.

From: Greilsamer, Alan
Sent: Thursday, June 20, 2019 3:34 PM
To: Cashour, Curtis (b)(6) @va.gov>
Cc: Eason, William J. (b)(6) @va.gov>; Screen, Gina (b)(6) @va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

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We will try to pin them down on a timeframe.

—
Alan Greilsamer
Director, Media Relations (10B2B)
Office of Communications
Veterans Health Administration
P: (b)(6)
E: (b)(6) @va.gov

From: Cashour, Curtis <(b)(6) @va.gov>
Date: Thursday, Jun 20, 2019, 3:18 PM
To: Greilsamer, Alan (b)(6) @va.gov>
Cc: Eason, William J.(b)(6) @va.gov>, Screen, Gina (b)(6) @va.gov>, VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Is there an update here?

The original question was when will VA make a decision about putting spravato on the formulary.

Thanks,

Curt Cashour
Press Secretary
Department of Veterans Affairs
(b)(6)
(b)(6) @va.gov
(b)(6)

From: Greilsamer, Alan
Sent: Wednesday, June 19, 2019 9:05 AM
To: Cashour, Curtis (b)(6) @va.gov>
Cc: Eason, William J. (b)(6) @va.gov>; Screen, Gina (b)(6) @va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

VHA clears

(b5)

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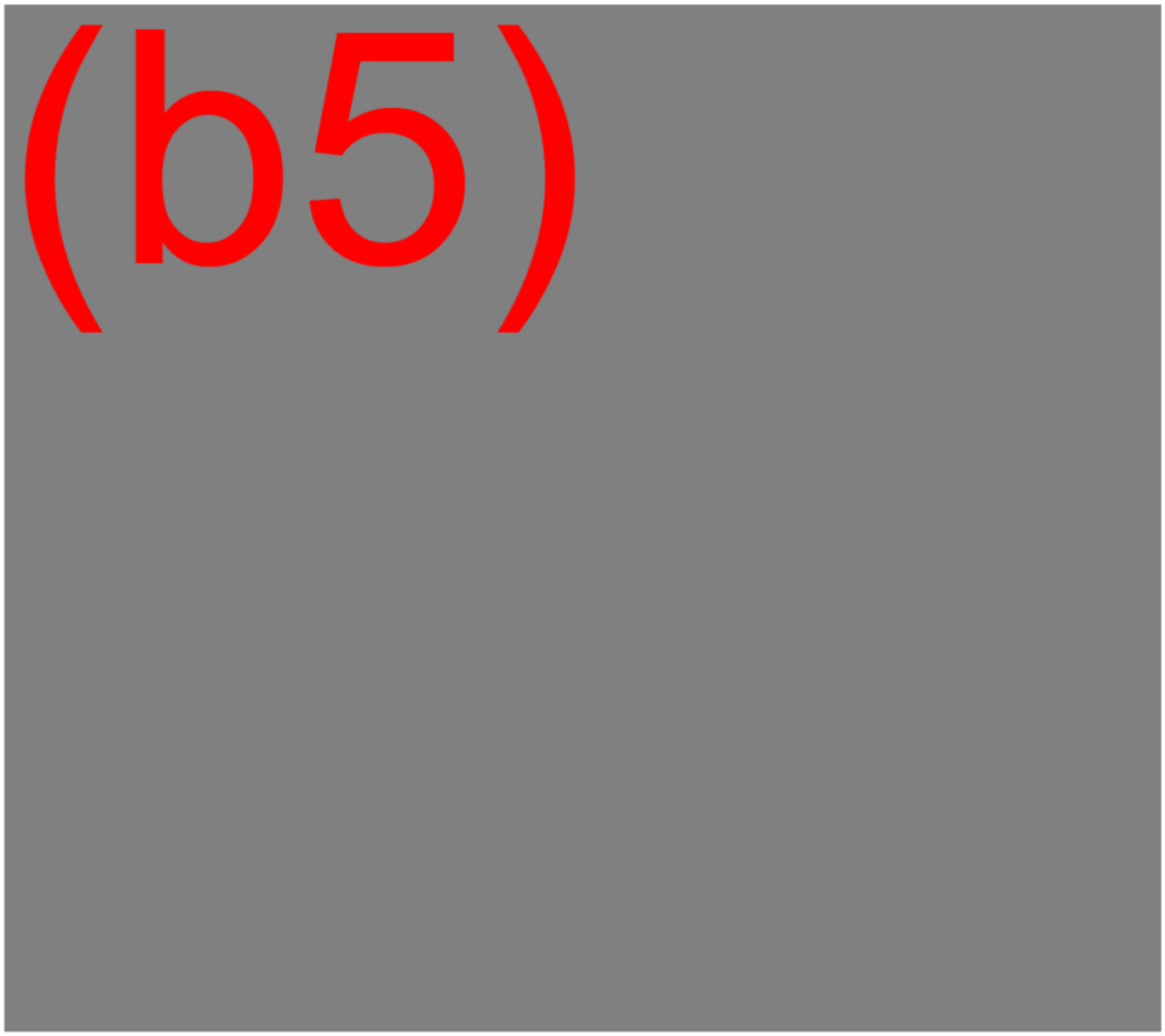

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Cc: Eason, William J. (b)(6) @va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Please let me know your recommended response to the below.

Thanks,

Curt Cashour
Press Secretary
Department of Veterans Affairs
(b)(6)

AMERICAN OVERSIGHT

(b)(6) @va.gov
(b)(6)

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Press Secretary
Department of Veterans Affairs
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We'll likely cover decision either way.

Sincerely,

Ben Carey

Sender:	Outlaw, William N. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C3E1067978634FBF96A382BDCD5C1115-OUTLAW, WIL

AMERICAN OVERSIGHT

	(b)(6) va.gov>
Recipient:	Snyder, Jill /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6e91ef72ee4a05acc63873c64570e1-Snyder, Jil (b)(6) @va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b)(6) @va.gov>; Cashour, Curtis /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dba510634baa46a085e28c62c254093f-Cashour, Cu (b)(6) @va.gov>; Greilsamer, Alan /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fc02807af08443fbb5c68c590d58fa4b-Greilsamer, (b)(6) @va.gov>
Sent Date:	2019/06/21 12:13:53
Delivered Date:	2019/06/21 12:13:55
Message Flags:	Unread

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From:	Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd.)/CN=RECIPIENTS/CN=0B6E91EF72EE4A05ACC63873C64570E1-SNYDER, JIL (b)(6) @va.gov>
To:	Copeland, Brittany R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0f1ebffbc694bb09b048ce0f296763e-Copeland, B (b)(6) @va.gov>
CC:	Greilsamer, Alan /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fc02807af08443fbb5c68c590d58fa4b-Greilsamer, (b)(6) @va.gov>; VHA CO 10B2B Media /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12e0caca48054b8da1e793651a89d81c-VHA CO 10B2 <VHACO10B2BMedia@va.gov>; VHA 10B /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e8da02703bf40af822fcc49b8463979-VHA 10B <vha10b@va.gov>
Subject:	RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision
Date:	2019/06/21 14:12:18
Priority:	Normal
Type:	Note

Thank you!!!!

From: Copeland, Brittany R.
Sent: Friday, June 21, 2019 2:11 PM
To: Snyder, Jill (b)(6) @va.gov>
Cc: Greilsamer, Alan <(b)(6) @va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>; VHA 10B <vha10b@va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Good afternoon Jill,

On behalf of Krystal Toles, 10B clears.

Thanks!

Brittany R. Copeland, MHA
Health System Specialist
Office of the VHA Chief of Staff (10B)
810 Vermont Ave NW | Washington, DC 20420
o: (b)(6) | c: (b)(6)

From: Snyder, Jill
Sent: Friday, June 21, 2019 12:47 PM
To: VHA 10B <vha10b@va.gov>
Cc: Greilsamer, Alan (b)(6) @va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Good afternoon 10B,

AMERICAN OVERSIGHT



From: Graham, Christopher L.
Sent: Friday, June 21, 2019 12:46 PM
To: Snyder, Jill (b)(6) @va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Cc: VHA 10P Actions <VHA10PActions@va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Jill-10P concurs with and clears the statement below.

Thanks,
Chris Graham, MHA
Health Systems Specialist
Department of Veterans Affairs
Office of the Deputy Under Secretary for Health for Policy and Services (10P)
Office (b)(6)

From: Cashour, Curtis
Sent: Friday, June 21, 2019 12:24 PM

AMERICAN OVERSIGHT

To: Valentino, Michael (VACO) (b)(6) @va.gov>; Wiechers, Ilse (b)(6) va.gov>; Snyder, Jill (b)(6) @va.gov>
Cc: Outlaw, William N. (b)(6) @va.gov>; Greilsamer, Alan (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) (b)(6) @va.gov>; Llorente, Maria D. (b)(6) va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Thanks. Does VHA concur with the following?



Curt Cashour
Press Secretary
Department of Veterans Affairs
(b)(6)
(b)(6) @va.gov
(b)(6)

From: Snyder, Jill
Sent: Friday, June 21, 2019 9:02 AM
To: Valentino, Michael (VACO) (b)(6) @va.gov>; Wiechers, Ilse (b)(6) @va.gov>; Cashour, Curtis (b)(6) @va.gov>
Cc: Outlaw, William N. (b)(6) @va.gov>; Greilsamer, Alan (b)(6) @va.gov>; Snyder, Jill (b)(6) @va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Good afternoon Mike and Ilse,

AMERICAN OVERSIGHT

I know you all are working on media responses regarding Ketamine, however we just received an email from the Boston Globe that the decision was made NOT to include it in the formulary. Please see email below and I am including Curt Cashour, VA Press Secretary, on this message to streamline responses.

Thank you,
Jill

From: Silverman, Ed <(b)(6) @statnews.com>
Sent: Friday, June 21, 2019 11:24 AM
To: VA Public Affairs <VAPublicAffairs@va.gov>
Subject: [EXTERNAL] question from a journalist

Hi ,

My name is Ed Silverman and I work for The Boston Globe's STAT News health site, where I track the pharmaceutical industry.

I understand a VA committee voted not to include a new Johnson&Johnson antidepressant spray drug called Spravato on its pharmacy list.

Can you please confirm and explain why the committee voted not to include it?

Thanks
ed silverman
(b)(6)
www.statnews.com/pharmalot/

From: Snyder, Jill
Sent: Friday, June 21, 2019 9:59 AM
To: Cashour, Curtis <(b)(6) @va.gov>; Greilsamer, Alan (b)(6) @va.gov>
Cc: Eason, William J. <(b)(6) @va.gov>; Screen, Gina (b)(6) @va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Hi Curt –

I am following this in Alan's absence, program office is still working on the response, I will continue to follow up.

Thanks,
Jill

AMERICAN OVERSIGHT

From: Cashour, Curtis
Sent: Friday, June 21, 2019 9:57 AM
To: Greilsamer, Alan (b)(6) @va.gov>; Snyder, Jill (b)(6) @va.gov>
Cc: Eason, William J. <(b)(6) @va.gov>; Screen, Gina (b)(6) @va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Just following up here. Thanks.

From: Greilsamer, Alan
Sent: Thursday, June 20, 2019 3:34 PM
To: Cashour, Curtis <(b)(6) @va.gov>
Cc: Eason, William J. <(b)(6) @va.gov>; Screen, Gina <(b)(6) @va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

We will try to pin them down on a timeframe.

—
Alan Greilsamer
Director, Media Relations (10B2B)
Office of Communications
Veterans Health Administration
P: (b)(6)
E: (b)(6) @va.gov

From: Cashour, Curtis <(b)(6) @va.gov>
Date: Thursday, Jun 20, 2019, 3:18 PM
To: Greilsamer, Alan <(b)(6) @va.gov>
Cc: Eason, William J. (b)(6) @va.gov>, Screen, Gina (b)(6) @va.gov>, VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Is there an update here?

The original question was when will VA make a decision about putting spravato on the formulary.

Thanks,

Curt Cashour
Press Secretary
Department of Veterans Affairs
(b)(6)
(b)(6) @va.gov
(b)(6)

AMERICAN OVERSIGHT

From: Greilsamer, Alan
Sent: Wednesday, June 19, 2019 9:05 AM
To: Cashour, Curtis <(b)(6) @va.gov>
Cc: Eason, William J. (b)(6) @va.gov>; Screen, Gina (b)(6) @va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

VHA clears

In March 2019, two weeks after the FDA approved intranasal esketamine for use in conjunction with an oral antidepressant for the treatment of treatment-resistant depression in adults, VA announced the treatment would be made available to Veterans based on their individual medical needs combined with providers' clinical assessments. VA is now preparing a thoughtful, step-wise approach to clinical implementation of esketamine that puts Veteran safety first and ensures close, careful monitoring of potential adverse events, including the risk of addiction. This reflects VA's commitment to seek new ways to provide the best health care available for our nation's Veterans.

Additional information

Steps VA has taken to date include:

- • The first dose of intranasal esketamine was safely administered today, June 18, 2019, to a Veteran with treatment-resistant depression at the VA Boston Healthcare System.
- • A standardized informed consent document and supporting patient education materials have been made available nationally through VHA's electronic signed consent platform.
- • VHA established a national Esketamine Clinical Implementation Workgroup, which has representation from key VA Central Office stakeholder groups, facility leadership, and subject matter experts in ketamine and esketamine treatments for mental health disorders.
- • VHA has launched the Esketamine Community of Practice, a virtual learning community that will combine regular teleconferences and a repository of resources to provide a forum for discussing progress in implementation and developing best practices while also ensuring clear communication across the organization.
- • 13 sites have confirmed their participation as Early Adopters, and will work together supported by the Esketamine Community of Practice and the Esketamine Clinical Implementation Workgroup to implement clinical use of esketamine at their sites this summer and fall.

Ongoing next steps include:

- • VA anticipates having final decisions about Pharmacy Benefits Management policies, including criteria for use, national protocol guidance, and formulary status by end of this week, pending ongoing deliberations of the Medical Advisory Panel and VISN Pharmacy Executive Committees.

- • Development of a Medication Use Evaluation (MUE) which focuses on safety monitoring is underway, with anticipated implementation of the data entry portal in July 2019. The MUE will facilitate data reporting for the FDA REMS and will gather additional safety and monitoring data on all use of esketamine within VHA.

AMERICAN OVERSIGHT

From: Cashour, Curtis
Sent: Tuesday, June 18, 2019 12:38 PM
To: Greilsamer, Alan (b)(6) @va.gov>; Screen, Gina (b)(6) @va.gov>
Cc: Eason, William J. (b)(6) @va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Please let me know your recommended response to the below.

Thanks,

Curt Cashour
Press Secretary
Department of Veterans Affairs
(b)(6)
(b)(6) @va.gov
(b)(6)

From: Ben Carey (b)(6) @nytimes.com>
Sent: Tuesday, June 18, 2019 12:35 PM
To: Cashour, Curtis <(b)(6) @va.gov>
Subject: Re: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Thanks Curt, please do. Main question for now is when is decision expected..? (i.e. how much time I got?)

Ben

Sent from my iPhone

On Jun 18, 2019, at 12:22 PM, Cashour, Curtis (b)(6) @va.gov>wrote:

Will keep you posted. Thanks, Ben.

Curt Cashour
Press Secretary
Department of Veterans Affairs
(b)(6)
(b)(6) @va.gov
(b)(6)

From: Carey, Ben (b)(6) @nytimes.com>
Sent: Tuesday, June 18, 2019 11:36 AM
To: Cashour, Curtis <(b)(6) @va.gov>
Subject: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Curt Cashour-

AMERICAN OVERSIGHT

Hello from New York. It's Ben Carey emailing. I am a reporter in science at the NY Times, I cover psych topics. I have your email from Jennifer Steinhauer, NYT reporter in DC.

I would love to hear what/ when on the VA's expected decision this week whether to put Spravato on its formulary. Keep me in the loop on this, kindly, would be good to know when decision will be made, with some notice, and anything else VA puts out on this.

We'll likely cover decision either way.

Sincerely,

Ben Carey

Sender:	Snyder, Jill /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0B6E91EF72EE4A05ACC63873C64570E1-SNYDER, JIL (b)(6) @va.gov>
Recipient:	Copeland, Brittany R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0f1ebffbc694bb09b048ce0f296763e-Copeland, B (b)(6) @va.gov>; Greilsamer, Alan /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fc02807af08443fbb5c68c590d58fa4b-Greilsamer, (b)(6) @va.gov>; VHA CO 10B2B Media /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12e0caca48054b8da1e793651a89d81c-VHA CO 10B2 <VHACO10B2BMedia@va.gov>; VHA 10B /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e8da02703bf40af822fcc49b8463979-VHA 10B <vha10b@va.gov>
Sent Date:	2019/06/21 14:12:17
Delivered Date:	2019/06/21 14:12:18
Message Flags:	Unread

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From:	Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd.DIBOHF23SPDLT)/CN=RECIPIENTS/CN=9027C425646E4DE8A7D196908016331B-ZACHER, JEN (b)(6) @va.gov>
To:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>
Subject:	RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision
Date:	2019/06/21 12:44:48
Priority:	Normal
Type:	Note

Ok. Usually we make our formulary announcement at the end of the month. That is where we would also update the non-promotable list. Let me find out what day that will be going out to the field, and then I will set up a call with J&J for later that day so that the field message goes out first, and then I let them know.

The good news is that I already told them they can't promote until they get a head's up from me, so they shouldn't be out in the field now anyway. I have a call with Ilse today too, and I will reaffirm that we shouldn't be sharing this information until the official field announcement goes out.

From: Valentino, Michael (VACO)
Sent: Friday, June 21, 2019 11:43 AM
To: Zacher, Jennifer L. (PBM) (b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

I think we should wait until the minutes are signed or until they are posted, whichever occurs first.

Also, I think the non-promotable requirement should wait until that is posted as well now that I think more about it

---

From: Zacher, Jennifer L. (PBM)
Sent: Friday, June 21, 2019 12:38 PM
To: Valentino, Michael (VACO) (b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Ok. They are going to ask for the documents. Since they will end up in the public domain, I don't see an issue with sharing the CFU now, do you?

From: Valentino, Michael (VACO)
Sent: Friday, June 21, 2019 11:27 AM
To: Zacher, Jennifer L. (PBM) (b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

I think you should contact them to let them know what the decision was.

They absolutely need to know that effective immediately, it is non-promotable in VA.

AMERICAN OVERSIGHT

Mike

From: Zacher, Jennifer L. (PBM)
Sent: Friday, June 21, 2019 12:25 PM
To: Valentino, Michael (VACO) <(b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

I'm so glad you did this. It looks good. Do you think I should proactively contact J&J at this point or wait until they contact me? Normally I wait until they contact me, but wondering if it will cause more problems if I wait and then all the non-promotable stuff comes out?

From: Valentino, Michael (VACO)
Sent: Friday, June 21, 2019 11:17 AM
To: Wiechers, Ilse <(b)(6) @va.gov>; Snyder, Jill (b)(6) @va.gov>; Cashour, Curtis (b)(6) @va.gov>
Cc: Outlaw, William N. <(b)(6) @va.gov>; Greilsamer, Alan <(b)(6) @va.gov>; Zacher, Jennifer L. (PBM) <(b)(6) @va.gov>; Llorente, Maria D. <(b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Dr. Llorente and I drafted a statement for the NYT inquiry and I believe it will be coming forward soon.

Here it is but please consider it DRAFT:

From: Wiechers, Ilse
Sent: Friday, June 21, 2019 12:07 PM
To: Snyder, Jill <(b)(6) @va.gov>; Valentino, Michael (VACO) <(b)(6) @va.gov>; Cashour, Curtis <(b)(6) @va.gov>
Cc: Outlaw, William N. <(b)(6) @va.gov>; Greilsamer, Alan <(b)(6) @va.gov>; Zacher, Jennifer L. (PBM) <(b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Adding Jen Zacher for coordination purposes.

From: Snyder, Jill
Sent: Friday, June 21, 2019 9:02 AM
To: Valentino, Michael (VACO) <(b)(6) @va.gov>; Wiechers, Ilse <(b)(6) @va.gov>; Cashour, Curtis <(b)(6) @va.gov>
Cc: Outlaw, William N. (b)(6) @va.gov>; Greilsamer, Alan <(b)(6) @va.gov>; Snyder, Jill <(b)(6) @va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Good afternoon Mike and Ilse,

AMERICAN OVERSIGHT

I know you all are working on media responses regarding Ketamine, however we just received an email from the Boston Globe that the decision was made NOT to include it in the formulary. Please see email below and I am including Curt Cashour, VA Press Secretary, on this message to streamline responses.

Thank you,
Jill

From: Silverman, Ed <(b)(6) @statnews.com>
Sent: Friday, June 21, 2019 11:24 AM
To: VA Public Affairs <VAPublicAffairs@va.gov>
Subject: [EXTERNAL] question from a journalist

Hi ,

My name is Ed Silverman and I work for The Boston Globe's STAT News health site, where I track the pharmaceutical industry.

I understand a VA committee voted not to include a new Johnson&Johnson antidepressant spray drug called Spravato on its pharmacy list.

Can you please confirm and explain why the committee voted not to include it?

Thanks
ed silverman
(b)(6)
www.statnews.com/pharmalot/

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To: Cashour, Curtis <(b)(6) @va.gov>; Greilsamer, Alan <(b)(6) @va.gov>
Cc: Eason, William J. <(b)(6) @va.gov>; Screen, Gina <(b)(6) @va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Hi Curt –

I am following this in Alan's absence, program office is still working on the response, I will continue to follow up.

Thanks,
Jill

AMERICAN OVERSIGHT

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Sent: Friday, June 21, 2019 9:57 AM
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Sent: Thursday, June 20, 2019 3:34 PM
To: Cashour, Curtis <(b)(6) @va.gov>
Cc: Eason, William J. (b)(6) @va.gov>; Screen, Gina <(b)(6) @va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

We will try to pin them down on a timeframe.

—
Alan Greilsamer
Director, Media Relations (10B2B)
Office of Communications
Veterans Health Administration
P: (b)(6)
E: (b)(6) @va.gov

From: Cashour, Curtis (b)(6) @va.gov>
Date: Thursday, Jun 20, 2019, 3:18 PM
To: Greilsamer, Alan <(b)(6) @va.gov>
Cc: Eason, William J. (b)(6) @va.gov>, Screen, Gina (b)(6) @va.gov>, VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Is there an update here?

The original question was when will VA make a decision about putting spravato on the formulary.

Thanks,

Curt Cashour
Press Secretary
Department of Veterans Affairs
(b)(6)
(b)(6) @va.gov
(b)(6)

AMERICAN OVERSIGHT

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Sent: Wednesday, June 19, 2019 9:05 AM
To: Cashour, Curtis <(b)(6) @va.gov>
Cc: Eason, William J. (b)(6) @va.gov>; Screen, Gina <(b)(6) @va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
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AMERICAN OVERSIGHT

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To: Greilsamer, Alan <(b)(6) @va.gov>; Screen, Gina <(b)(6) @va.gov>
Cc: Eason, William J. <(b)(6) @va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Please let me know your recommended response to the below.

Thanks,

Curt Cashour
Press Secretary
Department of Veterans Affairs
(b)(6)
(b)(6) @va.gov
(b)(6)

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To: Cashour, Curtis <(b)(6) @va.gov>
Subject: Re: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

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Ben

Sent from my iPhone

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Curt Cashour
Press Secretary
Department of Veterans Affairs
(b)(6)
(b)(6) @va.gov
(b)(6)

From: Carey, Ben (b)(6) @nytimes.com>
Sent: Tuesday, June 18, 2019 11:36 AM
To: Cashour, Curtis <(b)(6) @va.gov>
Subject: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Curt Cashour-

AMERICAN OVERSIGHT

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Sincerely,

Ben Carey

Sender:	Zacher, Jennifer L. (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9027C425646E4DE8A7D196908016331B-ZACHER, JEN (b)(6) @va.gov>
Recipient:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>
Sent Date:	2019/06/21 12:44:47
Delivered Date:	2019/06/21 12:44:48
Message Flags:	Unread

AMERICAN OVERSIGHT

From:	Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd.SPDLT)/CN=RECIPIENTS/CN=1156B622F1BA464FA61884615342FF18-TOLES, KRYS (b)(6) @va.gov>
To:	Copeland, Brittany R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0f1ebffbc694bb09b048ce0f296763e-Copeland, B (b)(6) @va.gov>
CC:	VHA 10B /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e8da02703bf40af822fcc49b8463979-VHA 10B <vha10b@va.gov>
Subject:	RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision
Date:	2019/06/21 14:07:44
Priority:	Normal
Type:	Note

Brittany this is cleared.

Sent with BlackBerry Work
(www.blackberry.com)

From: Copeland, Brittany R. (b)(6) @va.gov>
Date: Friday, Jun 21, 2019, 12:57 PM
To: Toles, Krystal M. (b)(6) @va.gov>
Cc: VHA 10B <vha10b@va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Hi Krystal,

For clearance, please see the statement below regarding VHA's decision not to include Spravato on the formulary, but to offer it on a non-formulary basis. This has been cleared by 10P4 and 10P.

Thank you,

Brittany R. Copeland, MHA
Health System Specialist
Office of the VHA Chief of Staff (10B)
810 Vermont Ave NW | Washington, DC 20420
o (b)(6) | c: (b)(6)

From: Snyder, Jill
Sent: Friday, June 21, 2019 12:47 PM
To: VHA 10B <vha10b@va.gov>
Cc: Greilsamer, Alan (b)(6) @va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Good afternoon 10B,

AMERICAN OVERSIGHT

Requesting your clearance on the below statement regarding VHA's decision NOT to include Spravato on the formulary, but to offer it on a non-formulary basis. This has been cleared by Pharmacy, 10P4, and 10P. Apologies, but hoping for a quick turn.

Statement



From: Graham, Christopher L.
Sent: Friday, June 21, 2019 12:46 PM
To: Snyder, Jill <(b)(6) @va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Cc: VHA 10P Actions <VHA10PActions@va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Jill-10P concurs with and clears the statement below.

Thanks,
Chris Graham, MHA
Health Systems Specialist
Department of Veterans Affairs
Office of the Deputy Under Secretary for Health for Policy and Services (10P)
Office: (b)(6)

From: Cashour, Curtis
Sent: Friday, June 21, 2019 12:24 PM
To: Valentino, Michael (VACO) (b)(6) @va.gov>; Wiechers, Ilse (b)(6) @va.gov>;

AMERICAN OVERSIGHT

Snyder, Jill (b)(6) @va.gov>
Cc: Outlaw, William N. (b)(6) @va.gov>; Greilsamer, Alan (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) (b)(6) @va.gov>; Llorente, Maria D. (b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Thanks. Does VHA concur with the following?



Curt Cashour
Press Secretary
Department of Veterans Affairs
(b)(6)
(b)(6) @va.gov
(b)(6)

From: Snyder, Jill
Sent: Friday, June 21, 2019 9:02 AM
To: Valentino, Michael (VACO) (b)(6) @va.gov>; Wiechers, Ilse (b)(6) @va.gov>; Cashour, Curtis <(b)(6) @va.gov>
Cc: Outlaw, William N. (b)(6) @va.gov>; Greilsamer, Alan (b)(6) @va.gov>; Snyder, Jill (b)(6) @va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Good afternoon Mike and Ilse,

AMERICAN OVERSIGHT

I know you all are working on media responses regarding Ketamine, however we just received an email from the Boston Globe that the decision was made NOT to include it in the formulary. Please see email below and I am including Curt Cashour, VA Press Secretary, on this message to streamline responses.

Thank you,
Jill

From: Silverman, Ed <(b)(6) @statnews.com>
Sent: Friday, June 21, 2019 11:24 AM
To: VA Public Affairs <VAPublicAffairs@va.gov>
Subject: [EXTERNAL] question from a journalist

Hi ,

My name is Ed Silverman and I work for The Boston Globe's STAT News health site, where I track the pharmaceutical industry.

I understand a VA committee voted not to include a new Johnson&Johnson antidepressant spray drug called Spravato on its pharmacy list.

Can you please confirm and explain why the committee voted not to include it?

Thanks
ed silverman
(b)(6)
www.statnews.com/pharmalot/

From: Snyder, Jill
Sent: Friday, June 21, 2019 9:59 AM
To: Cashour, Curtis <(b)(6) @va.gov>; Greilsamer, Alan (b)(6) @va.gov>
Cc: Eason, William J. (b)(6) @va.gov>; Screen, Gina(b)(6) @va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Hi Curt –

I am following this in Alan's absence, program office is still working on the response, I will continue to follow up.

Thanks,
Jill

AMERICAN OVERSIGHT

From: Cashour, Curtis
Sent: Friday, June 21, 2019 9:57 AM
To: Greilsamer, Alan <(b)(6) @va.gov>; Snyder, Jill (b)(6) @va.gov>
Cc: Eason, William J. <(b)(6) @va.gov>; Screen, Gina (b)(6) @va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Just following up here. Thanks.

From: Greilsamer, Alan
Sent: Thursday, June 20, 2019 3:34 PM
To: Cashour, Curtis <(b)(6) @va.gov>
Cc: Eason, William J.(b)(6) @va.gov>; Screen, Gina (b)(6) @va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

We will try to pin them down on a timeframe.

—
Alan Greilsamer
Director, Media Relations (10B2B)
Office of Communications
Veterans Health Administration
P: (b)(6)
E: (b)(6) @va.gov

From: Cashour, Curtis <(b)(6) @va.gov>
Date: Thursday, Jun 20, 2019, 3:18 PM
To: Greilsamer, Alan <(b)(6) @va.gov>
Cc: Eason, William J. <(b)(6) @va.gov>, Screen, Gina <(b)(6) @va.gov>, VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Is there an update here?

The original question was when will VA make a decision about putting spravato on the formulary.

Thanks,

Curt Cashour
Press Secretary
Department of Veterans Affairs
(b)(6)
(b)(6) @va.gov
(b)(6)

AMERICAN OVERSIGHT

From: Greilsamer, Alan
Sent: Wednesday, June 19, 2019 9:05 AM
To: Cashour, Curtis <(b)(6) @va.gov>
Cc: Eason, William J. <(b)(6) @va.gov>; Screen, Gina <(b)(6) @va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

VHA clears

In March 2019, two weeks after the FDA approved intranasal esketamine for use in conjunction with an oral antidepressant for the treatment of treatment-resistant depression in adults, VA announced the treatment would be made available to Veterans based on their individual medical needs combined with providers' clinical assessments. VA is now preparing a thoughtful, step-wise approach to clinical implementation of esketamine that puts Veteran safety first and ensures close, careful monitoring of potential adverse events, including the risk of addiction. This reflects VA's commitment to seek new ways to provide the best health care available for our nation's Veterans.

Additional information

Steps VA has taken to date include:

- • The first dose of intranasal esketamine was safely administered today, June 18, 2019, to a Veteran with treatment-resistant depression at the VA Boston Healthcare System.
- • A standardized informed consent document and supporting patient education materials have been made available nationally through VHA's electronic signed consent platform.
- • VHA established a national Esketamine Clinical Implementation Workgroup, which has representation from key VA Central Office stakeholder groups, facility leadership, and subject matter experts in ketamine and esketamine treatments for mental health disorders.
- • VHA has launched the Esketamine Community of Practice, a virtual learning community that will combine regular teleconferences and a repository of resources to provide a forum for discussing progress in implementation and developing best practices while also ensuring clear communication across the organization.
- • 13 sites have confirmed their participation as Early Adopters, and will work together supported by the Esketamine Community of Practice and the Esketamine Clinical Implementation Workgroup to implement clinical use of esketamine at their sites this summer and fall.

Ongoing next steps include:

- • VA anticipates having final decisions about Pharmacy Benefits Management policies, including criteria for use, national protocol guidance, and formulary status by end of this week, pending ongoing deliberations of the Medical Advisory Panel and VISN Pharmacy Executive Committees.

- • Development of a Medication Use Evaluation (MUE) which focuses on safety monitoring is underway, with anticipated implementation of the data entry portal in July 2019. The MUE will facilitate data reporting for the FDA REMS and will gather additional safety and monitoring data on all use of esketamine within VHA.

AMERICAN OVERSIGHT

From: Cashour, Curtis
Sent: Tuesday, June 18, 2019 12:38 PM
To: Greilsamer, Alan <(b)(6) @va.gov>; Screen, Gina <(b)(6) @va.gov>
Cc: Eason, William J. (b)(6) @va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Please let me know your recommended response to the below.

Thanks,

Curt Cashour
Press Secretary
Department of Veterans Affairs
(b)(6)
(b)(6) @va.gov
(b)(6)

From: Ben Carey (b)(6) @nytimes.com>
Sent: Tuesday, June 18, 2019 12:35 PM
To: Cashour, Curtis (b)(6) @va.gov>
Subject: Re: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Thanks Curt, please do. Main question for now is when is decision expected..? (i.e. how much time I got?)

Ben

Sent from my iPhone

On Jun 18, 2019, at 12:22 PM, Cashour, Curtis <(b)(6) @va.gov>wrote:

Will keep you posted. Thanks, Ben.

Curt Cashour
Press Secretary
Department of Veterans Affairs
(b)(6)
(b)(6) @va.gov
(b)(6)

From: Carey, Ben(b)(6) @nytimes.com>
Sent: Tuesday, June 18, 2019 11:36 AM
To: Cashour, Curtis <(b)(6) @va.gov>
Subject: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Curt Cashour-

AMERICAN OVERSIGHT

Hello from New York. It's Ben Carey emailing. I am a reporter in science at the NY Times, I cover psych topics. I have your email from Jennifer Steinhauer, NYT reporter in DC.

I would love to hear what/ when on the VA's expected decision this week whether to put Spravato on its formulary. Keep me in the loop on this, kindly, would be good to know when decision will be made, with some notice, and anything else VA puts out on this.

We'll likely cover decision either way.

Sincerely,

Ben Carey

Sender:	Toles, Krystal M. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1156B622F1BA464FA61884615342FF18-TOLES, KRYS *(b)(6)* @va.gov>
Recipient:	Copeland, Brittany R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0f1ebffbc694bb09b048ce0f296763e-Copeland, B *(b)(6)* @va.gov>; VHA 10B /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e8da02703bf40af822fcc49b8463979-VHA 10B <vha10b@va.gov>
Sent Date:	2019/06/21 14:07:44
Message Flags:	Unread

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From:	Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd.HF23SPDLT)/CN=RECIPIENTS/CN=182805D689894DA4B2D00810DA5E305C-STEWART, KA (b)(6) @va.gov>
To:	Greilsamer, Alan /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fc02807af08443fbb5c68c590d58fa4b-Greilsamer, (b)(6) @va.gov>; VHA CO 10B2B Media /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12e0caca48054b8da1e793651a89d81c-VHA CO 10B2 <VHACO10B2BMedia@va.gov>; VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>
CC:	VHA CO 10N Support Staff /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=49641c3663c04aa58d87f8b7fa6dd515-VHA CO 10N <VHACO10NSS@va.gov>; VHA CO 10NC Front Office HSSs /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcf91f73967a49c287d8747b7aee675e-VHA CO 10NC <VHACO10NCFOHSSs@va.gov>
Subject:	RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision
Date:	2019/06/20 16:33:57
Priority:	Normal
Type:	Note

Good Afternoon,

In light of the information below – 10NC respectfully defers to 10P.

Thank you,

Katie Stewart, MSW, LCSW
Health Systems Specialist
Office of the ADUSH for Clinical Operations (10NC)
(b)(6) (office)
(b)(6) (cell)

From: Greilsamer, Alan
Sent: Thursday, June 20, 2019 4:31 PM
To: Stewart, Katharine E. (b)(6) @va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>
Cc: VHA CO 10N Support Staff <VHACO10NSS@va.gov>; VHA CO 10NC Front Office HSSs <VHACO10NCFOHSSs@va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

VA Press Secretary is asking for a response to this question:

Q: When will VA make a decision about putting spravato on the formulary?

AMERICAN OVERSIGHT

—
Alan Greilsamer
Director, Media Relations (10B2B)
Office of Communications
Veterans Health Administration
P: (b)(6)
E: (b)(6) @va.gov

From: Stewart, Katharine E. <(b)(6) @va.gov>
Date: Thursday, Jun 20, 2019, 4:23 PM
To: Greilsamer, Alan <(b)(6) @va.gov>, VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>, VHA 10NC5 Action <VHA10NC5Action@va.gov>
Cc: VHA CO 10N Support Staff <VHACO10NSS@va.gov>, VHA CO 10NC Front Office HSSs <VHACO10NCFOHSSs@va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Good Afternoon Alan,

Would you be able to provide any further context about the inquiry? The program office noted that the timeline provided is already quite specific.

Thank you,

Katie Stewart, MSW, LCSW
Health Systems Specialist
Office of the ADUSH for Clinical Operations (10NC)
(b)(6) (office)
(b)(6) (cell)

From: Greilsamer, Alan
Sent: Thursday, June 20, 2019 3:42 PM
To: Stewart, Katharine E. (b)(6) @va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Cc: VHA CO 10N Support Staff <VHACO10NSS@va.gov>; VHA CO 10NC Front Office HSSs <VHACO10NCFOHSSs@va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Good afternoon

VA Press Secretary is asking if we can get more specific about the question below from the NY Times. Is there a timeframe that we can provide.

"Is there any more specific information that we can provide about timeline?"

Thanks, Alan
—
Alan Greilsamer
Director, Media Relations (10B2B)

AMERICAN OVERSIGHT

Office of Communications
Veterans Health Administration
P: (b)(6)
E: (b)(6) @va.gov

From: Stewart, Katharine E. <(b)(6) @va.gov>
Date: Tuesday, Jun 18, 2019, 5:01 PM
To: Greilsamer, Alan <(b)(6) @va.gov>, VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Cc: VHA CO 10N Support Staff <VHACO10NSS@va.gov>, VHA CO 10NC Front Office HSSs <VHACO10NCFOHSSs@va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Good Afternoon Alan/VHA Comms,

On behalf of 10N/10NC, Dr. Thomas O'Toole clears the below response from 10NC5 to your inquiry.

Thank you,

Katie Stewart, MSW, LCSW
Health Systems Specialist
Office of the ADUSH for Clinical Operations (10NC)
(b)(6) (office)
(b)(6) (cell)

From: O'Toole, Thomas P.
Sent: Tuesday, June 18, 2019 4:56 PM
To: Stewart, Katharine E. <(b)(6) @va.gov>; VHA 10NC Clearance <VHA10NCClearance2@va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

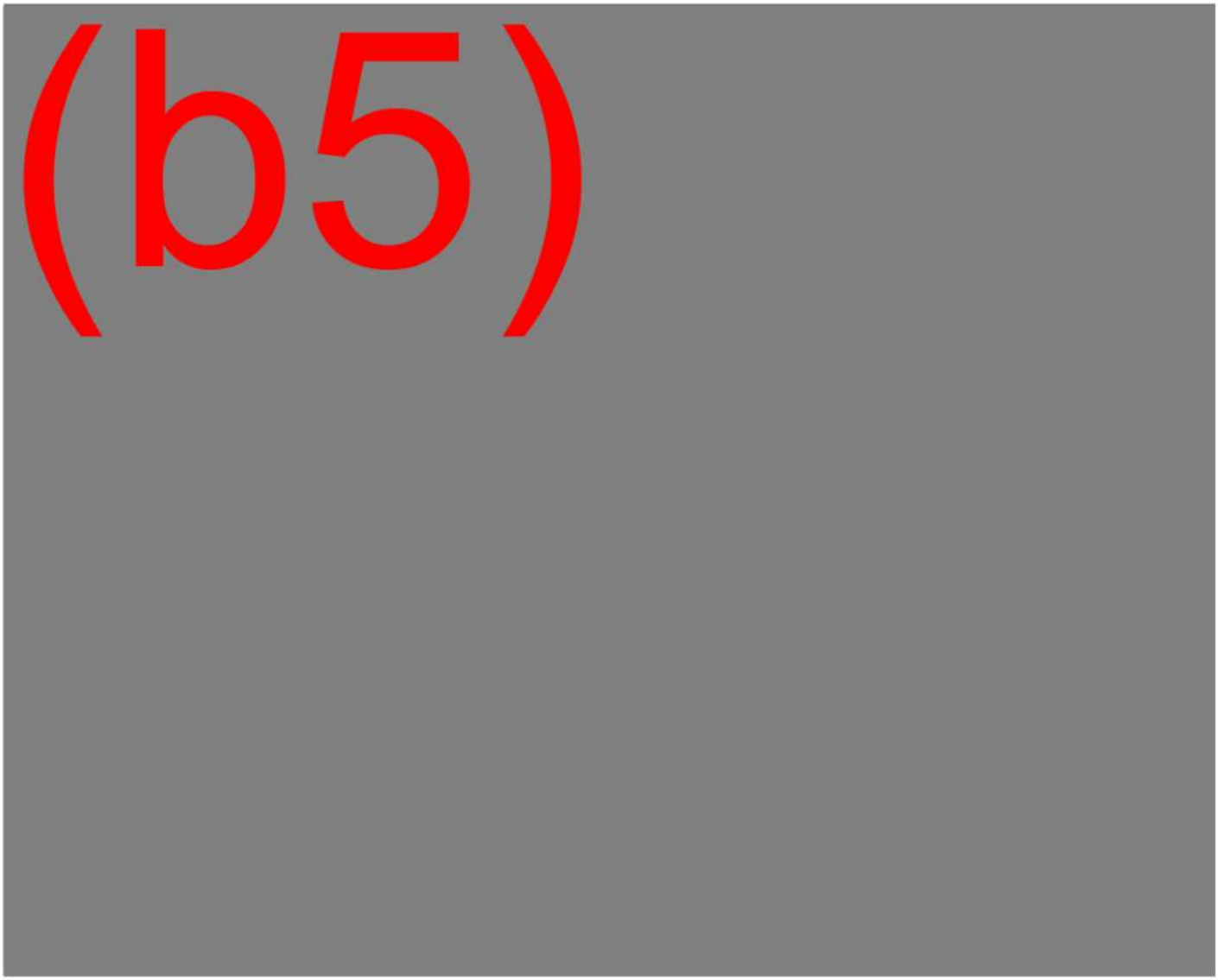
10NC clears

From: Strmiska, Jon G.
Sent: Tuesday, June 18, 2019 3:43 PM
To: Dudley, Tracy <(b)(6) @va.gov>
Cc: VHA CO 10NC Front Office HSSs <VHACO10NCFOHSSs@va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>; Wiechers, Ilse <(b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Dr. Carroll has cleared the following response:

(b5)

AMERICAN OVERSIGHT



Jon G. Strmiska
Business Operations Manager (10NC5)
VA Central Office – Washington, DC
Phone:*(b)(6)*
FAX: 202.495.5933

From: Greilsamer, Alan
Sent: Tuesday, June 18, 2019 12:46 PM
To: VHA 10N Action <VHA10NAction@va.gov>; VHA 10NC Action <vha10ncaction@va.gov>
Cc: VHA 10NC5 Action <VHA10NC5Action@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Good afternoon,

AMERICAN OVERSIGHT

New York Times is asking when a decision will be made as to when VA will be putting Spravato in its formulary. We recently provide the response below.

Is there any more specific information that we can provide about timeline?

FDA has approved the use of intranasal esketamine for adults with treatment-resistant depression (when used in conjunction with an oral antidepressant). VA has not yet administered esketamine to any patients, and is in the process of designing a clinical implementation plan optimized for safety and efficacy.

Requesting a response by today (June 18) NLT 5 p.m. ET.

Thanks, Alan

From: Cashour, Curtis
Sent: Tuesday, June 18, 2019 12:38 PM
To: Greilsamer, Alan <(b)(6) @va.gov>; Screen, Gina <(b)(6) @va.gov>
Cc: Eason, William J. (b)(6) @va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Please let me know your recommended response to the below.

Thanks,

Curt Cashour
Press Secretary
Department of Veterans Affairs
(b)(6)
(b)(6) @va.gov
(b)(6)

From: Ben Carey <(b)(6) @nytimes.com>
Sent: Tuesday, June 18, 2019 12:35 PM
To: Cashour, Curtis <(b)(6) @va.gov>
Subject: Re: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Thanks Curt, please do. Main question for now is when is decision expected..? (i.e. how much time I got?)

Ben

Sent from my iPhone

On Jun 18, 2019, at 12:22 PM, Cashour, Curtis (b)(6) @va.gov>wrote:

Will keep you posted. Thanks, Ben.

AMERICAN OVERSIGHT

Curt Cashour
Press Secretary
Department of Veterans Affairs
(b)(6)
(b)(6) @va.gov
(b)(6)

From: Carey, Ben (b)(6) @nytimes.com>
Sent: Tuesday, June 18, 2019 11:36 AM
To: Cashour, Curtis (b)(6) @va.gov>
Subject: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Curt Cashour-

Hello from New York. It's Ben Carey emailing. I am a reporter in science at the NY Times, I cover psych topics. I have your email from Jennifer Steinhauer, NYT reporter in DC.

I would love to hear what/ when on the VA's expected decision this week whether to put Spravato on its formulary. Keep me in the loop on this, kindly, would be good to know when decision will be made, with some notice, and anything else VA puts out on this.

We'll likely cover decision either way.

Sincerely,

Ben Carey

Sender:	Stewart, Katharine E. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=182805D689894DA4B2D00810DA5E305C-STEWART, KA (b)(6) @va.gov>
Recipient:	Greilsamer, Alan /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fc02807af08443fbb5c68c590d58fa4b-Greilsamer, (b)(6) @va.gov>; VHA CO 10B2B Media /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12e0caca48054b8da1e793651a89d81c-VHA CO 10B2 <VHACO10B2BMedia@va.gov>; VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>; VHA CO 10N Support Staff /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=49641c3663c04aa58d87f8b7fa6dd515-VHA CO 10N <VHACO10NSS@va.gov>; VHA CO 10NC Front Office HSSs /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcf91f73967a49c287d8747b7aee675e-VHA CO 10NC <VHACO10NCFOHSSs@va.gov>
Sent Date:	2019/06/20 16:33:56
Delivered Date:	2019/06/20 16:33:57

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From:	Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd.PDLT)/CN=RECIPIENTS/CN=9872F41BF2844C8085D371E21482B635-STRMISKA, J (b)(6) @va.gov>
To:	Dudley, Tracy /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2bef1c88d64447bc9087572c951d0cb1-Dudley, Tra (b)(6) @va.gov>
CC:	VHA CO 10NC Front Office HSSs /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcf91f73967a49c287d8747b7aee675e-VHA CO 10NC <VHACO10NCFOHSSs@va.gov>; VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b)(6) @va.gov>
Subject:	RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision
Date:	2019/06/18 15:43:04
Priority:	Normal
Type:	Note

Dr. Carroll has cleared the following response:

(b5)

AMERICAN OVERSIGHT

(b5)

Jon G. Strmiska
Business Operations Manager (10NC5)
VA Central Office – Washington, DC
Phone:*(b)(6)*
FAX: 202.495.5933

From: Dudley, Tracy
Sent: Tuesday, June 18, 2019 3:16 PM
To: VHA 10NC5 Action <VHA10NC5Action@va.gov>
Cc: VHA CO 10NC Front Office HSSs <VHACO10NCFOHSSs@va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Good Afternoon

Please provide a status.

Thank You!
Tracy

Tracy L. Dudley
Health System Specialist
ADUSH for Clinical Operations (10NC)
(b)(6) (Direct)
(b)(6) (iPhone)

From: Dudley, Tracy
Sent: Tuesday, June 18, 2019 1:00 PM
To: VHA 10NC5 Action <VHA10NC5Action@va.gov>
Cc: VHA CO 10NC Front Office HSSs <VHACO10NCFOHSSs@va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

GOOD Afternoon

Please see below and provide your response by **3pm today.**

AMERICAN OVERSIGHT

Thank You!
Tracy

Tracy L. Dudley
Health System Specialist
ADUSH for Clinical Operations (10NC)
(b)(6) (Direct)
(b)(6) (iPhone)

From: Greilsamer, Alan
Sent: Tuesday, June 18, 2019 12:46 PM
To: VHA 10N Action <VHA10NAction@va.gov>; VHA 10NC Action <vha10ncaction@va.gov>
Cc: VHA 10NC5 Action <VHA10NC5Action@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Good afternoon,

New York Times is asking when a decision will be made as to when VA will be putting Spravato in its formulary. We recently provide the response below.

Is there any more specific information that we can provide about timeline?

FDA has approved the use of intranasal esketamine for adults with treatment-resistant depression (when used in conjunction with an oral antidepressant). VA has not yet administered esketamine to any patients, and is in the process of designing a clinical implementation plan optimized for safety and efficacy.

Requesting a response by today (June 18) NLT 5 p.m. ET.

Thanks, Alan

From: Cashour, Curtis
Sent: Tuesday, June 18, 2019 12:38 PM
To: Greilsamer, Alan <(b)(6) @va.gov>; Screen, Gina <(b)(6) @va.gov>
Cc: Eason, William J. (b)(6) @va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Please let me know your recommended response to the below.

Thanks,

Curt Cashour
Press Secretary
Department of Veterans Affairs
(b)(6)

AMERICAN OVERSIGHT

(b)(6) @va.gov
(b)(6)

From: Ben Carey <(b)(6) @nytimes.com>
Sent: Tuesday, June 18, 2019 12:35 PM
To: Cashour, Curtis <(b)(6) @va.gov>
Subject: Re: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Thanks Curt, please do. Main question for now is when is decision expected..? (i.e. how much time I got?)

Ben

Sent from my iPhone

On Jun 18, 2019, at 12:22 PM, Cashour, Curtis <(b)(6) @va.gov>wrote:

Will keep you posted. Thanks, Ben.

Curt Cashour
Press Secretary
Department of Veterans Affairs
(b)(6)
(b)(6) @va.gov
(b)(6)

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Sent: Tuesday, June 18, 2019 11:36 AM
To: Cashour, Curtis <(b)(6) @va.gov>
Subject: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Curt Cashour-

Hello from New York. It's Ben Carey emailing. I am a reporter in science at the NY Times, I cover psych topics. I have your email from Jennifer Steinhauer, NYT reporter in DC.

I would love to hear what/ when on the VA's expected decision this week whether to put Spravato on its formulary. Keep me in the loop on this, kindly, would be good to know when decision will be made, with some notice, and anything else VA puts out on this.

We'll likely cover decision either way.

Sincerely,

Ben Carey

Sender:	Strmiska, Jon G. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (EXDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9872F41BF2844C8085D371E21482B635-STRMISKA, J (b)(6) @va.gov>

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Recipient:	Dudley, Tracy /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2bef1c88d64447bc9087572c951d0cb1-Dudley, Tra (b)(6) @va.gov>; VHA CO 10NC Front Office HSSs /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcf91f73967a49c287d8747b7aee675e-VHA CO 10NC <VHACO10NCFOHSSs@va.gov>; VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b)(6) va.gov>
Sent Date:	2019/06/18 15:43:02
Delivered Date:	2019/06/18 15:43:04

AMERICAN OVERSIGHT

From:	Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd.DIBOHF23SPDLT)/CN=RECIPIENTS/CN=519204DF507344AC8FA3045B2B4FC762-TORRISE, VI (b)(6) @va.gov>
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CC:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b)(6) @va.gov>; Strmiska, Jon G. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9872f41bf2844c8085d371e21482b635-Strmiska, J (b)(6) @va.gov>; Daniels, Lindsay /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ed253196fb6b4f32aa922c90dbd05f29-Daniels, Li (b)(6) @va.gov>
Subject:	RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision
Date:	2019/06/18 15:38:49
Priority:	Normal
Type:	Note

Agree, (b5)
(b5)

From: Wiechers, Ilse
Sent: Tuesday, June 18, 2019 3:32 PM
To: Torrise, Virginia (VHACO) (b)(6) @va.gov>; Carroll, David (VACO) (b)(6) @va.gov>; Pomerantz, Andrew (b)(6) @va.gov>
Cc: Valentino, Michael (VACO) (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) (b)(6) @va.gov>; Strmiska, Jon G. (b)(6) @va.gov>; Daniels, Lindsay (b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

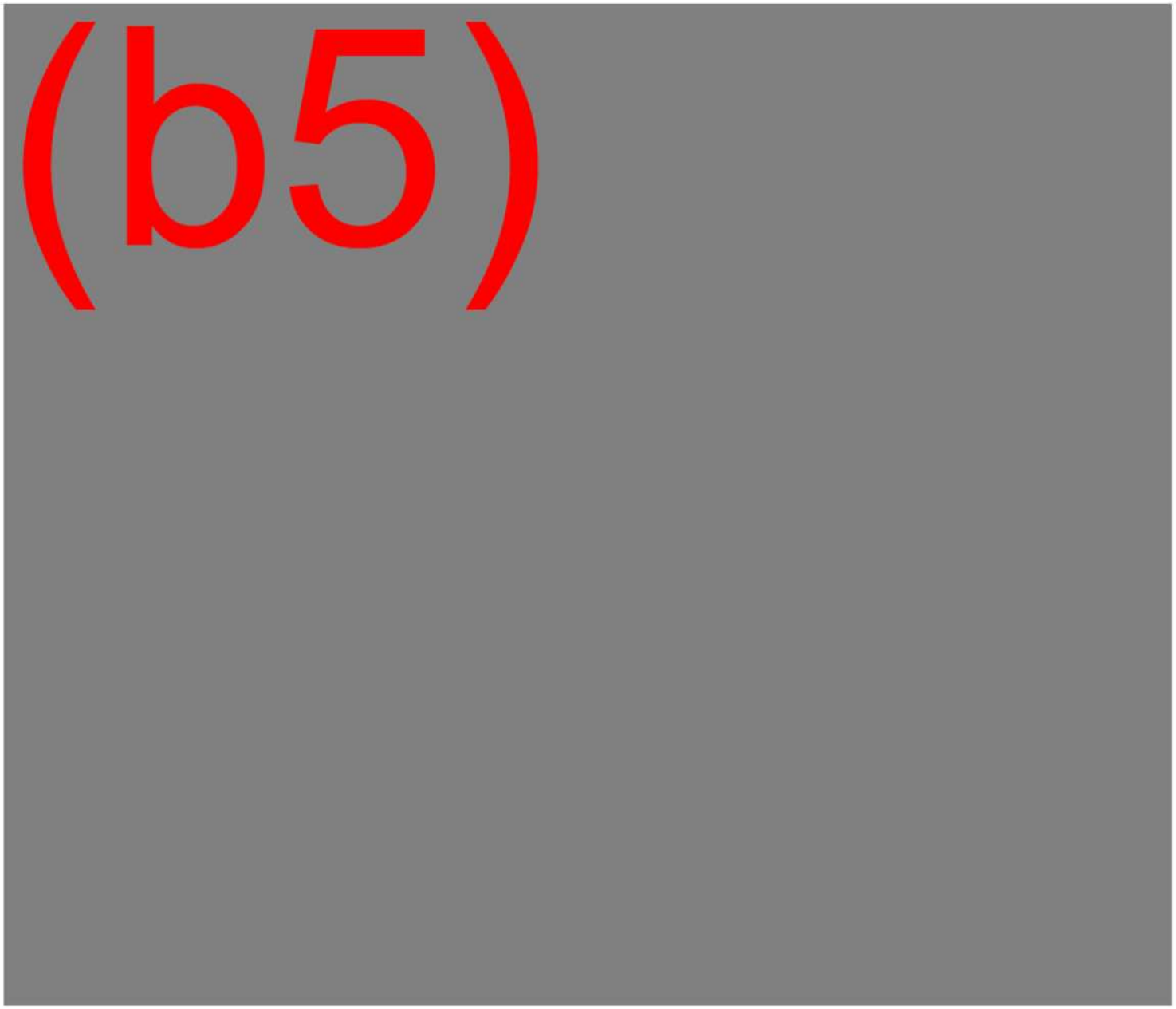
(b5)

Copy of my comments (sent to Dr. Boyd for internal briefings) below.

Thanks,
Ilse

AMERICAN OVERSIGHT

***



From: Lahl, Dennis
Sent: Tuesday, June 18, 2019 12:05 PM
To: Torrise, Virginia (VHACO) (b)(6) @va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>; Hastings, Patricia R. (b)(6) @va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Cc: Valentino, Michael (VACO) (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) (b)(6) @va.gov>; Strmiska, Jon G. <(b)(6) @va.gov>; Wiechers, Ilse (b)(6) @va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

AMERICAN OVERSIGHT

Dr. Hastings,

10NC5 received the below request for input, 10P4P submitted the noted response. Submitting this for clearance to 10NC5. I've cc'd 10P Actions and 10P4 Actions for tracking purposes. Let me know if you have any questions or concerns.

Feeder Response to OMHS: PBM provides this response to support OMHS statements (Dr Wiechers) regarding implementation timeline.

Question: Is there any more specific information that we can provide about timeline?

10P4P Response: We anticipate having final decisions about Pharmacy Benefits Management policies, including criteria for use, national protocol guidance, and formulary status by end of this week, pending ongoing deliberations of the Medical Advisory Panel (MAP) and VISN Pharmacy Executive (VPE) Committees.

Thanks. Have a great day.

Dennis

Dennis Lahl FAC-P/PM
Office of the Assistant Deputy Under Secretary for Health for Patient Care Services (10P4)
VACO PCS IT/BCAG/ISO Liaison
TMS OPCS DM
ph:(b)(6)
fax: 202-273-5483
Dennis Lahl

From: Torrise, Virginia (VHACO)
Sent: Tuesday, June 18, 2019 2:08 PM
To: Lahl, Dennis <(b)(6) @va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>
Cc: Valentino, Michael (VACO) (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) (b)(6) @va.gov>; Strmiska, Jon G. (b)(6) @va.gov>; Wiechers, Ilse (b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Medical Advisory Panel (MAP)
VISN Pharmacy Executive (VPE)

From: Lahl, Dennis
Sent: Tuesday, June 18, 2019 2:07 PM
To: Torrise, Virginia (VHACO) (b)(6) @va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>
Cc: Valentino, Michael (VACO) (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) (b)(6) @va.gov>; Strmiska, Jon G. <(b)(6) @va.gov>; Wiechers, Ilse

AMERICAN OVERSIGHT

(b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Ginny,

What does MAP and VPE stand for please?

Thanks. Have a great day.

Dennis

Dennis Lahl FAC-P/PM
Office of the Assistant Deputy Under Secretary for Health for Patient Care Services (10P4)
VACO PCS IT/BCAG/ISO Liaison
TMS OPCS DM
ph: (b)(6)
fax: 202-273-5483
Dennis Lahl

From: Torrise, Virginia (VHACO)
Sent: Tuesday, June 18, 2019 1:53 PM
To: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Cc: Valentino, Michael (VACO) (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) (b)(6) @va.gov>; Strmiska, Jon G. (b)(6) @va.gov>; Wiechers, Ilse (b)(6) @va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

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Question: Is there any more specific information that we can provide about timeline?

(b5)

From: Wiechers, Ilse
Sent: Tuesday, June 18, 2019 1:27 PM
To: Carroll, David (VACO) (b)(6) @va.gov>; Strmiska, Jon G. <(b)(6) @va.gov>; Ilse Wiechers (Yale (b)(6) >; Torrise, Virginia (VHACO) <(b)(6) @va.gov>
Cc: Daniels, Lindsay (b)(6) @va.gov>; Pomerantz, Andrew (b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Hi – I'm in office and online. I'm working on some high-level bullet points summarizing our progress and will have them up and out to folks shortly.

AMERICAN OVERSIGHT

Ginny – you can comment on the formulary decision, but I know that the MAP/VPE is considering esketamine on the agenda of this week's meeting on Thursday morning. I was planning to use language that states(b5)
(b5)
(b5) Please edit that statement as you feel most appropriate.

Ilse

From: Carroll, David (VACO)
Sent: Tuesday, June 18, 2019 10:23 AM
To: Strmiska, Jon G. <(b)(6) @va.gov>; Ilse Wiechers (Yale) (b)(6) Wiechers, Ilse (b)(6) @va.gov>; Torrise, Virginia (VHACO) <(b)(6) @va.gov>
Cc: Daniels, Lindsay (b)(6) @va.gov>; Pomerantz, Andrew (b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Actually – Ilse responded on a similar request from Dr. Boyd. Looks like she may have something together later this afternoon.

From: Strmiska, Jon G.
Sent: Tuesday, June 18, 2019 1:17 PM
To: Ilse Wiechers (Yale) (b)(6) Wiechers, Ilse(b)(6) @va.gov>; Torrise, Virginia (VHACO) (b)(6) @va.gov>
Cc: Daniels, Lindsay <(b)(6) @va.gov>; Pomerantz, Andrew (b)(6) @va.gov>; VHA 10P4P Action <vha10P4Paction@va.gov>; Carroll, David (VACO) (b)(6) @va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Ginny,

As discussed, your assistance is greatly appreciated with providing a response on this one. Ilse is out of the office until tomorrow. Please see below and provide your response by **3pm today.**

New York Times is asking when a decision will be made as to when VA will be putting Spravato in its formulary. We recently provide the response below, highlighted yellow.

Is there any more specific information that we can provide about timeline?

FDA has approved the use of intranasal esketamine for adults with treatment-resistant depression (when used in conjunction with an oral antidepressant). VA has not yet administered esketamine to any patients, and is in the process of designing a clinical implementation plan optimized for safety and efficacy.

Thanks!

AMERICAN OVERSIGHT

Jon G. Strmiska
Business Operations Manager (10NC5)
VA Central Office – Washington, DC
Phone:(b)(6)
FAX: 202.495.5933

From: Dudley, Tracy
Sent: Tuesday, June 18, 2019 1:00 PM
To: VHA 10NC5 Action <VHA10NC5Action@va.gov>
Cc: VHA CO 10NC Front Office HSSs <VHACO10NCFOHSSs@va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

GOOD Afternoon

Please see below and provide your response by **3pm today.**

Thank You!
Tracy

Tracy L. Dudley
Health System Specialist
ADUSH for Clinical Operations (10NC)
(b)(6) (Direct)
(b)(6) (iPhone)

From: Greilsamer, Alan
Sent: Tuesday, June 18, 2019 12:46 PM
To: VHA 10N Action <VHA10NAction@va.gov>; VHA 10NC Action <vha10ncaction@va.gov>
Cc: VHA 10NC5 Action <VHA10NC5Action@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

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Cc: Eason, William J. <(b)(6) @va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

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Department of Veterans Affairs
(b)(6)
(b)(6) @va.gov
(b)(6)

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Subject: Re: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

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Department of Veterans Affairs
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Sent: Tuesday, June 18, 2019 11:36 AM
To: Cashour, Curtis <(b)(6) @va.gov>
Subject: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

AMERICAN OVERSIGHT

Curt Cashour-

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Sincerely,

Ben Carey

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CC:	VHA CO 10NC Front Office HSSs /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcf91f73967a49c287d8747b7aee675e-VHA CO 10NC <VHACO10NCFOHSSs@va.gov>
Subject:	RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision
Date:	2019/06/18 15:28:11
Priority:	Normal
Type:	Note

Waiting for concurrence from 10P on the formulary component of response. I just got off the phone with them and Dr. Hastings. Response is coming soon.

Jon G. Strmiska
Business Operations Manager (10NC5)
VA Central Office – Washington, DC
Phone: (b)(6)
FAX: 202.495.5933

From: Dudley, Tracy
Sent: Tuesday, June 18, 2019 3:16 PM
To: VHA 10NC5 Action <VHA10NC5Action@va.gov>
Cc: VHA CO 10NC Front Office HSSs <VHACO10NCFOHSSs@va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Good Afternoon

Please provide a status.

Thank You!
Tracy

Tracy L. Dudley
Health System Specialist
ADUSH for Clinical Operations (10NC)
(b)(6) (Direct)
(b)(6) (iPhone)

AMERICAN OVERSIGHT

From: Dudley, Tracy
Sent: Tuesday, June 18, 2019 1:00 PM
To: VHA 10NC5 Action <VHA10NC5Action@va.gov>
Cc: VHA CO 10NC Front Office HSSs <VHACO10NCFOHSSs@va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

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To: Greilsamer, Alan (b)(6) @va.gov>; Screen, Gina <(b)(6) @va.gov>

AMERICAN OVERSIGHT

Cc: Eason, William J. <(b)(6) @va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

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Press Secretary
Department of Veterans Affairs
(b)(6)
(b)(6) @va.gov
(b)(6)

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Sent from my iPhone

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Department of Veterans Affairs
(b)(6)
(b)(6) @va.gov
(b)(6)

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AMERICAN OVERSIGHT

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Ben Carey

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From:	Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd.DIBOHF23SPDLT)/CN=RECIPIENTS/CN=519204DF507344AC8FA3045B2B4FC762-TORRISE, VI (b)(6) @va.gov>
To:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b)(6) @va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da (b)(6) @va.gov>; Strmiska, Jon G. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9872f41bf2844c8085d371e21482b635-Strmiska, J (b)(6) @va.gov>; Ilse Wiechers (Yale) (b)(6)
CC:	Daniels, Lindsay /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ed253196fb6b4f32aa922c90dbd05f29-Daniels, Li (b)(6) @va.gov>; Pomerantz, Andrew /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29a9288df9a34e84bddfd00cde79f11b-Pomerantz, (b)(6) @va.gov>
Subject:	RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision
Date:	2019/06/18 14:34:55
Priority:	Normal
Type:	Note

PBM concurs with the bulleted statements on VA formulary and MUE.

From: Wiechers, Ilse
Sent: Tuesday, June 18, 2019 2:17 PM
To: Torrise, Virginia (VHACO) <(b)(6) @va.gov>; Carroll, David (VACO) (b)(6) @va.gov>; Strmiska, Jon G. <(b)(6) @va.gov>; Ilse Wiechers (Yale) <(b)(6)
Cc: Daniels, Lindsay <(b)(6) @va.gov>; Pomerantz, Andrew <(b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

FYSA – here is the update I provided to Dr. Boyd. It included the statement Ginny concurred with, and one additional statement pending PBM approval re the status of the MUE.

Ilse

From: Torrise, Virginia (VHACO)
Sent: Tuesday, June 18, 2019 10:45 AM
To: Wiechers, Ilse <(b)(6) @va.gov>; Carroll, David (VACO) (b)(6) @va.gov>; Strmiska, Jon G. (b)(6) @va.gov>; Ilse Wiechers (Yale) (b)(6)
Cc: Daniels, Lindsay <(b)(6) @va.gov>; Pomerantz, Andrew (b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Ilse
This looks good. I will send through my end while you consider any other statements on implementation (original question)

AMERICAN OVERSIGHT

From: Wiechers, Ilse
Sent: Tuesday, June 18, 2019 1:27 PM
To: Carroll, David (VACO) (b)(6) @va.gov>; Strmiska, Jon G. (b)(6) @va.gov>; Ilse Wiechers (Yale) (b)(6) ; Torrise, Virginia (VHACO) (b)(6) @va.gov>
Cc: Daniels, Lindsay (b)(6) @va.gov>; Pomerantz, Andrew (b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Hi – I'm in office and online. I'm working on some high-level bullet points summarizing our progress and will have them up and out to folks shortly.

(b5)

Ilse

From: Carroll, David (VACO)
Sent: Tuesday, June 18, 2019 10:23 AM
To: Strmiska, Jon G. (b)(6) @va.gov>; Ilse Wiechers (Yale) (b)(6) ; Wiechers, Ilse <(b)(6) @va.gov>; Torrise, Virginia (VHACO) (b)(6) @va.gov>
Cc: Daniels, Lindsay (b)(6) @va.gov>; Pomerantz, Andrew (b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Actually – Ilse responded on a similar request from Dr. Boyd. Looks like she may have something together later this afternoon.

From: Strmiska, Jon G.
Sent: Tuesday, June 18, 2019 1:17 PM
To: Ilse Wiechers (Yale) <(b)(6) Wiechers, Ilse (b)(6) @va.gov>; Torrise, Virginia (VHACO) (b)(6) @va.gov>
Cc: Daniels, Lindsay (b)(6) @va.gov>; Pomerantz, Andrew <(b)(6) @va.gov>; VHA 10P4P Action <vha10P4Paction@va.gov>; Carroll, David (VACO) (b)(6) @va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Ginny,

As discussed, your assistance is greatly appreciated with providing a response on this one. Ilse is out of the office until tomorrow. Please see below and provide your response by **3pm today.**

New York Times is asking when a decision will be made as to when VA will be putting Spravato in its formulary. We recently provide the response below, highlighted yellow.

AMERICAN OVERSIGHT

Is there any more specific information that we can provide about timeline?

FDA has approved the use of intranasal esketamine for adults with treatment-resistant depression (when used in conjunction with an oral antidepressant). VA has not yet administered esketamine to any patients, and is in the process of designing a clinical implementation plan optimized for safety and efficacy.

Thanks!

Jon G. Strmiska
Business Operations Manager (10NC5)
VA Central Office – Washington, DC
Phone: *(b)(6)*
FAX: 202.495.5933

From: Dudley, Tracy
Sent: Tuesday, June 18, 2019 1:00 PM
To: VHA 10NC5 Action <VHA10NC5Action@va.gov>
Cc: VHA CO 10NC Front Office HSSs <VHACO10NCFOHSSs@va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

GOOD Afternoon

Please see below and provide your response by **3pm today.**

Thank You!
Tracy

Tracy L. Dudley
Health System Specialist
ADUSH for Clinical Operations (10NC)
(b)(6) (Direct)
(b)(6) (iPhone)

From: Greilsamer, Alan
Sent: Tuesday, June 18, 2019 12:46 PM
To: VHA 10N Action <VHA10NAction@va.gov>; VHA 10NC Action <vha10ncaction@va.gov>
Cc: VHA 10NC5 Action <VHA10NC5Action@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Good afternoon,

New York Times is asking when a decision will be made as to when VA will be putting Spravato in its formulary. We recently provide the response below.

AMERICAN OVERSIGHT

Is there any more specific information that we can provide about timeline?

FDA has approved the use of intranasal esketamine for adults with treatment-resistant depression (when used in conjunction with an oral antidepressant). VA has not yet administered esketamine to any patients, and is in the process of designing a clinical implementation plan optimized for safety and efficacy.

Requesting a response by today (June 18) NLT 5 p.m. ET.

Thanks, Alan

From: Cashour, Curtis
Sent: Tuesday, June 18, 2019 12:38 PM
To: Greilsamer, Alan <(b)(6) @va.gov>; Screen, Gina (b)(6) @va.gov>
Cc: Eason, William J. (b)(6) @va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Please let me know your recommended response to the below.

Thanks,

Curt Cashour
Press Secretary
Department of Veterans Affairs
(b)(6)
(b)(6) @va.gov
(b)(6)

From: Ben Carey (b)(6) @nytimes.com>
Sent: Tuesday, June 18, 2019 12:35 PM
To: Cashour, Curtis (b)(6) @va.gov>
Subject: Re: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Thanks Curt, please do. Main question for now is when is decision expected..? (i.e. how much time I got?)

Ben

Sent from my iPhone

On Jun 18, 2019, at 12:22 PM, Cashour, Curtis <(b)(6) @va.gov>wrote:

Will keep you posted. Thanks, Ben.

Curt Cashour
Press Secretary
Department of Veterans Affairs

AMERICAN OVERSIGHT

(b)(6)
(b)(6) @va.gov
(b)(6)

From: Carey, Ben <(b)(6)@nytimes.com>
Sent: Tuesday, June 18, 2019 11:36 AM
To: Cashour, Curtis <(b)(6) @va.gov>
Subject: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Curt Cashour-

Hello from New York. It's Ben Carey emailing. I am a reporter in science at the NY Times, I cover psych topics. I have your email from Jennifer Steinhauer, NYT reporter in DC.

I would love to hear what/ when on the VA's expected decision this week whether to put Spravato on its formulary. Keep me in the loop on this, kindly, would be good to know when decision will be made, with some notice, and anything else VA puts out on this.

We'll likely cover decision either way.

Sincerely,

Ben Carey

Sender:	Torrise, Virginia (VHACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=519204DF507344AC8FA3045B2B4FC762-TORRISE, VI (b)(6) @va.gov>
Recipient:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b)(6) @va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da (b)(6) @va.gov>; Strmiska, Jon G. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9872f41bf2844c8085d371e21482b635-Strmiska, J (b)(6) @va.gov>; Ilse Wiechers (Yale) (b)(6) Daniels, Lindsay /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ed253196fb6b4f32aa922c90dbd05f29-Daniels, Li (b)(6) @va.gov>; Pomerantz, Andrew /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29a9288df9a34e84bddfd00cde79f11b-Pomerantz, (b)(6) @va.gov>
Sent Date:	2019/06/18 14:34:53
Delivered Date:	2019/06/18 14:34:55

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From:	Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd.DIBOHF23SPDLT)/CN=RECIPIENTS/CN=95E14EBD3B6745C8952A823B04DABFF5-CARROLL, DA>
To:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b)(6) @va.gov>
Subject:	RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision
Date:	2019/06/21 18:16:00
Priority:	Normal
Type:	Note

thx

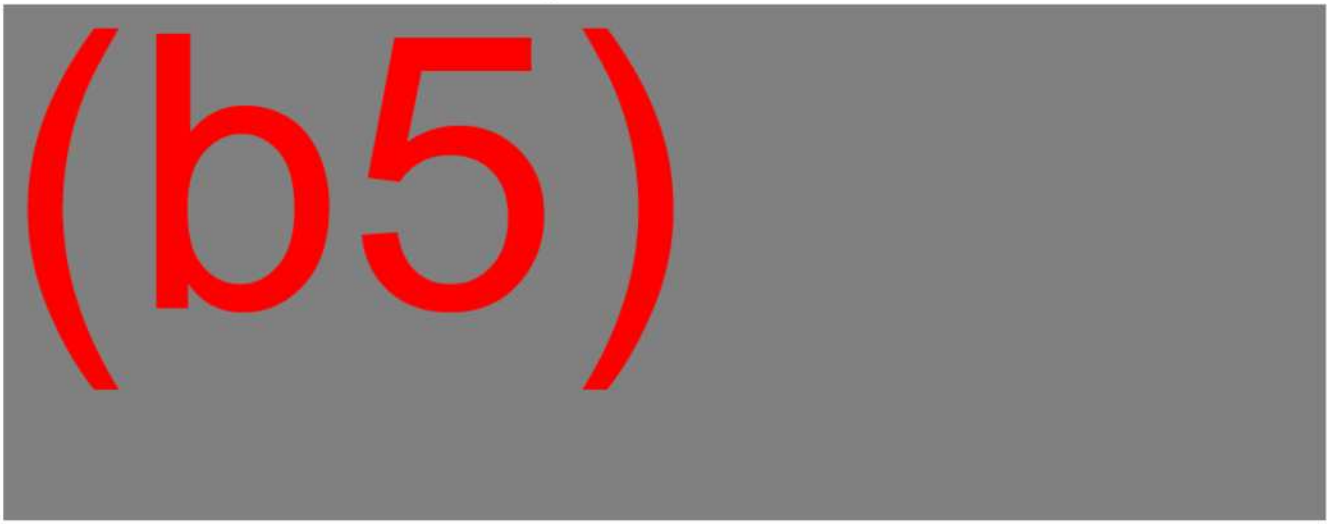
From: Wiechers, Ilse
Sent: Friday, June 21, 2019 12:45 PM
To: VHA 10NC5 Action <VHA10NC5Action@va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Heads up - this is going up and out via 10P clearance. I concur with the statement as written by Mike and Maria, below.

Sent with BlackBerry Work
(www.blackberry.com)

From: Cashour, Curtis <(b)(6) @va.gov>
Date: Friday, Jun 21, 2019, 9:24 AM
To: Valentino, Michael (VACO) <(b)(6) @va.gov>, Wiechers, Ilse (b)(6) @va.gov>, Snyder, Jill (b)(6) @va.gov>
Cc: Outlaw, William N. <(b)(6) @va.gov>, Greilsamer, Alan (b)(6) @va.gov>, Zacher, Jennifer L. (PBM) (b)(6) @va.gov>, Llorente, Maria D. <(b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Thanks. Does VHA concur with the following?



AMERICAN OVERSIGHT

(b5)

###

Curt Cashour
Press Secretary
Department of Veterans Affairs
(b)(6)
(b)(6) @va.gov
(b)(6)

From: Valentino, Michael (VACO)
Sent: Friday, June 21, 2019 12:17 PM
To: Wiechers, Ilse (b)(6) @va.gov>; Snyder, Jill (b)(6) @va.gov>; Cashour, Curtis (b)(6) @va.gov>
Cc: Outlaw, William N. (b)(6) @va.gov>; Greilsamer, Alan (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) (b)(6) @va.gov>; Llorente, Maria D. (b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Dr. Llorente and I drafted a statement for the NYT inquiry and I believe it will be coming forward soon.

Here it is but please consider it DRAFT:

From: Wiechers, Ilse
Sent: Friday, June 21, 2019 12:07 PM
To: Snyder, Jill (b)(6) @va.gov>; Valentino, Michael (VACO) (b)(6) @va.gov>; Cashour, Curtis (b)(6) @va.gov>
Cc: Outlaw, William N. <(b)(6) @va.gov>; Greilsamer, Alan (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) (b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Adding Jen Zacher for coordination purposes.

From: Snyder, Jill
Sent: Friday, June 21, 2019 9:02 AM
To: Valentino, Michael (VACO) (b)(6) @va.gov>; Wiechers, Ilse (b)(6) @va.gov>; Cashour, Curtis <(b)(6) @va.gov>
Cc: Outlaw, William N. (b)(6) @va.gov>; Greilsamer, Alan <(b)(6) @va.gov>; Snyder, Jill (b)(6) @va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

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Good afternoon Mike and Ilse,

I know you all are working on media responses regarding Ketamine, however we just received an email from the Boston Globe that the decision was made NOT to include it in the formulary. Please see email below and I am including Curt Cashour, VA Press Secretary, on this message to streamline responses.

Thank you,
Jill

From: Silverman, Ed (b)(6) @statnews.com>
Sent: Friday, June 21, 2019 11:24 AM
To: VA Public Affairs <VAPublicAffairs@va.gov>
Subject: [EXTERNAL] question from a journalist

Hi ,

My name is Ed Silverman and I work for The Boston Globe's STAT News health site, where I track the pharmaceutical industry.

I understand a VA committee voted not to include a new Johnson&Johnson antidepressant spray drug called Spravato on its pharmacy list.

Can you please confirm and explain why the committee voted not to include it?

Thanks
ed silverman
(b)(6)
www.statnews.com/pharmalot/

From: Snyder, Jill
Sent: Friday, June 21, 2019 9:59 AM
To: Cashour, Curtis <(b)(6) @va.gov>; Greilsamer, Alan (b)(6) @va.gov>
Cc: Eason, William J. (b)(6) @va.gov>; Screen, Gina (b)(6) @va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Hi Curt –

I am following this in Alan's absence, program office is still working on the response, I will continue to follow up.

Thanks,

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Jill

From: Cashour, Curtis
Sent: Friday, June 21, 2019 9:57 AM
To: Greilsamer, Alan <(b)(6) @va.gov>; Snyder, Jill (b)(6) @va.gov>
Cc: Eason, William J. (b)(6) @va.gov>; Screen, Gina (b)(6) @va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Just following up here. Thanks.

From: Greilsamer, Alan
Sent: Thursday, June 20, 2019 3:34 PM
To: Cashour, Curtis (b)(6) @va.gov>
Cc: Eason, William J. (b)(6) @va.gov>; Screen, Gina (b)(6) @va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

We will try to pin them down on a timeframe.

—
Alan Greilsamer
Director, Media Relations (10B2B)
Office of Communications
Veterans Health Administration
P: (b)(6)
E: (b)(6) @va.gov

From: Cashour, Curtis (b)(6) @va.gov>
Date: Thursday, Jun 20, 2019, 3:18 PM
To: Greilsamer, Alan (b)(6) @va.gov>
Cc: Eason, William J. (b)(6) @va.gov>, Screen, Gina (b)(6) @va.gov>, VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Is there an update here?

The original question was when will VA make a decision about putting spravato on the formulary.

Thanks,

Curt Cashour
Press Secretary
Department of Veterans Affairs
(b)(6)

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(b)(6) @va.gov
(b)(6)

From: Greilsamer, Alan
Sent: Wednesday, June 19, 2019 9:05 AM
To: Cashour, Curtis (b)(6) @va.gov>
Cc: Eason, William J. (b)(6) @va.gov>; Screen, Gina (b)(6) @va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

VHA clears

In March 2019, two weeks after the FDA approved intranasal esketamine for use in conjunction with an oral antidepressant for the treatment of treatment-resistant depression in adults, VA announced the treatment would be made available to Veterans based on their individual medical needs combined with providers' clinical assessments. VA is now preparing a thoughtful, step-wise approach to clinical implementation of esketamine that puts Veteran safety first and ensures close, careful monitoring of potential adverse events, including the risk of addiction. This reflects VA's commitment to seek new ways to provide the best health care available for our nation's Veterans.

Additional information

Steps VA has taken to date include:

- • The first dose of intranasal esketamine was safely administered today, June 18, 2019, to a Veteran with treatment-resistant depression at the VA Boston Healthcare System.
- • A standardized informed consent document and supporting patient education materials have been made available nationally through VHA's electronic signed consent platform.
- • VHA established a national Esketamine Clinical Implementation Workgroup, which has representation from key VA Central Office stakeholder groups, facility leadership, and subject matter experts in ketamine and esketamine treatments for mental health disorders.
- • VHA has launched the Esketamine Community of Practice, a virtual learning community that will combine regular teleconferences and a repository of resources to provide a forum for discussing progress in implementation and developing best practices while also ensuring clear communication across the organization.
- • 13 sites have confirmed their participation as Early Adopters, and will work together supported by the Esketamine Community of Practice and the Esketamine Clinical Implementation Workgroup to implement clinical use of esketamine at their sites this summer and fall.

Ongoing next steps include:

- • VA anticipates having final decisions about Pharmacy Benefits Management policies, including criteria for use, national protocol guidance, and formulary status by end of this week, pending ongoing deliberations of the Medical Advisory Panel and VISN Pharmacy Executive Committees.

- • Development of a Medication Use Evaluation (MUE) which focuses on safety monitoring is underway, with anticipated implementation of the data entry portal in July 2019. The MUE will

AMERICAN OVERSIGHT

facilitate data reporting for the FDA REMS and will gather additional safety and monitoring data on all use of esketamine within VHA.

From: Cashour, Curtis
Sent: Tuesday, June 18, 2019 12:38 PM
To: Greilsamer, Alan <(b)(6) @va.gov>; Screen, Gina <(b)(6) @va.gov>
Cc: Eason, William J. <(b)(6) @va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Please let me know your recommended response to the below.

Thanks,

Curt Cashour
Press Secretary
Department of Veterans Affairs
(b)(6)
(b)(6) @va.gov
(b)(6)

From: Ben Carey (b)(6) @nytimes.com>
Sent: Tuesday, June 18, 2019 12:35 PM
To: Cashour, Curtis <(b)(6) @va.gov>
Subject: Re: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Thanks Curt, please do. Main question for now is when is decision expected..? (i.e. how much time I got?)

Ben

Sent from my iPhone

On Jun 18, 2019, at 12:22 PM, Cashour, Curtis <(b)(6) @va.gov>wrote:

Will keep you posted. Thanks, Ben.

Curt Cashour
Press Secretary
Department of Veterans Affairs
(b)(6)
(b)(6) @va.gov
(b)(6)

From: Carey, Ben (b)(6) @nytimes.com>
Sent: Tuesday, June 18, 2019 11:36 AM

AMERICAN OVERSIGHT

To: Cashour, Curtis <(b)(6) @va.gov>
Subject: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Curt Cashour-

Hello from New York. It's Ben Carey emailing. I am a reporter in science at the NY Times, I cover psych topics. I have your email from Jennifer Steinhauer, NYT reporter in DC.

I would love to hear what/ when on the VA's expected decision this week whether to put Spravato on its formulary. Keep me in the loop on this, kindly, would be good to know when decision will be made, with some notice, and anything else VA puts out on this.

We'll likely cover decision either way.

Sincerely,

Ben Carey

Sender:	Carroll, David (VACO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=95E14EBD3B6745C8952A823B04DABFF5-CARROLL, DA>
Recipient:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b)(6) va.gov>
Sent Date:	2019/06/21 18:16:44
Delivered Date:	2019/06/21 18:16:00

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From:	Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd.)/CN=RECIPIENTS/CN=0B6E91EF72EE4A05ACC63873C64570E1-SNYDER, JIL (b)(6) @va.gov>
To:	Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M (b)(6) @va.gov>; Outlaw, William N. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3e1067978634fbf96a382bdcd5c1115-Outlaw, Wil (b)(6) @va.gov>; Cashour, Curtis /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dba510634baa46a085e28c62c254093f-Cashour, Cu <(b)(6) @va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b)(6) @va.gov>
CC:	Greilsamer, Alan /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fc02807af08443fbb5c68c590d58fa4b-Greilsamer, (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen (b)(6) @va.gov>
Subject:	RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision
Date:	2019/06/21 12:34:34
Priority:	Normal
Type:	Note

Thank you – hoping for quick 10P clearance so I can send to 10B for final approval.

From: Llorente, Maria D.
Sent: Friday, June 21, 2019 12:34 PM
To: Outlaw, William N. (b)(6) @va.gov>; Cashour, Curtis (b)(6) @va.gov>; Valentino, Michael (VACO) (b)(6) @va.gov>; Wiechers, Ilse (b)(6) @va.gov>; Snyder, Jill (b)(6) @va.gov>
Cc: Greilsamer, Alan (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) (b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Cleared for 10P4. Will forward to 10P Actions

From: Outlaw, William N.
Sent: Friday, June 21, 2019 12:30 PM
To: Cashour, Curtis (b)(6) @va.gov>; Valentino, Michael (VACO) <(b)(6) @va.gov>; Wiechers, Ilse (b)(6) @va.gov>; Snyder, Jill (b)(6) @va.gov>
Cc: Greilsamer, Alan <(b)(6) @va.gov>; Zacher, Jennifer L. (PBM) (b)(6) @va.gov>; Llorente, Maria D. (b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

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Per Mike Valentino, Pharmacy Benefits is good with the statement but will send up through clearance channels.

From: Cashour, Curtis
Sent: Friday, June 21, 2019 12:24 PM
To: Valentino, Michael (VACO) <(b)(6) @va.gov>; Wiechers, Ilse (b)(6) @va.gov>; Snyder, Jill (b)(6) @va.gov>
Cc: Outlaw, William N. (b)(6) @va.gov>; Greilsamer, Alan <(b)(6) @va.gov>; Zacher, Jennifer L. (PBM) <(b)(6) @va.gov>; Llorente, Maria D. (b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Thanks. Does VHA concur with the following?

###

(b5)

###

Curt Cashour
Press Secretary
Department of Veterans Affairs
(b)(6)
(b)(6) @va.gov
(b)(6)

From: Valentino, Michael (VACO)
Sent: Friday, June 21, 2019 12:17 PM
To: Wiechers, Ilse <(b)(6) @va.gov>; Snyder, Jill (b)(6) @va.gov>; Cashour, Curtis <(b)(6) @va.gov>
Cc: Outlaw, William N. <(b)(6) @va.gov>; Greilsamer, Alar (b)(6) @va.gov>;

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Zacher, Jennifer L. (PBM) <(b)(6) @va.gov>; Llorente, Maria D. <(b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Dr. Llorente and I drafted a statement for the NYT inquiry and I believe it will be coming forward soon.

Here it is but please consider it DRAFT:

From: Wiechers, Ilse
Sent: Friday, June 21, 2019 12:07 PM
To: Snyder, Jill <(b)(6) @va.gov>; Valentino, Michael (VACO) <(b)(6) @va.gov>; Cashour, Curtis <(b)(6) @va.gov>
Cc: Outlaw, William N. <(b)(6) @va.gov>; Greilsamer, Alan (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) (b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Adding Jen Zacher for coordination purposes.

From: Snyder, Jill
Sent: Friday, June 21, 2019 9:02 AM
To: Valentino, Michael (VACO) <(b)(6) @va.gov>; Wiechers, Ilse (b)(6) @va.gov>; Cashour, Curtis <(b)(6) @va.gov>
Cc: Outlaw, William N. <(b)(6) @va.gov>; Greilsamer, Alan <(b)(6) @va.gov>; Snyder, Jill <(b)(6) @va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Good afternoon Mike and Ilse,

I know you all are working on media responses regarding Ketamine, however we just received an email from the Boston Globe that the decision was made NOT to include it in the formulary. Please see email below and I am including Curt Cashour, VA Press Secretary, on this message to streamline responses.

Thank you,
Jill

From: Silverman, Ed <(b)(6) @statnews.com>
Sent: Friday, June 21, 2019 11:24 AM
To: VA Public Affairs <VAPublicAffairs@va.gov>
Subject: [EXTERNAL] question from a journalist

Hi ,

My name is Ed Silverman and I work for The Boston Globe's STAT News health site, where I track the pharmaceutical industry.

AMERICAN OVERSIGHT

I understand a VA committee voted not to include a new Johnson&Johnson antidepressant spray drug called Spravato on its pharmacy list.

Can you please confirm and explain why the committee voted not to include it?

Thanks
ed silverman
(b)(6)
www.statnews.com/pharmalot/

From: Snyder, Jill
Sent: Friday, June 21, 2019 9:59 AM
To: Cashour, Curtis <(b)(6) @va.gov>; Greilsamer, Alan <(b)(6) @va.gov>
Cc: Eason, William J. <(b)(6) @va.gov>; Screen, Gina <(b)(6) @va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Hi Curt –

I am following this in Alan's absence, program office is still working on the response, I will continue to follow up.

Thanks,
Jill

From: Cashour, Curtis
Sent: Friday, June 21, 2019 9:57 AM
To: Greilsamer, Alan <(b)(6) @va.gov>; Snyder, Jil(b)(6) @va.gov>
Cc: Eason, William J. <(b)(6) @va.gov>; Screen, Gina <(b)(6) @va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Just following up here. Thanks.

From: Greilsamer, Alan
Sent: Thursday, June 20, 2019 3:34 PM
To: Cashour, Curtis <(b)(6) @va.gov>
Cc: Eason, William J. (b)(6) @va.gov>; Screen, Gina <(b)(6) @va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

We will try to pin them down on a timeframe.

AMERICAN OVERSIGHT

—
Alan Greilsamer
Director, Media Relations (10B2B)
Office of Communications
Veterans Health Administration
P: (b)(6)
E: (b)(6) @va.gov

From: Cashour, Curtis (b)(6) @va.gov>
Date: Thursday, Jun 20, 2019, 3:18 PM
To: Greilsamer, Alan (b)(6) @va.gov>
Cc: Eason, William J. (b)(6) @va.gov>, Screen, Gina (b)(6) @va.gov>, VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Is there an update here?

The original question was when will VA make a decision about putting spravato on the formulary.

Thanks,

Curt Cashour
Press Secretary
Department of Veterans Affairs
(b)(6)
(b)(6) @va.gov
(b)(6)

From: Greilsamer, Alan
Sent: Wednesday, June 19, 2019 9:05 AM
To: Cashour, Curtis (b)(6) @va.gov>
Cc: Eason, William J. (b)(6) @va.gov>; Screen, Gina (b)(6) @va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

VHA clears

In March 2019, two weeks after the FDA approved intranasal esketamine for use in conjunction with an oral antidepressant for the treatment of treatment-resistant depression in adults, VA announced the treatment would be made available to Veterans based on their individual medical needs combined with providers' clinical assessments. VA is now preparing a thoughtful, step-wise approach to clinical implementation of esketamine that puts Veteran safety first and ensures close, careful monitoring of potential adverse events, including the risk of addiction. This reflects VA's commitment to seek new ways to provide the best health care available for our nation's Veterans.

Additional information

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Steps VA has taken to date include:

- • The first dose of intranasal esketamine was safely administered today, June 18, 2019, to a Veteran with treatment-resistant depression at the VA Boston Healthcare System.
- • A standardized informed consent document and supporting patient education materials have been made available nationally through VHA's electronic signed consent platform.
- • VHA established a national Esketamine Clinical Implementation Workgroup, which has representation from key VA Central Office stakeholder groups, facility leadership, and subject matter experts in ketamine and esketamine treatments for mental health disorders.
- • VHA has launched the Esketamine Community of Practice, a virtual learning community that will combine regular teleconferences and a repository of resources to provide a forum for discussing progress in implementation and developing best practices while also ensuring clear communication across the organization.
- • 13 sites have confirmed their participation as Early Adopters, and will work together supported by the Esketamine Community of Practice and the Esketamine Clinical Implementation Workgroup to implement clinical use of esketamine at their sites this summer and fall.

Ongoing next steps include:

- • VA anticipates having final decisions about Pharmacy Benefits Management policies, including criteria for use, national protocol guidance, and formulary status by end of this week, pending ongoing deliberations of the Medical Advisory Panel and VISN Pharmacy Executive Committees.

- • Development of a Medication Use Evaluation (MUE) which focuses on safety monitoring is underway, with anticipated implementation of the data entry portal in July 2019. The MUE will facilitate data reporting for the FDA REMS and will gather additional safety and monitoring data on all use of esketamine within VHA.

From: Cashour, Curtis
Sent: Tuesday, June 18, 2019 12:38 PM
To: Greilsamer, Alan <(b)(6) @va.gov>; Screen, Gina (b)(6) @va.gov>
Cc: Eason, William J. (b)(6) @va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Please let me know your recommended response to the below.

Thanks,

Curt Cashour
Press Secretary
Department of Veterans Affairs
(b)(6)
(b)(6) @va.gov
(b)(6)

From: Ben Carey <(b)(6) @nytimes.com>
Sent: Tuesday, June 18, 2019 12:35 PM

AMERICAN OVERSIGHT

To: Cashour, Curtis (b)(6) @va.gov>
Subject: Re: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Thanks Curt, please do. Main question for now is when is decision expected..? (i.e. how much time I got?)

Ben

Sent from my iPhone

On Jun 18, 2019, at 12:22 PM, Cashour, Curtis <(b)(6) @va.gov>wrote:

Will keep you posted. Thanks, Ben.

Curt Cashour
Press Secretary
Department of Veterans Affairs
(b)(6)
(b)(6) @va.gov
(b)(6)

From: Carey, Ben <(b)(6) @nytimes.com>
Sent: Tuesday, June 18, 2019 11:36 AM
To: Cashour, Curtis (b)(6) @va.gov>
Subject: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Curt Cashour-

Hello from New York. It's Ben Carey emailing. I am a reporter in science at the NY Times, I cover psych topics. I have your email from Jennifer Steinhauer, NYT reporter in DC.

I would love to hear what/ when on the VA's expected decision this week whether to put Spravato on its formulary. Keep me in the loop on this, kindly, would be good to know when decision will be made, with some notice, and anything else VA puts out on this.

We'll likely cover decision either way.

Sincerely,

Ben Carey

Sender:	Snyder, Jill /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0B6E91EF72EE4A05ACC63873C64570E1-SNYDER, JIL (b)(6) r@va.gov>
Recipient:	Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M (b)(6) @va.gov>; Outlaw, William N. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3e1067978634fbf96a382bdcd5c1115-Outlaw, Wil (b)(6) @va.gov>;

AMERICAN OVERSIGHT

	Cashour, Curtis /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dba510634baa46a085e28c62c254093f-Cashour, Cu (b)(6) @va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b)(6) @va.gov>; Greilsamer, Alan /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fc02807af08443fbb5c68c590d58fa4b-Greilsamer, (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen (b)(6) @va.gov>
Sent Date:	2019/06/21 12:34:33
Delivered Date:	2019/06/21 12:34:34

AMERICAN OVERSIGHT

From:	Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd.DIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO, (b)(6) @va.gov>
To:	Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M (b)(6) @va.gov>
CC:	Hastings, Patricia R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a504fbfe766048a5a65461c45f28e9de-Hastings, P (b)(6) @va.gov>
Subject:	RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision
Date:	2019/06/21 11:37:56
Priority:	Normal
Type:	Note

Better! I like it

Sent with BlackBerry Work
(www.blackberry.com)

From: Llorente, Maria D. <(b)(6) @va.gov>
Date: Friday, Jun 21, 2019, 11:12 AM
To: Valentino, Michael (VACO) <(b)(6) @va.gov>
Cc: Hastings, Patricia R. (b)(6) @va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Made some edits. Let me know what you think.
Maria

From: Valentino, Michael (VACO)
Sent: Friday, June 21, 2019 10:58 AM
To: Hastings, Patricia R. (b)(6) @va.gov>; Llorente, Maria D. (b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Some thoughts for a possible response….Bill Outlaw just told me the Media folks want this by noon today.

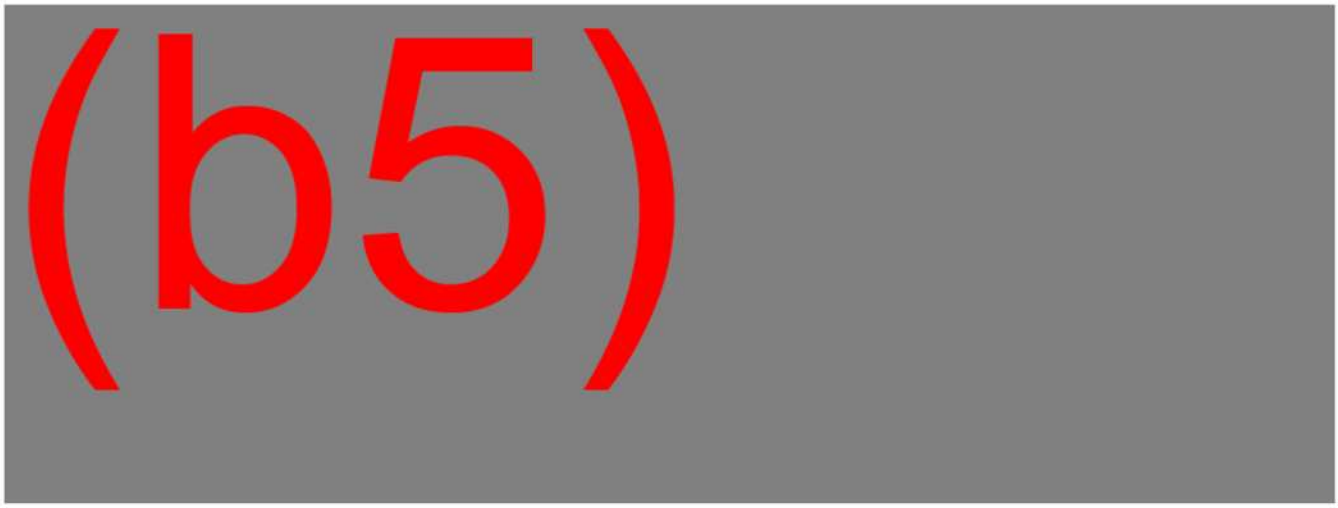
Mike

Question:
Curt Cashour-
Hello from New York. It's Ben Carey emailing. I am a reporter in science at the NY Times, I cover psych topics. I have your email from Jennifer Steinhauer, NYT reporter in DC.
I would love to hear what/ when on the VA's expected decision this week whether to put Spravato on its formulary. Keep me in the loop on this, kindly, would be good to know when decision will be made, with some notice, and anything else VA puts out on this.
We'll likely cover decision either way.
Sincerely,

AMERICAN OVERSIGHT

Ben Carey

Draft response:



From: Valentino, Michael (VACO)
Sent: Friday, June 21, 2019 10:04 AM
To: Hastings, Patricia R. (b)(6) @va.gov>; Llorente, Maria D. (b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision



?

Mike

From: Valentino, Michael (VACO)
Sent: Friday, June 21, 2019 9:57 AM
To: Graham, Christopher L. (b)(6) @va.gov>; Lahl, Dennis (b)(6) @va.gov>; Torrise, Virginia (VHACO) (b)(6) @va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>; Hastings, Patricia R. (b)(6) @va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Cc: Zacher, Jennifer L. (PBM) (b)(6) @va.gov>; Strmiska, Jon G. (b)(6) @va.gov>; Wiechers, Ilse (b)(6) @va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

We'll discuss in 10P4 later this AM and get back to you.

Mike

AMERICAN OVERSIGHT

From: Graham, Christopher L.
Sent: Friday, June 21, 2019 9:54 AM
To: Lahl, Dennis (b)(6) @va.gov>; Torrise, Virginia (VHACO) (b)(6) @va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>; Hastings, Patricia R. (b)(6) @va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Cc: Valentino, Michael (VACO) (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) (b)(6) @va.gov>; Strmiska, Jon G. (b)(6) @va.gov>; Wiechers, Ilse (b)(6) @va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Good morning,

Do these items still seem likely for today?

Thanks,
Chris Graham, MHA
Health Systems Specialist
Department of Veterans Affairs
Office of the Deputy Under Secretary for Health for Policy and Services (10P)
Office: (b)(6)

From: Lahl, Dennis
Sent: Tuesday, June 18, 2019 3:28 PM
To: Torrise, Virginia (VHACO) (b)(6) @va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>; Hastings, Patricia R. (b)(6) @va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Cc: Valentino, Michael (VACO) (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) (b)(6) @va.gov>; Strmiska, Jon G. <(b)(6) @va.gov>; Wiechers, Ilse (b)(6) @va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

All the below is cleared:

10P4P Response: (b5)

(b5)

Thanks. Have a great day.

Dennis

Dennis Lahl FAC-P/PM
Office of the Assistant Deputy Under Secretary for Health for Patient Care Services (10P4)
VACO PCS IT/BCAG/ISO Liaison
TMS OPCS DM

AMERICAN OVERSIGHT

ph: (b)(6)
fax: 202-273-5483
Dennis Lahl

From: Lahl, Dennis
Sent: Tuesday, June 18, 2019 3:05 PM
To: Torrise, Virginia (VHACO) (b)(6) @va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>; Hastings, Patricia R. <(b)(6) @va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Cc: Valentino, Michael (VACO) (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) (b)(6) @va.gov>; Strmiska, Jon G. (b)(6) @va.gov>; Wiechers, Ilse (b)(6) @va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Dr. Hastings,

10NC5 received the below request for input, 10P4P submitted the noted response. Submitting this for clearance to 10NC5. I've cc'd 10P Actions and 10P4 Actions for tracking purposes. Let me know if you have any questions or concerns.

Feeder Response to OMHS: PBM provides this response to support OMHS statements (Dr Wiechers) regarding implementation timeline.

Question: Is there any more specific information that we can provide about timeline?

(b5)

Thanks. Have a great day.

Dennis

Dennis Lahl FAC-P/PM
Office of the Assistant Deputy Under Secretary for Health for Patient Care Services (10P4)
VACO PCS IT/BCAG/ISO Liaison
TMS OPCS DM
ph: (b)(6)
fax: 202-273-5483
Dennis Lahl

From: Torrise, Virginia (VHACO)
Sent: Tuesday, June 18, 2019 2:08 PM
To: Lahl, Dennis (b)(6) @va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>
Cc: Valentino, Michael (VACO) (b)(6) @va.gov>; Zacher, Jennifer L. (PBM)

AMERICAN OVERSIGHT

(b)(6) @va.gov>; Strmiska, Jon G. <(b)(6) @va.gov>; Wiechers, Ilse (b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Medical Advisory Panel (MAP)
VISN Pharmacy Executive (VPE)

From: Lahl, Dennis
Sent: Tuesday, June 18, 2019 2:07 PM
To: Torrise, Virginia (VHACO) <(b)(6) @va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>
Cc: Valentino, Michael (VACO) (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) (b)(6) @va.gov>; Strmiska, Jon G. <(b)(6) @va.gov>; Wiechers, Ilse (b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Ginny,

What does MAP and VPE stand for please?

Thanks. Have a great day.

Dennis

Dennis Lahl FAC-P/PM
Office of the Assistant Deputy Under Secretary for Health for Patient Care Services (10P4)
VACO PCS IT/BCAG/ISO Liaison
TMS OPCS DM
ph: (b)(6)
fax: 202-273-5483
Dennis Lahl

From: Torrise, Virginia (VHACO)
Sent: Tuesday, June 18, 2019 1:53 PM
To: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Cc: Valentino, Michael (VACO) <(b)(6) @va.gov>; Zacher, Jennifer L. (PBM) (b)(6) @va.gov>; Strmiska, Jon G. <(b)(6) @va.gov>; Wiechers, Ilse (b)(6) @va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Feeder Response to OMHS: PBM provides this response to support OMHS statements (Dr Wiechers) regarding implementation timeline.

Question: Is there any more specific information that we can provide about timeline?

AMERICAN OVERSIGHT

(b5)

From: Wiechers, Ilse
Sent: Tuesday, June 18, 2019 1:27 PM
To: Carroll, David (VACO) (b)(6) @va.gov>; Strmiska, Jon G. (b)(6) @va.gov>; Ilse Wiechers (Yale) (b)(6) @yale.edu>; Torrise, Virginia (VHACO) (b)(6) @va.gov>
Cc: Daniels, Lindsay (b)(6) @va.gov>; Pomerantz, Andrew <(b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Hi – I'm in office and online. I'm working on some high-level bullet points summarizing our progress and will have them up and out to folks shortly.

Ginny – you can comment on the formulary decision, but I know that the MAP/VPE is considering esketamine on the agenda of this week's meeting on Thursday morning. I was planning to use language that states (b5)
(b5)
(b5) Please edit that statement as you feel most appropriate.

Ilse

From: Carroll, David (VACO)
Sent: Tuesday, June 18, 2019 10:23 AM
To: Strmiska, Jon G. (b)(6) @va.gov>; Ilse Wiechers (Yale) (b)(6) Wiechers, Ilse (b)(6) @va.gov>; Torrise, Virginia (VHACO) (b)(6) @va.gov>
Cc: Daniels, Lindsay <(b)(6) @va.gov>; Pomerantz, Andrew (b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Actually – Ilse responded on a similar request from Dr. Boyd. Looks like she may have something together later this afternoon.

From: Strmiska, Jon G.
Sent: Tuesday, June 18, 2019 1:17 PM
To: Ilse Wiechers (Yale) (b)(6) ; Wiechers, Ilse (b)(6) @va.gov>; Torrise, Virginia (VHACO) (b)(6) @va.gov>
Cc: Daniels, Lindsay (b)(6) @va.gov>; Pomerantz, Andrew <(b)(6) @va.gov>; VHA 10P4P Action <vha10P4Paction@va.gov>; Carroll, David (VACO) <(b)(6) @va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Ginny,

AMERICAN OVERSIGHT

As discussed, your assistance is greatly appreciated with providing a response on this one. Ilse is out of the office until tomorrow. Please see below and provide your response by **3pm today.**

New York Times is asking when a decision will be made as to when VA will be putting Spravato in its formulary. We recently provide the response below, highlighted yellow.

Is there any more specific information that we can provide about timeline?

FDA has approved the use of intranasal esketamine for adults with treatment-resistant depression (when used in conjunction with an oral antidepressant). VA has not yet administered esketamine to any patients, and is in the process of designing a clinical implementation plan optimized for safety and efficacy.

Thanks!

Jon G. Strmiska
Business Operations Manager (10NC5)
VA Central Office – Washington, DC
Phone: *(b)(6)*
FAX: 202.495.5933

From: Dudley, Tracy
Sent: Tuesday, June 18, 2019 1:00 PM
To: VHA 10NC5 Action <VHA10NC5Action@va.gov>
Cc: VHA CO 10NC Front Office HSSs <VHACO10NCFOHSSs@va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

GOOD Afternoon

Please see below and provide your response by **3pm today.**

Thank You!
Tracy

Tracy L. Dudley
Health System Specialist
ADUSH for Clinical Operations (10NC)
(b)(6) (Direct)
(b)(6) (iPhone)

From: Greilsamer, Alan
Sent: Tuesday, June 18, 2019 12:46 PM
To: VHA 10N Action <VHA10NAction@va.gov>; VHA 10NC Action <vha10ncaction@va.gov>
Cc: VHA 10NC5 Action <VHA10NC5Action@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

AMERICAN OVERSIGHT

Good afternoon,

New York Times is asking when a decision will be made as to when VA will be putting Spravato in its formulary. We recently provide the response below.

Is there any more specific information that we can provide about timeline?

FDA has approved the use of intranasal esketamine for adults with treatment-resistant depression (when used in conjunction with an oral antidepressant). VA has not yet administered esketamine to any patients, and is in the process of designing a clinical implementation plan optimized for safety and efficacy.

Requesting a response by today (June 18) NLT 5 p.m. ET.

Thanks, Alan

From: Cashour, Curtis
Sent: Tuesday, June 18, 2019 12:38 PM
To: Greilsamer, Alan <(b)(6) @va.gov>; Screen, Gina (b)(6) @va.gov>
Cc: Eason, William J. <William.Eason@va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Please let me know your recommended response to the below.

Thanks,

Curt Cashour
Press Secretary
Department of Veterans Affairs
(b)(6)
(b)(6) @va.gov
(b)(6)

From: Ben Carey <(b)(6) @nytimes.com>
Sent: Tuesday, June 18, 2019 12:35 PM
To: Cashour, Curtis <(b)(6) @va.gov>
Subject: Re: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Thanks Curt, please do. Main question for now is when is decision expected..? (i.e. how much time I got?)

Ben

Sent from my iPhone

On Jun 18, 2019, at 12:22 PM, Cashour, Curtis <(b)(6) @va.gov>wrote:

AMERICAN OVERSIGHT

Will keep you posted. Thanks, Ben.

Curt Cashour
Press Secretary
Department of Veterans Affairs
(b)(6)
(b)(6) @va.gov
(b)(6)

From: Carey, Ben (b)(6) @nytimes.com>
Sent: Tuesday, June 18, 2019 11:36 AM
To: Cashour, Curtis <(b)(6) @va.gov>
Subject: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Curt Cashour-

Hello from New York. It's Ben Carey emailing. I am a reporter in science at the NY Times, I cover psych topics. I have your email from Jennifer Steinhauer, NYT reporter in DC.

I would love to hear what/ when on the VA's expected decision this week whether to put Spravato on its formulary. Keep me in the loop on this, kindly, would be good to know when decision will be made, with some notice, and anything else VA puts out on this.

We'll likely cover decision either way.

Sincerely,

Ben Carey

Sender:	Valentino, Michael (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO, (b)(6) @va.gov>
Recipient:	Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b)(6) @va.gov>; Hastings, Patricia R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a504fbfe766048a5a65461c45f28e9de-Hastings, P (b)(6) @va.gov>
Sent Date:	2019/06/21 11:37:54
Delivered Date:	2019/06/21 11:37:56

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From:	Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd.SPDLT)/CN=RECIPIENTS/CN=F888D507D6C54EB5A92FC44199EB5838-LAW, CASSAN (b)(6) @va.gov>
To:	Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b)(6) @va.gov>
Subject:	RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision
Date:	2019/06/21 13:15:15
Priority:	Normal
Type:	Note

Terrific – 10B should clear soon and it'll be out of here.

From: Llorente, Maria D.
Sent: Friday, June 21, 2019 1:14 PM
To: Law, Cassandra M. <(b)(6) @va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

FYSA that it was run by OMH

From: Wiechers, Ilse
Sent: Friday, June 21, 2019 12:45 PM
To: Valentino, Michael (VACO) <(b)(6) @va.gov>; Snyder, Jill <(b)(6) @va.gov>; Cashour, Curtis <(b)(6) @va.gov>
Cc: Outlaw, William N. <(b)(6) @va.gov>; Greilsamer, Alan <(b)(6) @va.gov>; Zacher, Jennifer L. (PBM) <(b)(6) @va.gov>; Llorente, Maria D. <(b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Thanks so much, Mike and Maria. This looks great.

Sent with BlackBerry Work
(www.blackberry.com)

From: Valentino, Michael (VACO) <(b)(6) @va.gov>
Date: Friday, Jun 21, 2019, 9:17 AM
To: Wiechers, Ilse <(b)(6) @va.gov>, Snyder, Jill <(b)(6) @va.gov>, Cashour, Curtis <(b)(6) @va.gov>
Cc: Outlaw, William N. <(b)(6) @va.gov>, Greilsamer, Alan <(b)(6) @va.gov>, Zacher, Jennifer L. (PBM) <(b)(6) @va.gov>, Llorente, Maria D. <(b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Dr. Llorente and I drafted a statement for the NYT inquiry and I believe it will be coming forward soon.

Here it is but please consider it DRAFT:

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From: Wiechers, Ilse
Sent: Friday, June 21, 2019 12:07 PM
To: Snyder, Jill <(b)(6) @va.gov>; Valentino, Michael (VACO) <(b)(6) @va.gov>; Cashour, Curtis <(b)(6) @va.gov>
Cc: Outlaw, William N. <(b)(6) @va.gov>; Greilsamer, Alan (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) (b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Adding Jen Zacher for coordination purposes.

From: Snyder, Jill
Sent: Friday, June 21, 2019 9:02 AM
To: Valentino, Michael (VACO) (b)(6) @va.gov>; Wiechers, Ilse (b)(6) @va.gov>; Cashour, Curtis <(b)(6) @va.gov>
Cc: Outlaw, William N. (b)(6) @va.gov>; Greilsamer, Alan <(b)(6) @va.gov>; Snyder, Jill <(b)(6) @va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Good afternoon Mike and Ilse,

I know you all are working on media responses regarding Ketamine, however we just received an email from the Boston Globe that the decision was made NOT to include it in the formulary. Please see email below and I am including Curt Cashour, VA Press Secretary, on this message to streamline responses.

Thank you,
Jill

From: Silverman, Ed <(b)(6) @statnews.com>
Sent: Friday, June 21, 2019 11:24 AM
To: VA Public Affairs <VAPublicAffairs@va.gov>
Subject: [EXTERNAL] question from a journalist

Hi ,

My name is Ed Silverman and I work for The Boston Globe's STAT News health site, where I track the pharmaceutical industry.

I understand a VA committee voted not to include a new Johnson&Johnson antidepressant spray drug called Spravato on its pharmacy list.

Can you please confirm and explain why the committee voted not to include it?

Thanks
ed silverman

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(b)(6)

www.statnews.com/pharmalot/

From: Snyder, Jill
Sent: Friday, June 21, 2019 9:59 AM
To: Cashour, Curtis <(b)(6) @va.gov>; Greilsamer, Alan <(b)(6) @va.gov>
Cc: Eason, William J. <(b)(6) @va.gov>; Screen, Gina <(b)(6) @va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Hi Curt –

I am following this in Alan's absence, program office is still working on the response, I will continue to follow up.

Thanks,
Jill

From: Cashour, Curtis
Sent: Friday, June 21, 2019 9:57 AM
To: Greilsamer, Alan <(b)(6) @va.gov>; Snyder, Jill <(b)(6) @va.gov>
Cc: Eason, William J. (b)(6) @va.gov>; Screen, Gina <(b)(6) @va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Just following up here. Thanks.

From: Greilsamer, Alan
Sent: Thursday, June 20, 2019 3:34 PM
To: Cashour, Curtis (b)(6) @va.gov>
Cc: Eason, William J. (b)(6) @va.gov>; Screen, Gina <(b)(6) @va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

We will try to pin them down on a timeframe.

—
Alan Greilsamer
Director, Media Relations (10B2B)
Office of Communications
Veterans Health Administration
P: (b)(6)
E:(b)(6) @va.gov

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From: Cashour, Curtis (b)(6) @va.gov>
Date: Thursday, Jun 20, 2019, 3:18 PM
To: Greilsamer, Alan (b)(6) @va.gov>
Cc: Eason, William J (b)(6) @va.gov>, Screen, Gina (b)(6) @va.gov>, VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Is there an update here?

The original question was when will VA make a decision about putting spravato on the formulary.

Thanks,

Curt Cashour
Press Secretary
Department of Veterans Affairs
(b)(6)
(b)(6) @va.gov
(b)(6)

From: Greilsamer, Alan
Sent: Wednesday, June 19, 2019 9:05 AM
To: Cashour, Curtis <(b)(6) @va.gov>
Cc: Eason, William J. <(b)(6) @va.gov>; Screen, Gina (b)(6) @va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

VHA clears

In March 2019, two weeks after the FDA approved intranasal esketamine for use in conjunction with an oral antidepressant for the treatment of treatment-resistant depression in adults, VA announced the treatment would be made available to Veterans based on their individual medical needs combined with providers' clinical assessments. VA is now preparing a thoughtful, step-wise approach to clinical implementation of esketamine that puts Veteran safety first and ensures close, careful monitoring of potential adverse events, including the risk of addiction. This reflects VA's commitment to seek new ways to provide the best health care available for our nation's Veterans.

Additional information

Steps VA has taken to date include:

- • The first dose of intranasal esketamine was safely administered today, June 18, 2019, to a Veteran with treatment-resistant depression at the VA Boston Healthcare System.
- • A standardized informed consent document and supporting patient education materials have been made available nationally through VHA's electronic signed consent platform.
- • VHA established a national Esketamine Clinical Implementation Workgroup, which has representation from key VA Central Office stakeholder groups, facility leadership, and subject matter experts in ketamine and esketamine treatments for mental health disorders.

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- • VHA has launched the Esketamine Community of Practice, a virtual learning community that will combine regular teleconferences and a repository of resources to provide a forum for discussing progress in implementation and developing best practices while also ensuring clear communication across the organization.
- • 13 sites have confirmed their participation as Early Adopters, and will work together supported by the Esketamine Community of Practice and the Esketamine Clinical Implementation Workgroup to implement clinical use of esketamine at their sites this summer and fall.

Ongoing next steps include:

- • VA anticipates having final decisions about Pharmacy Benefits Management policies, including criteria for use, national protocol guidance, and formulary status by end of this week, pending ongoing deliberations of the Medical Advisory Panel and VISN Pharmacy Executive Committees.

- • Development of a Medication Use Evaluation (MUE) which focuses on safety monitoring is underway, with anticipated implementation of the data entry portal in July 2019. The MUE will facilitate data reporting for the FDA REMS and will gather additional safety and monitoring data on all use of esketamine within VHA.

From: Cashour, Curtis
Sent: Tuesday, June 18, 2019 12:38 PM
To: Greilsamer, Alan <(b)(6) @va.gov>; Screen, Gina <(b)(6) @va.gov>
Cc: Eason, William J. (b)(6) @va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Please let me know your recommended response to the below.

Thanks,

Curt Cashour
Press Secretary
Department of Veterans Affairs
(b)(6)
(b)(6) @va.gov
(b)(6)

From: Ben Carey <(b)(6) @nytimes.com>
Sent: Tuesday, June 18, 2019 12:35 PM
To: Cashour, Curtis <(b)(6) @va.gov>
Subject: Re: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Thanks Curt, please do. Main question for now is when is decision expected..? (i.e. how much time I got?)

Ben

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Sent from my iPhone

On Jun 18, 2019, at 12:22 PM, Cashour, Curtis <(b)(6) @va.gov>wrote:

Will keep you posted. Thanks, Ben.

Curt Cashour
Press Secretary
Department of Veterans Affairs
(b)(6)
(b)(6) @va.gov
(b)(6)

From: Carey, Ben <(b)(6) @nytimes.com>
Sent: Tuesday, June 18, 2019 11:36 AM
To: Cashour, Curtis <(b)(6) @va.gov>
Subject: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Curt Cashour-

Hello from New York. It's Ben Carey emailing. I am a reporter in science at the NY Times, I cover psych topics. I have your email from Jennifer Steinhauer, NYT reporter in DC.

I would love to hear what/ when on the VA's expected decision this week whether to put Spravato on its formulary. Keep me in the loop on this, kindly, would be good to know when decision will be made, with some notice, and anything else VA puts out on this.

We'll likely cover decision either way.

Sincerely,

Ben Carey

Sender:	Law, Cassandra M. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F888D507D6C54EB5A92FC44199EB5838-LAW, CASSAN <(b)(6) @va.gov>
Recipient:	Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b)(6) @va.gov>
Sent Date:	2019/06/21 13:15:14
Delivered Date:	2019/06/21 13:15:15

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From:	Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd.DIBOHF23SPDLT)/CN=RECIPIENTS/CN=519204DF507344AC8FA3045B2B4FC762-TORRISE, VI (b)(6) @va.gov>
To:	Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen (b)(6) @va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b)(6) @va.gov>
CC:	Torphy, Lisa /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43ab37387c5c4ed6bae3006dcde84582-Torphy, Lis (b)(6) @va.gov>; Szudarski, Lucy (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d92492f1757463da2417401f68a598e-Szudarski, (b)(6) @va.gov>
Subject:	RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision
Date:	2019/06/18 13:43:18
Priority:	Normal
Type:	Note

thanks

From: Zacher, Jennifer L. (PBM)
Sent: Tuesday, June 18, 2019 1:43 PM
To: Torrise, Virginia (VHACO) (b)(6) @va.gov>; Valentino, Michael (VACO) (b)(6) @va.gov>
Cc: Torphy, Lisa (b)(6) @va.gov>; Szudarski, Lucy (PBM) (b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Hi Ginny,
I am online. The statement looks good to me! Totally accurate.
JZ

From: Torrise, Virginia (VHACO)
Sent: Tuesday, June 18, 2019 12:32 PM
To: Zacher, Jennifer L. (PBM) (b)(6) @va.gov>; Valentino, Michael (VACO) (b)(6) @va.gov>
Cc: Torphy, Lisa (b)(6) @va.gov>; Szudarski, Lucy (PBM) (b)(6) @va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Lisa/Lucy
Are you able to contact Jenn to provide a statement? Proposed statement below.

From: Wiechers, Ilse
Sent: Tuesday, June 18, 2019 1:27 PM
To: Carroll, David (VACO) (b)(6) @va.gov>; Strmiska, Jon G. (b)(6) @va.gov>; Ilse Wiechers (Yale) (b)(6) @yale.edu>; Torrise, Virginia (VHACO) (b)(6) @va.gov>

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Cc: Daniels, Lindsay (b)(6) @va.gov>; Pomerantz, Andrew (b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Hi – I'm in office and online. I'm working on some high-level bullet points summarizing our progress and will have them up and out to folks shortly.

Ginny – you can comment on the formulary decision, but I know that the MAP/VPE is considering esketamine on the agenda of this week's meeting on Thursday morning. I was planning to use language that states (b5) [redacted] Please edit that statement as you feel most appropriate.

Ilse

From: Carroll, David (VACO)
Sent: Tuesday, June 18, 2019 10:23 AM
To: Strmiska, Jon G. (b)(6) @va.gov>; Ilse Wiechers (Yale) (b)(6) Wiechers, Ilse (b)(6) @va.gov>; Torrise, Virginia (VHACO) (b)(6) @va.gov>
Cc: Daniels, Lindsay (b)(6) @va.gov>; Pomerantz, Andrew (b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Actually – Ilse responded on a similar request from Dr. Boyd. Looks like she may have something together later this afternoon.

From: Strmiska, Jon G.
Sent: Tuesday, June 18, 2019 1:17 PM
To: Ilse Wiechers (Yale) (b)(6) Wiechers, Ilse (b)(6) @va.gov>; Torrise, Virginia (VHACO) (b)(6) @va.gov>
Cc: Daniels, Lindsay <(b)(6) @va.gov>; Pomerantz, Andrew <(b)(6) @va.gov>; VHA 10P4P Action <vha10P4Paction@va.gov>; Carroll, David (VACO) <(b)(6) @va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Ginny,

As discussed, your assistance is greatly appreciated with providing a response on this one. Ilse is out of the office until tomorrow. Please see below and provide your response by **3pm today.**

New York Times is asking when a decision will be made as to when VA will be putting Spravato in its formulary. We recently provide the response below, highlighted yellow.

Is there any more specific information that we can provide about timeline?

FDA has approved the use of intranasal esketamine for adults with treatment-resistant depression (when used in conjunction with an oral antidepressant). VA has not yet

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administered esketamine to any patients, and is in the process of designing a clinical implementation plan optimized for safety and efficacy.

Thanks!

Jon G. Strmiska
Business Operations Manager (10NC5)
VA Central Office – Washington, DC
Phone: *(b)(6)*
FAX: 202.495.5933

From: Dudley, Tracy
Sent: Tuesday, June 18, 2019 1:00 PM
To: VHA 10NC5 Action <VHA10NC5Action@va.gov>
Cc: VHA CO 10NC Front Office HSSs <VHACO10NCFOHSSs@va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

GOOD Afternoon

Please see below and provide your response by **3pm today.**

Thank You!
Tracy

Tracy L. Dudley
Health System Specialist
ADUSH for Clinical Operations (10NC)
(b)(6) (Direct)
(b)(6) (iPhone)

From: Greilsamer, Alan
Sent: Tuesday, June 18, 2019 12:46 PM
To: VHA 10N Action <VHA10NAction@va.gov>; VHA 10NC Action <vha10ncaction@va.gov>
Cc: VHA 10NC5 Action <VHA10NC5Action@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

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administered esketamine to any patients, and is in the process of designing a clinical implementation plan optimized for safety and efficacy.

Requesting a response by today (June 18) NLT 5 p.m. ET.

Thanks, Alan

From: Cashour, Curtis
Sent: Tuesday, June 18, 2019 12:38 PM
To: Greilsamer, Alan <(b)(6) @va.gov>; Screen, Gina <(b)(6) @va.gov>
Cc: Eason, William J. (b)(6) @va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Please let me know your recommended response to the below.

Thanks,

Curt Cashour
Press Secretary
Department of Veterans Affairs
(b)(6)
(b)(6) @va.gov
(b)(6)

From: Ben Carey (b)(6) @nytimes.com>
Sent: Tuesday, June 18, 2019 12:35 PM
To: Cashour, Curtis (b)(6) @va.gov>
Subject: Re: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Thanks Curt, please do. Main question for now is when is decision expected..? (i.e. how much time I got?)

Ben

Sent from my iPhone

On Jun 18, 2019, at 12:22 PM, Cashour, Curtis (b)(6) @va.gov>wrote:

Will keep you posted. Thanks, Ben.

Curt Cashour
Press Secretary
Department of Veterans Affairs
(b)(6)
(b)(6) @va.gov
(b)(6)

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From: Carey, Ben <(b)(6) @nytimes.com>
Sent: Tuesday, June 18, 2019 11:36 AM
To: Cashour, Curtis <(b)(6) @va.gov>
Subject: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Curt Cashour-

Hello from New York. It's Ben Carey emailing. I am a reporter in science at the NY Times, I cover psych topics. I have your email from Jennifer Steinhauer, NYT reporter in DC.

I would love to hear what/ when on the VA's expected decision this week whether to put Spravato on its formulary. Keep me in the loop on this, kindly, would be good to know when decision will be made, with some notice, and anything else VA puts out on this.

We'll likely cover decision either way.

Sincerely,

Ben Carey

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Sent Date:	2019/06/18 13:43:17
Delivered Date:	2019/06/18 13:43:18
Message Flags:	Unread

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From:	Fuller, Matthew A. (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=62D9CBB23B184CACB98895776E36A471-FULLER, MAT>
To:	Nazario, Mitchell /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e909581b30643148ba99ab7ff79cae0-Nazario, Mi (b)(6) @va.gov>
Subject:	RE: [EXTERNAL] ICER Releases Draft Evidence Report on Esketamine for Treatment-Resistant Depression
Date:	2019/03/25 09:00:00
Priority:	Normal
Type:	Note

Thanks Mitch! No, I have not seen the report. Thanks.

From: Nazario, Mitchell
Sent: Monday, March 25, 2019 8:17 AM
To: Fuller, Matthew A. (PBM) (b)(6) @va.gov>
Subject: FW: [EXTERNAL] ICER Releases Draft Evidence Report on Esketamine for Treatment-Resistant Depression

Hi Matt,

In case you didn't see this.

Mitch

From: Institute for Clinical and Economic Review <info@icer-review.org>
Sent: Thursday, March 21, 2019 4:22 PM
To: Nazario, Mitchell (b)(6) @va.gov>
Subject: [EXTERNAL] ICER Releases Draft Evidence Report on Esketamine for Treatment-Resistant Depression

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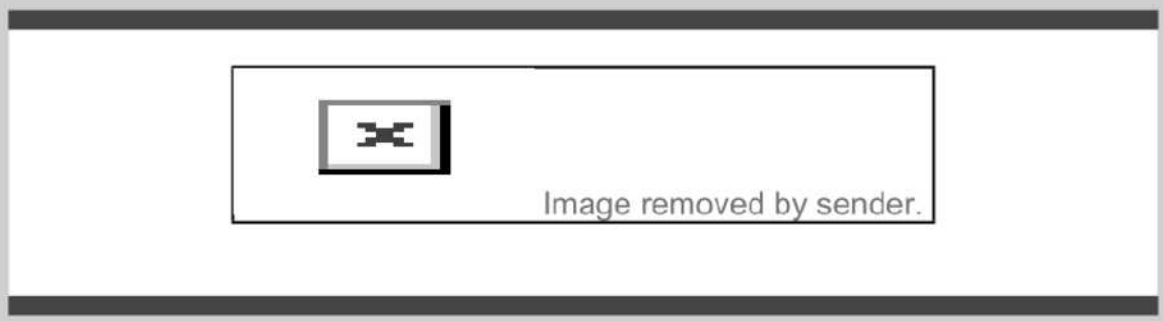

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Institute for Clinical and Economic Review Releases Draft Evidence Report on Esketamine for Treatment-Resistant Depression

-- Public comment period now open until April 17, 2019; Requests to make oral comment during public meeting also being accepted --

BOSTON, March 21, 2019 - The Institute for Clinical and Economic Review (ICER) today released a Draft Evidence Report assessing the clinical effectiveness and value of esketamine (Spravato™, Janssen) for treatment-resistant depression.

This draft report will be open to public comment until 5pm ET on April 17, 2019. Based on stakeholder feedback, ICER may revise key assumptions and findings for its Evidence Report, which will be published on May 9, 2019. The Evidence Report will be subject to deliberation during a public meeting of the Midwest Comparative Effectiveness Public Advisory Council (Midwest CEPAC), one of ICER's three independent evidence appraisal committees, on May 23, 2019.

ICER is committed to engaging with all stakeholders in a thorough and transparent manner. During this review, ICER has spoken with patients, clinical experts, insurers, and manufacturers. Public comments were also accepted on a Draft Scoping Document. The current draft report incorporates input received from patients, clinicians, and other stakeholders during each of these opportunities for engagement.

Submit a Public Comment

The Draft Evidence Report and Draft Voting Questions are now open to public comment until 5 PM ET on April 17, 2019. All stakeholders are invited to submit formal comments by email to publiccomments@icer-review.org. Guidelines for submitting public comments, including formatting specifications, are available on ICER's website. ICER's Manufacturer Engagement Guide and Patient Participation Guide provide additional detail on what types of information may be most informative to the report.

ICER will review all comments and incorporate any necessary changes in the Evidence Report and Revised Voting Questions that will be posted on or about May 9, 2019. All comments and ICER's response to comments will be posted publicly along with the Evidence Report.

Register for the Public Meeting

The Evidence Report will be the subject of a public meeting of the Midwest CEPAC on May 23, 2019 in Rosemont, IL. During the meeting, the independent council will vote on key questions raised in the report. Registration for the public meeting and live webcast is now open.

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Register to Make an Oral Comment

During the public meeting, there will be a limited amount of time available for interested stakeholders to make an oral comment on the report. Requests to submit oral comments must be emailed to publiccomments@icer-review.org by 5 PM ET on April 17, 2019. Individuals who wish to deliver oral comments must separately register to attend the meeting. For more information about registering for oral comment, please visit our website.

About ICER

The Institute for Clinical and Economic Review (ICER) is an independent non-profit research institute that produces reports analyzing the evidence on the effectiveness and value of drugs and other medical services. ICER's reports include evidence-based calculations of prices for new drugs that accurately reflect the degree of improvement expected in long-term patient outcomes, while also highlighting price levels that might contribute to unaffordable short-term cost growth for the overall health care system.

ICER's reports incorporate extensive input from all stakeholders and are the subject of public hearings through three core programs: the California Technology Assessment Forum (CTAF), the Midwest Comparative Effectiveness Public Advisory Council (Midwest CEPAC), and the New England Comparative Effectiveness Public Advisory Council (New England CEPAC). These independent panels review ICER's reports at public meetings to deliberate on the evidence and develop recommendations for how patients, clinicians, insurers, and policymakers can improve the quality and value of health care. For more information about ICER, please visit ICER's website.

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Sender:	Fuller, Matthew A. (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=62D9CBB23B184CACB98895776E36A471-FULLER, MAT>
Recipient:	Nazario, Mitchell /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e909581b30643148ba99ab7ff79cae0-Nazario, Mi (b)(6) @va.gov>
Sent Date:	2019/03/25 09:00:33
Delivered Date:	2019/03/25 09:00:00

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From:	Fuller, Matthew A. (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=62D9CBB23B184CACB98895776E36A471-FULLER, MAT>
To:	Glassman, Peter A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90608d43ef14423db308fb6c71ed750b-Glassman, P (b)(6) @va.gov>
Subject:	RE: [EXTERNAL] ICER Issues Final Report and Policy Recommendations on Esketamine for Treatment-Resistant Depression
Date:	2019/06/21 15:18:00
Priority:	Normal
Type:	Note

Completely agree and Thanks.

From: Glassman, Peter A.
Sent: Friday, June 21, 2019 3:17 PM
To: Fuller, Matthew A. (PBM) (b)(6) @va.gov>
Subject: RE: [EXTERNAL] ICER Issues Final Report and Policy Recommendations on Esketamine for Treatment-Resistant Depression

I believe so, too—(b) (6) [redacted] and thanks for all your effort on this.

"Given the considerable uncertainty that remains regarding the longer-term benefits and risks of esketamine, it is reasonable for insurers and other payers to develop prior authorization criteria to ensure that patients are carefully selected and managed by clinicians with the necessary expertise to ensure appropriate care."

From: Fuller, Matthew A. (PBM)
Sent: Friday, June 21, 2019 12:12 PM
To: Glassman, Peter A. (b)(6) @va.gov>
Subject: RE: [EXTERNAL] ICER Issues Final Report and Policy Recommendations on Esketamine for Treatment-Resistant Depression

Looks like we did the right thing.

From: Glassman, Peter A.
Sent: Thursday, June 20, 2019 7:35 PM
To: Fuller, Matthew A. (PBM) (b)(6) @va.gov>
Subject: FW: [EXTERNAL] ICER Issues Final Report and Policy Recommendations on Esketamine for Treatment-Resistant Depression

FYI

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From: Institute for Clinical and Economic Review <info@icer-review.org>
Date: Thursday, Jun 20, 2019, 4:47 PM
To: Glassman, Peter A. (b)(6) @va.gov>
Subject: [EXTERNAL] ICER Issues Final Report and Policy Recommendations on Esketamine for Treatment-Resistant Depression

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Institute for Clinical and Economic Review Issues Final Report and Policy Recommendations on Esketamine for Treatment-Resistant Depression

-- Independent appraisal committee votes that evidence is adequate to demonstrate clinical benefits of esketamine versus placebo, but concerns remain about the study criteria used to define treatment-resistant depression and the lack of longer-term data on esketamine's safety and effectiveness --

-- Esketamine's list price would require a 25-52% discount to reach a fair value-based price benchmark, and the potential short-term budget impact associated with treating the eligible patient population leads ICER to issue an Access and Affordability Alert --

BOSTON, June 20, 2019 - The Institute for Clinical and Economic Review (ICER) today released a Final Evidence Report and Report-at-a-Glance assessing the comparative clinical effectiveness and value of esketamine (Spravato™, Janssen), a nasal spray approved by the FDA in March as a therapy for treatment-resistant depression (TRD). Esketamine is one of the two mirror-image molecules (enantiomers) that make up ketamine, an anesthetic that is commonly used off-label to treat TRD.

ICER's report was reviewed at the May 2019 public meeting of the Midwest Comparative Effectiveness Public Advisory Council (Midwest CEPAC), one of ICER's three independent

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evidence appraisal committees. During the meeting, the CEPAC found that the evidence demonstrated esketamine plus background antidepressant to be clinically superior to background antidepressant alone. The CEPAC members found the evidence to be insufficient to demonstrate a difference in net health benefit between esketamine and ketamine, transcranial magnetic stimulation, electroconvulsive therapy, or augmentation with olanzapine.

During their deliberation, panel members weighed the therapies' other benefits and contextual considerations. They acknowledged that esketamine is intended to care for patients with a condition of high severity and a high lifetime burden of illness, and that esketamine offers a novel mechanism of action compared to other approved treatments for TRD, which may allow successful treatment of many patients for who other available treatments have failed. Nevertheless, a majority of the panel felt that there is uncertainty about the long-term benefits and risks of esketamine, citing the lack of long-term trial evidence.

ICER's evaluation of long-term cost-effectiveness found that the fair value-based price benchmark for esketamine is between $17,700 and $25,200 per year, a range that would require a 25-52% discount from the announced list price of $32,400. Consistent with ICER's value-assessment framework, esketamine is deemed to deliver a "low value for money" because the treatment's incremental cost-effectiveness ratio, using the current list price, exceeds $175,000 per quality-adjusted life year (QALY) gained.

"Treatment-resistant forms of major depression are common and have large negative effects on patient quality of life, so new therapies are badly needed," said David Rind, MD, ICER's Chief Medical Officer. "It is hard to understand how a price exceeding usual cost-effectiveness thresholds is appropriate for a treatment that could be very widely used, particularly when that price is an order of magnitude higher than that of intravenous generic ketamine, a closely related therapy."

Affordability &Access Alert

Given that the clinical goal for uptake would exceed the potential budget impact threshold at the national level, ICER is issuing an Affordability and Access Alert as part of its final report on esketamine. Clinical experts queried at the public meeting suggested that esketamine would not be viewed as an appropriate treatment for all patients with TRD, but that roughly half of eligible patients may be offered the option during consultation with their physician. However, at esketamine's current list price, only 16% of eligible Americans with TRD could receive the treatment before crossing ICER's potential budget threshold of $819 million per year. Even if esketamine's price was lowered to ICER's value-based price benchmark range for long-term cost-effectiveness, only 20-30% of all eligible patients with TRD could be treated with esketamine before exceeding the potential budget impact threshold.

The purpose of an ICER Affordability and Access Alert is to signal to stakeholders and policy makers that the amount of added health care costs associated with a new service may be difficult for the health system to absorb over the short term without displacing other needed services or contributing to rapid growth in health care insurance costs that threaten sustainable access to high-value care for all patients.

Key Policy Recommendations

Following the voting session, a policy roundtable of experts - including clinicians, patient

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VA-19-1109-B-001398

advocates, and payer representatives - convened to discuss the implications of the evidence for policy and practice. Key recommendations stemming from the roundtable discussion include:

- • Manufacturers and researchers should conduct studies directly comparing esketamine and other treatment options using standardized research protocols and outcomes that reflect what matters most to patients; this would allow real-world, long-term assessment of comparative effectiveness.

- • Given the considerable uncertainty that remains regarding the longer-term benefits and risks of esketamine, it is reasonable for insurers and other payers to develop prior authorization criteria to ensure that patients are carefully selected and managed by clinicians with the necessary expertise to ensure appropriate care.

- • Payers should develop mechanisms to adequately compensate clinicians for the expenses associated with monitoring and delivering esketamine within the specification of the REMS program.

ICER's detailed set of policy recommendations, including considerations for establishing prior authorization criteria, is available in the Final Evidence Report.

About ICER

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Recipient:	Glassman, Peter A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90608d43ef14423db308fb6c71ed750b-Glassman, P (b)(6) @va.gov>
Sent Date:	2019/06/21 15:18:10
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Subject:	RE: [EXTERNAL] ICER Issues Final Report and Policy Recommendations on Esketamine for Treatment-Resistant Depression
Date:	2019/06/21 08:09:00
Priority:	Normal
Type:	Note

Pete,

Thanks for sending.

Matthew

From: Glassman, Peter A.
Sent: Thursday, June 20, 2019 7:35 PM
To: Fuller, Matthew A. (PBM) (b)(6) @va.gov>
Subject: FW: [EXTERNAL] ICER Issues Final Report and Policy Recommendations on Esketamine for Treatment-Resistant Depression

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Date: Thursday, Jun 20, 2019, 4:47 PM
To: Glassman, Peter A. (b)(6) @va.gov>
Subject: [EXTERNAL] ICER Issues Final Report and Policy Recommendations on Esketamine for Treatment-Resistant Depression

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VA-19-1109-B-001402

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- • Given the considerable uncertainty that remains regarding the longer-term benefits

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VA-19-1109-B-001403

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Sent Date:	2019/06/21 08:09:04
Delivered Date:	2019/06/21 08:09:00

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From:	Carroll, David (VACO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=95E14EBD3B6745C8952A823B04DABFF5-CARROLL, DA>
To:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b)(6) @va.gov>
CC:	VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>
Subject:	RE: [EXTERNAL] 18 June Veterans Affairs Media Summary and News Clips
Date:	2019/06/18 10:33:00
Priority:	Normal
Type:	Note

Yes – and it is something that may come up at the SVAC hearing tomorrow (which about the Executive Order, but….). I sent Keita the statement that we prepared for VHA Comms last week, and noted that nothing in VA's work with J&J in 2017 was related to the development of Spravato.

Two weeks after the FDA approved intranasal esketamine for use in conjunction with an oral antidepressant for the treatment of treatment-resistant depression in adults, the VA announced the treatment would be made available to Veterans based on their individual medical needs combined with providers' clinical assessments. VA is now preparing a thoughtful, step-wise approach to clinical implementation of esketamine that puts Veteran safety first and ensures close, careful monitoring of potential adverse events, including the risk of addiction. This reflects our commitment to seek new ways to provide the best health care available for our nation's Veterans. Initial use of this treatment is anticipated for this summer at several sites across the country.

From: Wiechers, Ilse
Sent: Tuesday, June 18, 2019 10:22 AM
To: VHA 10NC5 Action <VHA10NC5Action@va.gov>
Subject: FW: [EXTERNAL] 18 June Veterans Affairs Media Summary and News Clips

FYI – item 1.4 appears to be the result of the media and FOIA requests re esketamine by the reporter with Center for Public Integrity.

From: Valentino, Michael (VACO)
Sent: Tuesday, June 18, 2019 5:00 AM
To: Llorente, Maria D. <(b)(6) @va.gov>; Wiechers, Ilse <(b)(6) @va.gov>; Glassman, Peter A. <(b)(6) @va.gov>; Zacher, Jennifer L. (PBM) <(b)(6) @va.gov>; Emmendorfer, Thomas (PBM) <(b)(6) @va.gov>
Subject: FW: [EXTERNAL] 18 June Veterans Affairs Media Summary and News Clips

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Article on VA and esketamine....item 1.4

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From: VA Media Analysis <VAMediaAnalysis@barbaricum.com>
Date: Tuesday, Jun 18, 2019, 5:18 AM
To: Barbaricum VA Media Analysis <VAMediaAnalysis@barbaricum.com>
Subject: [EXTERNAL] 18 June Veterans Affairs Media Summary and News Clips

Good morning,

Please find the attached Veterans Affairs Media Summary and News Clips.

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Recipient:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b)(6) @va.gov>; VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>
Sent Date:	2019/06/18 10:33:34
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From:	Glassman, Peter A. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90608D43EF14423DB308FB6C71ED750B-GLASSMAN, P (b)(6) @va.gov>
To:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M (b)(6) @va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen (b)(6) @va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>
Subject:	RE: [EXTERNAL] 18 June Veterans Affairs Media Summary and News Clips
Date:	2019/06/18 08:55:34
Priority:	Normal
Type:	Note

Thanks Mike.

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From: Valentino, Michael (VACO) <(b)(6) @va.gov>
Date: Tuesday, Jun 18, 2019, 7:00 AM
To: Llorente, Maria D. <(b)(6) @va.gov>, Wiechers, Ilse (b)(6) @va.gov>, Glassman, Peter A. <(b)(6) @va.gov>, Zacher, Jennifer L. (PBM) <(b)(6) @va.gov>, Emmendorfer, Thomas (PBM) <(b)(6) @va.gov>
Subject: FW: [EXTERNAL] 18 June Veterans Affairs Media Summary and News Clips

Article on VA and esketamine....item 1.4

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From: VA Media Analysis <VAMediaAnalysis@barbaricum.com>
Date: Tuesday, Jun 18, 2019, 5:18 AM
To: Barbaricum VA Media Analysis <VAMediaAnalysis@barbaricum.com>
Subject: [EXTERNAL] 18 June Veterans Affairs Media Summary and News Clips

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BARBARICUM http://fileshare.barbaricum.com.s3.amazonaws.com/BBCM.jpeg

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Recipient:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M (b)(6) @va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen (b)(6) @va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>
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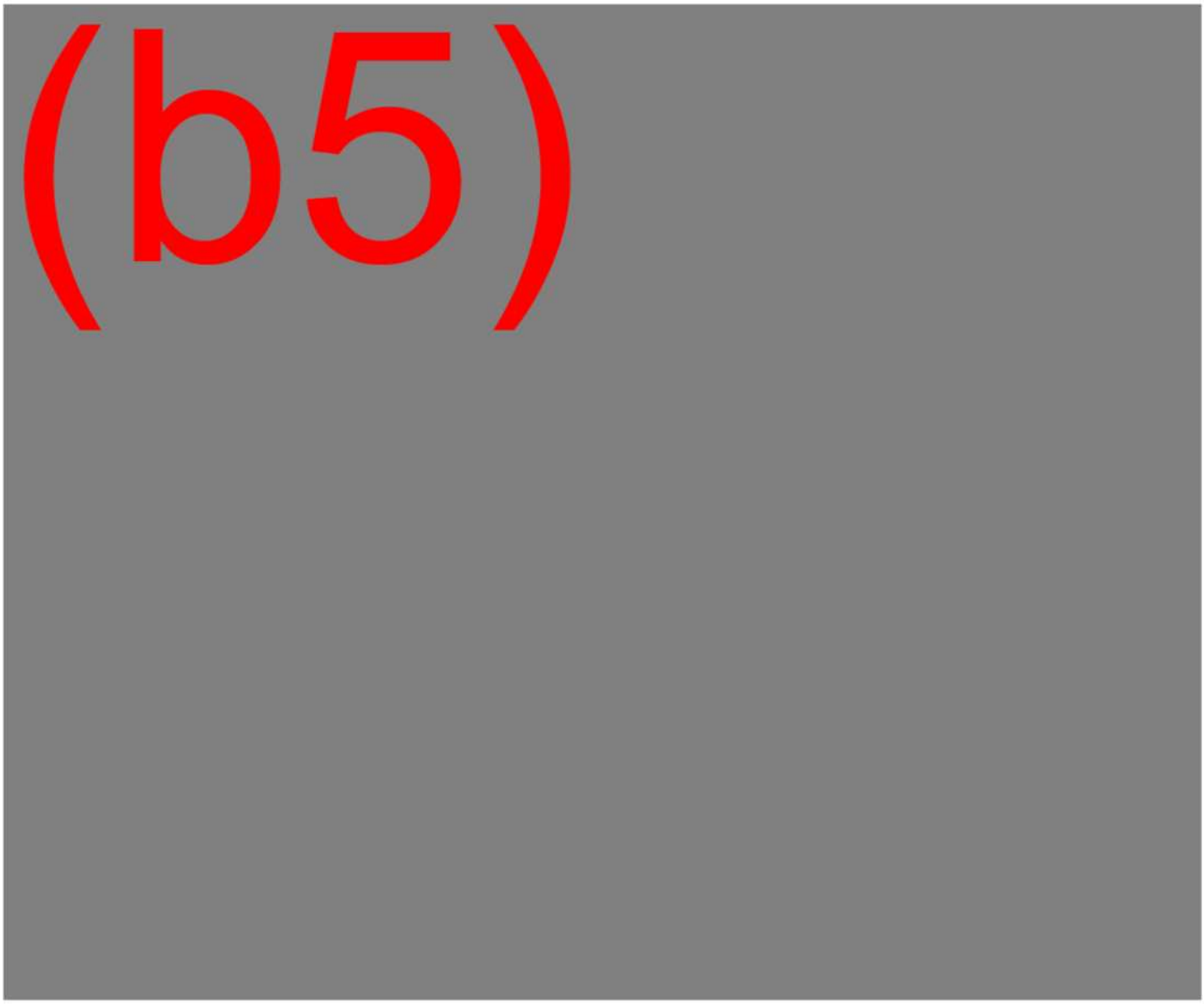
From:	Torphy, Lisa /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=43AB37387C5C4ED6BAE3006DCDE84582-TORPHY, LIS (b)(6) @va.gov>
To:	Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat (b)(6) @va.gov>
Subject:	Please edit June F2F minutes
Date:	2019/06/27 15:05:19
Priority:	Normal
Type:	Note

I apologize in advance if my notes are horrific...so please edit with extra scrutiny. ☹



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Sent Date:	2019/06/27 15:05:18
Delivered Date:	2019/06/27 15:05:19

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Spravato™ (esketamine) C III
nasal spray

Demonstrating the Value of SPRAVATO™ in Adult Patients With Treatment-Resistant Depression

SPRAVATO™ is a non-competitive N-methyl D-aspartate (NMDA) receptor antagonist indicated, in conjunction with an oral antidepressant, for the treatment of treatment-resistant depression (TRD) in adults

WARNING: SEDATION, DISSOCIATION; ABUSE AND MISUSE; and SUICIDAL THOUGHTS AND BEHAVIORS
See full prescribing information for complete boxed warning

- **Risk for sedation and dissociation after administration. Monitor patients for at least two hours after administration (5.1, 5.2).**
- **Potential for abuse and misuse. Consider the risks and benefits of using SPRAVATO™ prior to use in patients at higher risk of abuse. Monitor for signs and symptoms of abuse and misuse (5.3).**
- **SPRAVATO™ is only available through a restricted program called the SPRAVATO™ REMS (5.4).**
- **Increased risk of suicidal thoughts and behaviors in pediatric and young adult patients taking antidepressants. Closely monitor all antidepressant-treated patients for clinical worsening and emergence of suicidal thoughts and behaviors. SPRAVATO™ is not approved for use in pediatric patients (5.5).**

Please see Important Safety Information, including Boxed WARNINGS, on slides 31-35.
Please see full Prescribing Information, including Boxed WARNINGS for SPRAVATO™, available at this presentation.
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Presentation Purpose and Scope

Spravato™ (esketamine) CIII nasal spray

- This presentation is intended to discuss the use of SPRAVATO™ (esketamine) CIII nasal spray in conjunction with an oral AD in adult patients with treatment-resistant depression (TRD)
- The presentation is intended to enable population health decision makers (PHDMs) within treatment centers to make informed formulary decisions
- Population health decision makers are encouraged to review the full study methodology, results, and limitations for each study referenced in this presentation
- This presentation is not intended to imply, directly or indirectly, that medication alone will impact healthcare utilization in adult patients with TRD
- The intent of the clinical value section is to review the clinical efficacy and safety data from the short-and-long-term phase 3 trials of SPRAVATO™
- The intent of the disease burden and unmet need section is to review TRD-related healthcare utilization in the United States for adult patients with TRD
- This document contains data from studies sponsored or conducted by Janssen Research & Development and Janssen Scientific Affairs, LLC

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Disease Burden and Unmet Need >

Clinical Value >

Access and Operational Considerations >

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Disease Burden and Unmet Need

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Health Economics Study Limitations

- The information in this section is based on real-world data including medical and pharmacy claims and secondary survey database, and not on randomized controlled studies
- Results may be subject to biases from other confounding variables that were not recorded in the database. Records are subject to possible billing and coding errors and missing data
- Retrospective database analyses are subject to risk of bias (e.g., an association that is not true) and confounding (e.g., an association that is true but misleading)[1]
- Biases include selection bias (e.g., only patients with required follow-up included in analysis) and informational bias (e.g., patients receive the wrong diagnosis code)[1]
- Confounding occurs when the difference in baseline characteristics results in differences in the outcome apart from the exposure or intervention[1]
- Studies outlined in this presentation each have different definitions of TRD which are cited for each individual study within the presentation

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VA-19-1109-B-001416

Health Economics Study Limitations

- The information in this section is based on real-world data including medical and pharmacy claims and secondary survey database, and not on randomized controlled studies
- Results may be subject to biases from other confounding variables that were not recorded in the database. Records are subject to possible billing and coding errors and missing data
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Reference

1. Agency for Healthcare Research and Quality. Methods for effectiveness and comparative effectiveness reviews. https://effectivehealthcare.ahrq.gov/sites/default/files/pdf/cer-methods-guide_overview.pdf. Published January 2014. Accessed March 1, 2019.

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VA-19-1109-B-001417

Treatment-Resistant Depression (TRD) Adult Patient Population

Health Resource Utilization in Patients With TRD

Cost Consequences of TRD

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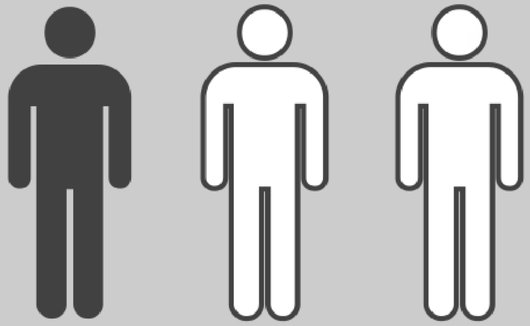
Two-thirds of Adult Patients With MDD May Achieve Remission of Depressive Symptoms; However, 1 in 3 May Not Achieve Remission Despite Multiple Treatment Steps[1]

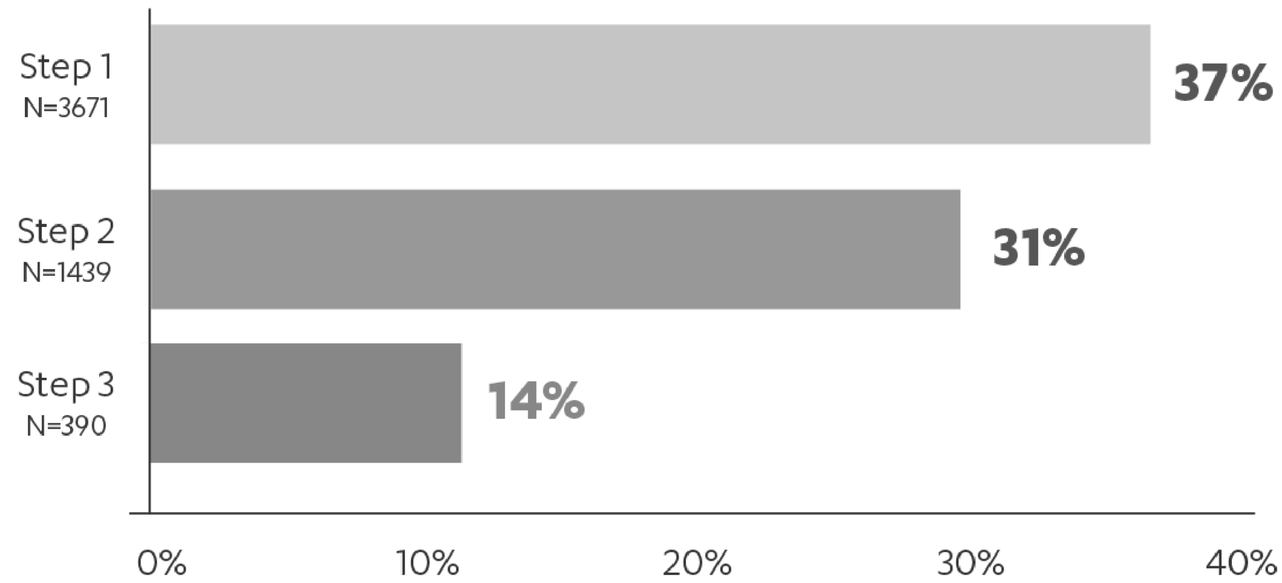
In the US, an estimated **16.2 million adults** had at least one major depressive episode in 2016[2*]



~1 in 3 patients with MDD may not respond to multiple treatment steps and may have treatment-resistant depression[1†]

At Step 3, 14% of patients achieved remission† in the STAR*D† trial

Remission rate† by treatment step in STAR*D[1]



Treatment-resistant depression (TRD) has been defined as a failure of treatment to produce response or remission for patients with MDD after 2 or more treatment attempts of adequate dose and duration during the current episode[3]

* Prevalence rate of MDD in 2010 = 6.7% of all US adults.

† The STAR*D trial, completed in 2006, was conducted to evaluate the effectiveness of current treatment approaches in patients with MDD. Remission was defined as QIDS-SR16 ≤5 at exit. Patients were evaluated across 4 successive steps of therapy, either switching or augmenting treatment if an adequate response was not achieved. Those who responded adequately at any step could enter a 12-month naturalistic follow-up phase. Over 3500 patients (N=3671) were evaluated.

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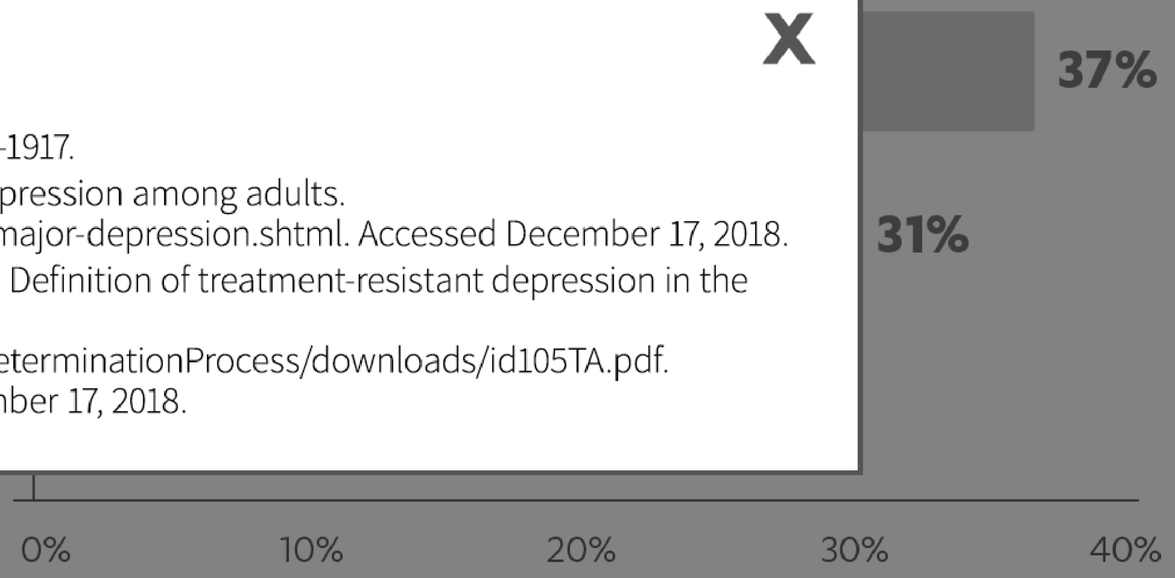

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1. Rush AJ et al. *AM J Psychiatry*. 2006;163:1905-1917.

2. National Institute of Mental Health. Major depression among adults. https://www.nihm.nih.gov/health/statistics/major-depression.shtml. Accessed December 17, 2018.

3. Agency for Healthcare Research and Quality. Definition of treatment-resistant depression in the Medicare population. https://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/id105TA.pdf. Published February 9, 2018. Accessed December 17, 2018.

Treatment-resistant depression (TRD) has been defined as a failure of treatment to produce response or remission for patients with MDD after 2 or more treatment attempts of adequate dose and duration during the current episode[3]

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Patients With TRD* Have Higher Rates of Comorbidities Compared to Patients With non-TRD MDD,† Which May Lead to Increased Healthcare Costs[1]



Hypertension[2]

52% vs 36%

TRD vs non-TRD MDD



Diabetes[2]

26% vs 17%

TRD vs non-TRD MDD



Rheumatoid arthritis[2]

6% vs 3%

TRD vs non-TRD MDD



Chronic heart failure[2]

5% vs 3%

TRD vs non-TRD MDD

Referenced studies were not designed to demonstrate that antidepressants had an effect on comorbidities described

*In this study, TRD refers to TRD non-remitters who have taken ≥2 antidepressants for at least 3 months and have a PHQ-9 severity score of "moderate," "moderately severe," or "severe."
† Non-TRD MDD refers to non-TRD MDD remitters who have taken ≥1 antidepressant(s) for at least 3 months and have a PHQ-9 severity score of "none to minimal."

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VA-19-1109-B-001421

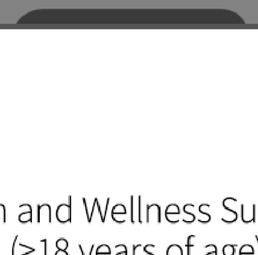
Patients With TRD* Have Higher Rates of Comorbidities Compared to Patients With non-TRD MDD,† Which May Lead to Increased Healthcare Costs[1]



6% vs 3%

TRD vs non-TRD MDD





5% vs 3%

TRD vs non-TRD MDD

Study Methodology

Data were drawn from the 2013 US National Health and Wellness Survey (NHWS), which is a cross-sectional, general health survey of US adults (≥18 years of age). Patients were included in the analysis sample if they self-reported a lifetime diagnosis of depression, were currently treated with ≥1 antidepressant medication for depression, did not screen positive on the mood disorder questionnaire (MDQ), and did not report a diagnosis of bipolar disorder or schizophrenia. Patients who met the above criteria were divided into 2 mutually exclusive analysis groups, pharmacologically treated depression remitters (non-TRD MDD) and TRD, based on their current treatments and their responses on the Patient Health Questionnaire (PHQ-9).[2]

Referenced studies were not designed to demonstrate that antidepressants had an effect on comorbidities described

*In this study, TRD refers to TRD non-remitters who have taken ≥2 antidepressants for at least 3 months and have a PHQ-9 severity score of "moderate," "moderately severe," or "severe."
† Non-TRD MDD refers to non-TRD MDD remitters who have taken ≥1 antidepressant(s) for at least 3 months and have a PHQ-9 severity score of "none to minimal."

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VA-19-1109-B-001422

Patients With TRD* Have Higher Rates of Comorbidities Compared to Patients With non-TRD MDD,† Which May Lead to Increased Healthcare Costs[1]

Hypertension[2]

6% vs 3%

TRD vs non-TRD MDD

Diabetes[2]

5% vs 3%

TRD vs non-TRD MDD

Referenced studies were not designed to demonstrate that antidepressants had an effect on comorbidities described

*In this study, TRD refers to TRD non-remitters who have taken ≥2 antidepressants for at least 3 months and have a PHQ-9 severity score of "moderate," "moderately severe," or "severe."
† Non-TRD MDD refers to non-TRD MDD remitters who have taken ≥1 antidepressant(s) for at least 3 months and have a PHQ-9 severity score of "none to minimal."

Study Limitations

The definition of analysis groups (TRD and non-TRD MDD) and outcomes was limited to the items measured within the National Health and Wellness Survey. The TRD definition hinged on self-reported antidepressant treatment history and depression symptoms. Because of this, the definition of these groups may not be as precise as a survey that is specifically designed for these purposes. This study is cross-sectional, and thus conclusions about causality cannot be inferred.[2]

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Patients With TRD* Have Higher Rates of Comorbidities Compared to Patients With non-TRD MDD,† Which May Lead to Increased Healthcare Costs[1]

Hypertension[2]

6% vs 3%

TRD vs non-TRD MDD

Diabetes[2]

5% vs 3%

TRD vs non-TRD MDD

Referenced studies were not designed to demonstrate that antidepressants had an effect on comorbidities described

*In this study, TRD refers to TRD non-remitters who have taken ≥2 antidepressants for at least 3 months and have a PHQ-9 severity score of "moderate," "moderately severe," or "severe."
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References

1. Kubitz N et al. *PLoS ONE*. 2013;8(10);e76882. Accessed December 17, 2018.
2. Amos T et al. Poster presented at: 29th Annual US Psychiatric & Mental Health Congress; October 21-24, 2016; San Antonio, TX.

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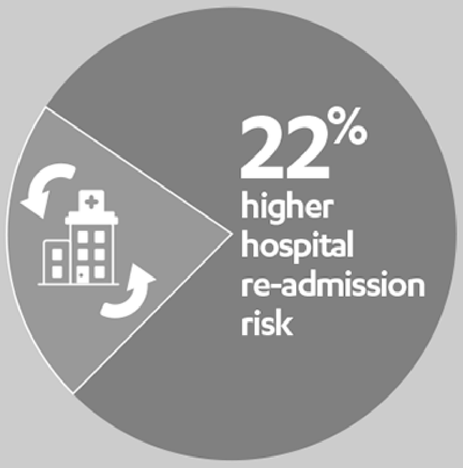
VA-19-1109-B-001424

Hospitalization in Patients With TRD* Is Associated With Substantial Healthcare Resource Utilization and Increased Costs[1]

TRD episodes may last over 2 years

In this study, patients with TRD† had a median time of 891 days per TRD episode vs 298 days for non-TRD MDD† episodes[2]

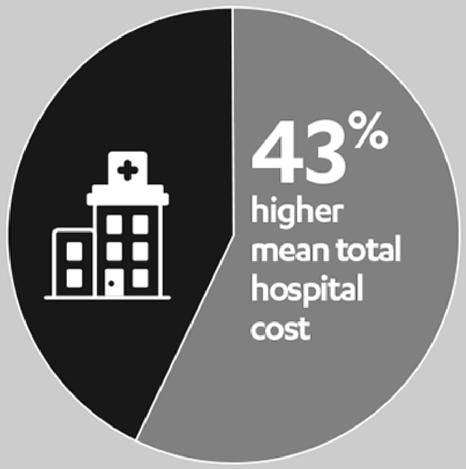
In a hospital database study of 204,575 patients with MDD,* of whom 45,127 had TRD,[1]* patients with TRD had:



TRD* vs non-TRD MDD*
HR=1.22; 95% CI: 1.19-1.25



TRD* vs non-TRD MDD*
P<0.0001



TRD* vs non-TRD MDD*
P<0.0001

Referenced studies were not designed to demonstrate an impact on the outcomes described

*In this study, patients with a primary discharge diagnosis of MDD, were defined as TRD based on the presence of any of the following: electroconvulsive therapy, transcranial magnetic stimulation, vagus nerve stimulation, receipt of Symbyax treatment, or any antidepressants and 1 of 4 antipsychotics (aripiprazole, brexpiprazole, olanzapine, quetiapine) during Day 1 or 2 of the index hospitalization. Patients with non-TRD MDD were identified based on the absence of the measures described.

† In this study, a non-TRD MDD episode was defined to begin on a first relevant date and end 120 days after the last relevant date, where the first relevant date was a date of inclusion diagnosis that was not preceded by any inclusion diagnosis or an antidepressant prescription claim in the preceding 120 days. An episode was classified as TRD if the episode contained at least 2 distinct failed regimens; failure was based on treatment switch or discontinuation.

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VA-19-1109-B-001425

Hospitalization in Patients With TRD* Is Associated With Substantial Healthcare Resource Utilization and Increased Costs[1]

TRD episodes may last over 2 years

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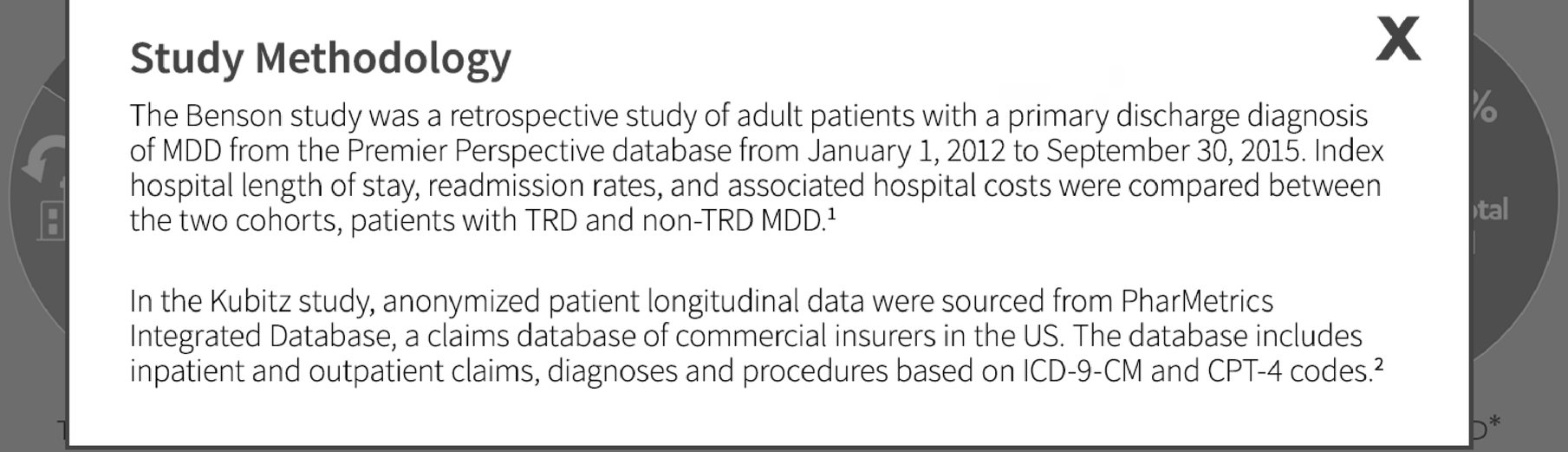

Study Methodology

The Benson study was a retrospective study of adult patients with a primary discharge diagnosis of MDD from the Premier Perspective database from January 1, 2012 to September 30, 2015. Index hospital length of stay, readmission rates, and associated hospital costs were compared between the two cohorts, patients with TRD and non-TRD MDD.[1]

In the Kubitz study, anonymized patient longitudinal data were sourced from PharMetrics Integrated Database, a claims database of commercial insurers in the US. The database includes inpatient and outpatient claims, diagnoses and procedures based on ICD-9-CM and CPT-4 codes.[2]

Referenced studies were not designed to demonstrate an impact on the outcomes described

*In this study, patients with a primary discharge diagnosis of MDD, were defined as TRD based on the presence of any of the following: electroconvulsive therapy, transcranial magnetic stimulation, vagus nerve stimulation, receipt of Symbyax treatment, or any antidepressants and 1 of 4 antipsychotics (aripiprazole, brexpiprazole, olanzapine, quetiapine) during Day 1 or 2 of the index hospitalization. Patients with non-TRD MDD were identified based on the absence of the measures described.

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Hospitalization in Patients With TRD* Is Associated With Substantial Healthcare Resource Utilization and Increased Costs[1]

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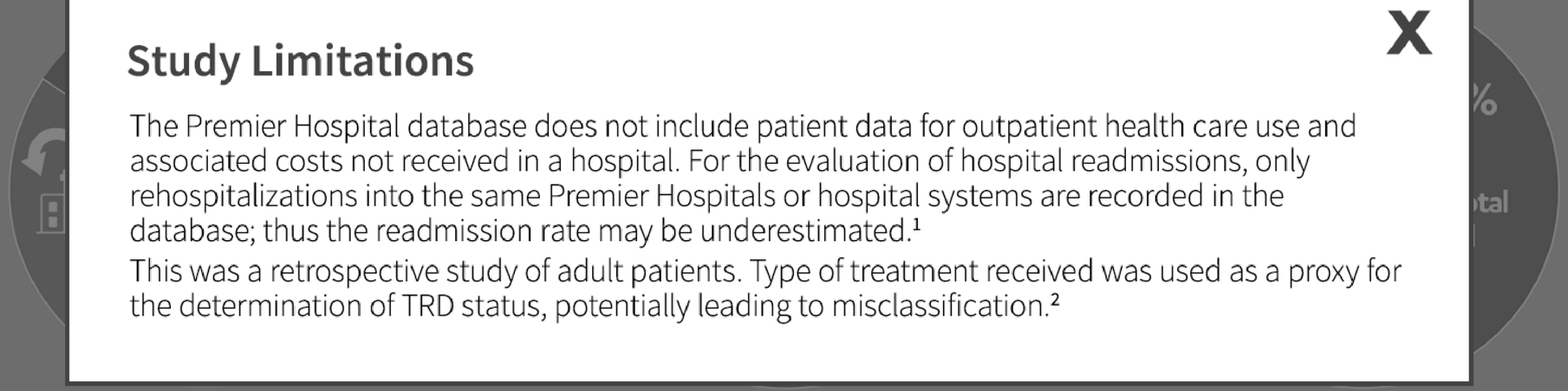

TRD* vs non-TRD MDD*
HR=1.22; 95% CI: 1.19-1.25

TRD* vs non-TRD MDD*
P<0.0001

TRD* vs non-TRD MDD*
P<0.0001

Study Limitations

The Premier Hospital database does not include patient data for outpatient health care use and associated costs not received in a hospital. For the evaluation of hospital readmissions, only rehospitalizations into the same Premier Hospitals or hospital systems are recorded in the database; thus the readmission rate may be underestimated.[1]

This was a retrospective study of adult patients. Type of treatment received was used as a proxy for the determination of TRD status, potentially leading to misclassification.[2]

Referenced studies were not designed to demonstrate an impact on the outcomes described

*In this study, patients with a primary discharge diagnosis of MDD, were defined as TRD based on the presence of any of the following: electroconvulsive therapy, transcranial magnetic stimulation, vagus nerve stimulation, receipt of Symbyax treatment, or any antidepressants and 1 of 4 antipsychotics (aripiprazole, brexpiprazole, olanzapine, quetiapine) during Day 1 or 2 of the index hospitalization. Patients with non-TRD MDD were identified based on the absence of the measures described.

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VA-19-1109-B-001427

Hospitalization in Patients With TRD* Is Associated With Substantial Healthcare Resource Utilization and Increased Costs[1]

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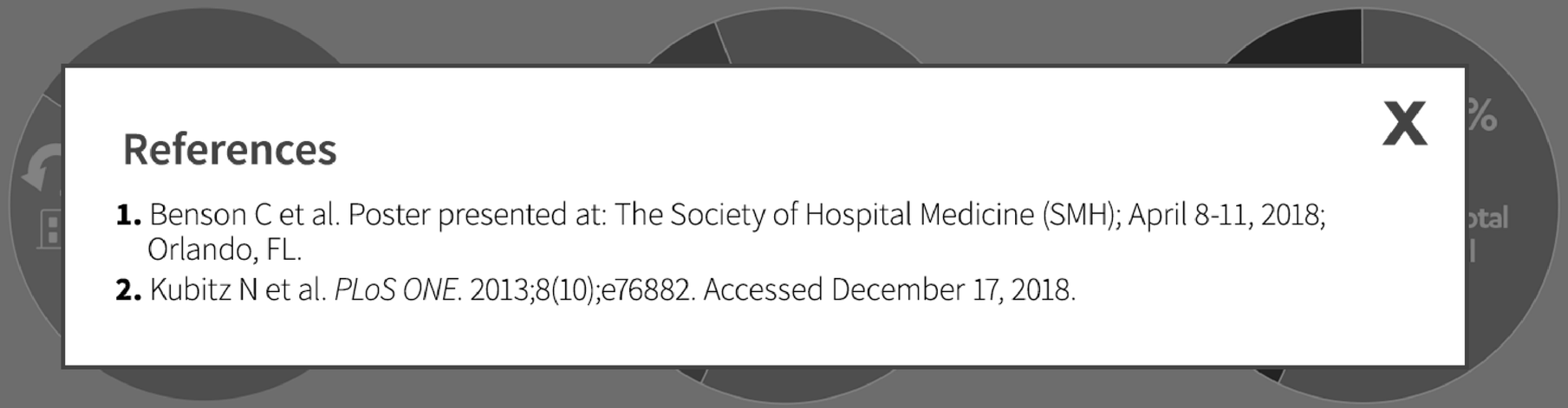

TRD* vs non-TRD MDD*
HR=1.22; 95% CI: 1.19-1.25

TRD* vs non-TRD MDD*
P<0.0001

TRD* vs non-TRD MDD*
P<0.0001

References

1. Benson C et al. Poster presented at: The Society of Hospital Medicine (SMH); April 8-11, 2018; Orlando, FL.

2. Kubitz N et al. *PLoS ONE*. 2013;8(10);e76882. Accessed December 17, 2018.

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*In this study, patients with a primary discharge diagnosis of MDD, were defined as TRD based on the presence of any of the following: electroconvulsive therapy, transcranial magnetic stimulation, vagus nerve stimulation, receipt of Symbyax treatment, or any antidepressants and 1 of 4 antipsychotics (aripiprazole, brexpiprazole, olanzapine, quetiapine) during Day 1 or 2 of the index hospitalization. Patients with non-TRD MDD were identified based on the absence of the measures described.

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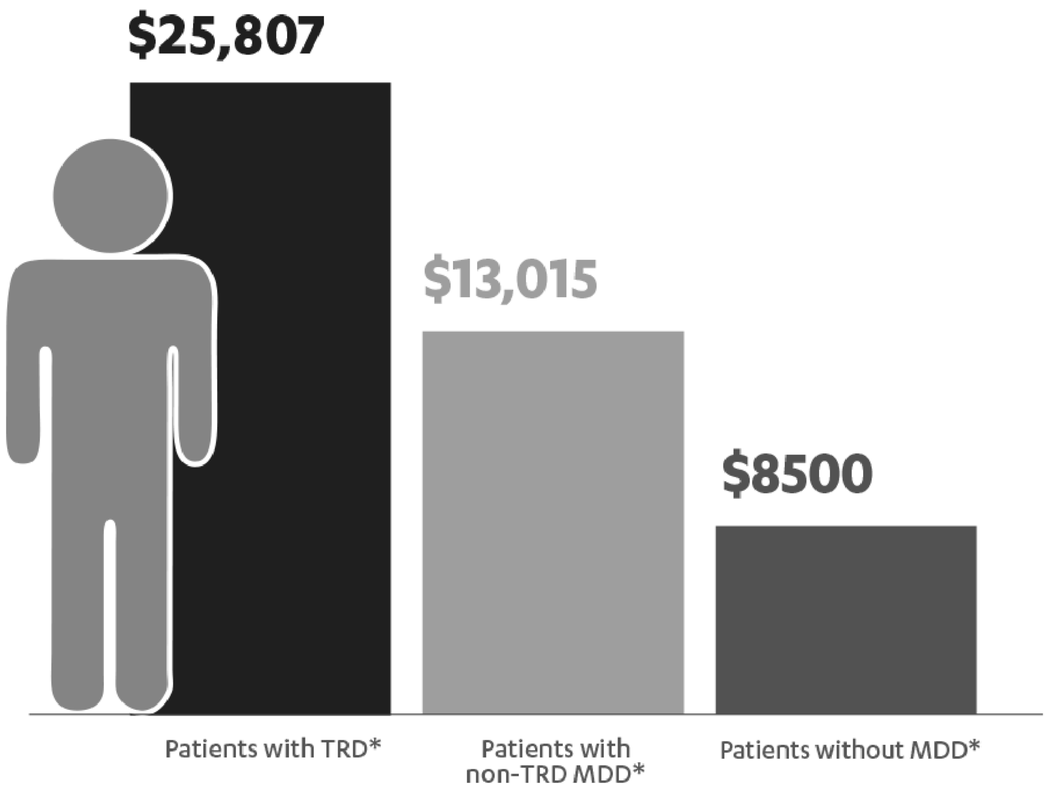
VA-19-1109-B-001428

Within US Integrated Delivery Networks (IDNs), Patients With TRD* Demonstrate 3X the All-Cause Direct Healthcare Costs vs Patients Without MDD[1]

All-cause direct healthcare costs per patient per year within US IDNs[1]



In a separate study, patients with TRD† missed **36 workdays per year**[2‡] as compared to patients with non-TRD MDD,† who missed **21 workdays per year**, and patients without MDD,† who missed **6 workdays per year**



TRD = treatment-resistant depression; IDNs = Integrated Delivery Networks

* In this study, adults with a MDD diagnosis code and antidepressant (AD) were defined as MDD. Patients who initiated a third AD, following the failure of 2 AD treatment regimens at adequate dose and duration (including augmentation therapy), were defined as TRD. Patients with MDD not defined as having TRD within 2 years of the index date were considered non-TRD MDD (patients with MDD). Patients without MDD excluded patients with MDD and patients with TRD.

† In this study, patients were considered to have TRD if they had at least 1 diagnosis for MDD and had at least 2 claims for AD treatment courses (including augmentation therapy with anticonvulsant, anxiolytic, antipsychotic, lithium, psychostimulant, and thyroid hormone medications with adequate dose and duration failed to improve their depression). Patients with MDD not defined as having TRD within 2 years of the index date were considered non-TRD MDD. The non-TRD MDD cohort consisted of a random sample of patients without an MDD diagnosis at any time.

‡ Workdays missed for patients were calculated using provided incidence rate ratios.

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VA-19-1109-B-001429

Within US Integrated Delivery Networks (IDNs), Patients With TRD* Demonstrate 3X the All-Cause Direct Healthcare Costs vs Patients Without MDD[1]

All-cause direct healthcare costs per patient per year within US IDNs[1]

$25,807



In a separate study, patients with

workdays

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RD MDD,† who

per year, and

D,† who

per year



Study Methodology

In the Pilon study, a retrospective matched cohort study, data was analyzed from the Optum Integrated Claims Electronic Health Records (EHRs) de-identified database (January 2011-June 2017). The index date was defined as the first antidepressant pharmacy claim on or after July 1, 2011, until June 30, 2017, for patients with TRD and non-TRD MDD, and was randomly imputed for patients without MDD.[1]

In the Amos study, a retrospective, longitudinal, matched cohort design consisting of 3 mutually exclusive cohorts (TRD, non-TRD MDD, and non-MDD) was analyzed. Claims data was taken using ICD-9 codes for MDD from the OptumHealth Care Solutions Inc, database (July 2009- March 2015). Baseline characteristics were evaluated in the 6 months pre-index date (baseline period), while outcomes were evaluated from the index date up to the earliest of 2 years post-index date, the end of continuous eligibility, or the end of data availability (observation period).[2]

TRD = treatment-resistant depression; IDNs = Integrated Delivery Networks

*In this study, adults with a MDD diagnosis code and antidepressant (AD) were defined as MDD. Patients who initiated a third AD, following the failure of 2 AD treatment regimens at adequate dose and duration (including augmentation therapy), were defined as TRD. Patients with MDD not defined as having TRD within 2 years of the index date were considered non-TRD MDD (patients with MDD). Patients without MDD excluded patients with MDD and patients with TRD.

†In this study, patients were considered to have TRD if they had at least 1 diagnosis for MDD and had at least 2 claims for AD treatment courses (including augmentation therapy with anticonvulsant, anxiolytic, antipsychotic, lithium, psychostimulant, and thyroid hormone medications with adequate dose and duration failed to improve their depression). Patients with MDD not defined as having TRD within 2 years of the index date were considered non-TRD MDD. The non-TRD MDD cohort consisted of a random sample of patients without an MDD diagnosis at any time.

‡Workdays missed for patients were calculated using provided incidence rate ratios.

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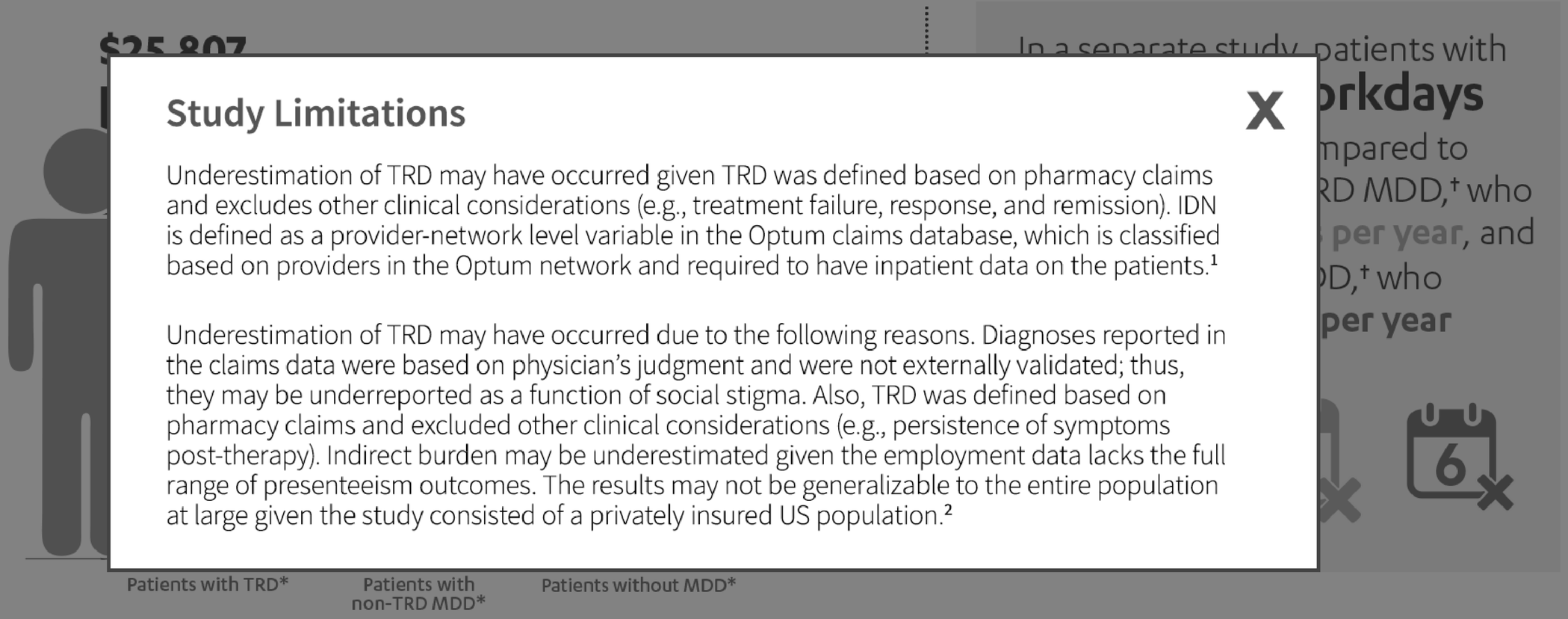
VA-19-1109-B-001430

Within US Integrated Delivery Networks (IDNs), Patients With TRD* Demonstrate 3X the All-Cause Direct Healthcare Costs vs Patients Without MDD[1]

All-cause direct healthcare costs per patient per year within US IDNs[1]



In a separate study, patients with
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Study Limitations

Underestimation of TRD may have occurred given TRD was defined based on pharmacy claims and excludes other clinical considerations (e.g., treatment failure, response, and remission). IDN is defined as a provider-network level variable in the Optum claims database, which is classified based on providers in the Optum network and required to have inpatient data on the patients.[1]

Underestimation of TRD may have occurred due to the following reasons. Diagnoses reported in the claims data were based on physician's judgment and were not externally validated; thus, they may be underreported as a function of social stigma. Also, TRD was defined based on pharmacy claims and excluded other clinical considerations (e.g., persistence of symptoms post-therapy). Indirect burden may be underestimated given the employment data lacks the full range of presenteeism outcomes. The results may not be generalizable to the entire population at large given the study consisted of a privately insured US population.[2]

TRD = treatment-resistant depression; IDNs = Integrated Delivery Networks

* In this study, adults with a MDD diagnosis code and antidepressant (AD) were defined as MDD. Patients who initiated a third AD, following the failure of 2 AD treatment regimens at adequate dose and duration (including augmentation therapy), were defined as TRD. Patients with MDD not defined as having TRD within 2 years of the index date were considered non-TRD MDD (patients with MDD). Patients without MDD excluded patients with MDD and patients with TRD.

† In this study, patients were considered to have TRD if they had at least 1 diagnosis for MDD and had at least 2 claims for AD treatment courses (including augmentation therapy with anticonvulsant, anxiolytic, antipsychotic, lithium, psychostimulant, and thyroid hormone medications with adequate dose and duration failed to improve their depression). Patients with MDD not defined as having TRD within 2 years of the index date were considered non-TRD MDD. The non-TRD MDD cohort consisted of a random sample of patients without an MDD diagnosis at any time.

‡ Workdays missed for patients were calculated using provided incidence rate ratios.

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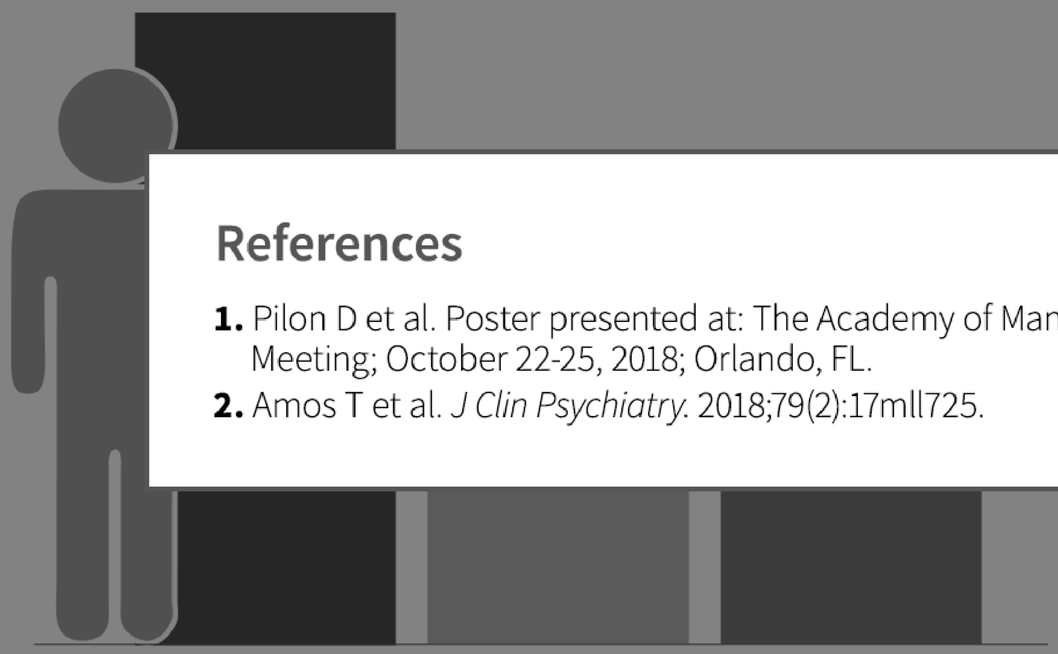
Within US Integrated Delivery Networks (IDNs), Patients With TRD* Demonstrate 3X the All-Cause Direct Healthcare Costs vs Patients Without MDD[1]

All-cause direct healthcare costs per patient per year within US IDNs[1]



In a separate study, patients with TRD† missed **36 workdays per year**[2‡] as compared to patients with non-TRD MDD,† who **per year**, and D,† who **per year**



References

1. Pilon D et al. Poster presented at: The Academy of Managed Care Pharmacy (AMCP) Nexus Meeting; October 22-25, 2018; Orlando, FL.
2. Amos T et al. *J Clin Psychiatry*. 2018;79(2):17m11725.

TRD = treatment-resistant depression; IDNs = Integrated Delivery Networks

* In this study, adults with a MDD diagnosis code and antidepressant (AD) were defined as MDD. Patients who initiated a third AD, following the failure of 2 AD treatment regimens at adequate dose and duration (including augmentation therapy), were defined as TRD. Patients with MDD not defined as having TRD within 2 years of the index date were considered non-TRD MDD (patients with MDD). Patients without MDD excluded patients with MDD and patients with TRD.

† In this study, patients were considered to have TRD if they had at least 1 diagnosis for MDD and had at least 2 claims for AD treatment courses (including augmentation therapy with anticonvulsant, anxiolytic, antipsychotic, lithium, psychostimulant, and thyroid hormone medications with adequate dose and duration failed to improve their depression). Patients with MDD not defined as having TRD within 2 years of the index date were considered non-TRD MDD. The non-TRD MDD cohort consisted of a random sample of patients without an MDD diagnosis at any time.

‡ Workdays missed for patients were calculated using provided incidence rate ratios.

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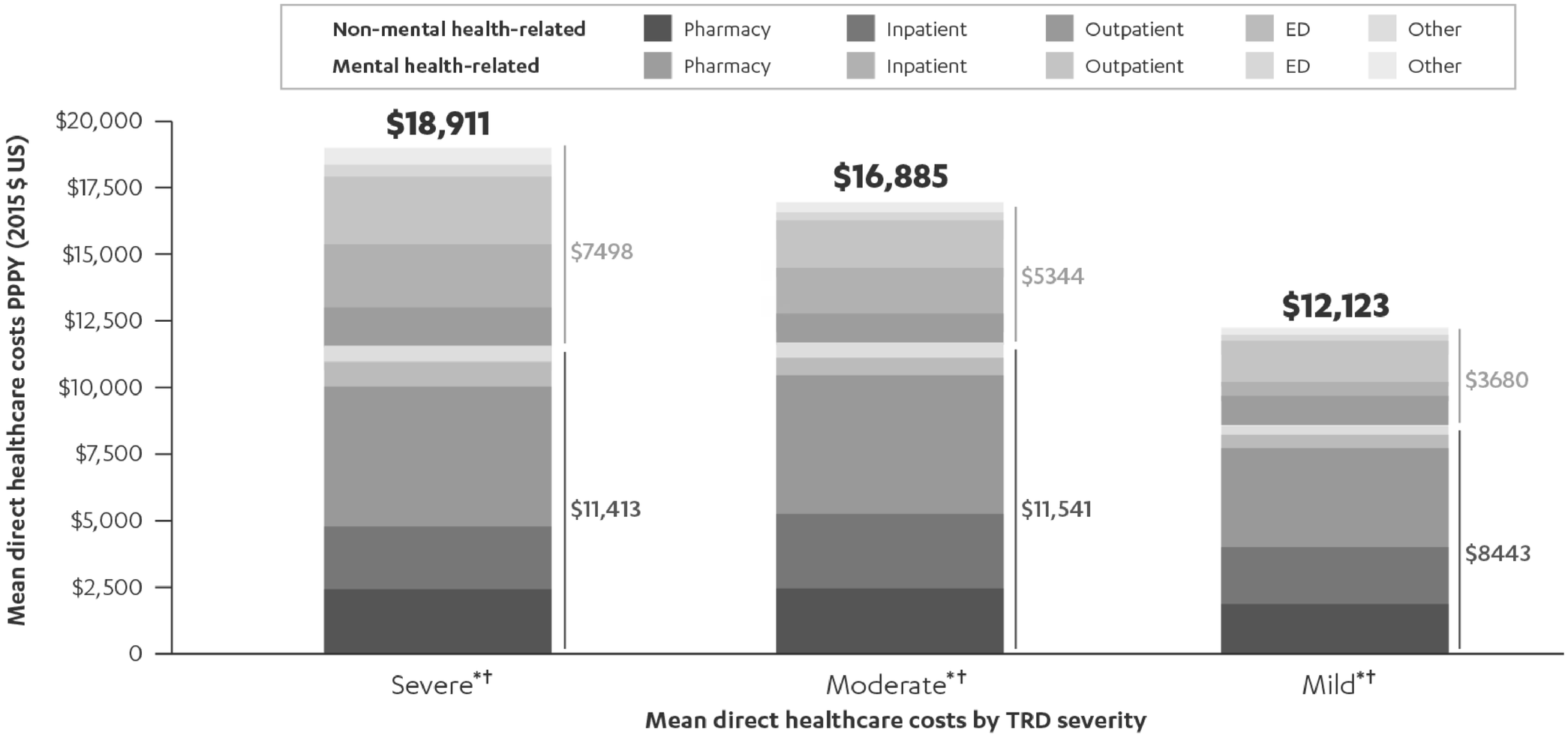
VA-19-1109-B-001432

Severity of Depression Significantly Increased Direct Healthcare Costs

Patients with TRD with severe disease status* demonstrated significantly higher direct healthcare costs compared to patients with TRD with mild disease status in a commercial population



ED = emergency department; PPPY = per-patient-per-year; TRD = treatment-resistant depression.

* Severity was defined as patients with TRD stratified into mild, moderate, and severe cohorts based on the information in the last observed MDD ICD-9-CM codes 296.2x or 296.3x.

† In this study, TRD was defined as patients with MDD who failed, within 2 years of the index date, 2 antidepressant treatment regimens of adequate dose and duration.

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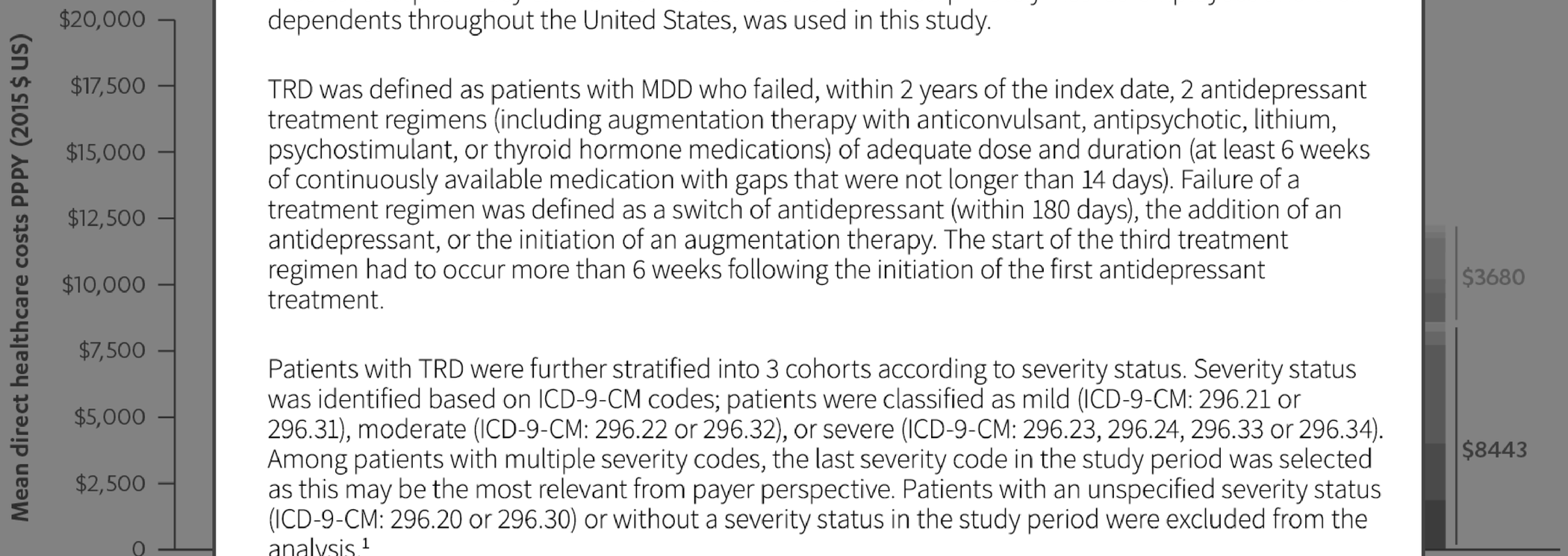
Severity of Depression Significantly Increased Direct Healthcare Costs



Study Methodology[1]

The OptumHealth Care Solutions, Inc., database (January 1, 2010–March 31, 2015), which comprises medical and pharmacy claims information for over 19 million privately insured employees and their dependents throughout the United States, was used in this study.

TRD was defined as patients with MDD who failed, within 2 years of the index date, 2 antidepressant treatment regimens (including augmentation therapy with anticonvulsant, antipsychotic, lithium, psychostimulant, or thyroid hormone medications) of adequate dose and duration (at least 6 weeks of continuously available medication with gaps that were not longer than 14 days). Failure of a treatment regimen was defined as a switch of antidepressant (within 180 days), the addition of an antidepressant, or the initiation of an augmentation therapy. The start of the third treatment regimen had to occur more than 6 weeks following the initiation of the first antidepressant treatment.

Patients with TRD were further stratified into 3 cohorts according to severity status. Severity status was identified based on ICD-9-CM codes; patients were classified as mild (ICD-9-CM: 296.21 or 296.31), moderate (ICD-9-CM: 296.22 or 296.32), or severe (ICD-9-CM: 296.23, 296.24, 296.33 or 296.34). Among patients with multiple severity codes, the last severity code in the study period was selected as this may be the most relevant from payer perspective. Patients with an unspecified severity status (ICD-9-CM: 296.20 or 296.30) or without a severity status in the study period were excluded from the analysis.[1]

ED = emergency department; PPPY = per-patient-per-year; TRD = treatment-resistant depression.
* Severity was defined as patients with TRD stratified into mild, moderate, and severe cohorts based on the information in the last observed MDD ICD-9-CM codes 296.2x or 296.3x.
† In this study, TRD was defined as patients with MDD who failed, within 2 years of the index date, 2 antidepressant treatment regimens of adequate dose and duration.

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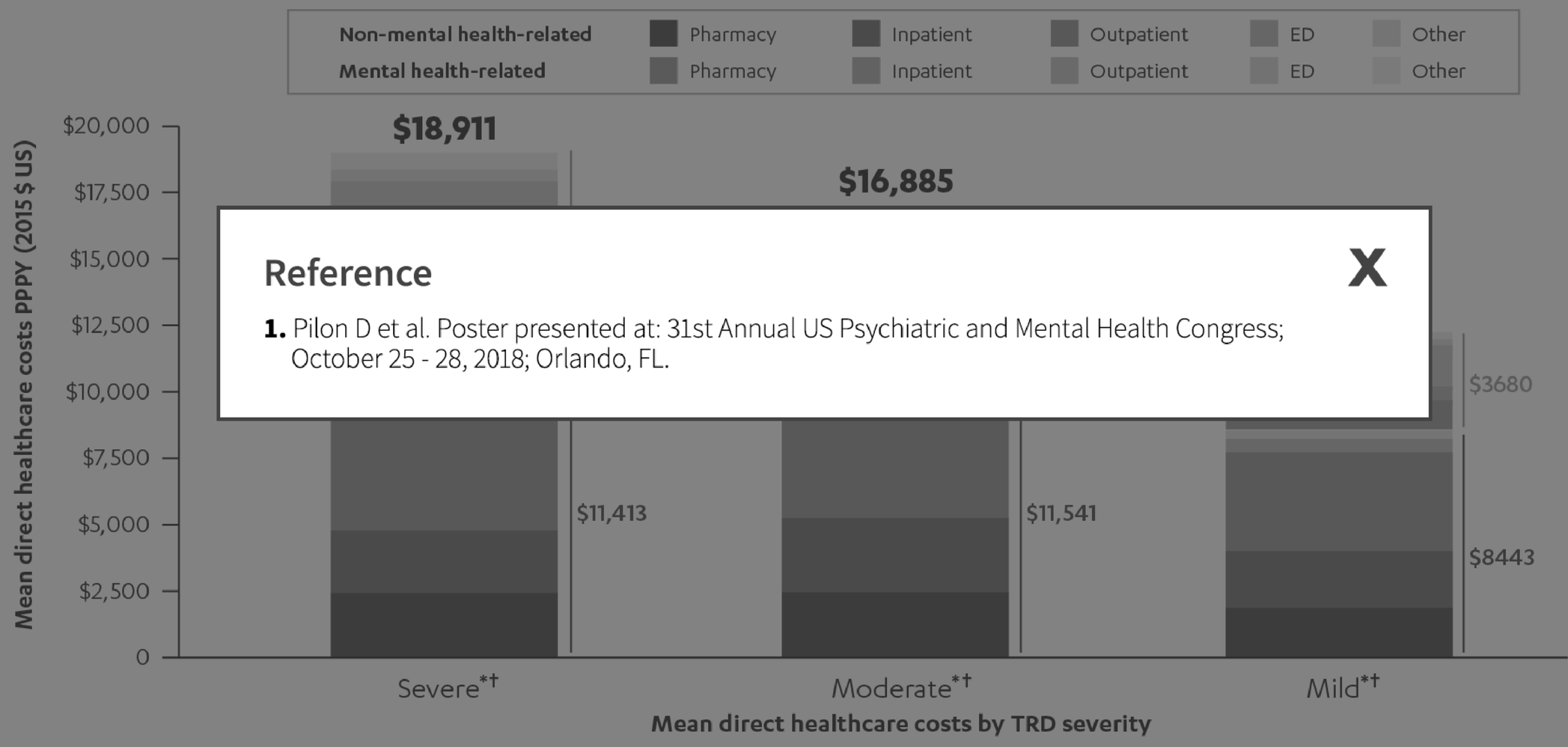
VA-19-1109-B-001434

Severity of Depression Significantly Increased Direct Healthcare Costs

Patients with TRD with severe disease status* demonstrated significantly higher direct healthcare costs compared to patients with TRD with mild disease status in a commercial population



Reference

1. Pilon D et al. Poster presented at: 31st Annual US Psychiatric and Mental Health Congress; October 25 - 28, 2018; Orlando, FL.

ED = emergency department; PPPY = per-patient-per-year; TRD = treatment-resistant depression.
* Severity was defined as patients with TRD stratified into mild, moderate, and severe cohorts based on the information in the last observed MDD ICD-9-CM codes 296.2x or 296.3x.
† In this study, TRD was defined as patients with MDD who failed, within 2 years of the index date, 2 antidepressant treatment regimens of adequate dose and duration.

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VA-19-1109-B-001435

Summary of Disease Burden and Unmet Need in Treatment-Resistant Depression

Based on STAR*D, two-thirds of adult patients with MDD may achieve remission of depressive symptoms; however, 1 in 3 may not achieve remission despite multiple treatment steps[1]

Patients with TRD have higher rates of comorbidities compared to patients with non-TRD MDD, which may lead to increased healthcare costs[2,3]

Hospitalization in patients with TRD is associated with substantial and disproportionately high healthcare resource utilization and increased costs[3,4]

3x Patients with TRD demonstrate 3X the all-cause direct healthcare costs vs patients without MDD[5]

Severity of TRD significantly increased direct healthcare costs[6]

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VA-19-1109-B-001436

Summary of Disease Burden and Unmet Need in Treatment-Resistant Depression

Based on STAR*D, two-thirds of adult patients with MDD may achieve remission of depressive symptoms; however, 1 in 3 may not achieve remission despite multiple treatment steps[1]

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3x Patients with TRD demonstrate 3X the all-cause direct healthcare costs vs patients without MDD[5]

Severity of TRD significantly increased direct healthcare costs[6]

References

1. Rush AJ et al. *AM J Psychiatry*. 2006;163:1905-1917.
2. Amos T et al. *J Clin Psychiatry*. 2018;79(2):17m11725.
3. Kubitz N et al. *PLos ONE*. 2013;8(10):e76882.
4. Benson C et al. Poster presented at: The Society of Hospital Medicine (SMH); April 8-11, 2018. Orlando, FL.
5. Pilon D et al. Poster presented at: The Academy of Managed Care Pharmacy (AMCP) Nexus Meeting; October 22-25, 2018; Orlando, FL.
6. Pilon D et al. Poster presented at: 31st Annual US Psychiatric and Mental Health Congress; October 25-28, 2018; Orlando, FL.

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VA-19-1109-B-001437

SPRAVATO™ Product Summary[1]

Spravato™ (esketamine) C III nasal spray

- SPRAVATO™ is a non-competitive N-methyl D-aspartate (NMDA) receptor antagonist indicated, in conjunction with an oral antidepressant, for the treatment of treatment-resistant depression (TRD) in adults[1]
- SPRAVATO™ nasal spray is a Schedule III controlled substance
- SPRAVATO™ nasal spray has a Risk Evaluation and Mitigation Strategy (REMS):
  - The goal of the REMS is to mitigate the risks of serious adverse outcomes resulting from sedation and dissociation caused by SPRAVATO™ administration, and abuse and misuse of SPRAVATO™
- SPRAVATO™ will not be delivered or dispensed directly to patients

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VA-19-1109-B-001438

SPRAVATO™ Product Summary[1]

Spravato™ (esketamine) C III nasal spray

- SPRAVATO™ is a non-competitive N-methyl D-aspartate (NMDA) receptor antagonist indicated, in conjunction with an oral antidepressant, for the treatment of treatment-resistant depression (TRD) in adults[1]
- SPRAVATO™ nasal spray is a Schedule III controlled substance
- SPRAVATO™ nasal spray has a Risk Evaluation and Mitigation Strategy (REMS):
  - The goal of the … issociation caused by SPRA…
- SPRAVATO™ will not be delivered or dispensed directly to patients

Reference

1. SPRAVATO™ [Prescribing Information]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; March 2019.

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VA-19-1109-B-001439

Spravato™ (esketamine) C III nasal spray

SPRAVATO™ Clinical Value

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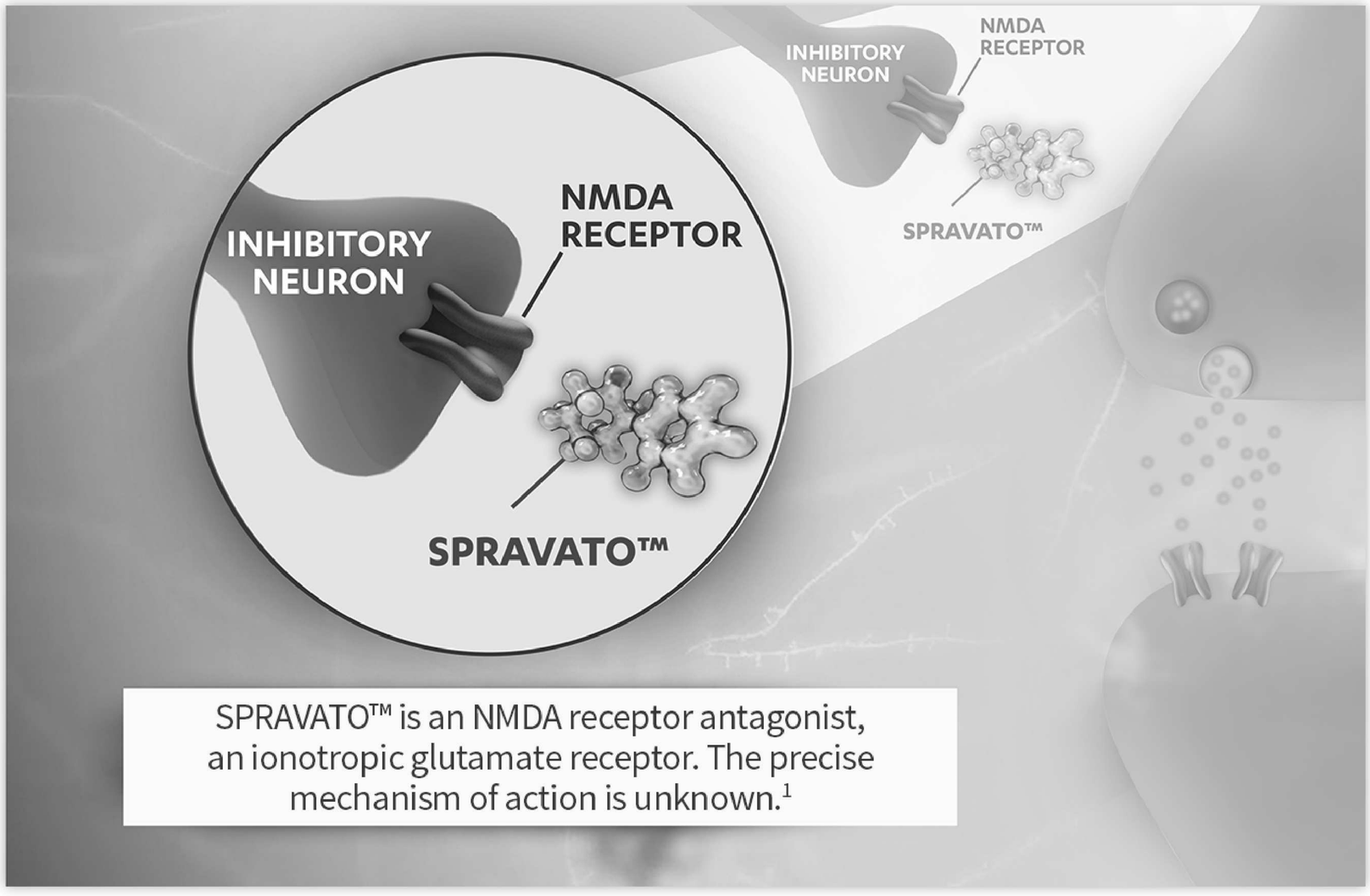
The First and Only NMDA Receptor Antagonist Approved for TRD in Adults[1]

Spravato™ (esketamine) C III
nasal spray

SPRAVATO™ hypothesized mechanism of action



SPRAVATO™ is an NMDA receptor antagonist, an ionotropic glutamate receptor. The precise mechanism of action is unknown.[1]

NMDA=*N*-methyl-D-aspartate.

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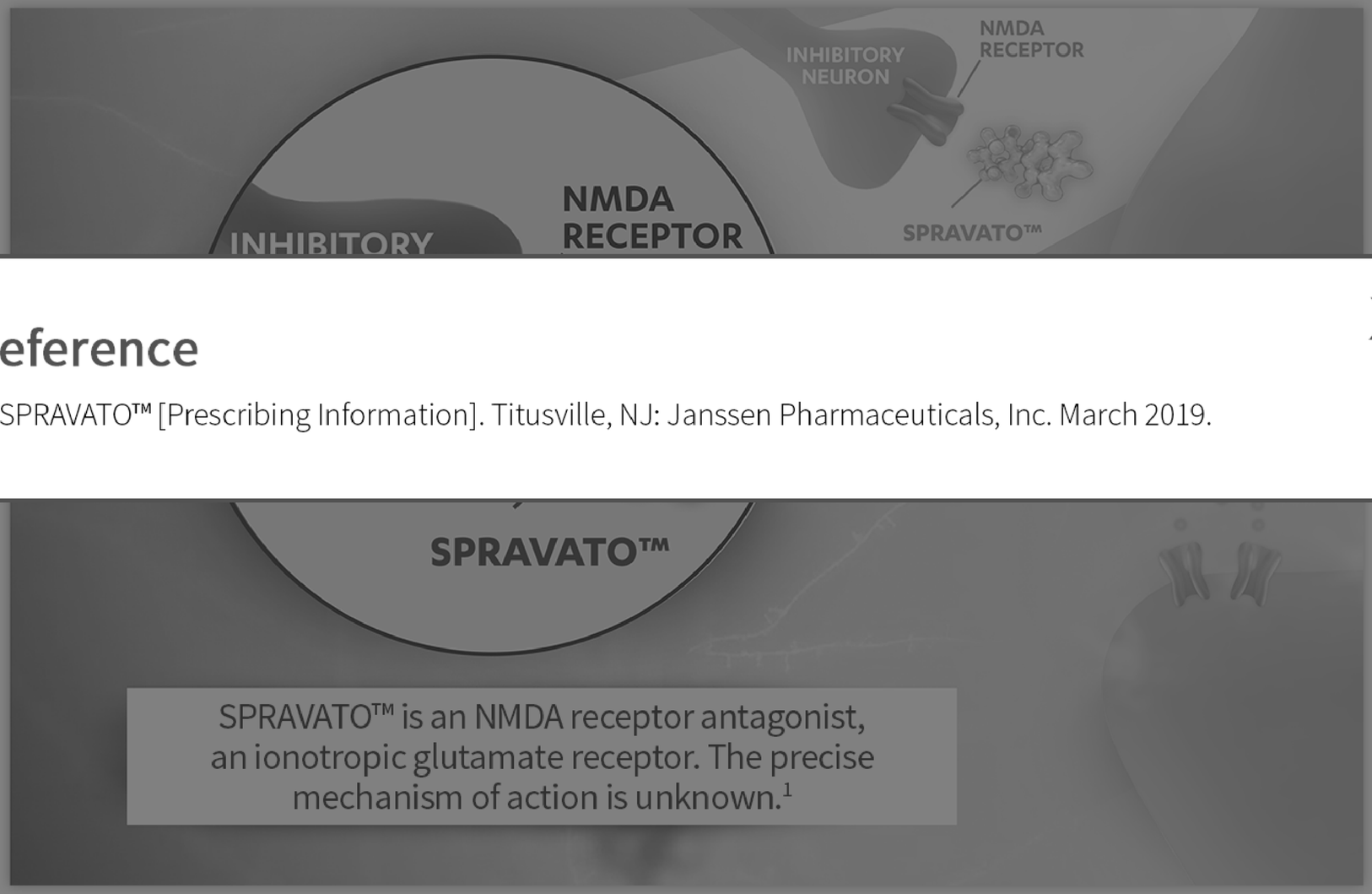
VA-19-1109-B-001441

SPRAVATO™ hypothesized mechanism of action



SPRAVATO™ is an NMDA receptor antagonist, an ionotropic glutamate receptor. The precise mechanism of action is unknown.[1]

NMDA=*N*-methyl-D-aspartate.

Reference

1. SPRAVATO™ [Prescribing Information]. Titusville, NJ: Janssen Pharmaceuticals, Inc. March 2019.

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VA-19-1109-B-001442

SPRAVATO™ Clinical Program Overview

Spravato™ (esketamine) CIII nasal spray

Studied in more than 1700 adult patients with treatment-resistant depression[1]

BASELINE PSYCHIATRIC PATIENT CHARACTERISTICS[1,2]

DID NOT RESPOND TO ≥2 ADs

- Adults with Major Depressive Disorder who had not responded adequately to ≥2 different antidepressants (ADs) of adequate dose and duration to treat the current depressive episode

MODERATELY TO SEVERELY DEPRESSED

- Patients included those with moderate to severe depression, based on MADRS scores
- A third of patients reported a history of suicidal ideation*

COMPARED TO NASAL SPRAY + ORAL AD[1]

Oral AD was newly initiated in short-term trials.

SPRAVATO™ NASAL SPRAY + NEWLY INITIATED ORAL AD

VS

PLACEBO NASAL SPRAY + NEWLY INITIATED ORAL AD

MADRS=Montgomery-Åsberg Depression Rating Scale.
* Observed at screening during Study 1. Patients with intent to act were excluded from the study.

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Studied in more than 1700 adult patients with treatment-resistant depression[1]

BASELINE PSYCHIATRIC PATIENT CHARACTERISTICS[1,2]

DID NOT RESPOND

MODERATELY TO SEVERELY

References

1. SPRAVATO™ [Prescribing Information]. Titusville, NJ: Janssen Pharmaceuticals, Inc. March 2019.
2. Data on file. Janssen Pharmaceuticals, Inc. Titusville, NJ.

COMPARED TO NASAL SPRAY + ORAL AD[1]

Oral AD was newly initiated in short-term trials.

SPRAVATO™ NASAL SPRAY + NEWLY INITIATED ORAL AD

VS

PLACEBO NASAL SPRAY + NEWLY INITIATED ORAL AD

MADRS=Montgomery-Åsberg Depression Rating Scale.
* Observed at screening during Study 1. Patients with intent to act were excluded from the study.

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VA-19-1109-B-001444

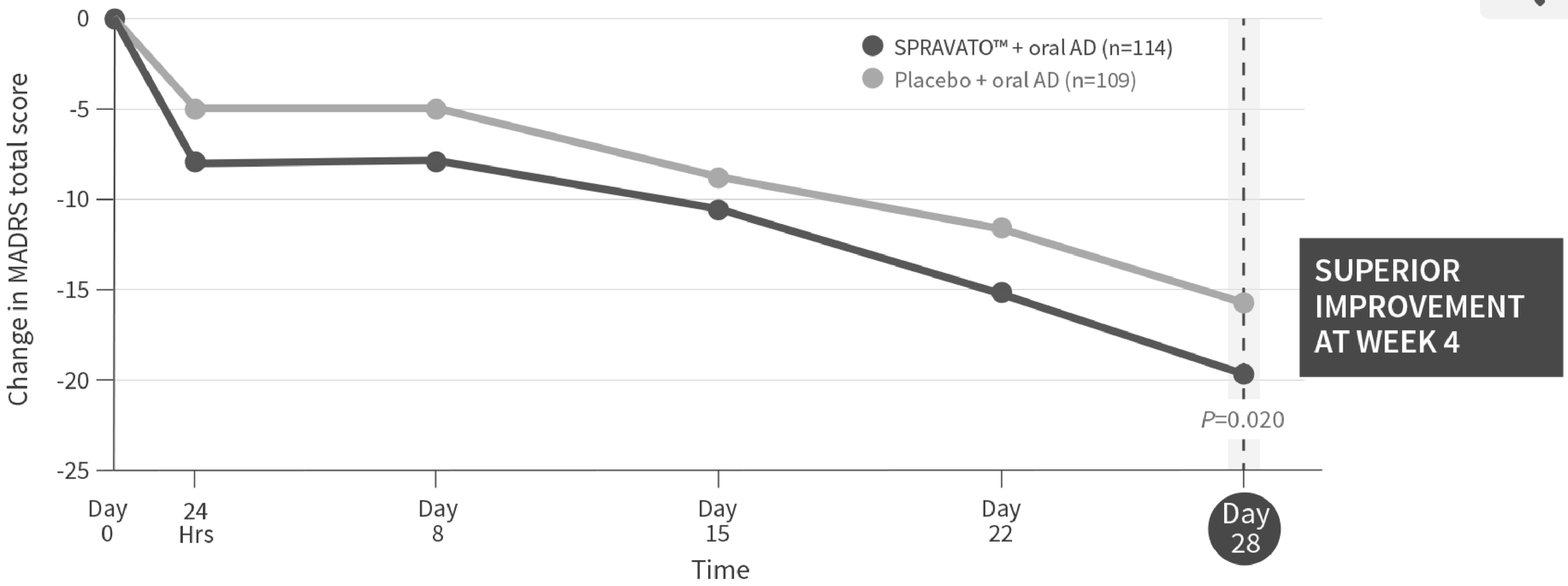
Superior Improvement in Depression Symptoms vs Oral Antidepressant (AD) Plus Placebo at Week 4[1,2]

Spravato™ (esketamine) CIII nasal spray

STUDY 1 (SHORT-TERM)

TIME COURSE OF TREATMENT RESPONSE

Study Design



SUPERIOR IMPROVEMENT AT WEEK 4

- Most of the treatment difference between SPRAVATO™ and placebo was observed at 24 hours
- Between 24 hours and Day 28, both SPRAVATO™ and placebo groups continued to improve
- The difference between the groups generally remained the same but did not appear to increase over time through Day 28

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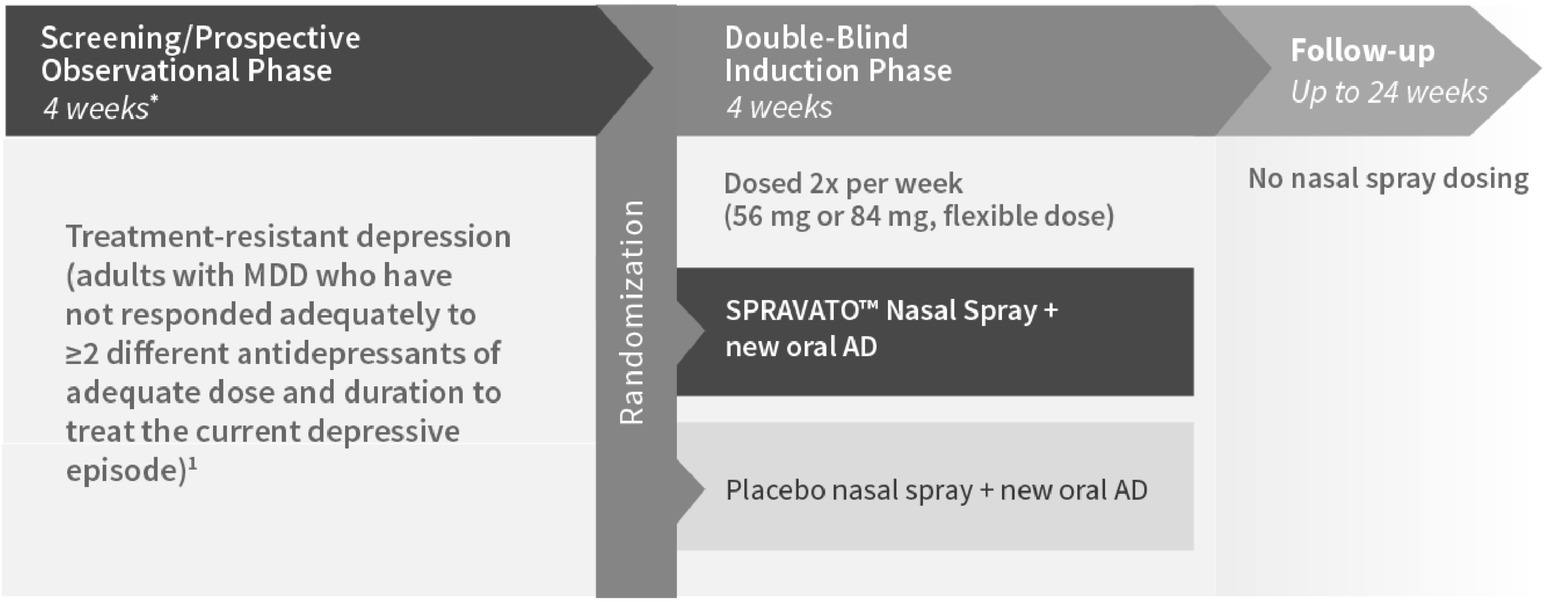
VA-19-1109-B-001445

STUDY 1 (SHORT-TERM) Study Design

STUDY 1 (N=223) WAS A PIVOTAL PHASE 3, SHORT-TERM (4-WEEK), RANDOMIZED, DOUBLE-BLIND, MULTICENTER, PLACEBO-CONTROLLED TRIAL OF ADULT PATIENTS WITH TREATMENT-RESISTANT DEPRESSION (TRD)[1,2]



Primary Endpoint

- Change from baseline (Day 1) to endpoint (Day 28) in Montgomery-Åsberg Depression Rating Scale (MADRS) score

Flexible Dosing

- Patients (aged 18-64 years) were randomized to receive treatment with SPRAVATO™ 56 mg or 84 mg plus a newly initiated oral AD or a newly initiated oral AD plus placebo nasal spray on Day 1
- Dosages could be titrated to 84 mg or maintained on 56 mg, and were adjusted on Day 4, 8, 11, or 15. Dosages remained stable after Day 15

Oral Antidepressant

- A newly initiated open-label oral AD (SSRIs: escitalopram, sertraline; SNRIs: duloxetine, venlafaxine extended-release) was initiated on Day 1
- The selection of the newly initiated oral AD was determined by the investigator based on patient's prior history

*Optional taper of up to 3 weeks.

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VA-19-1109-B-001446

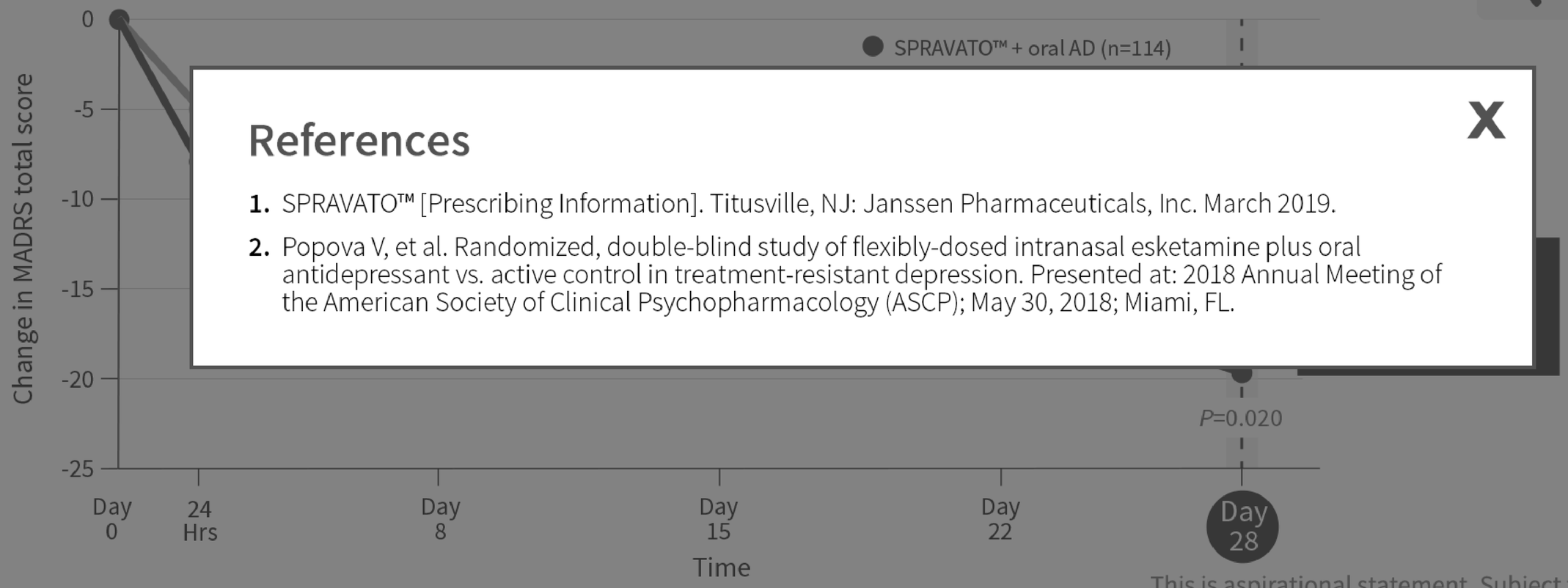
Superior Improvement in Depression Symptoms vs Oral Antidepressant (AD) Plus Placebo at Week 4[1,2]

Spravato™ (esketamine) CIII nasal spray

STUDY 1 (SHORT-TERM)

TIME COURSE OF TREATMENT RESPONSE

Study Design



This is aspirational statement. Subject to change

- Most of the treatment difference between SPRAVATO™ and placebo was observed at 24 hours
- Between 24 hours and Day 28, both SPRAVATO™ and placebo groups continued to improve
- The difference between the groups generally remained the same but did not appear to increase over time through Day 28

References

1. SPRAVATO™ [Prescribing Information]. Titusville, NJ: Janssen Pharmaceuticals, Inc. March 2019.
2. Popova V, et al. Randomized, double-blind study of flexibly-dosed intranasal esketamine plus oral antidepressant vs. active control in treatment-resistant depression. Presented at: 2018 Annual Meeting of the American Society of Clinical Psychopharmacology (ASCP); May 30, 2018; Miami, FL.

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VA-19-1109-B-001447

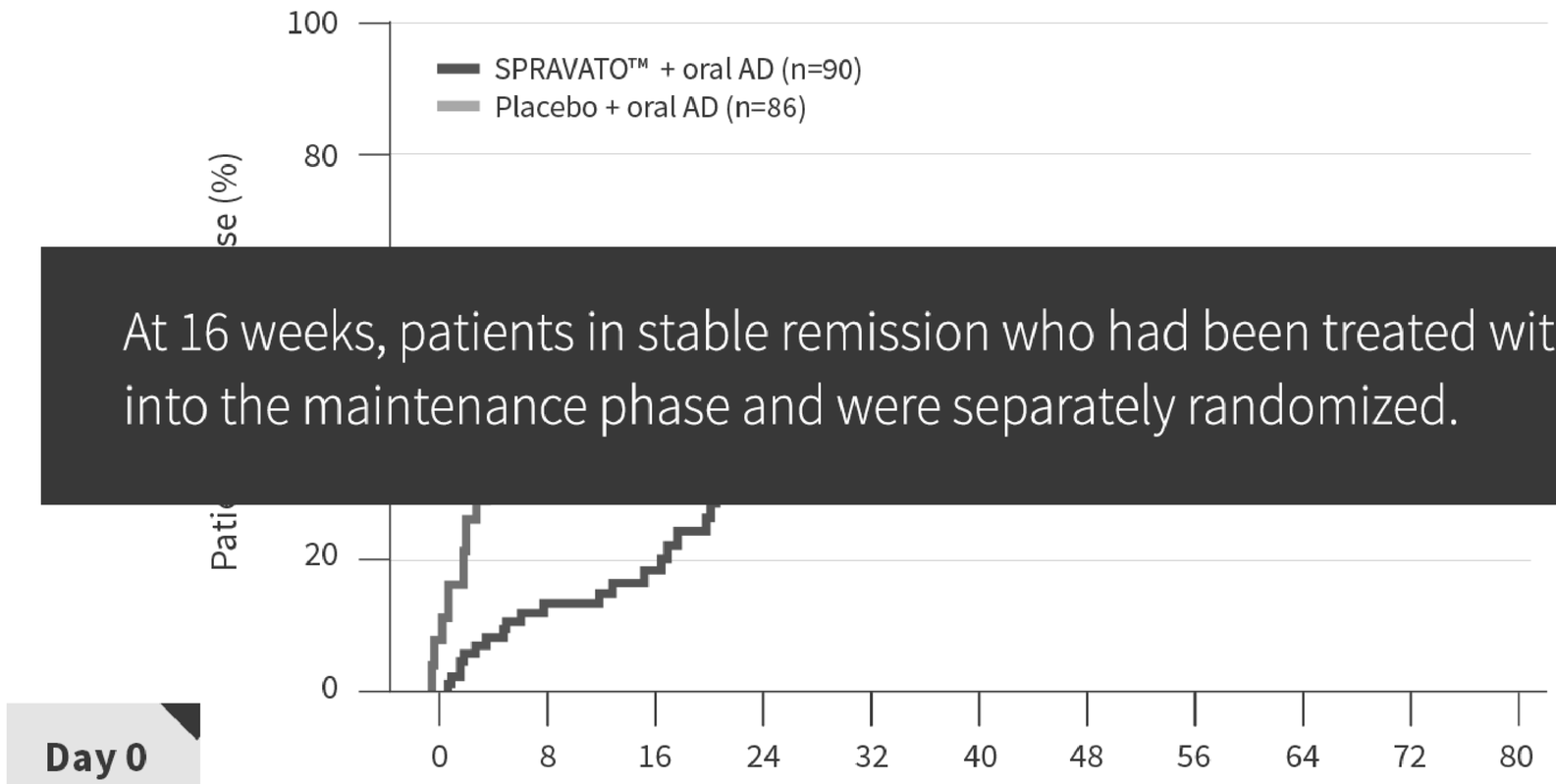
SPRAVATO™ Plus an Oral AD Significantly Delayed Time to Relapse in a Long-Term Maintenance Trial[1,2*]

Spravato™ (esketamine) CIII nasal spray

STUDY 2 (LONG-TERM)

PATIENTS IN STABLE REMISSION WHO CONTINUED SPRAVATO™

Study Design



HR=0.49 (95% CI: 0.29, 0.84)

Day 0

At 16 weeks, patients in stable remission who had been treated with SPRAVATO™ continued into the maintenance phase and were separately randomized.

X

- Remission was defined as a MADRS total score of ≤12 in at least 3 of the final 4 weeks of the optimization phase

*Relapse was defined as a MADRS total score of ≥22 for 2 consecutive assessments separated by 5 to 15 days and/or hospitalization for worsening depression, or any other clinically relevant event determined per clinical judgment to be suggestive of a relapse of depressive illness.

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VA-19-1109-B-001448

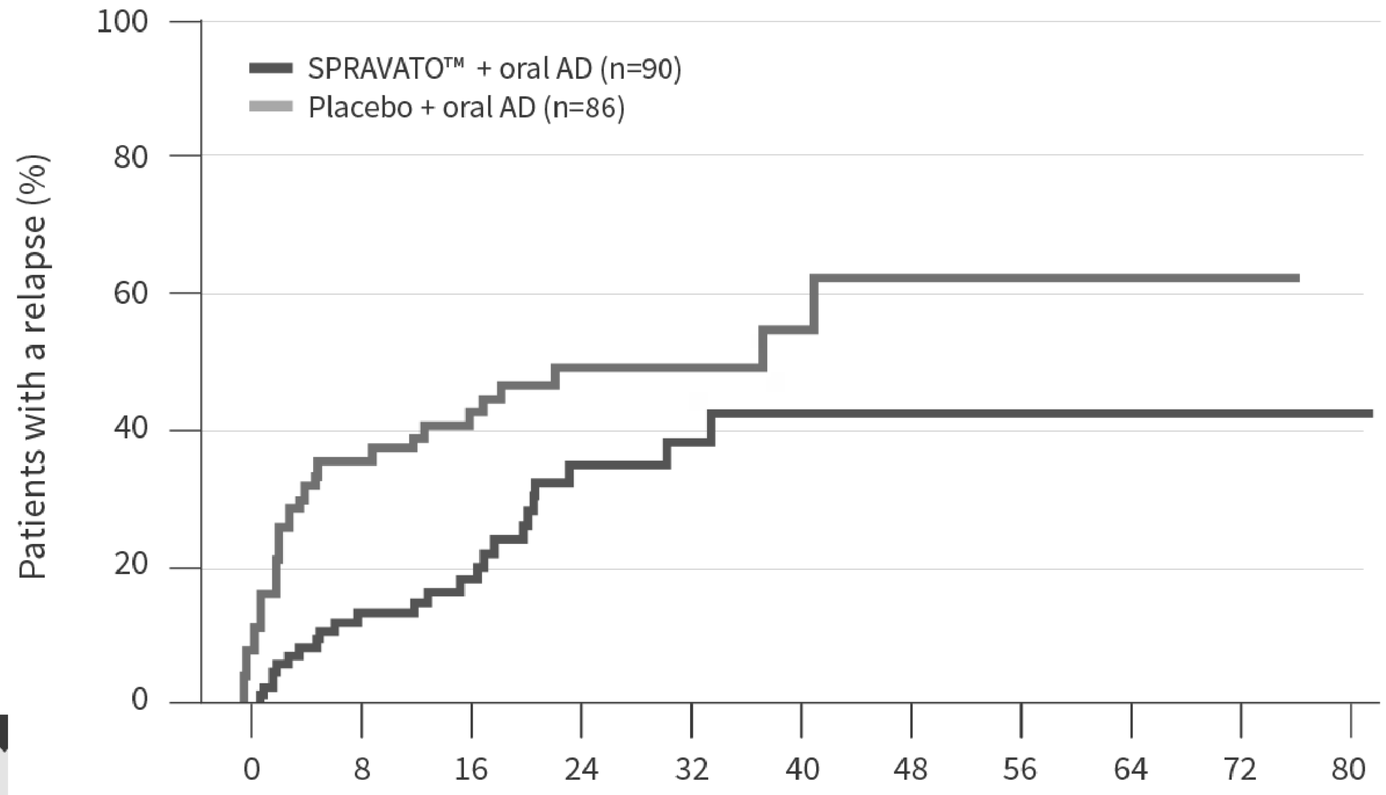
SPRAVATO™ Plus an Oral AD Significantly Delayed Time to Relapse in a Long-Term Maintenance Trial[1,2]*

Spravato™ (esketamine) C III nasal spray

STUDY 2 (LONG-TERM)

PATIENTS IN STABLE REMISSION WHO CONTINUED SPRAVATO™

Study Design



51% LESS LIKELY TO RELAPSE

HR=0.49 (95% CI: 0.29, 0.84)

- Remission was defined as a MADRS total score of ≤12 in at least 3 of the final 4 weeks of the optimization phase

*Relapse was defined as a MADRS total score of ≥22 for 2 consecutive assessments separated by 5 to 15 days and/or hospitalization for worsening depression, or any other clinically relevant event determined per clinical judgment to be suggestive of a relapse of depressive illness.

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VA-19-1109-B-001449

SPRAVATO™ Plus an Oral AD Significantly Delayed Time to Relapse in a Long-T

Spravato™ mine) III

STUDY 2 (LO

PATIENTS IN STAB

Study Design

Patients with a relapse (%)

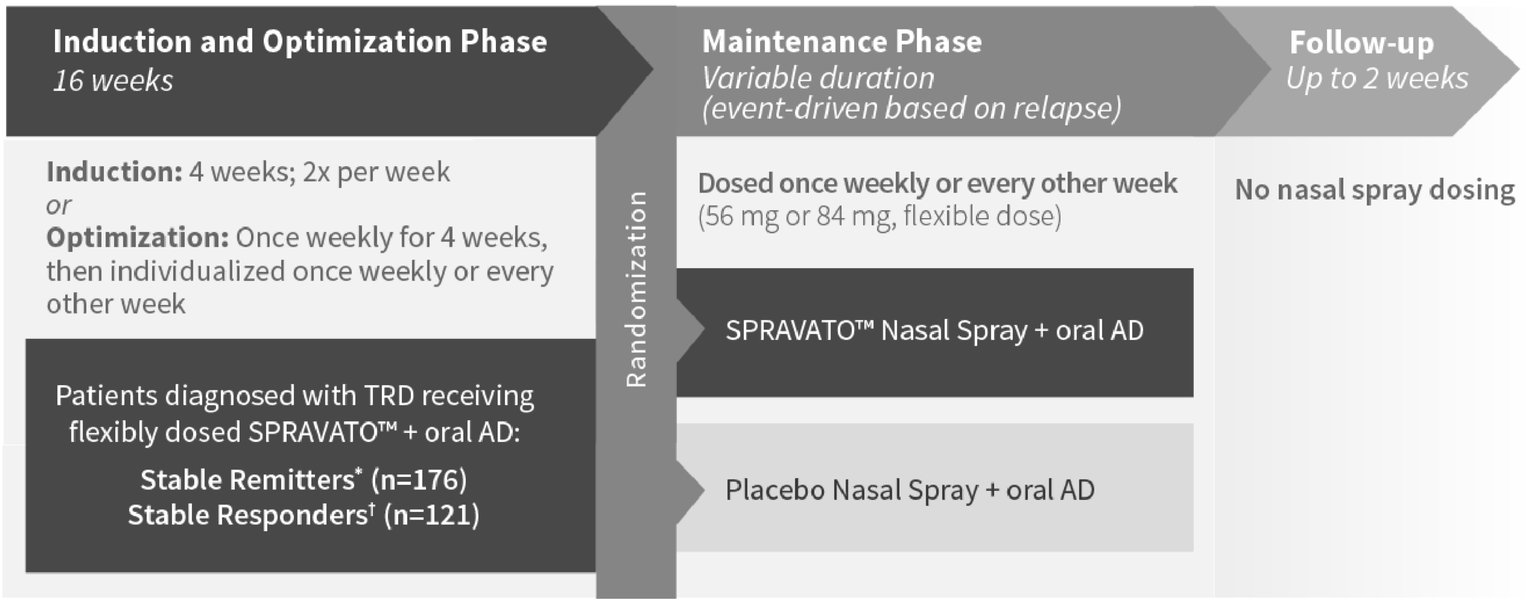
Day 0

• Remission was d

*Relapse was defined as a MADRS total score of ≥22 for 2 consecutive assessments separated by 5 to 15 days and/or hospitalization for worsening depression, or any other clinically relevant event determined per clinical judgment to be suggestive of a relapse of depressive illness.

STUDY 2 (LONG-TERM) Study Design

STUDY 2 (N=705) WAS A PIVOTAL PHASE 3, LONG-TERM, RANDOMIZED, DOUBLE-BLIND, PARALLEL-GROUP, CONTROLLED, MULTICENTER, MAINTENANCE-OF-EFFECT STUDY OF VARIABLE DURATION OF ADULT PATIENTS WITH TREATMENT-RESISTANT DEPRESSION (TRD)[1,2]



Primary Endpoint

- Time to relapse (cumulative distribution) during the maintenance phase among stable remitters
  - Relapse was defined as one of the following:
    - MADRS total score of ≥22 for 2 consecutive assessments separated by 5 to 15 days
    - Hospitalization for worsening depression, or any other clinically relevant event determined per clinical judgment to be suggestive of a relapse of depressive illness

Enrollment

- 437 patients (aged 18-64 years) were directly enrolled
  - Patients who were directly enrolled received SPRAVATO™ (56 mg or 84 mg twice/week) plus a new oral AD in a 4-week open-label induction phase before entering a 12-week optimization phase
- 268 patients (aged 18-64 years) were transferred from short-term studies

* Remission was defined as a MADRS total score of ≤12 in at least 3 of the final 4 weeks of the optimization phase.
† Response was defined as a MADRS total score reduction ≥ 50% for at least 3 of the last 4 weeks and not in remission.

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VA-19-1109-B-001450

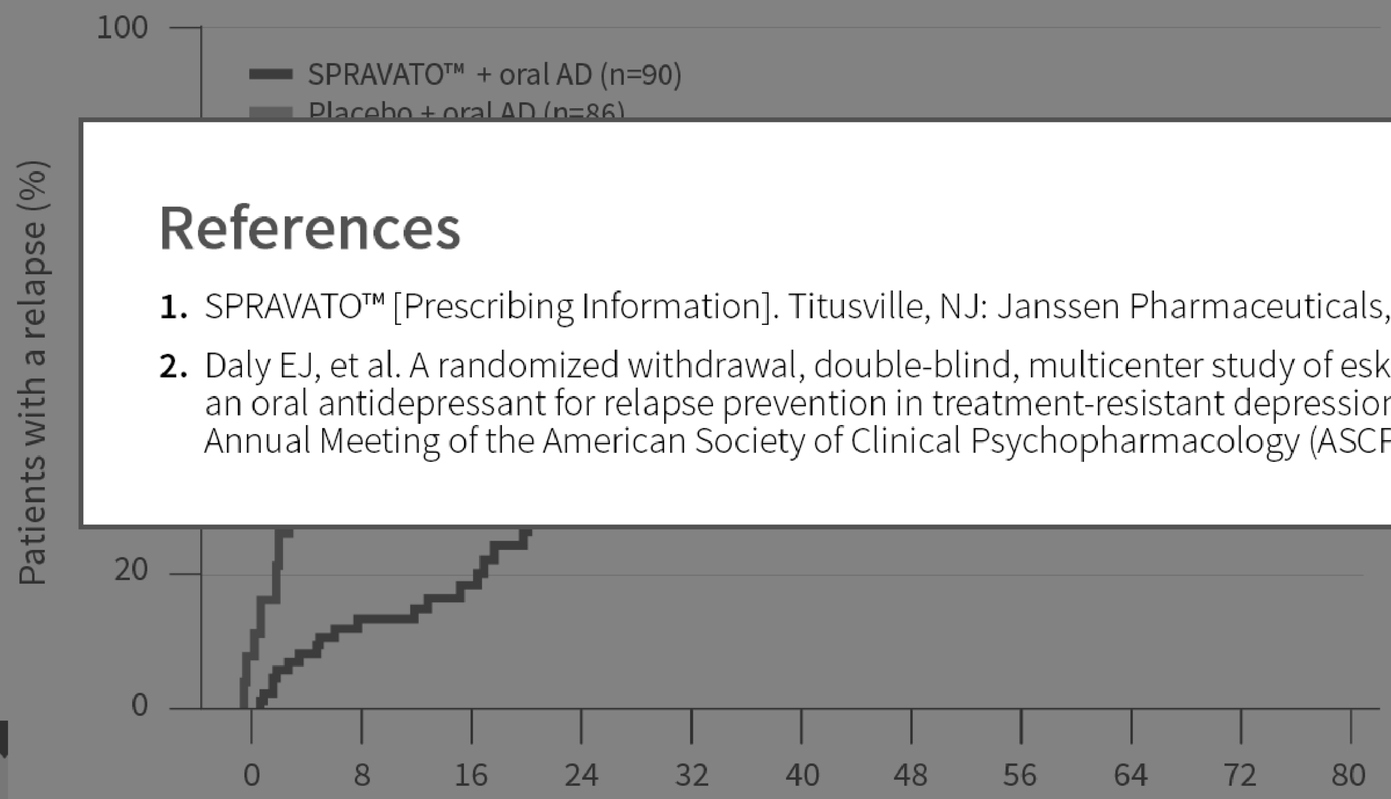
SPRAVATO™ Plus an Oral AD Significantly Delayed Time to Relapse in a Long-Term Maintenance Trial[1,2*]

Spravato™ (esketamine) C III nasal spray

STUDY 2 (LONG-TERM)

PATIENTS IN STABLE REMISSION WHO CONTINUED SPRAVATO™

Study Design



Day 0

- Remission was defined as a MADRS total score of ≤12 in at least 3 of the final 4 weeks of the optimization phase

*Relapse was defined as a MADRS total score of ≥22 for 2 consecutive assessments separated by 5 to 15 days and/or hospitalization for worsening depression, or any other clinically relevant event determined per clinical judgment to be suggestive of a relapse of depressive illness.

References

1. SPRAVATO™ [Prescribing Information]. Titusville, NJ: Janssen Pharmaceuticals, Inc. March 2019.
2. Daly EJ, et al. A randomized withdrawal, double-blind, multicenter study of esketamine nasal spray plus an oral antidepressant for relapse prevention in treatment-resistant depression. Presented at: 2018 Annual Meeting of the American Society of Clinical Psychopharmacology (ASCP); May 30, 2018; Miami, FL.

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VA-19-1109-B-001451

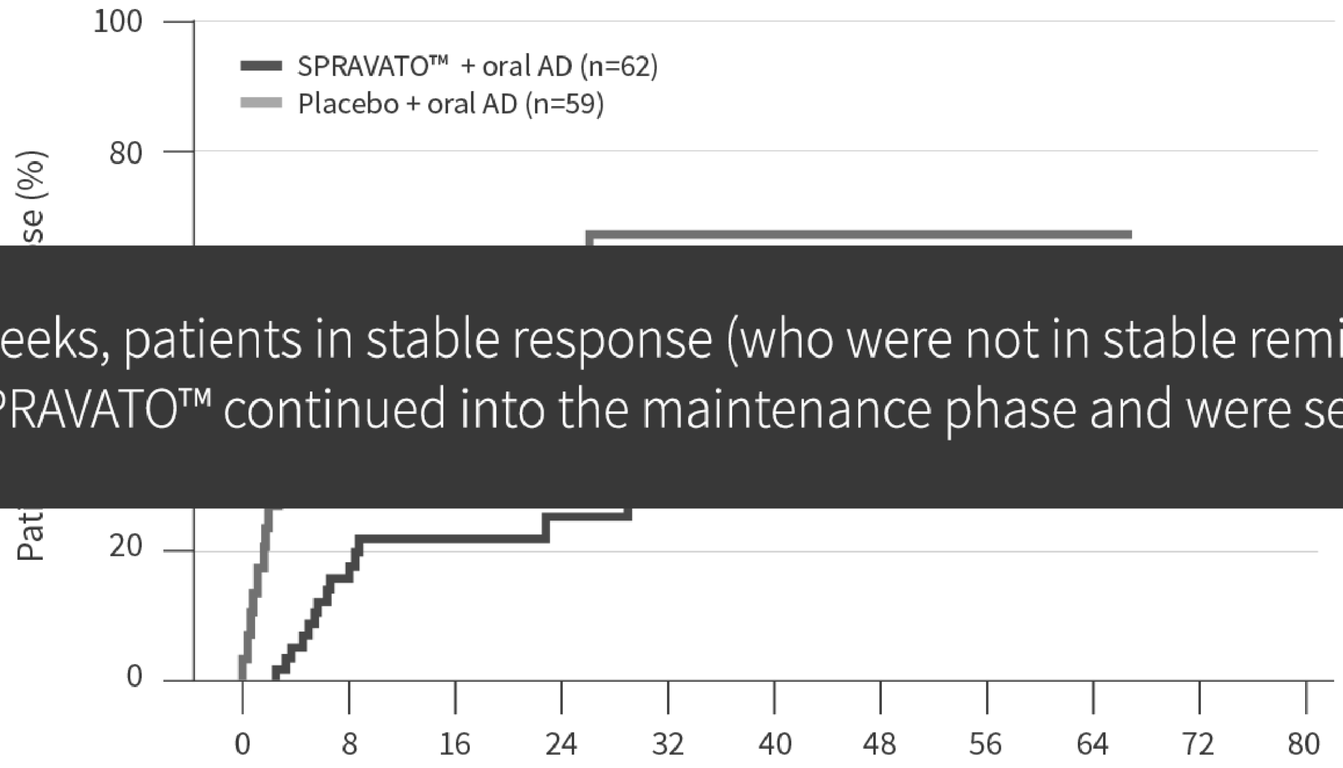
SPRAVATO™ Plus an Oral AD Significantly Delayed Time to Relapse in a Long-Term Maintenance Trial[1,2*]

Spravato™ (esketamine) CIII nasal spray

STUDY 2 (LONG-TERM)

PATIENTS IN STABLE RESPONSE WHO CONTINUED SPRAVATO™

Study Design



At 16 weeks, patients in stable response (who were not in stable remission) who had been treated with SPRAVATO™ continued into the maintenance phase and were separately randomized.

Day 0

- Response was defined as a MADRS total score reduction ≥ 50% for at least 3 of the last 4 weeks and not in remission.

*Relapse was defined as a MADRS total score of ≥22 for 2 consecutive assessments separated by 5 to 15 days and/or hospitalization for worsening depression, or any other clinically relevant event determined per clinical judgment to be suggestive of a relapse of depressive illness.

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VA-19-1109-B-001452

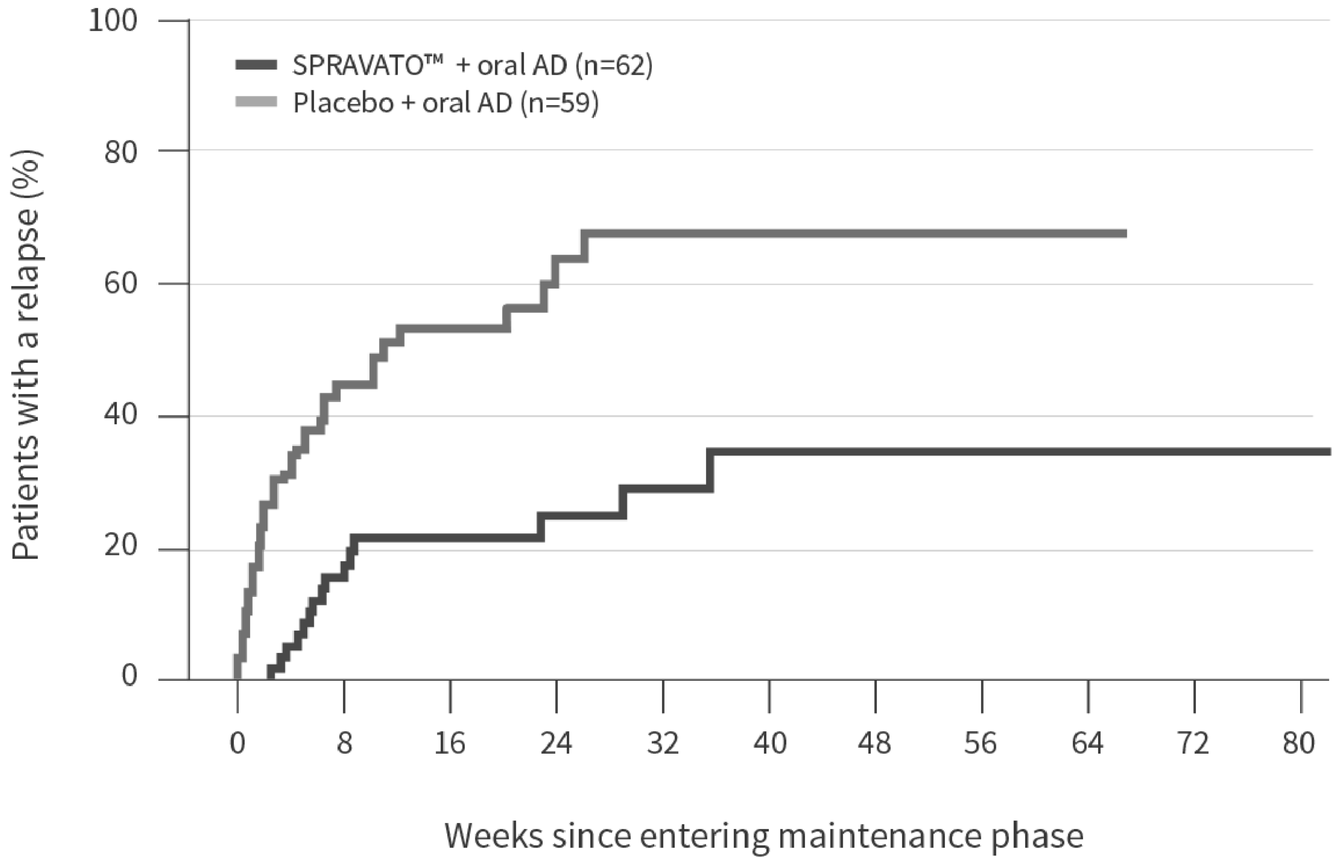
SPRAVATO™ Plus an Oral AD Significantly Delayed Time to Relapse in a Long-Term Maintenance Trial[1,2*]

Spravato™ (esketamine) CIII nasal spray

STUDY 2 (LONG-TERM)

PATIENTS IN STABLE RESPONSE WHO CONTINUED SPRAVATO™

Study Design



70% LESS LIKELY TO RELAPSE

HR=0.30 (95% CI: 0.16, 0.55)

Day 0

- Response was defined as a MADRS total score reduction ≥ 50% for at least 3 of the last 4 weeks and not in remission.

*Relapse was defined as a MADRS total score of ≥22 for 2 consecutive assessments separated by 5 to 15 days and/or hospitalization for worsening depression, or any other clinically relevant event determined per clinical judgment to be suggestive of a relapse of depressive illness.

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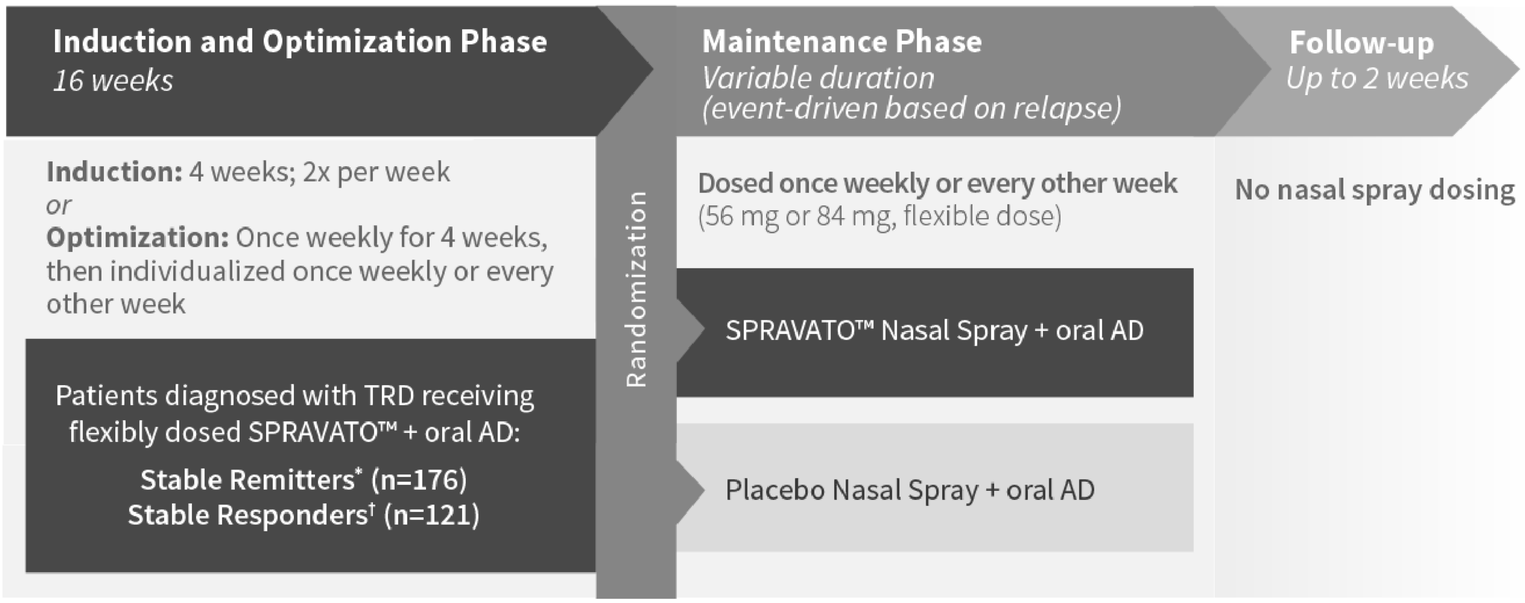
VA-19-1109-B-001453

STUDY 2 (LONG-TERM) Study Design

STUDY 2 (N=705) WAS A PIVOTAL PHASE 3, LONG-TERM, RANDOMIZED, DOUBLE-BLIND, PARALLEL-GROUP, CONTROLLED, MULTICENTER, MAINTENANCE-OF-EFFECT STUDY OF VARIABLE DURATION OF ADULT PATIENTS WITH TREATMENT-RESISTANT DEPRESSION (TRD)[1,2]



Primary Endpoint

- Time to relapse (cumulative distribution) during the maintenance phase among stable remitters
  - Relapse was defined as one of the following:
    - MADRS total score of ≥22 for 2 consecutive assessments separated by 5 to 15 days
    - Hospitalization for worsening depression, or any other clinically relevant event determined per clinical judgment to be suggestive of a relapse of depressive illness

Enrollment

- 437 patients (aged 18-64 years) were directly enrolled
  - Patients who were directly enrolled received SPRAVATO™ (56 mg or 84 mg twice/week) plus a new oral AD in a 4-week open-label induction phase before entering a 12-week optimization phase
- 268 patients (aged 18-64 years) were transferred from short-term studies

* Remission was defined as a MADRS total score of ≤12 in at least 3 of the final 4 weeks of the optimization phase.
† Response was defined as a MADRS total score reduction ≥ 50% for at least 3 of the last 4 weeks and not in remission.

*Relapse was defined as a MADRS total score of ≥22 for 2 consecutive assessments separated by 5 to 15 days and/or hospitalization for worsening depression, or any other clinically relevant event determined per clinical judgment to be suggestive of a relapse of depressive illness.

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VA-19-1109-B-001454

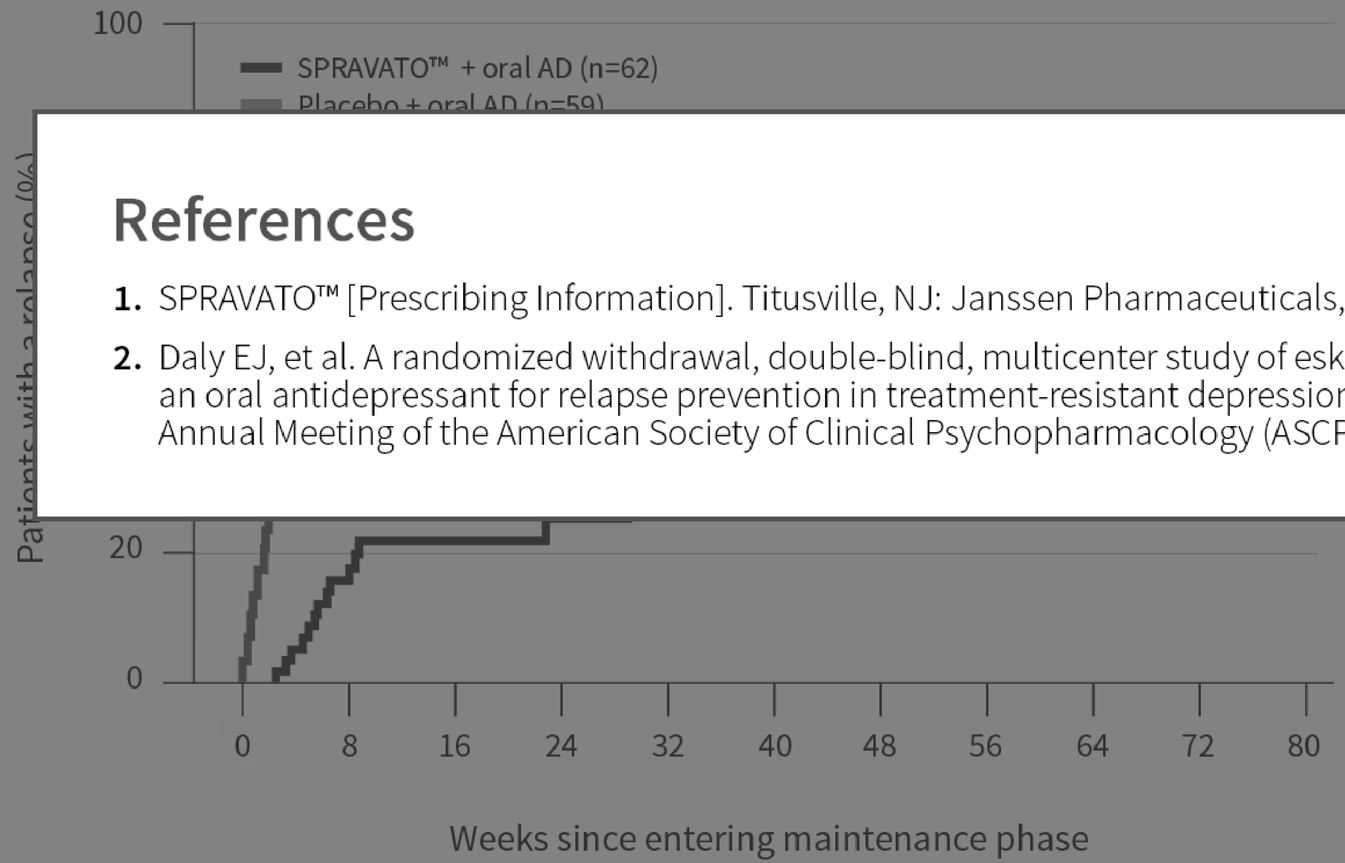
SPRAVATO™ Plus an Oral AD Significantly Delayed Time to Relapse in a Long-Term Maintenance Trial[1,2*]

Spravato™ (esketamine) C III nasal spray

STUDY 2 (LONG-TERM)

PATIENTS IN STABLE RESPONSE WHO CONTINUED SPRAVATO™

Study Design



Day 0

- Response was defined as a MADRS total score reduction ≥ 50% for at least 3 of the last 4 weeks and not in remission.

*Relapse was defined as a MADRS total score of ≥22 for 2 consecutive assessments separated by 5 to 15 days and/or hospitalization for worsening depression, or any other clinically relevant event determined per clinical judgment to be suggestive of a relapse of depressive illness.

References

1. SPRAVATO™ [Prescribing Information]. Titusville, NJ: Janssen Pharmaceuticals, Inc. March 2019.
2. Daly EJ, et al. A randomized withdrawal, double-blind, multicenter study of esketamine nasal spray plus an oral antidepressant for relapse prevention in treatment-resistant depression. Presented at: 2018 Annual Meeting of the American Society of Clinical Psychopharmacology (ASCP); May 30, 2018; Miami, FL.

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VA-19-1109-B-001455

Demonstrated Safety Profile[1]

Spravato™ (esketamine) C III nasal spray

ADVERSE REACTIONS IN ≥2% OF PATIENTS TREATED WITH SPRAVATO™ AND PLACEBO IN THE SHORT-TERM STUDIES*

Adverse reaction	n (% of population)		Adverse reaction	n (% of population)	
	SPRAVATO™ (N=346)	Placebo (N=222)		SPRAVATO™ (N=346)	Placebo (N=222)
Dissociation	**142 (41%)**	21 (9%)	Nasal discomfort	**23 (7%)**	11 (5%)
Dizziness	**101 (29%)**	17 (8%)	Throat irritation	**23 (7%)**	9 (4%)
Nausea	**98 (28%)**	19 (9%)	Feeling drunk	**19 (5%)**	1 (0.5%)
Sedation	**79 (23%)**	21 (9%)	Dry mouth	**19 (5%)**	7 (3%)
Vertigo	**78 (23%)**	6 (3%)	Hyperhidrosis	**14 (4%)**	5 (2%)
Headache	**70 (20%)**	38 (17%)	Euphoric mood	**15 (4%)**	2 (1%)
Dysgeusia	**66 (19%)**	30 (14%)	Dysarthria	**15 (4%)**	0 (0%)
Hypoesthesia	**63 (18%)**	5 (2%)	Tremor	**15 (4%)**	2 (1%)
Anxiety	**45 (13%)**	14 (6%)	Oropharyngeal pain	**9 (3%)**	5 (2%)
Lethargy	**37 (11%)**	12 (5%)	Mental impairment	**11 (3%)**	2 (1%)
Blood pressure increased	**36 (10%)**	6 (3%)	Constipation	**11 (3%)**	3 (1%)
Vomiting	**32 (9%)**	4 (2%)	Pollakiuria	**11 (3%)**	1 (0.5%)
Insomnia	**29 (8%)**	16 (7%)	Feeling abnormal	**12 (3%)**	0 (0%)
Diarrhea	**23 (7%)**	13 (6%)	Tachycardia	**6 (2%)**	1 (0.5%)

Discontinuation rates due to adverse events were <5% across all short- and long-term clinical studies[1]

*At any dose and at a greater rate than patients receiving placebo nasal spray

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VA-19-1109-B-001456

Demonstrated Safety Profile[1]

Spravato™ (esketamine) CIII nasal spray

ADVERSE REACTIONS IN ≥2% OF PATIENTS TREATED WITH SPRAVATO™ AND PLACEBO IN THE SHORT-TERM STUDIES*

Adverse reaction	n (% of population)		Adverse reaction	n (% of population)	
	SPRAVATO™ (N=346)	Placebo (N=222)		SPRAVATO™ (N=346)	Placebo (N=222)
Dissociation	**142 (41%)**	21 (9%)	Nasal discomfort	**23 (7%)**	11 (5%)
Dizziness	**101 (29%)**	17 (8%)	Throat irritation	**23 (7%)**	9 (4%)
Nausea	**98 (28%)**	19 (9%)	Feeling drunk	**19 (5%)**	1 (0.5%)
Hypoesthesia	**63 (18%)**	5 (2%)	Tremor	**15 (4%)**	2 (1%)
Anxiety	**45 (13%)**	14 (6%)	Oropharyngeal pain	**9 (3%)**	5 (2%)
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Blood pressure increased	**36 (10%)**	6 (3%)	Constipation	**11 (3%)**	3 (1%)
Vomiting	**32 (9%)**	4 (2%)	Pollakiuria	**11 (3%)**	1 (0.5%)
Insomnia	**29 (8%)**	16 (7%)	Feeling abnormal	**12 (3%)**	0 (0%)
Diarrhea	**23 (7%)**	13 (6%)	Tachycardia	**6 (2%)**	1 (0.5%)

Discontinuation rates due to adverse events were <5% across all short- and long-term clinical studies[1]

*At any dose and at a greater rate than patients receiving placebo nasal spray

Reference

1. SPRAVATO™ [Prescribing Information]. Titusville, NJ: Janssen Pharmaceuticals, Inc. March 2019.

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VA-19-1109-B-001457

Sedation[1]

Spravato™ (esketamine) C III nasal spray

- Sedation was reported in 2 ways in the clinical studies: through adverse event reports and by using the Modified Observer's Assessment of Alertness/Sedation Scale (MOAA/s)
  - Adverse events of sedation were reported in approximately 23% of patients treated with SPRAVATO™ at any dose (N=346)
  - Based on the MOAA/s, 49% to 61% of patients treated with SPRAVATO™ developed sedation
- 0.3% of patients treated with SPRAVATO™ experienced loss of consciousness*
- Because of the possibility of delayed or prolonged sedation, patients should be monitored by a healthcare professional for at least 2 hours at each treatment session, followed by an assessment to determine when the patient is considered clinically stable and ready to leave

* Based on the MOAA/s scale.

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VA-19-1109-B-001458

Sedation was reported in 2 ways in the clinical studies: through adverse event reports and by using the Modified Observer's Assessment of Alertness/Sedation Scale (MOAA/s)

- Adverse events of sedation were reported in approximately 23% of patients treated with SPRAVATO™ at any dose (N=346)

edation

- Because of the possibility of delayed or prolonged sedation, patients should be monitored by a healthcare professional for at least 2 hours at each treatment session, followed by an assessment to determine when the patient is considered clinically stable and ready to leave

* Based on the MOAA/s scale.

Reference

1. SPRAVATO™ [Prescribing Information]. Titusville, NJ: Janssen Pharmaceuticals, Inc. March 2019.

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VA-19-1109-B-001459

Dissociation[1]

Spravato™ (esketamine) C III nasal spray

Dissociation was reported in 2 ways in the clinical studies: through adverse event reports, and by using the Clinician-Administered Dissociative States Scale (CADSS)

- Adverse events of dissociation were reported in approximately 41% of patients treated with SPRAVATO™ at any dose (N=346)
- Based on the CADSS, 61% to 75% of patients treated with SPRAVATO™ developed dissociative or perceptual changes

- In clinical trials, dissociation was reported as transient and occurred on the day of dosing

- Because of the risks of dissociation, patients should be monitored by a healthcare professional for at least 2 hours at each treatment session, followed by an assessment to determine when the patient is considered clinically stable and ready to leave the healthcare setting
- Given its potential dissociative effects, carefully assess patients with psychosis before administering SPRAVATO™; treatment should be initiated only if the benefit outweighs the risk

WHAT IS DISSOCIATION?*

The most common psychological effects of SPRAVATO™ have been dissociative/perceptual changes (including distortion of time and space, and illusions), derealization, and depersonalization. Patients may describe these symptoms as feeling disconnected from themselves, their thoughts and feelings, and the things around them.

* Based on the CADSS.

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VA-19-1109-B-001460

Dissociation[1]

Spravato™ (esketamine) C III nasal spray

Dissociation was reported in 2 ways in the clinical studies: through adverse event reports, and by using the Clinician-Administered Dissociative States Scale (CADSS)

- Adverse events of dissociation were reported in approximately 41% of patients treated with SPRAVATO™ at any dose (N=346)
- Based on the CADSS, 61% to 75% of patients treated with SPRAVATO™ developed dissociative or perceptual changes

- I

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The most common psychological effects of SPRAVATO™ have been dissociative/perceptual changes (including distortion of time and space, and illusions), derealization, and depersonalization. Patients may describe these symptoms as feeling disconnected from themselves, their thoughts and feelings, and the things around them.

* Based on the CADSS.

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1. SPRAVATO™ [Prescribing Information]. Titusville, NJ: Janssen Pharmaceuticals, Inc. March 2019.

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VA-19-1109-P-001461

Additional Safety Information[1]

Spravato™ (esketamine) C III nasal spray

ABUSE AND MISUSE

- SPRAVATO™ is a Schedule III controlled substance and may be subject to abuse and diversion. Assess each patient's risk for abuse or misuse prior to prescribing SPRAVATO™, and monitor all patients receiving SPRAVATO™ for the development of these behaviors or conditions, including drug-seeking behavior, while on therapy
- Individuals with a history of drug abuse or dependence are at greater risk; therefore, use careful consideration prior to treatment of individuals with a history of substance use disorder. Monitoring for signs of abuse is recommended

DEPENDENCE

- Physical dependence has been reported with prolonged off-label use of ketamine. In Study 1, there were no withdrawal symptoms captured up to 4 weeks after cessation of SPRAVATO™ treatment. Monitor SPRAVATO™-treated patients for symptoms and signs of physical dependence upon discontinuation of the drug

EFFECT ON DRIVING

- Before SPRAVATO™ administration, instruct patients not to engage in potentially hazardous activities, such as driving a motor vehicle or operating machinery, until the next day after a restful sleep
- Patients will require transportation from the treatment center after administration

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VA-19-1109-B-001462

Additional Safety Information[1]

Spravato™ (esketamine) C-III nasal spray

ABUSE AND MISUSE

- SPRAVATO™ is a Schedule III controlled substance and may be subject to abuse and diversion. Assess each patient's risk for abuse or misuse prior to prescribing SPRAVATO™, and monitor all patients receiving SPRAVATO™ for the development of these behaviors or conditions, including drug-seeking behavior, while on therapy
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- Before SPRAVATO™ administration, instruct patients not to engage in potentially hazardous activities, such as driving a motor vehicle or operating machinery, until the next day after a restful sleep
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Reference

1. SPRAVATO™ [Prescribing Information]. Titusville, NJ: Janssen Pharmaceuticals, Inc. March 2019.

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VA-19-1109-B-001463

Additional Safety Information[1]

Spravato™ (esketamine) C III nasal spray

CONTRAINDICATIONS

- SPRAVATO™ is contraindicated in patients with:
  - Aneurysmal vascular disease (including thoracic and abdominal aorta, intracranial, and peripheral arterial vessels) or arteriovenous malformation
  - History of intracerebral hemorrhage
  - Hypersensitivity to esketamine, ketamine, or to any of the excipients.

DRUG INTERACTIONS

- **CNS depressants:** Closely monitor for sedation with concomitant use of SPRAVATO™ with CNS depressants, including benzodiazepines, opioids, and alcohol
- **Psychostimulants and monoamine oxidase inhibitors (MAOIs):** Closely monitor blood pressure with concomitant use of SPRAVATO™ with psychostimulants (including amphetamines, methylphenidate, modafinil, and armodafinil) and MAOIs

BLOOD PRESSURE

- SPRAVATO™ caused increases in systolic blood pressure (SBP) and/or diastolic blood pressure (DBP), which peak at approximately 40 minutes after administration and last approximately 4 hours:
  - 40 minutes post dose, mean placebo-adjusted increases in SBP = 7 to 9 mmHg and DBP = 4 to 6 mmHg
  - If blood pressure is decreasing and the patient appears clinically stable for at least 2 hours, the patient may be discharged at the end of the post-dose monitoring period
- Assess blood pressure prior to, and approximately 40 minutes after dosing with SPRAVATO™ and subsequently as clinically warranted until values decline
  - Do not administer SPRAVATO™ if an increase in blood pressure or intracranial pressure poses a serious risk
  - Before prescribing SPRAVATO™, patients with other cardiovascular and cerebrovascular conditions should be carefully assessed to determine whether the potential benefits of SPRAVATO™ outweigh its risks

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VA-19-1109-B-001464

Additional Safety Information[1]

Spravato™ (esketamine) nasal spray

CONTRAINDICATIONS

- SPRAVATO™ is contraindicated in patients with:
  - Aneurysmal vascular disease (including thoracic and abdominal aorta, intracranial, and peripheral arterial vessels) or arteriovenous malformation
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DRUG INTERACTIONS

- C … nts, including b…
- F… ncomitant use of S… finil) and MAOIs

BLOOD PRESSURE

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  - 40 minutes post dose, mean placebo-adjusted increases in SBP = 7 to 9 mmHg and DBP = 4 to 6 mmHg
  - If blood pressure is decreasing and the patient appears clinically stable for at least 2 hours, the patient may be discharged at the end of the post-dose monitoring period
- Assess blood pressure prior to, and approximately 40 minutes after dosing with SPRAVATO™ and subsequently as clinically warranted until values decline
  - Do not administer SPRAVATO™ if an increase in blood pressure or intracranial pressure poses a serious risk
  - Before prescribing SPRAVATO™, patients with other cardiovascular and cerebrovascular conditions should be carefully assessed to determine whether the potential benefits of SPRAVATO™ outweigh its risks

Reference

1. SPRAVATO™ [Prescribing Information]. Titusville, NJ: Janssen Pharmaceuticals, Inc. March 2019.

Home | References | Study Methodology | Study Limitations

Please see full Prescribing Information, including Boxed WARNINGS, available at this presentation.

Disease Burden and Unmet Need | Clinical Value | Access and Operational Considerations

Important Safety Information | Full Prescribing Information

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VA-19-1109-B-001465

Additional Safety Information[1]

Spravato™ (esketamine) C III nasal spray

PREGNANCY & LACTATION

- SPRAVATO™ is not recommended for women who are pregnant or may become pregnant, or in women who are breastfeeding. Women who become pregnant should stop taking SPRAVATO™ and the patient should be counseled about the potential risk to the fetus
- SPRAVATO™ was not assessed in pregnant women. SPRAVATO™ may cause fetal harm when administered to pregnant women

COGNITION

- In a study in healthy volunteers, a single dose of SPRAVATO™ caused cognitive performance decline 40 minutes post dose. Cognitive performance and mental effort were comparable between SPRAVATO™ and placebo at 2 hours post dose
- Long-term cognitive and memory impairment have been reported with repeated off-label ketamine misuse or abuse
- No adverse effects of SPRAVATO™ nasal spray on cognitive functioning were observed in a one-year open-label safety study; however, the long-term cognitive effects of SPRAVATO™ have not been evaluated beyond one year

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VA-19-1109-B-001466

Additional Safety Information[1]

Spravato™ (esketamine) C III nasal spray

PREGNANCY & LACTATION

- SPRAVATO™ is not recommended for women who are pregnant or may become pregnant, or in women who are breastfeeding. Women who become pregnant should stop taking SPRAVATO™ and the patient should be counseled about the potential risk to the fetus
- SPRAVATO™ was not assessed in pregnant women. SPRAVATO™ may cause fetal harm when administered to pregnant women

COGNITION

- misuse or abuse
- No adverse effects of SPRAVATO™ nasal spray on cognitive functioning were observed in a one-year open-label safety study; however, the long-term cognitive effects of SPRAVATO™ have not been evaluated beyond one year

Reference

1. SPRAVATO™ [Prescribing Information]. Titusville, NJ: Janssen Pharmaceuticals, Inc. March 2019.

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VA-19-1109-P-001467

Spravato™ (esketamine) CIII nasal spray

REMS

- **The goal of the REMS (Risk Evaluation and Mitigation Strategy) is to mitigate the risks of serious adverse outcomes resulting from sedation and dissociation caused by SPRAVATO™ administration, and abuse and misuse of SPRAVATO™, by:**
  - Ensuring that SPRAVATO™ is only dispensed and administered to patients in a medically supervised healthcare setting that monitors these patients
  - Ensuring pharmacies and healthcare settings that dispense SPRAVATO™ are certified
  - Ensuring that each patient is informed about the serious adverse outcomes resulting from sedation and dissociation and need for monitoring
  - Enrollment of all patients in the REMS (registry) to further characterize the risks and to support safe use

- Because of the possibility of delayed or prolonged sedation or dissociation in some cases, patients must be monitored by a healthcare professional for at least 2 hours following each treatment session, until the clinician determines the patient is safe to leave

SPRAVATO™ is intended for patient administration under the direct observation of a healthcare provider, and patients are required to be monitored by a healthcare provider for at least 2 hours after SPRAVATO™ administration. SPRAVATO™ must never be dispensed directly to a patient for home use.

For more information on the SPRAVATO™ REMS,
please call **855-382-6022** or visit **SPRAVATOrems.com.**

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- **The goal of the REMS (Risk Evaluation and Mitigation Strategy) is to mitigate the risks of serious adverse outcomes resulting from sedation and dissociation caused by SPRAVATO™ administration, and abuse and misuse of SPRAVATO™, by:**
  - Ensuring that SPRAVATO™ is only dispensed and administered to patients in a medically supervised healthcare setting that monitors these patients
  - Ensuring pharmacies and healthcare settings that dispense SPRAVATO™ are certified
  - Ensuring that each patient is informed about the serious adverse outcomes resulting from sedation
  - afe use
- tients
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Reference

1. SPRAVATO™ [Prescribing Information]. Titusville, NJ: Janssen Pharmaceuticals, Inc. March 2019.

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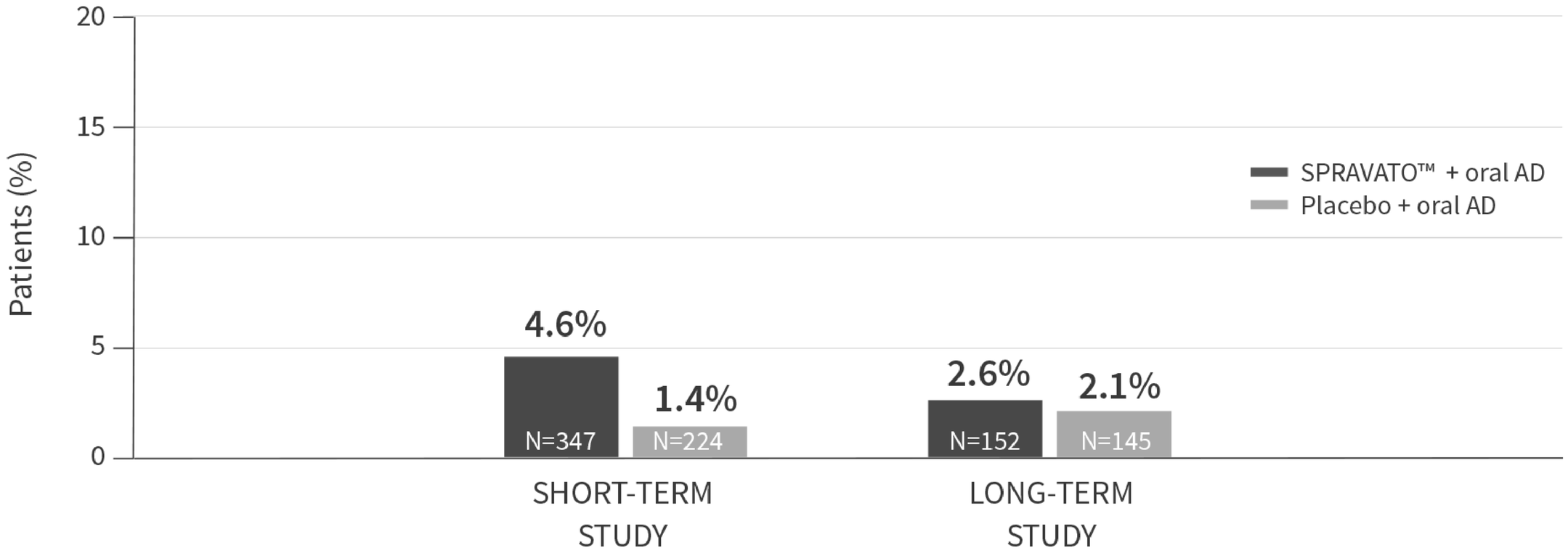
VA-19-1109-P-001469

Discontinuation Rates Due to Adverse Events Were <5% Across Short- and Long-Term Clinical Trials[1]

Spravato™ (esketamine) C III nasal spray

RATES OF DISCONTINUATION DUE TO ADVERSE EVENTS[1]



Adverse events leading to SPRAVATO™ discontinuation in more than 2 patients included anxiety (1.2%), depression (0.9%), blood pressure increased (0.6%), dizziness (0.6%), suicidal ideation (0.5%), dissociation (0.4%), nausea (0.4%), vomiting (0.4%), headache (0.3%), muscular weakness (0.3%), vertigo (0.2%), hypertension (0.2%), panic attack (0.2%), and sedation (0.2%).[1]

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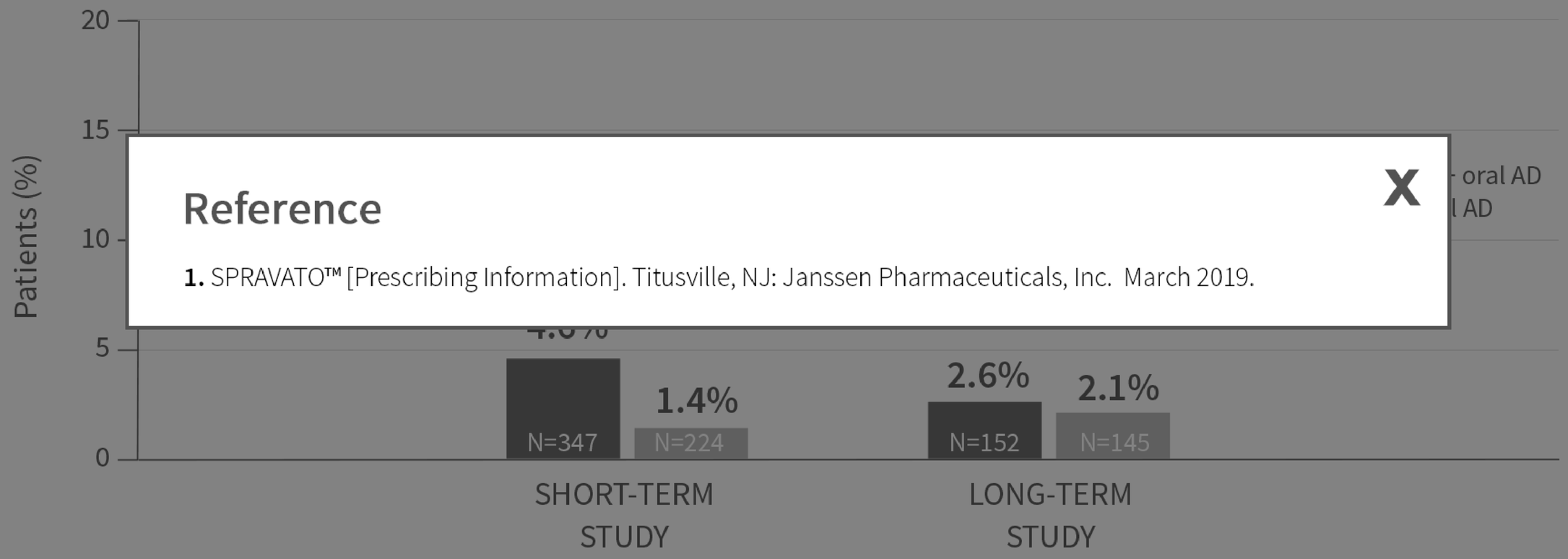
VA-19-1109-B-001470

Discontinuation Rates Due to Adverse Events Were <5% Across Short- and Long-Term Clinical Trials[1]

Spravato™ (esketamine) CIII nasal spray

RATES OF DISCONTINUATION DUE TO ADVERSE EVENTS[1]



Adverse events leading to SPRAVATO™ discontinuation in more than 2 patients included anxiety (1.2%), depression (0.9%), blood pressure increased (0.6%), dizziness (0.6%), suicidal ideation (0.5%), dissociation (0.4%), nausea (0.4%), vomiting (0.4%), headache (0.3%), muscular weakness (0.3%), vertigo (0.2%), hypertension (0.2%), panic attack (0.2%), and sedation (0.2%).[1]

Reference

1. SPRAVATO™ [Prescribing Information]. Titusville, NJ: Janssen Pharmaceuticals, Inc. March 2019.

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VA-19-1109-B-001471

Dosing and Administration Overview[1]

Spravato™ (esketamine) C III
nasal spray

1 Dosing

INDUCTION (twice weekly) | **MAINTENANCE** (once weekly) | (weekly or every 2 weeks)

WEEKS 1-4	WEEKS 5-8	WEEKS 9 AND AFTER*
Day 1 starting dose: **56 mg** Subsequent doses: **56 mg** or **84 mg**	**56 mg** or **84 mg** once weekly	**56 mg** or **84 mg** every 2 weeks or once weekly†

- In Study 2 (long-term), 39% of patients received 56-mg dose, and 61% received the 84-mg dose of SPRAVATO™
- SPRAVATO™ does not require daily dosing and should be administered in conjunction with an oral AD

2 Administration



- Patient-administered under supervision of a healthcare professional

3 Monitoring & Discharge



- Healthcare provider observation will be required for at least 2 hours until they determine the patient is safe to leave
- Patients should not drive or operate heavy machinery until the next day, following a restful sleep

Careful consideration is advised prior to treatment of individuals with a history of substance use disorder, including alcohol. Monitoring for signs of abuse and dependence is recommended.

* Dosing frequency should be individualized to the lowest frequency required to maintain remission/response.
† As determined by the prescribing physician.

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Dosing and Administration Overview[1]

Spravato™ (esketamine) C III nasal spray

1 Dosing

INDUCTION (twice weekly)	MAINTENANCE (once weekly)	(weekly or every 2 weeks)
WEEKS 1-4	WEEKS 5-8	WEEKS 9 AND AFTER*
Day 1 starting dose: **56 mg**	**56 mg** or **84 mg** once weekly	**56 mg** or **84 mg** every

Reference

1. SPRAVATO™ [Prescribing Information]. Titusville, NJ: Janssen Pharmaceuticals, Inc. March 2019.

2 Administration



- Patient-administered under supervision of a healthcare professional

3 Monitoring & Discharge



- Healthcare provider observation will be required for at least 2 hours until they determine the patient is safe to leave
- Patients should not drive or operate heavy machinery until the next day, following a restful sleep

Careful consideration is advised prior to treatment of individuals with a history of substance use disorder, including alcohol. Monitoring for signs of abuse and dependence is recommended.

* Dosing frequency should be individualized to the lowest frequency required to maintain remission/response.
† As determined by the prescribing physician.

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SPRAVATO™ Administration[1]

Spravato™ (esketamine) C III nasal spray



SPRAVATO™ should be self-administered by the patient under the supervision of a healthcare professional in a certified SPRAVATO™ treatment center

The Day 1 starting dose of SPRAVATO™ is 56 mg (2 devices).

84 mg

56 mg =



28 mg

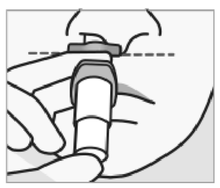


Each single-use device contains 2 sprays, 1 spray for each nostril.

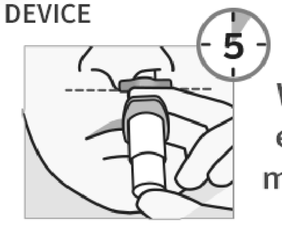


28 mg

FIRST DEVICE



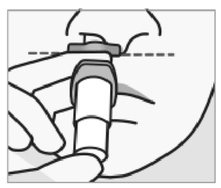
ONE SPRAY IN RIGHT NOSTRIL



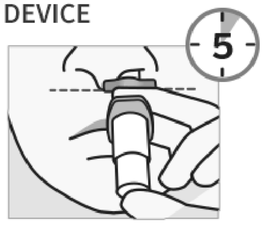
ONE SPRAY IN LEFT NOSTRIL

Wait 5 minutes after each device to allow medication to absorb.

SECOND DEVICE



ONE SPRAY IN RIGHT NOSTRIL



ONE SPRAY IN LEFT NOSTRIL

Please refer to the full Prescribing Information and Instructions for Use included in the SPRAVATO™ packaging.

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VA-19-1109-B-001474

SPRAVATO™ Administration[1]

Spravato™ (esketamine) C III nasal spray



SPRAVATO™ should be self-administered by the patient under the supervision of a healthcare professional in a certified SPRAVATO™ treatment center

X

For patients requiring an 84-mg dose, taken only after an initial starting dose of 56 mg, use 3 devices.

84 mg =



- Dosage adjustments should be made based on efficacy and tolerability of the previous dose



ONE SPRAY IN RIGHT NOSTRIL



ONE SPRAY IN LEFT NOSTRIL

each device to allow medication to absorb.



ONE SPRAY IN RIGHT NOSTRIL



ONE SPRAY IN LEFT NOSTRIL

Please refer to the full Prescribing Information and Instructions for Use included in the SPRAVATO™ packaging.

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VA-19-1109-B-001475

SPRAVATO™ should be self-administered by the patient under the supervision of a healthcare professional in a certified SPRAVATO™ treatment center



The Day 1 starting dose of SPRAVATO™ is 56 mg (2 devices).

56 mg = 28 mg + 28 mg

2 sprays, 1 spray for each nostril.

FIRST DEVICE



ONE SPRAY IN RIGHT NOSTRIL

ONE SPRAY IN LEFT NOSTRIL

Wait 5 minutes after each device to allow medication to absorb.

SECOND DEVICE



ONE SPRAY IN RIGHT NOSTRIL

ONE SPRAY IN LEFT NOSTRIL

Please refer to the full Prescribing Information and Instructions for Use included in the SPRAVATO™ packaging.

Reference

1. SPRAVATO™ [Prescribing Information]. Titusville, NJ: Janssen Pharmaceuticals, Inc. March 2019.

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VA-19-1109-B-001476

Summary of SPRAVATO™ Clinical Value

Spravato™ (esketamine) C III nasal spray

- The first and only NMDA receptor antagonist approved for adult patients with TRD in conjunction with an oral AD[1]
- Superior improvement in depression symptoms at Week 4[1]
- Significantly delayed time to relapse in a long-term study[1]
- Demonstrated safety in short- and long-term studies

NMDA=*N*-methyl-D-aspartate.

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Spravato™ (esketamine) C III nasal spray

- The first and only NMDA receptor antagonist approved for adult patients with TRD in conjunction with an oral AD[1]
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- Significantly delayed time to relapse in a long-term study[1]
- Demonstrated safety in short- and long-term studies

NMDA=*N*-methyl-D-aspartate.

Reference

1. SPRAVATO™ [Prescribing Information]. Titusville, NJ: Janssen Pharmaceuticals, Inc. March 2019.

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VA-19-1109-B-001478

Important Safety Information

Spravato™ (esketamine) C III nasal spray

Indication:

SPRAVATO™ (esketamine) CIII Nasal Spray is indicated, in conjunction with an oral antidepressant (AD), for the treatment of treatment-resistant depression (TRD) in adults.

SPRAVATO™ is not approved as an anesthetic agent. The safety and effectiveness of SPRAVATO™ as an anesthetic agent have not been established.

Important Safety Information

WARNING: SEDATION, DISSOCIATION; ABUSE AND MISUSE; and SUICIDAL THOUGHTS AND BEHAVIORS

See full prescribing information for complete boxed warning

- **Risk for sedation and dissociation after administration. Monitor patients for at least two hours after administration (5.1, 5.2).**
- **Potential for abuse and misuse. Consider the risks and benefits of using SPRAVATO™ prior to use in patients at higher risk of abuse. Monitor for signs and symptoms of abuse and misuse (5.3).**
- **SPRAVATO™ is only available through a restricted program called the SPRAVATO™ REMS (5.4).**
- **Increased risk of suicidal thoughts and behaviors in pediatric and young adult patients taking antidepressants. Closely monitor all antidepressant-treated patients for clinical worsening and emergence of suicidal thoughts and behaviors. SPRAVATO™ is not approved for use in pediatric patients (5.5).**

CONTRAINDICATIONS

SPRAVATO™ is contraindicated in patients with:

- Aneurysmal vascular disease (including thoracic and abdominal aorta, intracranial and peripheral arterial vessels) or arteriovenous malformation
- History of intracerebral hemorrhage
- Hypersensitivity to esketamine, ketamine, or any of the excipients

WARNINGS AND PRECAUTIONS

Sedation: In clinical trials, 49% to 61% of SPRAVATO™-treated patients developed sedation and 0.3% of SPRAVATO™-treated patients experienced loss of consciousness.

Because of the possibility of delayed or prolonged sedation, patients must be monitored by a healthcare provider for at least 2 hours at each treatment session, followed by an assessment to determine when the patient is considered clinically stable and ready to leave the healthcare setting.

Closely monitor for sedation with concomitant use of SPRAVATO™ with CNS depressants *[see Drug Interaction (7.1)]*.

SPRAVATO™ is available only through a restricted program under a REMS.

Dissociation: The most common psychological effects of SPRAVATO™ were dissociative or perceptual changes (including distortion of time, space and illusions), derealization and depersonalization (61% to 75% of SPRAVATO™-treated patients developed dissociative or perceptual changes). Given its potential to induce dissociative effects, carefully assess patients with psychosis before administering SPRAVATO™; treatment should be initiated only if the benefit outweighs the risk.

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VA-19-1109-B-001479

Important Safety Information

Spravato™ (esketamine) C III nasal spray

Because of the risks of dissociation, patients must be monitored by a healthcare provider for at least 2 hours at each treatment session, followed by an assessment to determine when the patient is considered clinically stable and ready to leave the healthcare setting.

SPRAVATO™ is available only through a restricted program under a REMS.

Abuse and Misuse: SPRAVATO™ contains esketamine, a Schedule III controlled substance (CIII), and may be subject to abuse and diversion. Assess each patient's risk for abuse or misuse prior to prescribing and monitor all patients for the development of these behaviors or conditions, including drug-seeking behavior, while on therapy. Individuals with a history of drug abuse or dependence are at greater risk; therefore, use careful consideration prior to treatment of individuals with a history of substance use disorder and monitor for signs of abuse or dependence.

SPRAVATO™ is available only through a restricted program under a REMS.

SPRAVATO™ Risk Evaluation and Mitigation Strategy (REMS): SPRAVATO™ is available only through a restricted program called the SPRAVATO™ REMS because of the risks of serious adverse outcomes from sedation, dissociation, and abuse and misuse.

Important requirements of the SPRAVATO™ REMS include the following:

- Healthcare settings must be certified in the program and ensure that SPRAVATO™ is:
  - Only dispensed in healthcare settings and administered to patients who are enrolled in the program.
  - Administered by patients under the direct observation of a healthcare provider and that patients are monitored by a healthcare provider for at least 2 hours after administration of SPRAVATO™.
- Pharmacies must be certified in the REMS and must only dispense SPRAVATO™ to healthcare settings that are certified in the program.

Further information, including a list of certified pharmacies, is available at www.SPRAVATOrems.com or 1-855-382-6022.

Suicidal Thoughts and Behaviors in Adolescents and Young Adults: In pooled analyses of placebo-controlled trials of antidepressant drugs (SSRIs and other antidepressant classes) that included adult and pediatric patients, the incidence of suicidal thoughts and behaviors in patients age 24 years and younger was greater than in placebo-treated patients. SPRAVATO™ is not approved in pediatric (<18 years of age) patients.

There was considerable variation in risk of suicidal thoughts and behaviors among drugs, but there was an increased risk identified in young patients for most drugs studied.

Monitor all antidepressant-treated patients for clinical worsening and emergence of suicidal thoughts and behaviors, especially during the initial few months of drug therapy and at times of dosage changes. Counsel family members or caregivers of patients to monitor for changes in behavior and to alert the healthcare provider. Consider changing the therapeutic regimen, including possibly discontinuing SPRAVATO™ and/or the concomitant oral antidepressant, in patients whose depression is persistently worse, or who are experiencing emergent suicidal thoughts or behaviors.

Increase in Blood Pressure: SPRAVATO™ causes increases in systolic and/or diastolic blood pressure (BP) at all recommended dosages. Increases in BP peak approximately 40 minutes after SPRAVATO™ administration and last approximately 4 hours.

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Spravato™ (esketamine) C III nasal spray

Approximately 8% to 17% of SPRAVATO™-treated patients experienced an increase of more than 40 mmHg in systolic BP and/or 25 mmHg in diastolic BP in the first 1.5 hours after administration at least once during the first 4 weeks of treatment. A substantial increase in blood pressure could occur after any dose administered even if smaller blood pressure effects were observed with previous administrations. SPRAVATO™ is contraindicated in patients for whom an increase in BP or intracranial pressure poses a serious risk (e.g., aneurysmal vascular disease, arteriovenous malformation, history of intracerebral hemorrhage). Before prescribing, patients with other cardiovascular and cerebrovascular conditions should be carefully assessed to determine whether the potential benefits of SPRAVATO™ outweigh its risk.

Assess BP prior to administration of SPRAVATO™. In patients whose BP is elevated prior to SPRAVATO™ administration (as a general guide: >140/90 mmHg), a decision to delay SPRAVATO™ therapy should be taken into account to balance the benefit and risk in individual patients.

BP should be monitored for at least 2 hours after SPRAVATO™ administration. Measure blood pressure around 40 minutes post-dose and subsequently as clinically warranted until values decline. If BP remains high, promptly seek assistance from practitioners experienced in BP management. Refer patients experiencing symptoms of a hypertensive crisis (e.g., chest pain, shortness of breath) or hypertensive encephalopathy (e.g., sudden severe headache, visual disturbances, seizures, diminished consciousness or focal neurological deficits) immediately for emergency care.

Closely monitor blood pressure with concomitant use of SPRAVATO™ with psychostimulants or monoamine oxidase inhibitors (MAOIs) *[see Drug Interactions (7.2, 7.3)]*.

In patients with history of hypertensive encephalopathy, more intensive monitoring, including more frequent blood pressure and symptom assessment, is warranted because these patients are at increased risk for developing encephalopathy with even small increases in blood pressure.

Cognitive Impairment

Short-Term Cognitive Impairment: In a study in healthy volunteers, a single dose of SPRAVATO™ caused cognitive performance decline 40 minutes post-dose. SPRAVATO™-treated subjects required a greater effort to complete the cognitive tests at 40 minutes post-dose. Cognitive performance and mental effort were comparable between SPRAVATO™ and placebo at 2 hours post-dose. Sleepiness was comparable after 4 hours post-dose.

Long-Term Cognitive Impairment: Long-term cognitive and memory impairment have been reported with repeated ketamine misuse or abuse. No adverse effects of SPRAVATO™ nasal spray on cognitive functioning were observed in a one-year open-label safety study; however, the long-term cognitive effects of SPRAVATO™ have not been evaluated beyond one year.

Impaired Ability to Drive and Operate Machinery: Before SPRAVATO™ administration, instruct patients not to engage in potentially hazardous activities requiring complete mental alertness and motor coordination, such as driving a motor vehicle or operating machinery, until the next day following a restful sleep. Patients will need to arrange transportation home following treatment with SPRAVATO™.

Ulcerative or Interstitial Cystitis: Cases of ulcerative or interstitial cystitis have been reported in individuals with long-term off-label use or misuse/abuse of ketamine. In clinical studies with SPRAVATO™ nasal spray, there

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was a higher rate of lower urinary tract symptoms (pollakiuria, dysuria, micturition urgency, nocturia, and cystitis) in SPRAVATO™-treated patients than in placebo-treated patients. No cases of esketamine-related interstitial cystitis were observed in any of the studies, which involved treatment for up to a year.

Monitor for urinary tract and bladder symptoms during the course of treatment with SPRAVATO™ and refer to an appropriate healthcare provider as clinically warranted.

Embryo-fetal Toxicity: SPRAVATO™ may cause fetal harm when administered to pregnant women. Advise pregnant women of the potential risk to an infant exposed to SPRAVATO™ *in utero*. Advise women of reproductive potential to consider pregnancy planning and prevention.

DRUG INTERACTIONS

CNS depressants (e.g., benzodiazepines, opioids, alcohol): Concomitant use may increase sedation. Closely monitor for sedation with concomitant use of CNS depressants.

Psychostimulants (e.g., amphetamines, methylphenidate, modafinil, armodafinil): Concomitant use may increase blood pressure. Closely monitor blood pressure with concomitant use of psychostimulants.

Monoamine oxidase inhibitors (MAOIs): Concomitant use may increase blood pressure. Closely monitor blood pressure with concomitant use of MAOIs.

USE IN SPECIFIC POPULATIONS

Pregnancy: SPRAVATO™ is not recommended during pregnancy. SPRAVATO™ may cause fetal harm when administered to pregnant women. Advise pregnant women of the potential risk to an infant exposed to SPRAVATO™ *in utero*. There are risks to the mother associated with untreated depression in pregnancy. If a woman becomes pregnant while being treated with SPRAVATO™, treatment with SPRAVATO™ should be discontinued and the patient should be counseled about the potential risk to the fetus.

Pregnancy Exposure Registry: There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to antidepressants, including SPRAVATO™, during pregnancy. Healthcare providers are encouraged to register patients by contacting the National Pregnancy Registry for Antidepressants at 1-844-405-6185 or online at *https://womensmentalhealth.org/clinical-and-research-programs/pregnancyregistry/antidepressants/*.

Lactation: SPRAVATO™ is present in human milk. Because of the potential for neurotoxicity, advise patients that breastfeeding is not recommended during treatment with SPRAVATO™.

Females and Males of Reproductive Potential: SPRAVATO™ may cause embryo-fetal harm when administered to a pregnant woman. Consider pregnancy planning and prevention for females of reproductive potential during treatment with SPRAVATO™.

Pediatric Use: The safety and effectiveness of SPRAVATO™ in pediatric patients have not been established.

Geriatric Use: Of the total number of patients in Phase 3 clinical studies exposed to SPRAVATO™, 12% were 65 years of age and older, and 2% were 75 years of age and older. No overall differences in the safety profile were observed between patients 65 years of age and older and patients younger than 65 years of age.

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The mean esketamine C_{max} and AUC values were higher in elderly patients compared with younger adult patients.

The treatment of TRD in geriatric patients was evaluated in a 4-week, randomized, double-blind study comparing flexibly-dosed intranasal SPRAVATO™ plus a newly initiated oral antidepressant compared to intranasal placebo plus a newly initiated oral antidepressant in patients ≥65 years of age. At the end of four weeks, there was no statistically significant difference between groups on the primary efficacy endpoint of change from baseline to Week 4 on the Montgomery-Åsberg Depression Rating Scale (MADRS).

Hepatic Impairment: SPRAVATO™-treated patients with moderate hepatic impairment may need to be monitored for adverse reactions for a longer period of time.

SPRAVATO™ has not been studied in patients with severe hepatic impairment (Child-Pugh class C). Use in this population is not recommended.

DRUG ABUSE AND DEPENDENCE

Controlled Substance: SPRAVATO™ contains esketamine hydrochloride, the (S)-enantiomer of ketamine and a Schedule III controlled substance under the Controlled Substances Act.

Abuse: Individuals with a history of drug abuse or dependence may be at greater risk for abuse and misuse of SPRAVATO™. Abuse is the intentional, non-therapeutic use of a drug, even once, for its psychological or physiological effects. Misuse is the intentional use, for therapeutic purposes, of a drug by an individual in a way other than prescribed by a healthcare provider or for whom it was not prescribed. Careful consideration is advised prior to use of individuals with a history of substance use disorder, including alcohol.

SPRAVATO™ may produce a variety of symptoms including anxiety, dysphoria, disorientation, insomnia, flashback, hallucinations, and feelings of floating, detachment and to be "spaced out." Monitoring for signs of abuse and misuse is recommended.

ADVERSE REACTIONS

The most common adverse reactions with SPRAVATO™ plus oral AD (incidence ≥5% and at least twice that of placebo nasal spray plus oral AD) were dissociation, dizziness, nausea, sedation, vertigo, hypoesthesia, anxiety, lethargy, blood pressure increased, vomiting, and feeling drunk.

Please see full Prescribing Information, including Boxed WARNINGS, and Medication Guide for SPRAVATO™.

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VA-19-1109-B-001483

SPRAVATO™ Product Summary[1]

Spravato™ (esketamine) C III nasal spray

- SPRAVATO™ is a non-competitive N-methyl D-aspartate (NMDA) receptor antagonist indicated, in conjunction with an oral antidepressant, for the treatment of treatment-resistant depression (TRD) in adults[1]
- SPRAVATO™ nasal spray is a Schedule III controlled substance
- SPRAVATO™ nasal spray has a Risk Evaluation and Mitigation Strategy (REMS):
  - The goal of the REMS is to mitigate the risks of serious adverse outcomes resulting from sedation and dissociation caused by SPRAVATO™ administration, and abuse and misuse of SPRAVATO™
- SPRAVATO™ will not be delivered or dispensed directly to patients

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VA-19-1109-B-001484

SPRAVATO™ Product Summary[1]

Spravato™ (esketamine) C III nasal spray

- SPRAVATO™ is a non-competitive N-methyl D-aspartate (NMDA) receptor antagonist indicated, in conjunction with an oral antidepressant, for the treatment of treatment-resistant depression (TRD) in adults[1]
- SPRAVATO™ nasal spray is a Schedule III controlled substance
- SPRAVATO™ nasal spray has a Risk Evaluation and Mitigation Strategy (REMS):
  - The goal of the RE… ociation caused by SPRAVA…
- SPRAVATO™ will not …

Reference

1. SPRAVATO™ [Prescribing Information]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; March 2019.

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Spravato™ (esketamine) C III nasal spray

SPRAVATO™ Access and Operational Considerations

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REMS

REMS Information for SPRAVATO™

Spravato™ (esketamine) C III nasal spray

Why Does SPRAVATO™ Have A REMS?

The goal of the REMS is to mitigate the risks of serious adverse outcomes resulting from sedation and dissociation caused by SPRAVATO™ administration, and abuse and misuse of SPRAVATO™, by:

- Ensuring that SPRAVATO™ is only dispensed and administered to patients in a medically supervised healthcare setting that monitors these patients
- Ensuring pharmacies and healthcare settings that dispense SPRAVATO™ are certified
- Ensuring that each patient is informed about the serious adverse outcomes resulting from sedation and dissociation and need for monitoring
- Enrollment of all patients in the REMS (registry) to further characterize the risks and support safe use

SPRAVATO™ is intended for patient administration under the direct observation of a healthcare provider, and patients are required to be monitored by a healthcare provider for at least 2 hours after SPRAVATO™ administration. SPRAVATO™ must never be dispensed directly to a patient for home use.

What are the REMS Requirements?

1 HEALTHCARE SETTING CERTIFICATION

Healthcare Settings must be certified in the REMS in order to treat patients with SPRAVATO™

2 PHARMACY CERTIFICATION

Pharmacies must be certified in the REMS in order to order and dispense SPRAVATO™. SPRAVATO™ should not be dispensed directly to the patient

3 PATIENT ENROLLMENT BY HCP

Patients must be enrolled in the REMS in order to receive SPRAVATO™ treatment

To get started or find more information on how to certify your Healthcare Setting and/or Pharmacy, and enroll your patients to receive SPRAVATO™ treatment, visit SPRAVATOrems.com or call 1-855-382-6022

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VA-19-1109-B-001487

Considerations and Requirements for Establishing a Certified SPRAVATO™ Treatment Center

Spravato™ (esketamine) C III nasal spray

SPRAVATO™ Acquisition



- SPRAVATO™ REMS
- Controlled distribution network

Operational Considerations



- SPRAVATO™ treatment steps
- Controlled-substance requirements
- Capacity and staffing considerations
- Post-administration observation and monitoring requirements

Access & Reimbursement



- SPRAVATO™ benefit design
- Reimbursement and billing & coding for SPRAVATO™
- Janssen resources

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SPRAVATO™ Acquisition



Operational Considerations

Access & Reimbursement

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Implementing a Controlled Distribution Network for SPRAVATO™

Spravato™ (esketamine) C III nasal spray

JOM Pharmaceutical Services*

Full-Line Wholesaler

No Retail Pharmacy dispensing to patient

Anticipated limited number of Specialty Pharmacies

Institutions (Hospitals)

In- and out-of-network psychiatry treatment referrals to institutions

REMS-certified institutions can acquire SPRAVATO™ directly from full-line wholesalers via standard buy-and-bill practice

Outpatient Pharmacies

Community Mental Health Centers with a co-located pharmacy

REMS-certified outpatient pharmacies will follow standard acquisition protocols via full-line wholesalers and dispense SPRAVATO™ to REMS-certified treatment centers

Outpatient Healthcare Settings

Outpatient large group practices/clinics, without a co-located pharmacy

At launch, the only acquisition pathway for REMS-certified outpatient healthcare settings without a co-located pharmacy is through a buy-and-bill model via a specialty distributor. In the future, REMS-certified outpatient healthcare settings can acquire SPRAVATO™ via certified Specialty Pharmacies,† provided the outpatient healthcare centers meet the REMS requirements

Current (Primary) Product Flow

Future Product Flow

No Product Flow

REMS Patient Enrollment

HCP for Patient Self-Administration

The controlled distribution model would deliver product directly to the certified SPRAVATO™ treatment center, where the product would be self-administered by the patient under the supervision of an HCP

JOM = Janssen Ortho McNeil

* JOM Pharmaceutical Services, Inc. is a distribution center and service provider dedicated to providing delivery of products for Janssen Pharmaceuticals, Inc. https://www.jom.com. Accessed on February 11, 2019.

† Janssen will update customers when this channel is available for REMS-certified outpatient settings without a co-located pharmacy.

SPRAVATO™ Distributor List

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Authorized SPRAVATO™ Distributor List

X

The following are authorized SPRAVATO™ Full-Line Wholesalers

Full-Line Wholesalers	Phone Number	Fax	Website
Amerisource Bergen	1-844-222-2273	1-888-292-9774	www.AmerisourceBergen.com
Cardinal Health	1-800-926-3161	—	www.cardinalhealth.com
McKesson Pharmaceutical Distribution	1-855-625-7385	—	www.mckesson.com

The following are authorized SPRAVATO™ Specialty Distributors

Specialty Distributors	Phone Number	Fax	Website
Besse Medical	1-800-543-2111	1-800-543-8695	www.Besse.com
Cardinal Health Specialty Distribution	1-877-453-3972	1-877-274-9897	https://www.cardinalhealth.com/en/services/acute/logistics-solutions-acute/distribution/specialty-distribution
CuraScript Specialty Distribution	1-877-599-7748	1-800-862-6208	www.curascriptsd.com
McKesson Specialty Health	1-855-477-9800	—	www.mckessonspecialtyhealth.com

† Janssen will update customers when this channel is available for REMS-certified outpatient settings without a co-located pharmacy.

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SPRAVATO™ Acquisition

Operational Considerations



Access & Reimbursement

Please see full Prescribing Information, including Boxed WARNINGS, available at this presentation.

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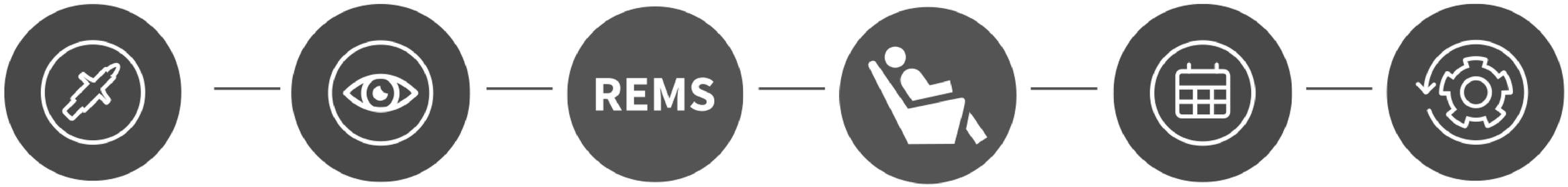
VA-19-1109-B-001492

SPRAVATO™ Treatment Steps

Spravato™ (esketamine) C III nasal spray

Certified SPRAVATO™ treatment centers are required to conduct REMS certification and establish REMS-specific policies and procedures to acquire and treat patients with SPRAVATO™

Treatment With SPRAVATO™ (esketamine) Nasal Spray



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VA-19-1109-B-001493

SPRAVATO™ Treatment Steps

Spravato™ (esketamine) C III nasal spray

Certified SPRAVATO™ treatment centers are required to conduct REMS certification and establish REMS-specific policies and procedures to acquire and treat patients with SPRAVATO™

Treatment With SPRAVATO™ (esketamine) Nasal Spray

SEEKING NEW TREATMENT

Discuss SPRAVATO™ in conjunction with an oral AD as a treatment option for adult patients with TRD

Communicate the benefits and risks associated with SPRAVATO™ to patients and caregivers

Select a certified SPRAVATO™ treatment center

SCREENING AND PLANNING

Initiate a consultation to discuss the benefits and risks associated with SPRAVATO™, and discuss REMS patient enrollment

Schedule the induction appointments for patients to self-administer SPRAVATO™ and plan patients' transportation

Conduct patient benefits investigation for both medical and pharmacy benefits

SITE READINESS AND REMS REQUIREMENTS

REMS

Enroll patients eligible for SPRAVATO™ into the REMS registry prior to treatment

Prescribe SPRAVATO™ for appropriate adult patients with TRD for use in conjunction with an oral AD

Support patient access to SPRAVATO™, as well as appropriate reimbursement for drug product, observation, and monitoring

Dispense, handle, and store SPRAVATO™ in compliance with federal, state, and local regulations for Schedule III recommendations

SPRAVATO™ SELF-ADMINISTRATION AND MONITORING

Educate patients and caregivers about treatment expectations and upcoming administration sessions

Observe and monitor patient self-administration of SPRAVATO™ under the supervision of a healthcare professional, per REMS requirements

RELEASE AND REPEAT

Consider patient transportation after each SPRAVATO™ administration

Prepare for the next SPRAVATO™ administration appointment

MAINTENANCE

Support care continuity

Discuss changes in dosing, appointment scheduling, and session frequency based on clinician judgment and patient response

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VA-19-1109-B-001494

SPRAVATO™ Treatment Steps

Spravato™ (esketamine) C III nasal spray

Certified SPRAVATO™ treatment centers are required to conduct REMS certification and establish REMS-specific policies and procedures to acquire and treat patients with SPRAVATO™

Treatment With SPRAVATO™ (esketamine) Nasal Spray

SEEKING NEW TREATMENT

Discuss SPRAVATO™ in conjunction with an oral AD as a treatment option for adult patients with TRD

Communicate the benefits and risks associated with SPRAVATO™ to patients and caregivers

Select a certified SPRAVATO™ treatment center

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Initiate a consultation to discuss the benefits and risks associated with SPRAVATO™, and discuss REMS patient enrollment

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Educate patients and caregivers about treatment expectations and upcoming administration sessions

Observe and monitor patient self-administration of SPRAVATO™ under the supervision of a healthcare professional, per REMS requirements

RELEASE AND REPEAT

Consider patient transportation after each SPRAVATO™ administration

Prepare for the next SPRAVATO™ administration appointment

MAINTENANCE

Support care continuity

Discuss changes in dosing, appointment scheduling, and session frequency based on clinician judgment and patient response

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VA-19-1109-B-001495

Controlled Substance Regulations Must Be Followed to Manage SPRAVATO™

Spravato™ (esketamine) C III nasal spray

Patients will require 2 or 3 devices per sessions

56 mg Dose Kit	
NDC #	50458-028-02
How Supplied	Two nasal spray devices each containing 28 mg of esketamine
Package Dimensions	4.6 in x 2.5in x 4.1in
Package Weight	0.18 lbs
Case Quantity	18 x 56 mg Dose Kits
Case Dimensions	4.75 in x 15.3 in x 8.1 in
Case Weight	4 lbs

84 mg Dose Kit	
NDC #	50458-028-03
How Supplied	Three nasal spray devices each containing 28 mg of esketamine
Package Dimensions	4.6 in x 2.5 in x 2.9 in
Package Weight	0.22 lbs
Case Quantity	12 x 84 mg Dose Kits
Case Dimensions	4.75 in x 15.3 in x 9.1 in
Case Weight	3.6 lbs

- SPRAVATO™ is a Schedule III controlled substance
- Certified SPRAVATO™ treatment center protocols should be followed for handling Schedule III products in accordance with federal, state, and local regulations and laws
  - Healthcare professionals must be properly licensed and hold an active DEA registration at the site of care
  - Pharmacies must be properly licensed and actively registered with the DEA

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Capacity and Staffing Should Be Evaluated to Accommodate Multiple SPRAVATO™ Treatment Sessions[1]

Spravato™ (esketamine) C III nasal spray

Ability and Capacity for Scheduling Frequent Appointments

INDUCTION (twice weekly)		MAINTENANCE (once weekly)		(weekly or every 2 weeks)
WEEKS 1–4 **8 sessions**		**WEEKS 5–8** **4 sessions**		**WEEKS 9 and after***
Day 1 starting dose: **56 mg** Subsequent doses: **56 mg** or **84 mg**		**56 mg** or **84 mg** once weekly		**56 mg** or **84 mg** every 2 weeks or once weekly†

- In Study 2 (long-term), 39% of patients received the 56-mg dose, and 61% received the 84-mg dose, of SPRAVATO™
- SPRAVATO™ does not require daily dosing and should be administered in conjunction with an oral AD.[1]

* Dosing frequency should be individualized to the lowest frequency required to maintain remission/response.

† As determined by the prescribing physician

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Capacity and Staffing Should Be Evaluated to Accommodate Multiple SPRAVATO™ Treatment Sessions[1]

Spravato™ (esketamine) C III nasal spray

Ability and Capacity for Scheduling Frequent Appointments

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Subsequent doses: **56 mg** or **84 mg**

56 mg or **84 mg** once weekly

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- SPRAVATO™ does not require daily dosing and should be administered in conjunction with an oral AD.[1]

* Dosing frequency should be individualized to the lowest frequency required to maintain remission/response.
† As determined by the prescribing physician

Reference

1. SPRAVATO™ [Prescribing Information]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; March 2019.

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VA-19-1109-B-001498

Treatment Centers Will Be Required to Provide Appropriate Observation and Monitoring According to REMS

Spravato™ (esketamine) CIII nasal spray

SPRAVATO™ is intended for patient administration under the direct observation of a healthcare provider, and patients are required to be monitored by a healthcare provider for at least 2 hours after SPRAVATO™ administration.

Before SPRAVATO™ administration, instruct patients not to engage in potentially hazardous activities, such as driving a motor vehicle or operating machinery, until the next day after a restful sleep. Patients will require transportation from the treatment center after administration.[1]

Considerations for Observation of Self-Administration and Monitoring

Sedation[1]*

Sedation was reported in 2 ways in the clinical studies: through adverse event reports, and using the Modified Observer's Assessment of Alertness/Sedation Scale (MOAA/s).

- Adverse events of sedation were reported in approximately 23% of patients treated with SPRAVATO™ at any dose (N=346)
- Based on the MOAA/s, 49% to 61% of patients treated with SPRAVATO™ developed sedation

- 0.3% of patients treated with SPRAVATO™ experienced loss of consciousness†

- Because of the possibility of delayed or prolonged sedation, patients must be monitored by a healthcare professional for at least 2 hours following each treatment session, followed by an assessment to determine when the patient is considered clinically stable and ready to leave

- Consider staffing and equipment needs to conduct ongoing blood pressure monitoring during the post-administration phase of treatment
- Consider space and environment requirements for SPRAVATO™ administration, observation and monitoring
- The healthcare professional should assess when the patient is considered clinically stable and ready to leave the office/healthcare setting

*Does not reflect the full list of adverse events for SPRAVATO™.
† Based on the MOAA/s scale

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Treatment Centers Will Be Required to Provide Appropriate Observation and Monitoring According to REMS

Spravato™ (esketamine) C III nasal spray

SPRAVATO™ is intended for patient administration under the direct observation of a healthcare provider, and patients are required to be monitored by a healthcare provider for at least 2 hours after SPRAVATO™ administration.

Before SPRAVATO™ administration, instruct patients not to engage in potentially hazardous activities, such as driving a motor vehicle or operating machinery, until the next day after a restful sleep. Patients will require transportation from the treatment center after administration.[1]

Considerations for Observation of Self-Administration and Monitoring

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requirements for SPRAVATO™ administration, observation and monitoring

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Reference

1. SPRAVATO™ [Prescribing Information]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; March 2019.

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VA-19-1109-B-001500

Treatment Centers Will Be Required to Provide Appropriate Observation and Monitoring According to REMS

Spravato™ (esketamine) CIII nasal spray

SPRAVATO™ is intended for patient administration under the direct observation of a healthcare provider, and patients are required to be monitored by a healthcare provider for at least 2 hours after SPRAVATO™ administration.

Before SPRAVATO™ administration, instruct patients not to engage in potentially hazardous activities, such as driving a motor vehicle or operating machinery, until the next day after a restful sleep. Patients will require transportation from the treatment center after administration.[1]

Considerations for Observation of Self-Administration and Monitoring

Dissociation[1]*

Dissociation was reported in 2 ways in the clinical studies: through adverse event reports, and using the Clinician-Administered Dissociative States Scale (CADSS)

- Adverse events of dissociation were reported in approximately 41% of patients treated with SPRAVATO™ at any dose (N=346)
- Based on the CADDS, 61% to 75% of patients treated with SPRAVATO™ developed dissociative or perceptual changes

- In clinical trials, dissociation was reported as transient and occurred on the day of dosing

- Because of the risks of dissociation, patients should be monitored by a healthcare professional for at least 2 hours at each treatment session, followed by an assessment to determine when the patient is considered clinically stable and ready to leave the healthcare setting
- Given its potential dissociative effects, carefully assess patients with psychosis before administering SPRAVATO™; treatment should be initiated only if the benefit outweighs the risk

- Consider staffing and equipment needs to conduct ongoing blood pressure monitoring during the post-administration phase of treatment
- Consider space and environment requirements for SPRAVATO™ administration, observation and monitoring
- The healthcare professional should assess when the patient is considered clinically stable and ready to leave the office/healthcare setting

* Does not reflect the full list of adverse events for SPRAVATO™.

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VA-19-1109-B-001501

Treatment Centers Will Be Required to Provide Appropriate Observation and Monitoring According to REMS

Spravato™ (esketamine) C III nasal spray

SPRAVATO™ is intended for patient administration under the direct observation of a healthcare provider, and patients are required to be monitored by a healthcare provider for at least 2 hours after SPRAVATO™ administration.

Before SPRAVATO™ administration, instruct patients not to engage in potentially hazardous activities, such as driving a motor vehicle or operating machinery, until the next day after a restful sleep. Patients will require transportation from the treatment center after administration.[1]

Considerations for Observation of Self-Administration and Monitoring

Dissociation[1]*

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* Does not reflect the full list of adverse events for SPRAVATO™.

Reference

1. SPRAVATO™ [Prescribing Information]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; March 2019.

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VA-19-1109-B-001502

Treatment Centers Will Be Required to Provide Appropriate Observation and Monitoring According to REMS

Spravato™ (esketamine) C III
nasal spray

SPRAVATO™ is intended for patient administration under the direct observation of a healthcare provider, and patients are required to be monitored by a healthcare provider for at least 2 hours after SPRAVATO™ administration.

Before SPRAVATO™ administration, instruct patients not to engage in potentially hazardous activities, such as driving a motor vehicle or operating machinery, until the next day after a restful sleep. Patients will require transportation from the treatment center after administration.[1]

Considerations for Observation of Self-Administration and Monitoring

Changes in blood pressure

- SPRAVATO™ caused increases in systolic blood pressure (SBP) and/or diastolic blood pressure (DBP), which peak at approximately 40 minutes after administration and last approximately 4 hours:
  - 40 minutes post dose, mean placebo-adjusted increases in SBP = 7 to 9 mmHg and DBP = 4 to 6 mmHg
  - If blood pressure is decreasing and the patient appears clinically stable for at least 2 hours, the patient may be discharged at the end of the post-dose monitoring period
- Assess blood pressure prior to, and approximately 40 minutes after dosing with SPRAVATO™ and subsequently as clinically warranted until values decline
  - Do not administer SPRAVATO™ if an increase in blood pressure or intracranial pressure poses a serious risk
  - Before prescribing SPRAVATO™, patients with other cardiovascular and cerebrovascular conditions should be carefully assessed to determine whether the potential benefits of SPRAVATO™ outweigh its risks

Adverse reactions in ≥2% of patients treated with SPRAVATO™ in the short-term studies*

SPRAVATO™ has also been reported to cause dissociation, dizziness, nausea, sedation, vertigo, headache, dysgeusia, hypoesthesia, anxiety, lethargy, blood pressure increased, vomiting, insomnia, diarrhea, nasal discomfort, throat irritation, feeling drunk, dry mouth, hyperhidrosis, euphoric mood, dysarthria, tremor, oropharyngeal pain, mental impairment, constipation, pollakiuria, feeling abnormal, and tachycardia

- Consider staffing and equipment needs to conduct ongoing blood pressure monitoring during the post-administration phase of treatment
- Consider space and environment requirements for SPRAVATO™ administration, observation and monitoring
- The healthcare professional should assess when the patient is considered clinically stable and ready to leave the office/healthcare setting

* Adverse reactions occurring in ≥2% of TRD patients treated with SPRAVATO™ + oral AD at any dose and at a greater rate than patients treated with placebo nasal spray + oral AD. Does not reflect the full list of adverse events for SPRAVATO™.

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Treatment Centers Will Be Required to Provide Appropriate Observation and Monitoring According to REMS

Spravato™ (esketamine) C III
nasal spray

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Considerations for Observation of Self-Administration and Monitoring

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1. SPRAVATO™ [Prescribing Information]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; March 2019.

*Adverse reactions occurring in ≥2% of TRD patients treated with SPRAVATO™ + oral AD at any dose and at a greater rate than patients treated with placebo nasal spray + oral AD. Does not reflect the full list of adverse events for SPRAVATO™.

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SPRAVATO™ Acquisition

Operational Considerations

Access & Reimbursement



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Reimbursement and Billing & Coding for SPRAVATO™ and Associated Observation and Monitoring

Spravato™ (esketamine) CIII nasal spray

1 Diagnosis Codes

- **There are currently no TRD diagnosis codes**
- **Select MDD ICD-10 codes will be used**

2 Drug + **Observation and Monitoring**

- **Medical**: Miscellaneous J-Code, Permanent J-Code
- **Pharmacy**: Pharmacy claim
- Observation and Monitoring: Self-Administration HCP Monitoring Codes

- Diagnosis codes may vary by payer; certified SPRAVATO™ treatment centers will need to confirm appropriate codes for each patient
- Prescribing clinicians should exercise their clinical judgment and work with the payer when determining the appropriate ICD-10 code

3 Benefit Design

- **Existing evaluation and monitoring codes will be used**

Medical Benefit* and/or Pharmacy Benefit

Medical Benefit*

* Some plans may require the use of an independent mental health benefit for treatment reimbursement under medical benefit and patient monitoring associated with treatment with SPRAVATO™.

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VA-19-1109-B-001506

Both Patient Benefit Design and Certified SPRAVATO™ Treatment Center Location Will Influence Reimbursement for SPRAVATO™

Spravato™ (esketamine) C-III nasal spray

Patients will likely receive care in a variety of healthcare settings, which may be reimbursed through a singular or combined medical, pharmacy, or independent mental health benefit design

Future Distribution Pathway

	Institutions (Hospitals)	Outpatient Pharmacies	Outpatient Healthcare Settings*
Different certified SPRAVATO™ treatment center options	In- and out-of-network psychiatry treatment referrals to institutions	Community Mental Health Centers with a co-located pharmacy	Outpatient large group practices/ clinics without a co-located pharmacy
Product Management	Centralized Pharmacy	On-site Pharmacy	Order & Store Product
Product Reimbursement	Medical Benefit; Pharmacy Benefit	Pharmacy Benefit	Pharmacy Benefit; Medical Benefit

* Not anticipated to be a certified SPRAVATO™ treatment center location at launch.

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Janssen CarePath Provides Resources to Support Patients on SPRAVATO™

Spravato™ (esketamine) C III nasal spray

Janssen CarePath is the one source for access, affordability, and treatment support for patients

Janssen CarePath helps verify insurance coverage for patients, provides reimbursement information, helps find financial assistance options for eligible patients, and provides ongoing support to help patients start and stay on prescribed SPRAVATO™ treatment.

- **Access support** to help navigate payer processes
  - Janssen CarePath helps verify insurance coverage for patients taking SPRAVATO™ and provides reimbursement information
  - Request benefits investigation and prior authorization support at **SpravatoESubmission.com**

- **Affordability support** to help patients start and stay on the prescribed Janssen treatment
  - Janssen CarePath can help you find out what affordability assistance may be available for patients taking SPRAVATO™
  - Visit **JanssenCarePath.com** to learn more about affordability options

- **Treatment support** to help patients get informed and stay on SPRAVATO™
  - Janssen CarePath provides additional support to patients, including patient education, web-based resources, and assistance finding a location that offers SPRAVATO™ treatment

Call a Janssen CarePath Care Coordinator at 844-777-2828, Monday-Friday, 8:00 AM to 8:00 PM ET.
Visit JanssenCarePath.com/hcp/Spravato

Janssen Patient Access Specialists may be available to address access related questions, and provide information and assistance on the benefits investigation process and the Janssen CarePath Savings Program. Appropriate patient authorization is required.

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Summary of SPRAVATO™ Operational Considerations

Spravato™ (esketamine) C III nasal spray

SPRAVATO™ Acquisition

- The goal of the REMS is to mitigate the risks of serious adverse outcomes resulting from sedation and dissociation caused by SPRAVATO™ administration, and abuse and misuse of SPRAVATO™
- Janssen will be implementing a controlled-distribution network to ensure appropriate delivery of SPRAVATO™ to certified treatment centers

Operational Considerations

- Treatment with SPRAVATO™ will require appropriate treatment center staffing, capacity, and ongoing care coordination. Per the REMS requirements, patients are required to be monitored by an HCP during and after their session for a minimum of 2 hours. Additionally, controlled-substance regulations must be followed to handle SPRAVATO™

Access & Reimbursement

- Reimbursement will be required for both the SPRAVATO™ drug and for observation and monitoring, and may be covered under medical benefit or pharmacy benefit

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VA-19-1109-B-001509

From:	Stone, Richard A., MD /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BD16619615D64ADEA22E45E63FF6462A-STONE, RICH (b)(6) @va.gov>
SentVia:	Howard, Kristi /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B8D0AFC371994181883D8861127791C3-HOWARD, KRI (b)(6) @va.gov>
To:	Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M (b)(6) @va.gov>; Beck, Lucille B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=845480228a8b43e7a5fef5716ded04c2-Beck, Lucil (b)(6) @va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>; Jensen, Jon M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddeb735ace76400db5c3f10603188a14-Jensen, Jon (b)(6) @va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>; Connell, Lawrence B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a3e7233376344045980ad214122389f4-Connell, La (b)(6) @va.gov>
Subject:	PBM Nasal Spray Follow-Up
Date:	2019/03/11 15:45:53
Start Date:	2019/04/01 11:00:00
End Date:	2019/04/01 11:30:00
Priority:	Normal
Type:	Schedule.Meeting.Request
Location:	VACO 802 or VANTS 1-800-767-1750 A/C 22021
Attendees:	Llorente, Maria D.; Beck, Lucille B.; Emmendorfer, Thomas (PBM); Jensen, Jon M.; Valentino, Michael (VACO); Connell, Lawrence B.

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Sent Date:	2019/03/11 15:45:51

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Follow-up to March 8th PBM meeting.

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Subject:	PBM Nasal Spray Follow-Up
Date:	2019/03/11 15:45:52
Start Date:	2019/04/08 11:30:00
End Date:	2019/04/08 12:00:00
Priority:	Normal
Type:	Appointment
Location:	VACO 802 or VANTS 1-800-767-1750 A/C 22021
Attendees:	Llorente, Maria D.; Beck, Lucille B.; Emmendorfer, Thomas (PBM); Jensen, Jon M.; Valentino, Michael (VACO); Connell, Lawrence B.

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Location:	VACO 802 or VANTS 1-800-767-1750 A/C 22021
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SentVia:	Felan, Leilani /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=62469214402347E690A6DCA6E028F1D6-FELAN, LEIL (b)(6) @va.gov>
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AMERICAN OVERSIGHT

From:	Stone, Richard A., MD /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BD16619615D64ADEA22E45E63FF6462A-STONE, RICH (b)(6) @va.gov>
To:	Stone, Richard A., MD /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bd16619615d64adea22e45e63ff6462a-Stone, Rich (b)(6) @va.gov>; Llorente, Maria D. <(b)(6) @va.gov>; Beck, Lucille B. <(b)(6) @va.gov>; Emmendorfer, Thomas (PBM) (b)(6) @va.gov>; Jensen, Jon M. (b)(6) @va.gov>; Valentino, Michael (VACO) (b)(6) @va.gov>; Connell, Lawrence B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a3e7233376344045980ad214122389f4-Connell, La (b)(6) @va.gov>
Subject:	PBM Nasal Spray Follow-Up
Date:	2019/03/11 15:45:54
Start Date:	2019/04/01 11:00:00
End Date:	2019/04/01 11:30:00
Priority:	Normal
Type:	Appointment
Location:	VACO 802 or VANTS 1-800-767-1750 A/C 22021
Attendees:	Llorente, Maria D.; Beck, Lucille B.; Emmendorfer, Thomas (PBM); Jensen, Jon M.; Valentino, Michael (VACO); Connell, Lawrence B.

Sender:	Stone, Richard A., MD /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BD16619615D64ADEA22E45E63FF6462A-STONE, RICH (b)(6) @va.gov>
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SentVia:	Felan, Leilani /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=62469214402347E690A6DCA6E028F1D6-FELAN, LEIL (b)(6) @va.gov>
To:	Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M (b)(6) @va.gov>; Beck, Lucille B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=845480228a8b43e7a5fef5716ded04c2-Beck, Lucil (b)(6) @va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>; Jensen, Jon M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddeb735ace76400db5c3f10603188a14-Jensen, Jon (b)(6) @va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>; Connell, Lawrence B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a3e7233376344045980ad214122389f4-Connell, La (b)(6) @va.gov>
Subject:	PBM Nasal Spray Follow-Up
Date:	2019/03/20 12:31:42
Start Date:	2019/04/08 11:30:00
End Date:	2019/04/08 12:00:00
Priority:	Normal
Type:	Schedule.Meeting.Request
Location:	VACO 802 or VANTS 1-800-767-1750 A/C 22021
Attendees:	Llorente, Maria D.; Beck, Lucille B.; Emmendorfer, Thomas (PBM); Jensen, Jon M.; Valentino, Michael (VACO); Connell, Lawrence B.

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Recipient:	Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b)(6) @va.gov>; Beck, Lucille B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=845480228a8b43e7a5fef5716ded04c2-Beck, Lucil (b)(6) @va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>; Jensen, Jon M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddeb735ace76400db5c3f10603188a14-Jensen, Jon (b)(6) @va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>; Connell, Lawrence B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a3e7233376344045980ad214122389f4-Connell, La (b)(6) @va.gov>
Sent Date:	2019/03/20 12:31:36

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Delivered Date:	2019/03/20 12:31:42

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End Date:	2019/04/08 12:00:00
Priority:	Normal
Type:	Appointment
Location:	VACO 802 or VANTS 1-800-767-1750 A/C 22021
Attendees:	Llorente, Maria D.; Beck, Lucille B.; Emmendorfer, Thomas (PBM); Jensen, Jon M.; Valentino, Michael (VACO); Connell, Lawrence B.

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Recipient:	Stone, Richard A., MD /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bd16619615d64adea22e45e63ff6462a-Stone, Rich (b)(6) @va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M (b)(6) @va.gov>; Beck, Lucille B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=845480228a8b43e7a5fef5716ded04c2-Beck, Lucil (b)(6) @va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>; Jensen, Jon M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddeb735ace76400db5c3f10603188a14-Jensen, Jon (b)(6) @va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>; Connell, Lawrence B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a3e7233376344045980ad214122389f4-Connell, La (b)(6) @va.gov>

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SentVia:	Williams, Jessica D. </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=007F83F1989E48888DAB9C5D712C99B4-WILLIAMS, J>
To:	Stone, Richard A., MD /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bd16619615d64adea22e45e63ff6462a-Stone, Rich (b)(6) @va.gov>; Llorente, Maria D. (b)(6) @va.gov>; Beck, Lucille B. (b)(6) @va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>; Jensen, Jon M. (b)(6) @va.gov>; Valentino, Michael (VACO) (b)(6) @va.gov>; Connell, Lawrence B. (b)(6) @va.gov>
CC:	Zacher, Jennifer L. (PBM) (b)(6) @va.gov>
Subject:	PBM Nasal Spray Follow-Up
Date:	2019/03/11 15:45:53
Start Date:	2019/04/08 11:30:00
End Date:	2019/04/08 12:00:00
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Type:	Appointment
Location:	VACO 802 | VANTS 1-800-767-1750 AC 22021#
Attendees:	Stone, Richard A., MD; Llorente, Maria D.; Beck, Lucille B.; Emmendorfer, Thomas (PBM); Jensen, Jon M.; Valentino, Michael (VACO); Connell, Lawrence B.; Zacher, Jennifer L. (PBM)

Sender:	Stone, Richard A., MD /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BD16619615D64ADEA22E45E63FF6462A-STONE, RICH (b)(6) @va.gov>; Williams, Jessica D. </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=007F83F1989E48888DAB9C5D712C99B4-WILLIAMS, J>
Recipient:	Stone, Richard A., MD /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bd16619615d64adea22e45e63ff6462a-Stone, Rich (b)(6) @va.gov>; Llorente, Maria D. (b)(6) @va.gov>; Beck, Lucille B. (b)(6) @va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>; Jensen, Jon M. <(b)(6) @va.gov>; Valentino, Michael (VACO) (b)(6) @va.gov>; Connell, Lawrence B. (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) (b)(6) @va.gov>
Sent Date:	2019/04/08 08:10:33
Delivered Date:	2019/03/11 15:45:53

AMERICAN OVERSIGHT

From:	Stone, Richard A., MD </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BD16619615D64ADEA22E45E63FF6462A-STONE, RICH>
SentVia:	Howard, Kristi </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B8D0AFC371994181883D8861127791C3-HOWARD, KRI>
To:	Stone, Richard A., MD /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bd16619615d64adea22e45e63ff6462a-Stone, Rich (b)(6) @va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M (b)(6) @va.gov>; Beck, Lucille B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=845480228a8b43e7a5fef5716ded04c2-Beck, Lucil (b)(6) @va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>; Jensen, Jon M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddeb735ace76400db5c3f10603188a14-Jensen, Jon (b)(6) @va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>; Connell, Lawrence B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a3e7233376344045980ad214122389f4-Connell, La (b)(6) @va.gov>
Subject:	PBM Nasal Spray Follow-Up
Date:	2019/03/11 15:45:46
Start Date:	2019/04/08 11:30:00
End Date:	2019/04/08 12:00:00
Priority:	Normal
Type:	Appointment
Location:	VACO 802 or VANTS 1-800-767-1750 A/C 22021

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SentVia:	Howard, Kristi </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B8D0AFC371994181883D8861127791C3-HOWARD, KRI>
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SentVia:	Felan, Leilani </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=62469214402347E690A6DCA6E028F1D6-FELAN, LEIL>
To:	Stone, Richard A., MD /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bd16619615d64adea22e45e63ff6462a-Stone, Rich (b)(6) @va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M (b)(6) @va.gov>; Beck, Lucille B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=845480228a8b43e7a5fef5716ded04c2-Beck, Lucil (b)(6) @va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>; Jensen, Jon M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddeb735ace76400db5c3f10603188a14-Jensen, Jon (b)(6) @va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>; Connell, Lawrence B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a3e7233376344045980ad214122389f4-Connell, La (b)(6) @va.gov>
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Type:	Appointment
Location:	VACO 802 or VANTS 1-800-767-1750 A/C 22021
Attendees:	Llorente, Maria D.; Beck, Lucille B.; Emmendorfer, Thomas (PBM); Jensen, Jon M.; Valentino, Michael (VACO); Connell, Lawrence B.

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Subject:	News Release: VA to make new nasal spray drug available for treatment - resistant depression
Date:	2019/03/20 16:23:33
Priority:	Normal
Type:	Note

FOR IMMEDIATE RELEASE
March 20, 2019

VA to make new nasal spray drug available for treatment-resistant depression

WASHINGTON — Today the U.S. Department of Veterans Affairs (VA) announced its health care providers will now be able to offer the newly approved Spravato naval spray for treatment-resistant depression.

The treatment will be made available to Veterans based on their individual medical needs combined with providers' clinical assessments.

The move follows the March 5 Food and Drug Administration (FDA) approval of Spravato (esketamine) nasal spray. Spravato was approved for use in conjunction with an oral antidepressant for the treatment of treatment-resistant depression in adults.

"We're pleased to be able to expand options for Veterans with depression who have not responded to other treatments," said VA Secretary Robert Wilkie. "It reflects our commitment to seek new ways to provide the best health care available for our nation's Veterans."

Spravato will be available through a restricted distribution system under an FDA-approved Risk Evaluation and Mitigation Strategy (REMS). The purpose of the REMS is to mitigate the risks of serious adverse outcomes and the potential abuse and misuse of Spravato.

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VA health care providers will monitor Veterans for serious adverse outcomes, such as sedation and difficulty with attention, judgment and thinking (dissociation), abuse and misuse, worsening of depression and suicidal thoughts and behaviors.

Veterans will self-administer Spravato nasal spray under the direct observation of a health care provider in a certified medical facility, and then must be monitored by a health care provider for at least two hours after receiving their dose. Spravato cannot be dispensed directly to Veterans for use at home.

For additional information on access to Mental Health Support for Veterans, visit VA Mental Health. Veterans in immediate crisis may call the Veterans Crisis Line at 800-273-8255 and press 1, text to 838255 or chat online at Veterans Crisis Line.

###

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cid:image001.png@01D2F700.D68C1110

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Subject:	need input on Cerner transition and ketamine/esketamine documentation
Date:	2019/08/28 14:14:16
Priority:	Normal
Type:	Note

Hi everyone –

I need some help working to prepare for the Cerner electronic health record transition and how ketamine infusions and Spravato treatments are captured by Cerner. After a conversation with Rani Hoff (who is one of our OMHSP leads on the Mental Health Council with the Cerner transition team), we believe the best way to do this will either be to create a Care Pathway (an algorithm that will walk people through steps in treatment, including order entry, rating/assessment scale entry, results reporting, etc) and a PowerForm (essentially like a template that supports data elements being entered, then generates a progress note and allows for additional narrative data entry).

A couple initial requests for your help:

- • Facility esketamine POCs - If your site has existing note templates you are using for IV ketamine or Spravato treamtents, can you please forward them to me?
- • Fran – I've already forwarded Rani the MUET v2.0 draft (b5)
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Next step: set up a call with the Cerner team to get some demos of what these types of tools may look like. Facility esketamine POCs who are cc'd can join if you are able (I'll cc you on the meeting invite, but understand you are all extremely busy with clinical care). I'll be back in touch to work on arranging a time for this soon.

Thanks!
Ilse

***

Ilse R. Wiechers, MD, MPP, MHS
National Director, Psychotropic Drug Safety Initiative (PDSI)
National Lead, Esketamine Clinical Implementation
Associate Director, Northeast Program Evaluation Center
Office of Mental Health and Suicide Prevention (10NC5), Department of Veterans Affairs
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From:	FDA
Subject:	Nasal Spray and Inhalation Solution, Suspension, and Spray Drug Products--Chemistry, Manufacturing, and Controls Documentation
Date:	2019/08/15 14:08:15
Priority:	Normal
Type:	Post.Rss

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VA-19-1109-B-001551

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Type:	Note

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Email Display Name:	SPRAVATO REMS
Email Address:	SPRAVATOrems@ubc.com

Sent Date:	2019/03/12 12:02:59

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Date:	2019/08/15 07:53:36
Priority:	Normal
Type:	Recall.Report.Success

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Date:	2019/08/23 16:01:47
Priority:	Normal
Type:	Recall.Report.Success

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From:	Emmendorfer, Thomas (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC96BB44E7AE2C94C43B55D094-EMMENDORFER>
To:	Smith, Monica (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=511ea9e77a234375a91a7b34ce23719d-Smith, Moni (b)(6) @va.gov>
Subject:	Message Recall Failure: HHS bought a nasal spray for depression - DRAFT News Release
Date:	2019/03/12 13:05:33
Priority:	Normal
Type:	Recall.Report.Failure

Sender:	Emmendorfer, Thomas (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC96BB44E7AE2C94C43B55D094-EMMENDORFER>
Recipient:	Smith, Monica (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=511ea9e77a234375a91a7b34ce23719d-Smith, Moni (b)(6) @va.gov>
Sent Date:	2019/03/12 13:05:33

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From:	Cork, Travis J. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=11CAA312168F421BB4145BBA3D4D92AD-CORK, TRAVI (b)(6) @va.gov>
To:	VISN5 Mental Health Directors /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=42384154cf1a413f8291554eec80b0af-VISN5 Menta <VISN5MentalHealthDirectors@va.gov>; VISN5 Pharmacy Managers /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=11c1a0951a524e8c9dbf86205c7ad520-VISN5 Pharm <VISN5PharmacyManagers@va.gov>; VISN5 COS /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=497c83296bc946cdbca57a649b3d6ddd-VISN5 COS <VISN5COS@med.va.gov>
CC:	VISN5 Academic Detailing /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c6605da81752450484555f1711f463f0-VISN5 Acade <VISN5AcademicDetailing@va.gov>; Lowman, Cheryl A. Ph.d. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6c940f7024c945629f5bb87a3f283a3a-Lowman, Che (b)(6) @va.gov>
Subject:	MEMORANDUM: Certification with SPRAVATO™ Risk Evaluation and Mitigation Strategy (REMS)
Date:	2019/03/18 17:50:04
Importance:	High
Priority:	Urgent
Type:	Note

Good evening,

Please find the attached memorandum requirement both health care setting risk Evaluation and Mitigation Strategy (REMS) as well as pharamcy enrollment for esketamine (Stravato). Both certifications are required to be completed within 30 days. An EV is forthcoming that will require action on the part of Mental Health Directors and Pharmacy Chiefs. I provided a summary of attachments, key points regaridng the medication/REMS enrollment, as well as the instructions that will be referenced in the EV. Please note that as of now we don't have guidance regarding pharmacy enrollment but that is anticiapted to be relased this week.

Attachments:

- • Acting DUSHOM Memo dated 3/18/2019 – *Certification with SPRAVATO Risk Evaluation and Mitigation Strategy*.
- • Attachment A – SPRAVATO (Esketamine) Frequently Asked Questions dated 3/14/2019
- • Attachment B – SPRAVATO REMS Healthcare Setting Certification Guidance
- • Attachment C1 – Consent for Clinical Treatment/Procedure (Esketamine)
- • Attachment C2 – SPRAVATO Package Insert
- • Attachment C3 – SPRAVATO Medication Guide

NOTES:

(b5)

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(b5)

INSTRUCTIONS/ACTIONS:

1. • Review attached documents and ensure they are distributed to applicable staff at the facility level.
2. • Healthcare System Enrollment
   a. • VAMC should designate the Mental Health Service Line Chief or the Chief of Psychiatry as the Authorized Representative for the Healthcare Setting Certification.
   b. • The Authorized Representative should review forms and materials available on the Spravato® REMS webpage (www.SPRAVATOrems.com.) and then complete and submit the Spravato® REMS Healthcare Setting Enrollment Form to the REMS as per instructions provided on the form (https://www.spravatorems.com/pdfs/SPRAVATO(TM)_REMS_Healthcare_Setting_Enrollment_Form.pdf).
   c. • Provide via response to EV confirming enrollment in Spravato REMS Healthcare Setting Certification.
3. • Pharmacy Enrollment
   a. • Specific guidance regarding pharmacy enrollment will be provided by Pharmacy Benefits Management (PBM) service with anticipated release the week of 3/18/2019. Upon release, this EV ticket will be updated with specific instructions for completion of that process.
   b. • After guidance is provided, the Chief Pharmacy Service shall provide via response to EV confirmation of pharmacy enrollment in Stravato REMS program.

Please contact Travis Cork ((b)(6) @va.gov) and Cheryl Lowman (b)(6) @va.gov) for any questions.

Thanks,

Travis

Travis J. Cork, PharmD, BCPS | VISN 5 – VA CAPITOL HEALTH CARE NETWORK
VISN Pharmacist Executive (VPE)| office (b)(6) cell (b)(6)
(b)(6) @va.gov|



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From: Graham, Keenya (VISN 5)
Sent: Monday, March 18, 2019 1:00 PM
To: Cork, Travis J. (b)(6) @va.gov>; Lowman, Cheryl A. Ph.d. (b)(6) @va.gov>
Cc: VISN5 Action Team – CMO <VISN5ActionTeamCMO@va.gov>
Subject: FW: Memorandum: Certification with SPRAVATO™ Risk Evaluation and Mitigation Strategy (REMS)

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Hi Travis and Dr. Lowman!

For action. Who wants the lead?

Keenya Graham
VISN 5 Network Office
Tel: (b)(6)

#Be There
Veterans Crisis Line – (800)273-8255, press 1 or Text to 838255

From: Office of the DUSHOM Communications
Sent: Monday, March 18, 2019 2:15 PM
To: VHA VISN Directors <VHAVISNDirectors@va.gov>; VHACLE BVAC Group <VHACLEBVACGroup@va.gov>
Cc: VHA VISN Admin Reps <VHAVISNAdminReps@va.gov>; VHA 10NC Action <vha10ncaction@va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>; Wiechers, Ilse (b)(6) @va.gov>; VHA CO 10N Support Staff <VHACO10NSS@va.gov>; McCarthy, Brian (b)(6) @va.gov>
Subject: Memorandum: Certification with SPRAVATO™ Risk Evaluation and Mitigation Strategy (REMS)

Good Afternoon,

Please see the attached memorandum "Certification with SPRAVATO™ Risk Evaluation and Mitigation Strategy (REMS)."

1. The purpose of this memorandum and its attachments is to outline the procedures for the use of Spravato® (eskatamine) nasal spray which was approved by the Food and Drug Administration (FDA) on March 5, 2019, to be used in conjunction with an oral antidepressant, for the treatment of depression in adults who have tried other antidepressant medicines but have not benefited from them (see Attachment A for Esketamine Frequently Asked Questions).

2. Because of the risk of serious adverse outcomes resulting from sedation and dissociation caused by Spravato® administration, and the potential for abuse and misuse of the drug, it is only available through a restricted distribution system, under an FDA approved Risk Evaluation and Mitigation Strategy (REMS). Please see and follow instructions in Attachment B for REMS Healthcare Setting Certification Guidance.

3. All medical centers must become a Spravato® REMS certified Healthcare Setting and certified Pharmacy. *Within 30 days of this memorandum*, facilities should report completion of REMS Healthcare Setting certification to their VISN Chief Mental Health Officer, who should then report VISN-wide REMS certification by email to Dr. Ilse Wiechers at (b)(6) @va.gov.

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4. There are resource requirements that facilities must plan to accommodate. Spravato® is intended for patient self-administration under the direct observation of a healthcare provider, and patients are required to be monitored by a healthcare provider for at least 2 hours after Spravato® administration. Spravato® must never be dispensed directly to a patient for home use.

5. • No special privileges are required to prescribe Spravato®.

6. Once educational materials from the manufacturer of Spravato® are made available to VA to review, the review and use of those materials will be consistent with VHA Directive, 1108.10, Promotion of Drugs and Drug-Related Supplies By Pharmaceutical Company Representatives (PCR) located at: https://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=6435.

7. Please contact Ilse Wiechers, MD, Office of Mental Health and Suicide Prevention at *(b)(6)* @va.gov with any questions related to this request.

Renee Oshinski

Attachments

Sender:	Cork, Travis J. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=11CAA312168F421BB4145BBA3D4D92AD-CORK, TRAVI *(b)(6)* @va.gov>
Recipient:	VISN5 Mental Health Directors /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=42384154cf1a413f8291554eec80b0af-VISN5 Menta <VISN5MentalHealthDirectors@va.gov>; VISN5 Pharmacy Managers /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=11c1a0951a524e8c9dbf86205c7ad520-VISN5 Pharm <VISN5PharmacyManagers@va.gov>; VISN5 COS /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=497c83296bc946cdbca57a649b3d6ddd-VISN5 COS <VISN5COS@med.va.gov>; VISN5 Academic Detailing /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c6605da81752450484555f1711f463f0-VISN5 Acade <VISN5AcademicDetailing@va.gov>; Lowman, Cheryl A. Ph.d. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6c940f7024c945629f5bb87a3f283a3a-Lowman, Che *(b)(6)* @va.gov>
Sent Date:	2019/03/18 17:50:00
Delivered Date:	2019/03/18 17:50:04

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This 'viewpoint' appears to be subtle marketing for esketamine.

VIEWPOINT

Evolving Issues in the Treatment of Depression

Ole Köhler-Forsberg, MD
Psychosis Research Unit, Aarhus University Hospital–Psychiatry, Aarhus, Denmark; and Department of Clinical Medicine, Aarhus University Hospital, Aarhus, Denmark.

Cristina Cusin, MD
Depression Clinic and Research Program, Department of Psychiatry, Massachusetts General Hospital, Boston; and Harvard Medical School, Boston, Massachusetts.

Andrew A. Nierenberg, MD
Harvard Medical School, Boston, Massachusetts; and Dauten Family Center for Bipolar Treatment Innovation, Department of Psychiatry, Massachusetts General Hospital, Boston.

Author Audio Interview

Corresponding Author: Andrew A. Nierenberg, MD, Massachusetts General Hospital, Harvard Medical School, 55 Fruit St, Boston, MA 02114 (anierenberg@mgh.harvard.edu).

Major depressive disorder (MDD) has a lifetime incidence of 10% to 15%.[1] The main treatment options include pharmacological and psychological interventions, with many patients receiving combination treatment. Although randomized clinical trials (RCTs) have established the efficacy of antidepressants,[2] acute and long-term effectiveness is limited, and one-third of patients develop treatment resistance. New interventions are needed in the field and this Viewpoint examines novel interventions, with a specific focus on exercise, nutrition, and ketamine.

Exercise

Exercise is an attractive option to prevent or treat MDD, given the hypothesis that links exercise, brain-derived neurotrophic factor, and neuroprotection. However, the evidence for efficacy and effectiveness of exercise for MDD is mixed.

A meta-analysis of 33 RCTs (N = 1877) showed that resistance exercise training, compared with nonactive control conditions, was associated with a significant reduction in depressive symptoms, with a moderate effect size and a number needed to treat of 4.[3] The findings were independent of health status, prescribed volume of training, and improvements in strength. However, 20 RCTs included patients with depressive symptoms and only 4 included patients with a diagnosis of MDD. Furthermore, the reduction in depressive symptoms became significantly smaller when only RCTs with blinded allocation were included. Nevertheless, analyses restricted to patients with mild to moderate MDD indicated a large effect size.

An intriguing study investigated the potential causal association between exercise and MDD via a mendelian randomization approach. Mendelian randomization techniques use gene variants as instrumental variables to investigate possible causal relationships between risk factors (eg, exercise) and health outcomes (eg, depression). Because genes are randomly allocated, mendelian randomization is thought to minimize the risk for confounding and reverse causality. By including data from 611 583 adults, 91 084 of whom had activity measured by accelerometer, Choi and colleagues[4] found a protective relationship between accelerometer-based activity and MDD by an odds ratio of 0.74 (95% CI, 0.59-0.92). This means that replacing a sedentary lifestyle with 15 minutes of strenuous activity daily or 1 hour of moderate activity was associated with a potential relative reduction in the odds of developing depression by 26%.

Implementing regular exercise is difficult for most people and is even more challenging for those with MDD because of their symptoms of low energy and motivation. Nevertheless, encouraging or prescribing regular exercise can be worthwhile even if just for improved cardiovascular health.

Nutrition

Numerous studies have explored the effect of diet on mood, but the results have been difficult to interpret due to mixed findings and large differences in diets, research designs, and study populations. Observational studies seem to support a positive relationship between mood and a diet consisting of higher contents of plant foods (eg, vegetables, fruits, whole grains) and lean proteins (eg, fish), which has been found across different countries and age groups. However, few studies have specifically investigated the effect of diet in patients with MDD.

The SMILES trial represents one of the first well-performed RCTs and investigated the effect of structured dietary support focusing on a Mediterranean diet.[5] Among 56 adult patients with moderate to severe MDD, a 12-week individual intervention (7 60-minute sessions) investigated the effect of dietary advice and support by a dietician (ie, motivational interviewing, goal setting, and mindful eating) vs social support. The dietary support group, compared with the social support group, was associated with significantly greater improvement. This finding is consistent with other recent studies among patients with MDD, and some results have indicated an even greater effect among patients with MDD and type 2 diabetes.

Two recent RCTs investigated the effects of dietary interventions on depressive symptoms among obese patients.[6,7] The RAINBOW trial (N = 409; mean age, 51) studied behavioral weight loss treatment and problem-solving therapy[6] among individuals with a body mass index of 30 or greater and moderate to severe depressive symptoms. Compared with treatment as usual, the intervention group showed significantly greater decline in mean body mass index (from 36.7 to 35.9 vs 36.6 to 36.6) and in depressive symptoms (from 1.5 to 1.1 vs 1.5 to 1.4) after 12 months.

The MooDFOOD trial (N = 1025; mean age, 46.5 years) studied multinutrient supplementation and food-related behavioral activation therapy promoting a Mediterranean-style diet among patients with a body mass index of 25 to 40 without MDD but with at least mild depressive symptoms.[7] A total of 105 patients (10%) developed MDD within 12 months, with no difference between the 4 intervention groups (9.7% in the placebo-only group, 10.2% in the placebo plus therapy group, 12.5% in the supplement-only group, and 8.6% in the supplement plus therapy group; $P = .48$ for interaction). The findings from the RAINBOW trial indicated significant but only modest effects on weight and depressive symptoms, whereas the MooDFOOD results did not support the use of supplemental nutrients to prevent onset of MDD.

The initial evidence regarding structured dietary support on MDD is promising and seems to favor a Mediterranean diet. A recent Editorial[8] discussed the previous 2 RCTs and suggested that evidence-based lifestyle interventions (eg, diet, exercise, and smoking cessation) should be

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used in addition to first-line pharmacological and psychological treatment but not alone to treat depression. Future studies need to include larger study populations and use similar approaches and dietary patterns as previous trials to yield comparable results. In addition, studies with longer follow-up (ie, several years) would be necessary to explore the long-term effects on mood and health status in general.

Ketamine

Esketamine approved, but don't mention the low effect size from its pivotal clinical trials. Cite instead the larger effect from IV ketamine. Clever.

On March 5, 2019, the Food and Drug Administration approved nasal ketamine (Spravato) as a drug for treatment-resistant depression (TRD). Ketamine has been used as an anesthetic drug since the 1970s and has been investigated for use in MDD for 2 decades.[9] Ketamine has attracted widespread attention since early trials (with sample sizes ranging from 9 to 73) found large (ie, up to 60%) improvement in depressive symptoms and suicidal ideation among severely depressed and otherwise treatment-resistant patients. The large therapeutic effect was experienced within hours after a slow intravenous administration of a subanesthetic dose (0.5 mg/kg) and these effects were transient, with patients returning to their baseline severity within a few weeks. These initial findings have led to increasing off-label use of ketamine for mood disorders and particularly TRD in the United States.

Regarding potential adverse effects, intravenous administration of ketamine at these doses generally does not significantly affect the respiratory or cardiovascular status of physically healthy individuals with MDD. Because patients may experience sedation, confusion, and dissociation, monitoring is required during and after administration. Potential long-term risks include tolerance, abuse, and misuse.

Clinical trials have established that more than half of the patients with TRD experience antidepressant effect of intranasal or intravenous ketamine in addition to their treatment as usual. However, patients with psychotic features or active substance use disorders have been excluded from RCTs, and long-term safety data are limited. Ketamine represents a promising drug that potentially can help alleviate TRD, but further studies are necessary to identify which patients will receive sustained benefit. Ketamine infusions are costly, and often not covered by insurance, while ketamine intranasal is much less expensive but requires frequent administrations (twice weekly or weekly). Even though the addition of esketamine (the patented s-enantiomer of ketamine that represents 50% of the racemic mix of the generic drug) to the therapeutic armamentarium was anticipated, whether esketamine will become a common treatment for depression is unclear and it will be modulated by availability of specialty centers for administration and insurance coverage.

Infusions are expensive, but nasal esketamine is only $35,000 / year.

Another investigational drug with a related mechanism of action through the glutamate system, rapastinel, demonstrated rapid onset of antidepressant effects following intravenous administration in preliminary studies. However, recently reported interim analyses of 3 pivotal clinical trials of rapastinel as treatment for MDD showed no difference, compared with placebo, on the primary outcome and key secondary end points.

Other Approaches

Several other treatments for MDD have attracted increasing attention. Anti-inflammatory drugs have shown promising results, with a recent meta-analysis of 36 RCTs (N = 9422) indicating medium to large effect sizes for several anti-inflammatory drugs as add-on to antidepressants.[10] The effect sizes of anti-inflammatory agents added to antidepressants (standardized mean difference = 0.64) were larger than the effect sizes of antidepressant drugs alone (SMDs ranging from 0.17 to 0.49).[2] Another drug with novel mechanisms, brexanolone, an allosteric modulator of the $GABA_A$ receptor, was recently approved by the FDA for postpartum depression, leading the path to the development of similar compounds for MDD. Psilocybin was found to produce significant antidepressant effects in combination with psychological support in a small open-label study (N = 20), with effects persisting after 6 months.

In conclusion, several new pharmacological and nonpharmacological potential interventions for MDD have become available or are being evaluated. In particular, the evidence regarding lifestyle modification (ie, exercise and diet) is promising, although the core symptoms of severe depression make implementation challenging. Further research is necessary to determine how to provide the right intervention at the right time for each patient, while considering individual needs and preferences, together with important factors such as somatic and psychiatric comorbidities, severity of depression, previous treatment trials, patient adherence, and the availability of the treatment options.

ARTICLE INFORMATION

Published Online: May 24, 2019. doi:10.1001/jama.2019.4990

Conflict of Interest Disclosures: Dr Cusin reported being a site principal investigator of a Janssen esketamine study in 2016 and currently being a site principal investigator for a study sponsored by Shenox Pharmaceuticals on development of a ketamine patch. Dr Nierenberg reported receiving personal fees from Alkermes, Assurex Belvior, Clexio, Jazz Pharmacueticals, Neurocrine, NeuroRx, Neurostar, Otsuka, Sage, Chire, Sunovion, and Supernus and grants and personal fees from Janssen. No other disclosures were reported.

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Intranasal Esketamine for Treatment Resistant Depression

National Protocol Guidance

June 2019

VA Pharmacy Benefits Management Services, Medical Advisory Panel, VISN Pharmacist Executives, and Office of Mental Health and Suicide Prevention

Purpose: To provide general guidance on ensuring access to intranasal esketamine for the treatment of treatment resistant major depressive disorder under a National VA protocol that will facilitate collection of safety and effectiveness outcomes via a prospective medication use evaluation (MUE).

Disclaimer: To be consistent with the purpose of this general guidance and not to be overly proscriptive, this guidance allows facilities the flexibility to exercise modifications to the protocol as necessary to operationalize the use of intranasal esketamine for treating treatment-resistant depression.

Background

Esketamine is the S-enantiomer of racemic ketamine, a non-selective, non-competitive antagonist of the N-methyl-D-aspartate (NMDA) receptor, an ionotropic glutamate receptor. The mechanism by which esketamine exerts its antidepressant effect is unknown. Spravato® (esketamine) nasal spray was approved by the Food and Drug Administration (FDA) on March 5, 2019, to be used in conjunction with an oral antidepressant for the treatment of depression in adults who have tried other antidepressants medicines but have not benefited from them.

Because of the risk of serious adverse outcomes resulting from possible sedation and/or dissociation caused by Spravato® administration, and the potential for abuse and misuse of the drug, it is only available through a restricted distribution system, under an FDA approved Risk Evaluation and Mitigation Strategy (REMS).

- The Spravato® REMS can be accessed at www.SPRAVATOrems.com.
- All healthcare settings and pharmacies are required to enroll in the Spravato® REMS via a designated authorized representative before they can purchase product from a distributor, dispense, or supervise administration of Spravato®.
- All patients must be enrolled in the Spravato® REMS before they can receive Spravato®

A summary of the efficacy data for FDA-approved indications is available in the VA PBM Drug Monograph for esketamine. (Esketamine (SPRAVATO) Monograph) Esketamine provides similar therapeutic effects to ketamine. VA PBM developed a national protocol for the use of intravenous ketamine in treatment resistant depression and severe suicidal ideation which was published in December 2017. (Ketamine Infusion for Treatment Resistant Depression). The national protocol for intravenous ketamine is consistent with the VA PBM Guidance on Off Label Prescribing of drugs that was published in August 2013 and can be accessed at: (Guidance on Off Label Prescribing).

Departments Affected: Pharmacy, Nursing, Mental Health

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Procedure:

- Patients can either be treated as outpatients or inpatients

Patient Selection

Inclusion Criteria

The answers to **ALL** of the following must be fulfilled in order to meet criteria.

- All REMS requirements have been met.
- Adults <65 years of age with current diagnosis of unipolar major depressive disorder by DSM-5.
- The patient did not achieve remission from at least four adequate therapeutic trials (dose and duration) of antidepressants, either alone or in combination with evidence-based psychotherapy, and in the current episode of depression is experiencing moderate to severe depressive symptomatology based on a depression rating scale within the last 30 days. At least two trials must include an antidepressant augmented with an additional agent (e.g. antipsychotic, second antidepressant, lithium, or thyroid supplementation).
- Antidepressant treatment trials are considered unsuccessful if the patient has not responded to at least 6 weeks of an antidepressant at half maximum dose or greater.
- The patient has been considered for electroconvulsive therapy (ECT).
- The patient has started and is currently receiving a new antidepressant that has not previously failed in the current depressive episode.
- A psychiatrist has evaluated the patient and determined and documented in the patient's medical records that the patient qualifies for esketamine treatment.
- The prescriber is a psychiatrist.
- The patient agrees to stay and be monitored for at least two hours after esketamine administration and agrees not to drive or operate heavy machinery/equipment and not to make major financial or legal decisions for the remainder of the day in which esketamine is administered.
- The patient or their legal representative can provide signed informed consent.
- The patient has an adult who can accompany him/her and assist with transportation, or another method of safe transport has been arranged and documented.
- For women of childbearing potential
    - Pregnancy should be excluded prior to receiving esketamine and the patient provided contraceptive counseling on potential risks vs. benefits of taking esketamine if patient were to become pregnant.

Exclusion Criteria

If the answer to **ANY** item below is met, then the patient should **NOT** receive esketamine.

- Hypersensitivity to esketamine, ketamine, or any of the excipients.
- Aneurysmal vascular disease (including thoracic and abdominal aorta, intracranial, and peripheral arterial vessels) or arteriovenous malformation.
- History of intracerebral hemorrhage.

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- History of seizures
- Current or recent (within 30 days) delirium.
- Current uncontrolled hypertension (systolic blood pressure >140 mm Hg or diastolic blood pressure > 90 mm Hg).
- Severe cardiac decompensation (Class IV heart failure or unstable angina).
- Severe hepatic impairment (Child-Pugh class C).
- Current or previous interstitial or ulcerative cystitis.
- Active suicidal ideation.
- Comorbid psychiatric condition is present (schizophrenia, schizoaffective disorder, MDD with psychotic symptoms, bipolar disorder, obsessive-compulsive disorder, intellectual disability, autism, cluster B personality disorder, or a major neurocognitive disorder diagnosis).
- History of non-response to ketamine, esketamine, or ECT.
- History of VNS or deep brain stimulation in current episode of depression.
- Current or previous abuse of ketamine or esketamine.
- Clinical evidence for current substance abuse except tobacco use (e.g. confirmed UDS).
- Current barbiturate, cannabis or opioid use.
- Current moderate or severe substance use disorder (SUD).
- Pregnancy (known pregnancy or positive pregnancy test).
- Patient is breastfeeding.

Issues for Consideration

- Patients prescribed a benzodiazepine, a non-benzodiazepine sedative hypnotic or a monoamine oxidase inhibitor are eligible to receive esketamine; however, it is advised that concurrent use while receiving esketamine may cause sedation or blood pressure changes.
- Carefully review prior to use of esketamine, patients who are less than 6 months in remission from Substance Use Disorder. Review Prescription Drug Monitoring Program (PDMP).
- May cause fetal harm. Consider pregnancy planning and prevention in females of reproductive potential.

Screening and Referral

- Each facility will be responsible for developing and operationalizing a procedure to screen and refer potential candidates for treatment with esketamine.
- Screening should be completed no more than 30 days prior to acceptance and administration of the first dose of esketamine.
- Screening will include the following: signed informed consent; inclusion/exclusion criteria; psychiatric examination including a depression rating scale (e.g. PHQ-9), evaluation of cognitive status (e.g., St. Louis University Mental Status exam (SLUMS) or Montreal Cognitive Assessment (MoCA)), and assessment of suicidality (e.g. Columbia Risk Assessment (CRA)); and physical examination including vitals (blood pressure, heart rate), relevant laboratory measures, and urine toxicology and pregnancy screens.
    - Patients with a SBP >140 mm Hg or a DBP >90 mm Hg at screening should be considered at higher risk and treatment for hypertension should be considered prior to initiating

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treatment with esketamine. Patients with a diagnosis of hypertension are to be adequately treated prior to receiving a dose of esketamine.
    - Patients with a history of cardiopulmonary or cerebrovascular disease, recent myocardial infarction, symptomatic ischemic heart disease, dyspnea marked by shortness of breath or wheezing, poor exercise capacity (<6 metabolic equivalent of tasks (METs); bicycling – light effort (10-12 mph) =6.0), or any disease that could be associated with increased risk of acute cardiac demand or blood pressure or respiratory depression should be considered on an individual case basis, considering risk/benefit ratios.
    - Patients with a baseline heart rate of <60 beat per minute (bradycardia) or >100 beats per minute (tachycardia) should be considered on a case-by-case basis for the relative risks of esketamine.
- Other physical and laboratory screening procedures should be determined according to the patient's individual risk factors based on his/her demographics, medical history and review of systems and is the responsibility of the prescribing psychiatrist.
- Whether to obtain medical clearance from the patient's primary care provider or consults from a cardiologist, or other medical specialist should be based on the patient's risk factors and is the responsibility of the prescribing psychiatrist.
- Concurrent use or abuse of CNS depressants and other psychoactive substances
    - Considering esketamine's known addictive potential, a history of substance abuse or dependence including ketamine or esketamine, extent of past and current alcohol use, smoking history, a history of medication misuse, and a positive urine drug screen are important factors to consider. Patients with a history of SUD are at risk for relapse or development of a new SUD when exposed to psychoactive substances and may not be able to give informed consent because of long-lasting brain changes that affect decisions involving psychoactive substances. There are case reports of recent substance abuse associated with the risk of relapse with ketamine, one that resulted in death in a single motor vehicle accident. While length of sobriety may be considered when making a decision, at a minimum, all patients in recovery from SUD should be warned of the risk of inducing a relapse to previous SUD or a new addiction to esketamine or ketamine with this treatment. Other strategies for managing treatment-resistant depression including monoamine oxidase inhibitors, tricyclic antidepressants, ECT, repetitive transcranial magnetic stimulation, or augmentation with lithium, T_3, atypical antipsychotics, or pramipexole should be prioritized over strategies involving potentially addictive substances, especially for those with a history of SUD. If esketamine treatment is chosen, close monitoring for signs of substance use including random, monitored urine drug testing is recommended.
    - Due to the theoretical potential for benzodiazepines and nonbenzodiazepine, benzodiazepine receptor agonists hypnotics (e.g., zolpidem) to attenuate ketamine's antidepressant effects, patients taking benzodiazepines should be allowed adequate time for the last dose of benzodiazepine to washout prior to receiving esketamine.
- Completion and submission of REMS Patient Enrollment Form.

Location of Administration, Monitoring and Recovery

- The facility is responsible for identifying a physical location for the dosing of esketamine and monitoring the patient during and after the dosing. The place for administration and recovery

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should be private and large enough to accommodate the patient and required personnel. The space must have available a way for the patient to recline his/her head at a 45 degree during the dosing procedure.

- The treatment setting should be able to provide immediate care if necessary. A crash cart should be readily accessible and rapid access/code team available for response if needed. The facility must have the means to monitor basic cardiovascular functions (including electrocardiogram and blood pressure) and respiratory function (oxygen saturation or end-tidal CO_2).
- The facility must also be capable of administering oxygen, medication and restraints to manage potentially dangerous behavioral symptoms.
- The facility must have a plan to rapidly address any sustained alterations in cardiovascular function including advanced cardiac life support or transfer to a hospital capable of caring for acute cardiovascular events.
- Patients determined to be at high risk for complications based on pretreatment evaluation should be treated at a facility equipped and staffed to manage any cardiovascular or respiratory events that may occur.

Esketamine Procurement, Dosing, and Day of Administration Monitoring

- The facility is responsible for determining the procedure by which the esketamine is ordered, prepared and transported to the place of administration.
- A psychiatrist will order the intranasal esketamine and follow the facility's policy for ordering/handling schedule III-controlled substances.
- Patients self-administer intranasal esketamine under the direct observation of a health care provider in a certified medical facility and patients must be monitored by a health care provider for at least two hours after receiving their esketamine dose. Esketamine cannot be dispensed directly to a patient for use at home.
- The ordering psychiatrist will be physically present during the dosing procedure. The psychiatrist can leave once the dosing is completed and the patient considered stable based on vital signs and cognitive status. A healthcare provider is to remain with the patient for ongoing monitoring of possible adverse events until discharge evaluation. The psychiatrist must return at 120 minutes after the end of the dosing to administer the PHQ-9 (or other depression scale), SLUMS/MoCA, the Clinician-Administered Dissociative States Scale (CADSS), the Columbia Risk Assessment (CRA) and vital sign assessment to clear the patient for discharge.



CADSS.pdf



PHQ-9_English.pdf



MOCA-Test-English.pdf



slumsexam_05.pdf

- The REMS Patient Monitoring/Esketamine Safety Form shall be completed after every treatment session and submitted to VAMedSAFE online (esketamine safety InfoPath link) or via fax (1-708-786-xxxx).
- Esketamine dose administration timeline
  - T-2 days or sooner: Urine drug screen and pregnancy tests are collected.
  - T-120 minutes: Patient to avoid further food intake.
  - T-60 minutes : Patient to avoid use of intranasal sprays and medications.

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- T-30 minutes : Patient to avoid further fluid intake. Psychiatrist administers PHQ-9 (or other depression scale), SLUMS/MoCA, CADSS, and CRA as baseline measures. Patient is instructed to blow nose. Number of devices needed for dose administration is confirmed, expiration date is checked on all device packaging (if expired, get a new device). Perform vital signs (sitting/standing blood pressure, sitting/standing pulse, respiratory rate, and oxygen saturation). In patients whose BP is elevated prior to esketamine administration (as a general guide: >140/90 mmHg) a decision to delay therapy should consider the balance of benefit and risk in individual patients.
- T-5 minutes: Time out
- T-0 minutes : Provided vitals are acceptable and urine drug screen and pregnancy tests are negative (see Exclusion Criteria), ordering psychiatrist/or health care provider opens blister pack, removes device, DOES NOT PRIME DEVICE, confirms 2 green dots on the device indicator, and hands device to patient. Patient is instructed on how to hold device, reclines head at 45-degree angle, and self-administers a spray into each nostril in accordance with the instructions provided by the device manufacturer (see REMS Prescribing Information). The ordering psychiatrist takes the device from the patient, checks that the indicator shows no green dots (if you see a green dot, have patient spray a second time in the second nostril). The patient rests in a semi-reclined position for 5 minutes. The procedure is repeated with the next device(s) as needed to achieve appropriate dose delivery (2 total devices = 56 mg, 3 total devices = 84 mg). Ensure the patient waits 5 minutes after each dose to allow medication to absorb. Used device(s) are disposed per facility procedure for a Schedule III drug product per applicable federal, state, and local regulations.
- T+1-120 minutes : Monitor for onset and resolution of sedation, dissociation, and other possible adverse events.
- T+20 minutes : Check vital signs
- T+40 minutes : Check vital signs and patient's cognitive status if indicated.
- T+90 minutes : Check vital signs
- T+120 minutes : Check vital signs, repeat administration of PHQ-9 (or other depression scale), SLUMS/MoCA, CADSS, and CRA.

- Parameters for dose administration (serial use of multiple devices)
  - The appearance of any of the following necessitates stopping the dosing: 1) pallor, cyanosis, or any symptoms of poor perfusion, 2) respiratory symptoms such as shortness of breath, wheezing, 3) the appearance of chest, jaw or arm pain suggesting cardiac involvement, or 4) the patient's desire to stop.
- Discharge procedures
  - The ordering Psychiatrist confirms the following to assure the patient is safe to leave with a safe method of transport.
    - Vital signs are stable (BP <140/90 mmHg) and possible adverse effects (e.g. sedation, dissociation) have resolved by T+120 minutes or a later time point.
    - Follow up assessment of symptoms of depression, cognitive impairment, and suicidality have been completed and are determined to be appropriate for discharge.
    - The patient has an adult who can accompany him/her and assist with transportation, or another method of safe transport has been arranged and documented.

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- The patient agrees to stay and be monitored for at least two hours after esketamine administration and agrees not to drive or operate heavy machinery/equipment and not to make major financial or legal decisions for the remainder of the day in which esketamine is administered.

Repeat Dosing Schedule

- The FDA-approved, recommended dosage for intranasal esketamine is as follows:

Induction Phase	**Weeks 1-4**	**Dosage**
	Administer twice per week	Day 1 starting dose: 56 mg Subsequent doses: 56 mg or 84 mg
Maintenance Phase		
	Weeks 5-8	
	Administer once weekly	56 mg or 84 mg
	Week 9 and after	
	Administer every 2 weeks or once weekly	56 mg or 84 mg

- Dosing frequency in week 9 and after during maintenance phase should be individualized to the least frequent dosing to maintain remission/response.
- At present the time frame for maintenance use is undefined.

Longitudinal Monitoring of Esketamine Patients

- The REMS Patient Monitoring/Esketamine Safety Form shall be completed after every treatment session and submitted to VAMedSAFE online (esketamine safety InfoPath link) or via fax (1-708-786-xxxx).
- All sites providing intranasal esketamine treatment must submit information in accordance with the VA PBM Real-time Medication Use Evaluation (MUE) on Intranasal Esketamine for Treatment Resistant Depression (esketamine MUE InfoPath link). MUE data should be submitted:
    - **Each time** a patient returns for an esketamine dose.
    - Any time a patient is hospitalized during or between dosing appointments.
    - Within 180 and 365 days from first dose to assess for diagnosis of substance use disorder (SUD).
    - At completion of a treatment course.
    - If patient dies between doses or within 120 days after final infusion.
- Following discontinuation of esketamine treatment for any reason, patients require weekly suicide risk assessment for 4 weeks, with an additional suicide risk assessment at 3 months after completion of treatment course. These suicide risk assessments may occur as part of existing suicide prevention protocols at facilities (e.g. high-risk flag patient outreach).

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Esketamine Treatment Failure/Discontinuation

- If the patient does not respond to nasal esketamine after one week, discontinue.
    - An adequate response is defined as a 50% or greater decline in the depression rating scale score from baseline.
- If a woman taking esketamine becomes pregnant, the drug should be stopped, and the patient counseled about the risk to the fetus.
- If the patient has a positive urine drug screen for specified drugs of abuse (cannabinoids, barbiturates, methadone, opioids, cocaine, phencyclidine, and amphetamine/methamphetamine), while receiving esketamine, then discontinue esketamine.
- Discontinue if signs/symptoms of new or recurrent substance use disorder emerge and refer to SUD specialty care.

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From:	Wiechers, Ilse /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0C7B1428D9E4233A641F125C5B6FC4F-WIECHERS, I (b)(6) @va.gov>
To:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b)(6) @va.gov>; Ilse Wiechers (Yale) (b)(6) Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat (b)(6) @va.gov>
Subject:	Ilse <> Matthew re esketamine
Date:	2019/03/21 12:29:04
Start Date:	2019/03/22 14:00:00
End Date:	2019/03/22 14:30:00
Priority:	Normal
Type:	Appointment
Location:	cell 708-786-7976
Attendees:	Ilse Wiechers (Yale); Fuller, Matthew A. (PBM)

Sender:	Wiechers, Ilse /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0C7B1428D9E4233A641F125C5B6FC4F-WIECHERS, I (b)(6) @va.gov>
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Date:	2019/03/21 12:29:04
Start Date:	2019/03/22 14:00:00
End Date:	2019/03/22 14:30:00
Priority:	Normal
Type:	Schedule.Meeting.Request
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Sent Date:	2019/03/21 12:29:02
Delivered Date:	2019/03/21 12:29:04

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Sent Date:	2019/03/21 12:29:02
Delivered Date:	2019/03/21 12:29:04

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From:	Stone, Richard A., MD /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BD16619615D64ADEA22E45E63FF6462A-STONE, RICH (b)(6) @va.gov>
To:	Stone, Richard A., MD /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bd16619615d64adea22e45e63ff6462a-Stone, Rich (b)(6) @va.gov>; Beck, Lucille B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=845480228a8b43e7a5fef5716ded04c2-Beck, Lucil (b)(6) @va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>; Jensen, Jon M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddeb735ace76400db5c3f10603188a14-Jensen, Jon (b)(6) @va.gov>
Subject:	HHS Nasal Spray
Date:	2019/03/07 08:14:08
Start Date:	2019/03/07 09:00:00
End Date:	2019/03/07 09:30:00
Priority:	Normal
Type:	Appointment
Location:	VACO 800
Attendees:	Beck, Lucille B.; Emmendorfer, Thomas (PBM); Jensen, Jon M.

Sender:	Stone, Richard A., MD /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BD16619615D64ADEA22E45E63FF6462A-STONE, RICH (b)(6) @va.gov>
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Sent Date:	2019/03/07 08:14:08

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From:	Stone, Richard A., MD /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BD16619615D64ADEA22E45E63FF6462A-STONE, RICH (b)(6) @va.gov>
SentVia:	Williams, Jessica D. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=007F83F1989E48888DAB9C5D712C99B4-WILLIAMS, J (b)(6) @va.gov>
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Date:	2019/03/07 08:14:08
Start Date:	2019/03/07 09:00:00
End Date:	2019/03/07 09:30:00
Priority:	Normal
Type:	Schedule.Meeting.Request
Location:	VACO 800
Attendees:	Beck, Lucille B.; Emmendorfer, Thomas (PBM); Jensen, Jon M.

Sender:	Stone, Richard A., MD /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BD16619615D64ADEA22E45E63FF6462A-STONE, RICH (b)(6) @va.gov>; Williams, Jessica D. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=007F83F1989E48888DAB9C5D712C99B4-WILLIAMS, J (b)(6) @va.gov>
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Start Date:	2019/03/07 09:00:00
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Priority:	Normal
Type:	Appointment
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Type:	Appointment
Location:	VACO 800
Attendees:	Stone, Richard A., MD; Beck, Lucille B.; Emmendorfer, Thomas (PBM); Jensen, Jon M.; Valentino, Michael (VACO)

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Date:	2019/03/07 08:14:07
Start Date:	2019/03/07 09:00:00
End Date:	2019/03/07 09:30:00
Priority:	Normal
Type:	Appointment
Location:	VACO 800
Attendees:	Beck, Lucille B.; Emmendorfer, Thomas (PBM); Jensen, Jon M.

Purpose: Discussion HHS Nasal Spray

Sender:	Stone, Richard A., MD /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BD16619615D64ADEA22E45E63FF6462A-STONE, RICH (b)(6) @va.gov>
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Subject:	Group just voted to change ketamine to match Esketamine
Date:	2019/06/20 14:43:57
Priority:	Normal
Type:	Note

Just as an FYI

Sent with BlackBerry Work
(www.blackberry.com)

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Subject:	gabapentinoids and suicide
Date:	2019/06/18 08:21:00
Priority:	Normal
Type:	Note

Bruce,

FYI, something other than esketamine...

Matthew

Sender:	Fuller, Matthew A. (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=62D9CBB23B184CACB98895776E36A471-FULLER, MAT>
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Associations between gabapentinoids and suicidal behaviour, unintentional overdoses, injuries, road traffic incidents, and violent crime: population based cohort study in Sweden

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ABSTRACT

OBJECTIVE

To examine associations between gabapentinoids and adverse outcomes related to coordination disturbances (head or body injuries, or both and road traffic incidents or offences), mental health (suicidal behaviour, unintentional overdoses), and criminality.

DESIGN

Population based cohort study.

SETTING

High quality prescription, patient, death, and crime registers, Sweden.

PARTICIPANTS

191 973 people from the Swedish Prescribed Drug Register who collected prescriptions for gabapentinoids (pregabalin or gabapentin) during 2006 to 2013.

MAIN OUTCOME MEASURES

Primary outcomes were suicidal behaviour, unintentional overdoses, head/body injuries, road traffic incidents and offences, and arrests for violent crime. Stratified Cox proportional hazards regression was conducted comparing treatment periods with non-treatment periods within an individual. Participants served as their own control, thus accounting for time invariant factors (eg, genetic and historical factors), and reducing confounding by indication. Additional adjustments were made by age, sex, comorbidities, substance use, and use of other antiepileptics.

RESULTS

During the study period, 10 026 (5.2%) participants were treated for suicidal behaviour or died from suicide, 17 144 (8.9%) experienced an unintentional overdose, 12 070 (6.3%) had a road traffic incident or offence, 70 522 (36.7%) presented with head/body injuries, and 7984 (4.1%) were arrested for a violent crime. In within-individual analyses, gabapentinoid treatment was associated with increased hazards of suicidal behaviour and deaths from suicide (age adjusted hazard ratio 1.26, 95% confidence interval 1.20 to 1.32), unintentional overdoses (1.24, 1.19 to 1.28), head/body injuries (1.22, 1.19 to 1.25), and road traffic incidents and offences (1.13, 1.06 to 1.20). Associations with arrests for violent crime were less clear (1.04, 0.98 to 1.11). When the drugs were examined separately, pregabalin was associated with increased hazards of all outcomes, whereas gabapentin was associated with decreased or no statistically significant hazards. When stratifying on age, increased hazards of all outcomes were associated with participants aged 15 to 24 years.

CONCLUSIONS

This study suggests that gabapentinoids are associated with an increased risk of suicidal behaviour, unintentional overdoses, head/body injuries, and road traffic incidents and offences. Pregabalin was associated with higher hazards of these outcomes than gabapentin.

WHAT IS ALREADY KNOWN ON THIS TOPIC

Studies have linked gabapentinoids to suicidal behaviour and overdose related deaths

Research has been inconsistent and conclusions have been limited by methodological problems

Evidence about associations between gabapentinoids and other adverse outcomes is limited

WHAT THIS STUDY ADDS

This study suggests that gabapentinoids were associated with increased risks of suicidal behaviour, unintentional overdoses, head/body injuries, and road traffic incidents and offences

Pregabalin was associated with higher hazards of these outcomes than gabapentin, and these associations were strongest in those aged 15 to 24, where hazards were increased for all outcomes

Guidelines for gabapentinoid treatment in young people may need review

Introduction

Gabapentinoids have anticonvulsant, analgesic, and anxiolytic properties. The two main gabapentinoids, gabapentin and pregabalin, are currently approved for the treatment of epilepsy and neuropathic pain disorders in Europe (including Sweden). Pregabalin is also approved for treating generalised anxiety disorder in Europe, and has received approval for treating fibromyalgia in the United States.[1] Prescriptions have risen steeply in recent years,[2] and gabapentinoids are among the top 15 drugs globally in terms of revenue.[3-5] Concerns have, however, been expressed about overprescription, particularly for pain relief,[2 3] as well as adverse effects,[6 7] including dizziness, somnolence, balance problems, blurred vision,[1 6 8-12] coordination problems, and impairments in cognitive performance.[6 13] Although a 2008 Food and Drug Administration study of antiepileptic drugs reported an increased suicidal risk, separate analyses for pregabalin and gabapentin did not show clear effects.[14] However, suicidal ideation accounted for most reported events; suicidal behaviour was rare.[14] Since the FDA investigation, pharmacoepidemiological studies have used administrative data with larger sample sizes to examine suicidal outcomes for gabapentin.[15 16] Results have been inconsistent, with increased,[17] decreased,[18] and no changes in suicide risk.[19-21] Furthermore, conclusions have been limited owing to confounding

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by indication[16] (ie, the reason for prescribing the drug is also associated with the adverse outcome studied).

Gabapentinoids have been linked to overdoses and related deaths.[22] In a nested case-control study of opioid users, concomitant gabapentin use was associated with a 60% increase in opioid related death compared with no concomitant use.[23] In the United Kingdom, gabapentinoids are being reclassified as a class C controlled substance.[24 25] Evidence is, however, limited and is based on a small number of reported deaths.[26] Little data exist on the association between gabapentinoids and other psychosocial adverse outcomes. Isolated cases of aggression have been reported for gabapentin in children with psychiatric morbidity.[27-29] Most of this research is based on case reports, limiting conclusions about causality. Thus, evidence about adverse outcomes associated with gabapentinoids is limited, despite broadening clinical indications and increasing use.[6] Furthermore, gabapentinoids are widely used off-label, which could account for up to 90% of prescriptions for pregabalin.[9] Reliable information about adverse outcomes is required to test whether these concerns are valid, as inaccurate findings may influence prescribing practices.[13 16]

To address these shortcomings, we applied a within-individual design to a large population based sample to examine associations between gabapentinoids and adverse outcomes related to coordination disturbances (head or body injuries, or both and road traffic incidents and offences), mental health (suicidal behaviour, unintentional overdoses), and criminality (violent crime).

Methods

Design

We carried out a population based cohort study using Swedish registers with national coverage, linked through unique identification numbers.[30] A within-individual design was used, where participants acted as their own control, thus more fully accounting for confounding by indication and time invariant factors such as individual vulnerability or psychiatric history. Furthermore, we examined associations for specific subgroups based on sex, age, substance use disorders, use of other antiepileptic drugs, and pre-existing comorbidities to further clarify risks and benefits of gabapentinoids.

Participants and setting

In the total population of Sweden aged 15 and older during the study period (n=8 945 712), we identified all those who had collected at least two consecutive prescriptions for gabapentinoids. Follow-up started on 1 January 2006 (or on the date of immigration to Sweden) and ended on 31 December 2013. Single prescriptions were not included in the main analyses owing to uncertainty over drug adherence or tolerance. We also collected demographic data (see Methods section in supplementary file). Our cohort included both prevalent users (ie, participants who used gabapentinoids before follow-up started) and new users.

Drugs

All citizens in Sweden are insured through a common non-claims healthcare insurance, and drugs are subsidised. Our data consisted of dispensed drugs (filled prescriptions) from Swedish pharmacies, obtained from the Swedish Prescribed Drug Register. This register includes information on all prescriptions dispensed by pharmacies in Sweden since July 2005, with less than 0.3% missing information.[31] We extracted information on prescriptions for pregabalin (Anatomical Therapeutic Chemical code N03AX16) and gabapentin (N03AX12) from the Swedish Prescribed Drug Register. The Swedish Pharmaceutical Benefits allows for a maximum of three months' supply for each prescription.[32] To ensure treatment continuity, we defined treatment periods as at least two consecutively collected prescriptions no more than three months apart. Participants were considered to have used the drugs from the date of the first prescription to the date of the last prescription within that treatment period (which could last from a few weeks to up to eight years). We considered prescriptions if they were dispensed more than three months apart to be the start of a new treatment period, and we investigated each treatment period in the analyses.[33]

Outcomes

Information on suicidal behaviour, unintentional overdoses, head or body injuries, and road traffic incidents was collected from the Swedish Patient Register,[34] which includes all admissions to hospitals in Sweden, as well as outpatient contacts with specialised secondary care. This register includes the primary diagnoses listed in 99% of all hospital discharges. In validation studies, the positive predictive value of diagnoses in this register is between 85% and 95%.[34] Only diagnoses received during unplanned (emergency) visits were used in our analyses, and diagnoses received during planned visits (follow-ups and referrals) were excluded. Although this is a more conservative approach, we used this measure to avoid overestimation of the diagnoses, as the diagnosis that is the reason for treatment initiation could also be coded during follow-ups and referrals regardless of current symptoms. Information on death by suicide, unintentional overdoses, head or body injuries, and road traffic incidents was collected from the Cause of Death Register—a register of all deaths in Sweden; the underlying cause is specified in 96% of the cases.[35] For violent crime, we used arrests as the primary outcome because some investigations may be dropped by the prosecution.[36] Furthermore, the decision to discontinue criminal proceedings might or might not be influenced by the charged person taking psychotropic medication. In sensitivity analyses we used convictions (rather than arrests) as an outcome. We extracted information on suspected offences from the Register of People Suspected of Offences, including all those

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arrested of a crime after a completed investigation by police, customs authority, or prosecution service.[37] Information on convicted offences came from the National Crime Register, including all convictions in Swedish district courts.[37]

Suicidal behaviour—suicidal behaviour was defined as emergency hospital visits due to self injurious behaviour or suicide attempt, or death by suicide (international classification of diseases, 10th revision (ICD-10) codes X60-X84).

Unintentional overdoses—unintentional overdoses were defined as emergency hospital visits or death due to poisoning by illicit drugs, medications, and biological substances (ICD-10: T36-T50), accidental poisoning by noxious substances (X40-X49), and acute intoxications and overdoses by alcohol and illicit drugs (F10.0, F11.0, F12.0, F13.0, F14.0), excluding intentional self poisoning (ICD-10: X60-X69).

Head/body injuries—head/body injuries were defined as emergency hospital visits or death due to superficial, open, or crushing injuries, dislocations, fractures, and amputations (ICD-10: S00-T14), with intentional self injuries (ICD-10: X70-X84) excluded. In sensitivity analyses, we stratified injuries into two separate categories; injuries to the head or neck (ICD-10: S00-S19) and injuries to the body (ICD-10: S20-T14).

Road traffic incidents and offences—road traffic incidents and offences were defined as emergency hospital visits or death due to road traffic accidents (ICD-10: V00-V99), or arrests or convictions of traffic offences (including reckless driving, hit and run offences, causing death or injury by driving, and moving violations, as in previous work[38]). In sensitivity analyses, we investigated hospital treatment for road traffic incidents and arrests or convictions for road traffic offences separately.

Violent crime—violent crime was defined as crimes against people, as in previous work,[39] and included attempted, completed, and aggravated forms of murder, manslaughter, unlawful threats, harassment, robbery, arson, assault, assault on an official, kidnapping, stalking, coercion, and all sexual offences.

Statistical analyses

All observable follow-up time was split into periods of treatment and non-treatment. We censored observations at the end of follow-up, or in the event of death or permanent emigration from Sweden. When a treatment period ended, the participant crossed over to a non-treatment period. If adverse outcomes were experienced during a period, this period was further split into the period before the first outcome, period between outcomes, and period after the last outcome. We measured time at risk from the start of all periods. To account for unobserved time—that is, periods where gabapentinoid use or adverse outcomes, or both might not have been captured in the registers—we removed (truncated) periods of intermittent emigration, prison stay, stay in secure residential homes for juveniles, and hospital admission. Time after immigration, hospital discharge, and release from prison or secure residential homes was added to the observed time again, and we measured time at risk from the start of this period.

We used a within-individual design, which was analysed by stratified Cox proportional hazards regression. This design is a variant of self controlled cases series, where participants serve as their own control.[40 41] In this design, the rate of adverse outcomes during all treatment periods is compared with the rate of adverse outcomes during all non-treatment periods within each participant. This reduces the potential for unmeasured confounding that is time invariant during the study period, such as due to genetics and historical factors. In the model, only those who change drug status contribute directly to the estimate. All others contribute indirectly through the estimate of the association with age. To adjust for age as a categorical time varying covariate, we coded age with one category for each whole year. We used restricted cubic splines to allow for non-linear effects of age.[42] In sensitivity analyses, we stratified on predetermined age bands (15-24, 25-34, 35-44, 45-54, 55-64, and ≥65 years). Because the unadjusted covariates in the stratified Cox proportional hazards regression are time varying, we did not test for the proportional hazards assumption.

We initially analysed gabapentinoids as one class and examined associations for the whole sample. Then we analysed pregabalin and gabapentin separately. These samples were not mutually exclusive, as certain participants were dispensed both drugs during follow-up. Subsequent stratifications were made on sex and predetermined age bands.

Several additional analyses were carried out. To account for the potential effect of other antiepileptics, we excluded participants who had been dispensed another antiepileptic (ATC codes N03AA-AG, N03AX03-11, N03AX13-15, and N03AX17-30) during follow-up. To account for the influence of alcohol and drug use, we excluded all those with diagnosed substance use disorders (ICD-10: F10-F19, not including overdoses and acute intoxications F10.0, F11.0, F12.0, F13.0, F14.0). To examine if single prescriptions (ie, not part of a treatment period) were differently associated with adverse outcomes, we examined adverse outcomes 30 days after a single prescription was dispensed. We also carried out analyses where we examined participants who had collected only one gabapentinoid prescription during follow-up. In our main analyses, we used a more conservative measure to define the end of a treatment period—that is, we considered treatment to end at the date of the last prescription. To account for the possibility that participants take gabapentinoids for up to three months after their last dispensed prescription (as the Swedish Pharmaceutical Benefits allows for a maximum of three months' supply for each prescription), we repeated the main models with a different definition of a treatment period, by extending the end of a treatment period to three months after the last collected prescription. To account for previous use of gabapentinoids, we included a two year wash-out period to include only those who had been treatment-

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free for at least 24 months before starting their first treatment during our follow-up (a new user design). To examine new onsets of adverse outcomes, we excluded those who had experienced an event of the examined outcome before starting gabapentinoid treatment.

To estimate dose of gabapentinoids used, we calculated the defined daily dose by summing dispensed drugs and then dividing the sum by the number of days in the treatment period. We then categorised defined daily doses into three separate treatment interval categories; low use (<1 defined daily dose), moderate use (1-2 defined daily doses), and high use (>2 defined daily doses), and we compared each treatment interval category to intervals with no use.

For all analyses, 95% confidence intervals are presented. We used SAS version 9.4 and STATA version 14.1. The Methods section in the supplementary file provides more information on statistical analyses, including sensitivity analyses. The strengthening the reporting of observational studies in epidemiology (STROBE) reporting guidelines were followed (see supplementary file).

Sensitivity analyses

Separately, we analysed only participants who had a pre-existing comorbidity before the start of gabapentinoid treatment,[43 44] including epilepsy (n=10 891), psychiatric disorders (n=61 526), or musculoskeletal disorders (n=91 932) (ie, all approved indications for gabapentinoids in Sweden). We also carried out analyses where we excluded those with any of these pre-existing comorbidities (n=60 797). We studied long term associations by comparing all time before the first collected gabapentinoid to all time after, using a conditional fixed effects Poisson regression analysis. We tested if gabapentinoids were differentially associated with hospital treatment for road traffic incidents (when it is undetermined who caused the incident) and arrests or convictions for road traffic offences (which would be caused by the individual) by examining these separately. Similarly, we examined differential associations for head or neck injuries and body injuries separately. Finally, we examined convictions (as opposed to arrests) of violent crime.

Patient and public involvement

No patients were involved in setting the research question or the outcome measures, nor were they involved in developing plans for recruitment, design, or implementation of the study. No patients were asked to advise on interpretation or writing up of results. There are no plans to disseminate the results of the research to study participants or the relevant patient community.

Results

Overall 191 973 participants collected prescriptions of gabapentinoids on at least two consecutive occasions. Of those, 120 664 were dispensed pregabalin and 85 360 were dispensed gabapentin (n=14 051 were dispensed both drugs). In the gabapentinoid cohort, 59.1% (n=113 497) were women, and most of the sample was 45 years or older (table 1). During 2006 to 2013, 5.2% (n=10 026) of the treatment cohort presented to secondary medical services with suicidal behaviour or died from suicide, 8.9% (n=17 144) experienced an unintentional overdose, 6.3% (n=12 070) had a road traffic incident or offence, 36.7% (n=70 522) presented with head/body injuries, and 4.1% (n=7984) were arrested for a violent crime. Pregabalin users were younger and associated with a higher prevalence of all outcomes compared with gabapentin users (table 1).

In within-individual analyses, when treatment and non-treatment periods were compared in the same participant, gabapentinoids were associated with increased hazards of suicidal behaviour and deaths from suicide (age adjusted hazard ratio 1.26, 95% confidence interval 1.20 to 1.32), unintentional overdoses (1.24, 1.19 to 1.28), head/body injuries (1.22, 1.19 to 1.25), and road traffic incidents and offences (1.13, 1.06 to 1.20). Associations for arrests for violent crime were less clear (1.04, 0.98 to 1.11). When stratified on type of gabapentinoid, pregabalin was associated with increased hazards of all outcomes. In contrast, gabapentin treatment was associated with reductions in road traffic incidents and offences (0.81, 0.70 to 0.94) and arrests for violent crime (0.80, 0.67 to 0.95). No statistically significant associations were found for gabapentin and other outcomes (fig 1).

By age band, results for gabapentinoids showed increased hazards of suicidal behaviour in people younger than age 55 and reduced or no associations in those aged 55 and older. The highest hazards were in the age group 15-24 years (1.67, 1.52 to 1.84). Patterns were similar for other outcomes; younger participants (15-34 years) showed increased hazards, whereas older participants (≥55 years) showed reduced or no associations (fig 2).

When drugs were examined separately, pregabalin treatment was associated with increases in all outcomes for younger participants (15-34 years), and suicidal behaviour, unintentional overdoses, and head/body injuries for those aged 35 to 44. Those aged 55 and older showed no or decreased associations with outcomes. Gabapentin treatment was associated with increased hazards of unintentional overdoses in participants younger than 25, and head/body injuries in participants aged 15-54. Reduced or no associations were found for participants aged 55 and older (see supplementary figures 1 and 2).

When participants who were prescribed another antiepileptic were excluded, the hazards increased for all outcomes except violent crime (table 2). After removing those with substance use disorders, we found attenuated associations between gabapentinoids and suicidal behaviour and head/body injuries, no statistically significant associations with unintentional overdoses and road traffic incidents and offences, and reduced associations with violent crime (table 2).

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Table 1 | Sociodemographic and medical characteristics of participants prescribed and dispensed gabapentinoids. Values are numbers (percentages)

Characteristics	Gabapentinoid cohort (n=191 973)	Pregabalin cohort (n=120 664)*	Gabapentin cohort (n=85 360)*	Only one prescription collected (n=80 998)
Sex:				
Men	40.9 (78 476)	40.4 (48 796)	41.5 (35 457)	40.0 (32 037)
Women	59.1 (113 497)	59.6 (71 868)	58.5 (49 923)	60.0 (48 039)
Age at start of treatment (years):				
<25	3.7 (7117)	4.8 (5830)	1.8 (1574)	3.6 (2939)
25-34	8.1 (15 488)	10.4 (12 538)	4.6 (3910)	7.5 (6053)
35-44	12.8 (24 486)	15.2 (18 299)	9.4 (8008)	14.5 (11 764)
45-54	16.7 (32 115)	18.5 (22 343)	14.3 (12 235)	18.7 (15 109)
55-64	17.6 (33 805)	17.6 (21 239)	17.9 (15 302)	20.0 (16 202)
≥65	41.1 (78 962)	33.5 (40 415)	51.9 (44 331)	35.7 (28 931)
Occupation in 2006†:				
Employed	34.6 (66 469)	36.6 (44 123)	31.5 (26 864)	43.4 (33 619)
Student	4.6 (8840)	6.0 (7192)	2.5 (2089)	4.3 (3338)
Receiving state benefits‡	7.9 (15 230)	9.8 (11 869)	5.2 (4451)	7.7 (5943)
Receiving benefits owing to disability	24.7 (47 364)	26.4 (31 867)	23.5 (20 071)	22.0 (17 077)
Outcomes 2006-13:				
Suicidal behaviour and deaths from suicide	5.2 (10 026)	7.3 (8800)	2.5 (2091)	2.4 (1922)
Unintentional overdoses	8.9 (17 144)	11.7 (14 099)	5.4 (4605)	4.7 (3776)
Head/body injuries	36.7 (70 522)	37.8 (45 633)	35.9 (30 635)	32.5 (26 018)
Road traffic incidents and offences	6.3 (12 070)	7.3 (8828)	4.9 (4170)	5.7 (4524)
Convictions for violent crime	2.5 (4787)	3.8 (4070)	1.3 (1085)	1.7 (1347)
Arrests for violent crime	4.1 (7984)	5.6 (6763)	2.2 (1863)	2.9 (2283)
Health status before start of treatment:				
Epilepsy	5.7 (10 891)	5.4 (6483)	6.4 (5442)	2.5 (2009)
Psychiatric disorders	32.1 (61 526)	40.9 (49 384)	20.0 (17 031)	20.8 (16 808)
Musculoskeletal disorders	47.9 (91 932)	46.2 (55 714)	52.1 (45 340)	43.7 (35 375)
Concurrent drugs and substance use disorders 2006-13:				
Other antiepileptic drugs	17.4 (33 411)	19.8 (23 892)	15.0 (12 762)	9.7 (7858)
Substance use disorders	11.1 (21 344)	15.0 (18 038)	6.1 (5195)	7.7 (6249)

*Pregabalin and gabapentin cohorts are not mutually exclusive; 14 051 participants were dispensed both drugs during follow-up.
†Missing information on 54 070 participants.
‡Housing and basic allowance for those below a certain income threshold.

We analysed 30 day treatment periods on the basis of single prescriptions, and found that single treatment periods were associated with increased hazards of suicidal behaviour, unintentional overdoses, and head/body injuries (table 3). Similarly, being dispensed only one prescription during follow-up was associated with increased hazards of these three outcomes.

We accounted for late treatment effects by extending the end of a treatment period to three months after the last collected prescription. Results showed increased associations with all outcomes, including violent crime. We included a two year wash-out period (a new user design) by including only those who had been treatment-free for at least 24 months before starting their first treatment during the study follow-up. These analyses showed increased associations with all outcomes except for violent crime, and hazards remained similar to those of the main analyses (table 3). Furthermore, we excluded those with a past event of the examined outcome before starting gabapentinoid treatment to examine new onset adverse outcomes. Hazards increased for all outcomes, ranging between 3.21 (95% confidence interval 2.89 to 3.57) for unintentional overdoses to 7.31 (5.57 to 9.59) for road traffic incidents and offences.

Finally, we examined associations between gabapentinoid dose and outcomes (table 4). For suicidal behaviour and unintentional overdoses, low and moderate doses were associated with similar hazards and high doses were associated with increased hazard ratios. For head/body injuries and road traffic incidents and offences, hazard ratios increased with use of higher dose. No clear links were found between dose and violent crime arrests.

Sensitivity analyses

On stratification by sex, results for men and women mostly followed the same patterns as for the overall analyses (see supplementary table 1).

We analysed participants who had a diagnosis of comorbid epilepsy, psychiatric disorders, or musculoskeletal disorders before the start of gabapentinoid treatment (see supplementary table 2). In comorbid epilepsy, gabapentinoids were associated with reduced hazards for all outcomes apart from suicidal behaviour. In comorbid psychiatric disorders, gabapentinoids were associated with lower risk for all outcomes. In comorbid musculoskeletal disorders, gabapentinoids were associated with reductions in head/body injuries, road traffic incidents and offences, and arrests for

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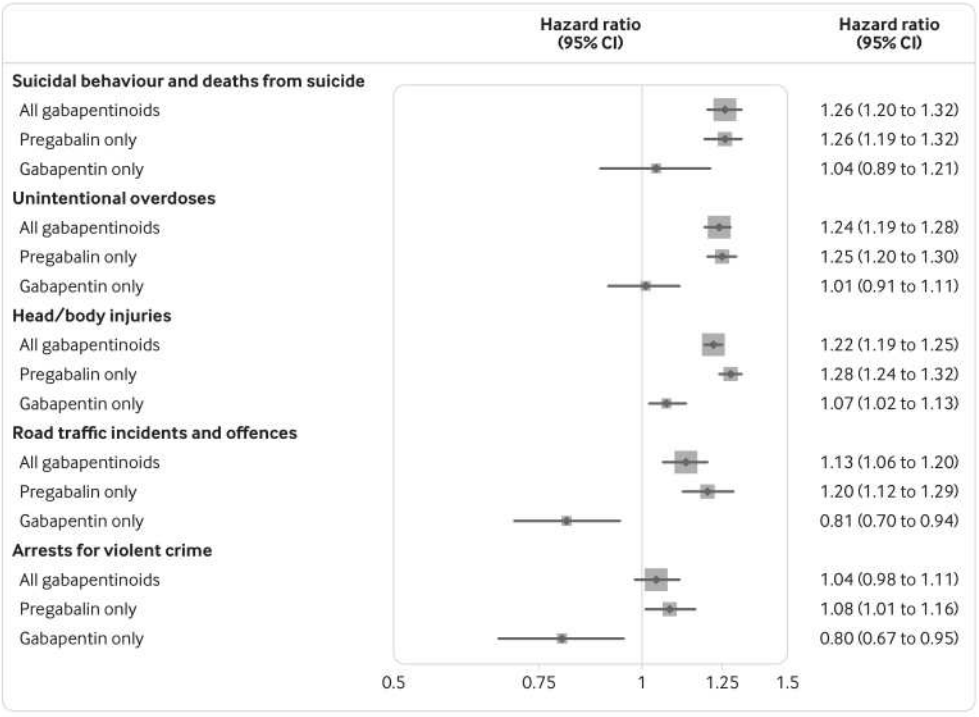

Fig 1 | Within-individual associations between gabapentinoid treatment and adverse outcomes

violent crime. When participants without any of these pre-existing comorbidities were examined, the hazards associated with suicidal behaviour and overdoses increased and the hazards associated with head/body injuries decreased.

We examined long term associations and found that compared with time before the first dispensed gabapentinoid, time after was associated with higher incidence rate ratios of all outcomes, apart from road traffic incidents and offences (see supplementary table 3). When traffic incidents and offences were analysed separately, gabapentin was associated with decreased hazards of road traffic offences, whereas pregabalin was associated with increased hazards of both road traffic incidents and offences. When stratifying on type of injury, gabapentinoids were associated with both head or neck and body injuries. No statistically significant associations for convictions for violent crime were shown (see supplementary table 4).

Discussion

Gabapentinoid treatment in those aged 55 and older was associated with decreased hazards or no clear associations with suicidal behaviour, unintentional overdoses, head/body injuries, road traffic incidents or offences, and arrests for violent crime. Associations were, however, increased for all outcomes among the youngest cohort members (15-24 years). Participants in the other age bands showed heterogeneous associations, with increased hazards of suicidal behaviour, unintentional overdoses, and head/body injuries, and no associations with road traffic incidents or offences and arrests for violent crimes. When analysing gabapentinoids separately, pregabalin use was associated with increased hazards of all outcomes, whereas there were decreased or no associations for gabapentin.

Strengths and limitations of this study

The strengths of this study include a large population based cohort, examination of a wide range of outcomes, inclusion of clinical outcomes from high quality nationwide registers, and comprehensive information on gabapentinoid treatment, as each collected prescription is registered. By using a within-individual design, we could adjust for time invariant covariates and more fully deal with unobserved confounders such as confounding by indication. This report does, however, have several limitations. As we principally examined associations, caution needs to be exercised when drawing causal inferences. We also lacked information on time varying covariates, such as alcohol or drug use, that could modify associations. To address this, we performed analyses where we excluded participants with substance use disorders. Furthermore, we did not have information on treatment adherence, which is a similar limitation in clinical trials, although this study is an improvement on studies that use solely prescription data as we had information on dispensed (ie, collected) drugs. To account for this, we excluded those who collected single prescriptions.

Results could further be affected by a potential bias towards the null owing to misclassification of gabapentinoid use. Our measure on treatment discontinuation was based on a more conservative assumption; the date of the last collected prescription. This assumption could result in slightly lower

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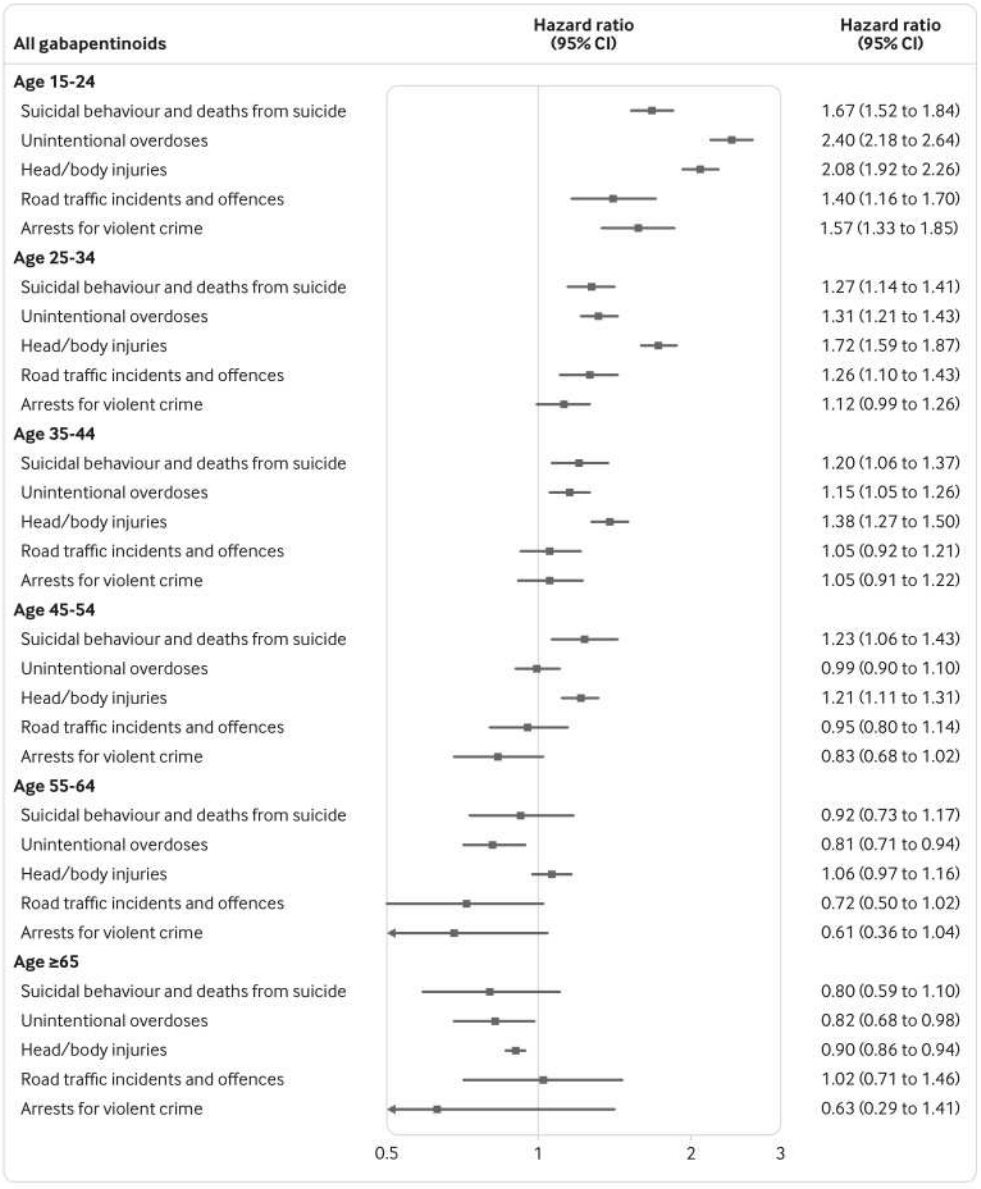

Fig 2 | Within-individual associations between gabapentinoid treatment and adverse outcomes by age

sensitivity, thus underestimating associations. We did, however, also carry out analyses where we extended the end of a treatment period to three months after the last collected prescription, and these results showed a clearer association with violent crime.

Table 2 | Within-individual associations between gabapentinoid treatment and adverse outcomes, excluding participants who used other antiepileptics or with substance use disorders during follow-up

Adverse outcomes by excluded participants	Hazard ratio (95% CI)
Excluding those who used other antiepileptics during follow-up (n=158 562):	
Suicidal behaviour and deaths from suicide	1.30 (1.18 to 1.40)
Unintentional overdoses	1.24 (1.17 to 1.32)
Head/body injuries	1.13 (1.10 to 1.17)
Road traffic incidents and offences	1.10 (1.02 to 1.18)
Arrests for violent crime	1.01 (0.94 to 1.11)
Excluding those with substance use disorders during follow-up (n=170 629):	
Suicidal behaviour and deaths from suicide	1.14 (1.04 to 1.24)
Unintentional overdoses	0.99 (0.91 to 1.08)
Head/body injuries	1.09 (1.06 to 1.12)
Road traffic incidents and offences	0.94 (0.85 to 1.04)
Arrests for violent crime	0.83 (0.71 to 0.96)

The use of register data might involve selection effects and potentially underestimate rates of underlying disorders and outcomes but at the same time it captures information with associated healthcare and other costs. We did not have information on indications for gabapentinoids, as this is not specified in the Swedish Prescribed Drug Register. Furthermore, this register started in July 2005, and previous dispenses are not recorded. Although we excluded treatment periods from July 2005 to 1 January 2006 (start of follow-up), participants could have been treated with gabapentinoids before that time. We did, however, include a wash-out period of two years. That is, in separate analyses we examined only those who had been treatment-free for at least 24 months before

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Table 3 | Within-individual associations between gabapentinoid treatment and adverse outcomes

Adverse outcomes by included participants	Hazard ratio (95% CI)
Single prescription treatment periods (n=102 363):	
Suicidal behaviour and deaths from suicide	4.40 (1.70 to 11.42)
Unintentional overdoses	4.94 (1.91 to 12.75)
Head/body injuries	2.27 (1.40 to 3.67)
Road traffic incidents and offences	1.33 (0.51 to 3.44)
Arrests for violent crime	1.20 (0.26 to 5.46)
Collected one prescription only (n=80 076):	
Suicidal behaviour and deaths from suicide	8.19 (1.58 to 42.42)
Unintentional overdoses	4.25 (1.19 to 15.15)
Head/body injuries	1.83 (1.07 to 3.13)
Road traffic incidents and offences	1.38 (0.43 to 4.38)
Arrests for violent crime	1.99 (0.18 to 22.00)
Adding three months after last collected prescription (n=191 973):	
Suicidal behaviour and deaths from suicide	1.36 (1.30 to 1.42)
Unintentional overdoses	1.31 (1.26 to 1.35)
Head/body injuries	1.25 (1.21 to 1.28)
Road traffic incidents and offences	1.18 (1.11 to 1.25)
Arrests for violent crime	1.12 (1.05 to 1.19)
Two year wash-out period (n=152 497):	
Suicidal behaviour and deaths from suicide	1.29 (1.23 to 1.36)
Unintentional overdoses	1.26 (1.21 to 1.31)
Head/body injuries	1.27 (1.23 to 1.30)
Road traffic incidents and offences	1.17 (1.10 to 1.25)
Arrests for violent crime	1.05 (0.99 to 1.12)
New onsets only:	
Suicidal behaviour and deaths from suicide (n=182 226)	5.13 (4.33 to 6.09)
Unintentional overdoses (n=176 278)	3.21 (2.89 to 3.57)
Head/body injuries (n=125 719)	4.19 (3.87 to 4.54)
Road traffic incidents and offences (n=172 766)	7.31 (5.57 to 9.59)
Arrests for violent crime (n=184 114)	3.79 (2.98 to 4.81)

starting their first treatment during our follow-up. Results from these analyses were similar to the overall findings.

Finally, differences in prescription practices and outcome rates might affect the generalisability of findings. Sweden and the UK reported the lowest rates in Europe of road traffic incidents during the study period. While the UK had median levels of fatal falls among older adults, the rate in Sweden was among the highest in Europe.[45 46] Sweden and the UK are among the countries with the highest rates of drug induced mortality (50 to 60 per million population during the study period); however, rates have increased more steeply in Sweden in recent years.[47] Sweden reports above both global and UK average rates for suicide mortality but below the regional rate (average rates per 100 000: 14.8 in Sweden, 8.9 in the UK, 15.4 in Europe, and 10.6 globally).[48] During the study period, pregabalin was among the most commonly prescribed drugs in Sweden and the UK, as well as globally.[49 50]

Relation to previous studies

Previous research on gabapentinoids and suicidal behaviour has been inconsistent because of differing definitions, methods, and the extent of adjustment for confounding. Our use of a within-individual design allowed for further adjustments to handle confounding by indication. In our study, pregabalin but not gabapentin was associated with an increased hazard of suicidal behaviour. The differential results of the two gabapentinoids could be due to their different pharmacodynamic and pharmacokinetic profiles[1]; pregabalin has a higher potency, greater bioavailability, and quicker absorption than gabapentin.[8 51 52] Pregabalin has also been associated with withdrawal symptoms following rapid discontinuation, which could be related to suicidal behaviour.[9 11 53 54] Several reports about gabapentinoid related overdoses and deaths have appeared.[3 11 22 24 52 54-58] Notably, when excluding participants with substance use disorders from our analyses, associations with suicidal behaviour were attenuated, and no associations remained for overdoses. This could suggest that simultaneous substance use increases the risk. This is in line with research showing that the prevalence of gabapentinoid misuse is higher among people who misuse opioids,[57] and that overdoses of gabapentinoids are associated with respiratory depression and cardiac insufficiency if combined with sedatives or opioids.[23 58]

Pregabalin and gabapentin also showed contrasting associations with road traffic incidents and offences and violent crime; gabapentin was associated with decreased hazards of these outcomes, whereas pregabalin was associated with increases. These differences are in keeping with the motor disturbances observed in clinical trials for pregabalin, but not for gabapentin.[6 13] Variations in the use of pregabalin and gabapentin (eg, off-label prescription, concomitant alcohol or drug use, or other time varying covariates) could also explain these differences. Furthermore, when we excluded participants with substance use disorders, we found no associations with unintentional overdoses and road traffic incidents and offences, which is in line with the suggestion that concurrent use of illicit drugs (particularly opioids) increases the risk of overdoses.[23] A dose related effect has been suggested for pregabalin, with increases in adverse outcomes for larger doses.[9] Our results were broadly consistent with a dose-response relation, although low doses of gabapentinoids were also associated with adverse events. Moreover, gabapentinoids were associated with greater hazards

Table 4 | Within-individual associations between gabapentinoid treatment and adverse outcomes in individuals treated with gabapentinoids stratified by defined daily dose (DDD)

Adverse outcomes	Low use (<1 DDD)	Moderate use (1-2 DDDs)	High use (>2 DDDs)
Suicidal behaviour and deaths from suicide	1.33 (1.26 to 1.41)	1.31 (1.22 to 1.40)	1.38 (1.27 to 1.50)
Unintentional overdoses	1.25 (1.20 to 1.30)	1.25 (1.18 to 1.32)	1.39 (1.30 to 1.48)
Head/body injuries	1.17 (1.14 to 1.20)	1.28 (1.23 to 1.34)	1.42 (1.34 to 1.50)
Road traffic incidents and offences	1.15 (1.06 to 1.25)	1.21 (1.09 to 1.34)	1.32 (1.19 to 1.47)
Arrests for violent crime	1.10 (1.01 to 1.20)	1.06 (0.96 to 1.18)	1.24 (1.12 to 1.37)

Reference category was periods with no use.
Number of intervals with no use (16 071 061, 81.8%), low use (2 288 928, 11.7%), moderate use (788 068, 4.0%), and high use (496 935, 2.5%).

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when we excluded participants who had experienced an adverse event (eg, unintentional overdose) before starting gabapentinoid treatment, suggesting stronger associations with new onsets of adverse outcomes.

Associations with adverse outcomes were mainly shown in those aged 15 to 24 years. Participants within this age band consistently presented increased rates of all adverse outcomes across several sensitivity analyses, particularly for suicidal behaviour, unintentional overdoses, and head/body injuries. This may be an age related pharmacodynamic effect, as has been suggested for selective serotonin reuptake inhibitors.[33 59] Young people have faster metabolism, which could lead to withdrawal problems, affecting impulsivity and emotion.[60] Previous studies show that young people more often experience psychotropic drug induced behavioural difficulties, including hyperactivity and aggression.[13 60] Associations in young people might also be mediated by impulsivity and risk taking, or by different indications for their use. The increased associations with adverse outcomes among 15 to 24 year olds could also suggest that young people use alcohol or illicit drugs together with gabapentinoids, and that this combination increases the risk of adverse outcomes. Notably, the strongest association for unintentional overdoses was shown among young people, and associations decreased with age. Because of the suggested increased risk of overdoses when combining gabapentinoids with other substances,[23 57] our results could suggest that younger people use gabapentinoids with alcohol or drugs to a greater extent. The reduced hazards in older people could reflect pharmacodynamic differences related to age,[61 62] less concurrent use of alcohol or drugs, different indications for treatment, or reduced symptom severity of underlying conditions. These age related differences warrant further examinations across new samples and designs. Similarly, more research is needed to identify possible risk factors that mediate or moderate associations with adverse outcomes in younger people, as well as head-to-head comparisons between pregabalin and gabapentin.

Conclusions

We found that gabapentinoids were associated with both increased and decreased risks of important adverse outcomes. These associations varied with age and type of gabapentinoid. Overall, gabapentinoids seem to be safe for a range of outcomes in older people. However, the increased risks found in adolescents and young adults (ages 15-24 years) prescribed gabapentinoids, particularly for suicidal behaviour and unintentional overdoses, warrant further research. If our findings are triangulated with other forms of evidence, clinical guidelines may need review regarding prescriptions for young people, and those with substance use disorders. Further restrictions for off-label prescription may need consideration.

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Contributors: YM and SF conceived and designed the study with input from HL, BDM, and DJS. YM analysed the data. YM had full access to all the data and carried out the data analyses. YM and SF wrote the first draft of the paper. All authors interpreted the data and contributed to the writing of the paper. All authors revised and approved the final version. YM and SF act as guarantors. The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted.

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Competing interests: All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work. Henrik Larsson reports grants from Shire and Evolan, and has served as a speaker for Shire, all outside of the submitted work.

Ethical approval: This study was approved by the regional ethics review board in Stockholm, Sweden (2013/5:8) and follows the Declaration of Helsinki.

Data sharing: The Public Access to Information and Secrecy Act in Sweden prohibits us from making individual level data publicly available. Researchers who are interested in replicating our work can apply for individual level data at Statistics Sweden: www.scb.se/en/services/guidance-for-researchers-and-universities/.

Transparency The lead authors (YM and SF) affirm that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

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Supplementary information: additional methods, tables, and figures

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From:	Brooks, Aja /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5C59E6730234420DA11251416B699F1C-BROOKS, AJA (b)(6) @va.gov>
To:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>
Subject:	FW: VA's availability of Spravato (ketamine) linked to BeThere campaign
Date:	2019/06/18 10:03:40
Priority:	Normal
Type:	Note

SecVA –

Formulary meeting is this week. On the agenda -

From: Lakso, Wendy
Sent: Tuesday, June 18, 2019 8:01 AM
To: Franklin, Keita (b)(6) @va.gov>
Cc: Actions <actions@dcgcommunications.com>; Jones, Taunya (b)(6) @va.gov>
Subject: VA's availability of Spravato (esketamine) linked to BeThere campaign

Dr. Franklin,
Head's up as the SVAC is tomorrow – the below link is an article on J&J about esketamine. I've added a paragraph I pulled from the article which mentions #BeThere and as part of the campaign it was mentioned in a PSA that J&J and the VA are undertaking a new clinical trial process……" This may come up in the hearing.

https://www.theguardian.com/us-news/2019/jun/17/spravato-ketamine-like-drug-that-experts-doubt-and-trump-is-pushing-on-veterans

"While it was under development, J&J's and Janssen's relationships at the VA deepened. As trials for the drug went forward in late 2017, Johnson &Johnson joined the VA's suicide prevention campaign, #BeThere. A public service announcement on the campaign said J&J and the VA will "undertake new clinical trial processes in hopes of providing access to the latest and most innovative treatments to help veterans in need".

Wendy Lakso
Acting Deputy Director, Suicide Prevention Program
Office of Mental Health and Suicide Prevention
Veterans Health Administration
Cell: (b)(6)

Sender:	Brooks, Aja /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5C59E6730234420DA11251416B699F1C-BROOKS, AJA (b)(6) @va.gov>

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Recipient:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer *(b)(6)* va.gov>
Sent Date:	2019/06/18 10:03:39
Delivered Date:	2019/06/18 10:03:40

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To:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>
Subject:	FW: VA's availability of Spravato (esketamine) linked to BeThere campaign
Date:	2019/06/18 10:13:37
Priority:	Normal
Type:	Note

Hi Mike,

Aja just called and they want a couple of draft p:

Draft Bullet Points:

- • The

From: Brooks, Aja
Sent: Tuesday, June 18, 2019 10:07 AM
To: Emmendorfer, Thomas (PBM) (b)(6) @va.gov>
Subject: FW: VA's availability of Spravato (esketamine) linked to BeThere campaign

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From: Lane, Ca-Asia A.
Sent: Tuesday, June 18, 2019 10:04 AM
To: Franklin, Keita (b)(6) @va.gov>
Cc: Brooks, Aja (b)(6) @va.gov>
Subject: FW: VA's availability of Spravato (esketamine) linked to BeThere campaign

Thanks maam.

Brooks mentioned that we should probably spend a moment discussing just to bring the Sec. into awareness of our J&J relationship as well.....

Also including my colleague Aja to reach out to her portfolio folks to ensure its FDA, irregularity etc.....

Very Respectfully,
Ca-Asia A. Lane
Congressional Relations Officer
Office of Congressional &Legislative Affairs
Department of Veterans Affairs
(b)(6) @va.gov
Office: (b)(6)
Work Cell: (b)(6)

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From: Franklin, Keita
Sent: Tuesday, June 18, 2019 8:53 AM
To: Lane, Ca-Asia A. (b)(6) @va.gov>; Carroll, David (VACO) (b)(6) @va.gov>
Subject: FW: VA's availability of Spravato (esketamine) linked to BeThere campaign

From: Lakso, Wendy
Sent: Tuesday, June 18, 2019 8:01 AM
To: Franklin, Keita (b)(6) @va.gov>
Cc: Actions <actions@dcgcommunications.com>; Jones, Taunya (b)(6) @va.gov>
Subject: VA's availability of Spravato (esketamine) linked to BeThere campaign

Dr. Franklin,
Head's up as the SVAC is tomorrow – the below link is an article on J&J about esketamine. I've added a paragraph I pulled from the article which mentions #BeThere and as part of the campaign it was mentioned in a PSA that J&J and the VA are undertaking a new clinical trial process....." This may come up in the hearing.

https://www.theguardian.com/us-news/2019/jun/17/spravato-ketamine-like-drug-that-experts-doubt-and-trump-is-pushing-on-veterans

"While it was under development, J&J's and Janssen's relationships at the VA deepened. As trials for the drug went forward in late 2017, Johnson &Johnson joined the VA's suicide prevention campaign, #BeThere. A public service announcement on the campaign said J&J and the VA will "undertake new clinical trial processes in hopes of providing access to the latest and most innovative treatments to help veterans in need".

Wendy Lakso
Acting Deputy Director, Suicide Prevention Program
Office of Mental Health and Suicide Prevention
Veterans Health Administration
Cell: (b)(6)

Recipient:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>
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To:	Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da (b)(6) @va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b)(6) @va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M (b)(6) @va.gov>
Subject:	FW: VA to make new nasal spray drug available for treatment-resistant depression_15MARCH2019 OCLA
Date:	2019/03/18 12:35:48
Priority:	Normal
Type:	Note

Hello – is the attached edit ok with you? It includes more details on the drug, copied from

(b5)

From: Ledesma, Mark P.
Sent: Monday, March 18, 2019 12:30 PM
To: Smith, Monica (VACO) <(b)(6) @va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Cc: Greilsamer, Alan <(b)(6) @va.gov>; Ledesma, Mark P. <(b)(6) @va.gov>
Subject: FW: VA to make new nasal spray drug available for treatment-resistant depression_15MARCH2019 OCLA

Hi Monica,

Can 10P please help address OCLA’s feedback in the attached release? Thanks.

Regards,

Mark

From: Paige, Paula
Sent: Monday, March 18, 2019 10:06 AM
To: Ledesma, Mark P. <(b)(6) @va.gov>
Cc: Carter, Susan <(b)(6) @va.gov>; Noller, Randal <(b)(6) @va.gov>; Christian, Tatjana <(b)(6) @va.gov>; Greilsamer, Alan <(b)(6) @va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>

AMERICAN OVERSIGHT

Subject: VA to make new nasal spray drug available for treatment-resistant depression_15MARCH2019 OCLA

Mark,

Please see feedback from OCLA. OGC had no issues.

Respectfully,

Paula A. Paige
Public Affairs Officer
Office of Media Relations, Office of Public and Intergovernmental Affairs
U.S. Department of Veterans Affairs
810 Vermont Ave. NW, Room 913
Washington, D.C. 20420
(b)(6) @va.gov
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www.vets.gov
VA on Facebook. Twitter. YouTube. Flickr. Blog

Sender:	Smith, Monica (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=511ea9e77a234375a91a7b34ce23719d-Smith, Moni (b)(6) @va.gov>
Recipient:	Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da (b)(6) @va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b)(6) @va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M (b)(6) @va.gov>
Sent Date:	2019/03/18 12:35:47
Delivered Date:	2019/03/18 12:35:48

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From:	Llorente, Maria D. </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F5C91F577D894BD9A0F09305DB34DD4F-LLORENTE, M>
To:	(b)(6)
Subject:	FW: VA Insider: Secretary on FY2020 Budget Request, Nasal Spray for Depression, 3D Printing Saves Veteran's Leg, Tele-ICU Partnership, Female WWII Veteran Honored in Puerto Rico, and more
Date:	2019/03/21 17:12:00
Priority:	Normal
Type:	Note

Check out the story on the veteran from PR.

From: US Department of Veterans Affairs
Sent: Thursday, March 21, 2019 4:20 PM
To: VAAllEXOMailboxes <VAAllEXOMailboxes@va.gov>
Subject: VA Insider: Secretary on FY2020 Budget Request, Nasal Spray for Depression, 3D Printing Saves Veteran's Leg, Tele-ICU Partnership, Female WWII Veteran Honored in Puerto Rico, and more



A MESSAGE FROM
OFFICE OF PUBLIC AND INTERGOVERNMENTAL AFFAIRS (OPIA)
Office of Internal Communications

- In Puerto Rico: Female WWII Veteran, 96, honored by San Juan Regional Office

Sender:	Llorente, Maria D. </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F5C91F577D894BD9A0F09305DB34DD4F-LLORENTE, M>
Recipient:	(b)(6)
Sent Date:	2019/03/21 17:12:09
Delivered Date:	2019/03/21 17:12:00

AMERICAN OVERSIGHT

From:	Lowe, Joette /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2CDA61A196F849548A246B80455099D9-LOWE, JOETT (b)(6) @va.gov>
To:	VHAPBM VPE Formulary Committee /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fcba1f4b52e048838d3053091f54eb4e-VHAPBH VPE <VPEFormularyCommttee@va.gov>; VHAPBM MAP Committee /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51be394a33f2409a9fb44ce631b751b3-VHAPBH MAP <pbm.map@med.va.gov>
CC:	Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen (b)(6) @va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>
Subject:	FW: The controversial ketamine-like drug that Trump is pushing on veterans
Date:	2019/06/19 08:55:10
Priority:	Normal
Type:	Note

(b) (6)

Joette S. Lowe, PharmD
VISN 7 Pharmacist Executive
3701 Loop Rd East
Tuscaloosa, AL 35404
(b)(6)

2.1 - Connecting Vets: VA fast-tracking controversial new antidepressant (18 June, 1.8M uvm; Washington, DC)

A VA panel that determines which drugs the VA carries and prescribes will vote Wednesday on the depression drug Spravato – which is also known as esketamine.

The drug – which has been put on the fast track for VA approval – has been touted as a "novel treatment" for those with treatment-resistant depression. The drug - which is administered by nasal spray - is an antidepressant which is so fast-acting, the results can be felt in less than 24 hours.

But critics complain that President Donald Trump and his friends, known as the "Mar-A-Lago Crowd" have influenced the process, causing VA to fast-track incomplete clinical trials, according to a report in The Guardian.

Spravato, a derivative of ketamine, a party drug that has already been used to treat depression, is produced by a subsidiary of Johnson and Johnson. The treatment would be expensive as it requires

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patients to be monitored by medical staff. Analysts told The Guardian that Johnson and Johnson stands to make $600 million by 2022 if VA approves the drug.

The Guardian also reports that Trump wanted VA to buy "truckloads" of the drug, according to an unnamed source. Bloomberg reports that the president met with VA Secretary Robert Wilkie last week, offering to help broker a deal for the drug for VA.

An FDA joint advisory committee has already voted 14-2 to approve the drug for public release, defending the drug in The New England Journal of Medicine as a "novel treatment for a severe and life-threatening condition." The drug is meant for adults with severe depression and suicidality that has not been responsive to other treatments.

But the drug has had controversial reactions from academics and health care professionals, including an op-ed piece written for Vice last month. Healthline reports that physicians are concerned that side effects - including suicidal tendencies - have been ignored.

Publicly, there is concern that Trump's connections to the "Mar-A-Lago Crowd" - three friends of his who've been accused of influencing VA decisions and procedures - are now affecting treatment decisions for veterans.

https://www.theguardian.com/us-news/2019/jun/17/spravato-ketamine-like-drug-that-experts-doubt-and-trump-is-pushing-on-veterans?CMP=share_btn_link

See link above for an interesting article on VA's rapid rollout of Esketamine.(b) (6)
(b) (6)

Sender:	Lowe, Joette /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2CDA61A196F849548A246B80455099D9-LOWE, JOETT (b)(6) @va.gov>
Recipient:	VHAPBM VPE Formulary Committee /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fcba1f4b52e048838d3053091f54eb4e-VHAPBH VPE <VPEFormularyCommttee@va.gov>; VHAPBM MAP Committee /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51be394a33f2409a9fb44ce631b751b3-VHAPBH MAP <pbm.map@med.va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen (b)(6) @va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>
Sent Date:	2019/06/19 08:55:08
Delivered Date:	2019/06/19 08:55:10

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From:	Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd.DLT/CN=RECIPIENTS/CN=A2A0091F85FF4E6E8042219F6027A842-KRAEMER, JO (b)(6) @va.gov>
To:	VHA 10P4P Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8dc3dab451414f59b9797e8ed199c1e8-VHA 10P4P A <vha10P4Paction@va.gov>
CC:	VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>
Subject:	FW: SVAC-Majority Inquiry for Info re: Esketamine
Date:	2019/06/21 14:57:05
Priority:	Normal
Type:	Note

10P4P, please see the question below from 10P. You have already submitted a response.

From: Graham, Christopher L.
Sent: Friday, June 21, 2019 2:51 PM
To: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Cc: Valentino, Michael (VACO) (b)(6) @va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Subject: RE: SVAC-Majority Inquiry for Info re: Esketamine

10P4-I believe what we cleared earlier to Curt covers this, do you agree?

Thanks,
Chris Graham, MHA
Health Systems Specialist
Department of Veterans Affairs
Office of the Deputy Under Secretary for Health for Policy and Services (10P)
Office: (b)(6)

From: Brooks, Aja
Sent: Friday, June 21, 2019 2:44 PM
To: VHA 10P Actions <VHA10PActions@va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Subject: FW: SVAC-Majority Inquiry for Info re: Esketamine
Importance: High

Adding 10P

From: Brooks, Aja
Sent: Friday, June 21, 2019 2:41 PM
To: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Cc: Michael Valentino (VACO) (b)(6) @va.gov) <(b)(6) @va.gov>

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Subject: FW: SVAC-Majority Inquiry for Info re: Esketamine
Importance: High

VHA 10P4 –

OCLA request a response on the inquiry regarding Spravato. Do we have any information we can share with the committee regarding this drug. Committee staff are under the assumption that this drug was rejected. Any previously cleared language would be much appreciated. We'd like to share something with them today, if possible.

v/r
AJ

From: Blair, Emily (Veterans Affairs) (b)(6) @vetaff.senate.gov>
Sent: Friday, June 21, 2019 12:50 PM
To: Wilson, Joe (VHA) (b)(6) @va.gov>
Subject: [EXTERNAL] SVAC-Majority Inquiry for Info re: Esketamine

Hi Joe,

I'm just reaching out to request info on the VA health oversight committee's rejection of Spravato/Esketamine, the ketamine-based drug used to treat treatment-resistant depression. I know the decision by the oversight committee was just made today, but any quick info you can provide on this today would be great.

Thank you!

Emily

Emily Blair
Professional Staff Member
U.S. Senate Committee on Veterans' Affairs
412 Russell Senate Office Building
Washington, DC 20510
(b)(6)

Sender:	Kraemer, John E /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A2A0091F85FF4E6E8042219F6027A842-KRAEMER, JO (b)(6) @va.gov>
Recipient:	VHA 10P4P Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8dc3dab451414f59b9797e8ed199c1e8-VHA 10P4P A <vha10P4Paction@va.gov>; VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>
Sent Date:	2019/06/21 14:57:04
Delivered Date:	2019/06/21 14:57:05

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From:	Snyder, Jill /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0B6E91EF72EE4A05ACC63873C64570E1-SNYDER, JIL (b)(6) @va.gov>
To:	Cashour, Curtis /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dba510634baa46a085e28c62c254093f-Cashour, Cu (b)(6) @va.gov>; Law, Cassandra M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f888d507d6c54eb5a92fc44199eb5838-Law, Cassan (b)(6) @va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M (b)(6) @va.gov>; VHA 10P Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5098b521b1f34f8a97f74be24709d62f-VHA 10P Act <VHA10PActions@va.gov>; Beck, Lucille B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=845480228a8b43e7a5fef5716ded04c2-Beck, Lucil (b)(6) @va.gov>; Mojay, Ndidi /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35a1d15ff686495394e4380cf3c8eb63-Mojay, Ndid (b)(6) @va.gov>
CC:	Outlaw, William N. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3e1067978634fbf96a382bdcd5c1115-Outlaw, Wil (b)(6) @va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b)(6) @va.gov>; Greilsamer, Alan /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fc02807af08443fbb5c68c590d58fa4b-Greilsamer, (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen (b)(6) @va.gov>; Hastings, Patricia R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a504fbfe766048a5a65461c45f28e9de-Hastings, P (b)(6) @va.gov>; VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>
Subject:	RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision
Date:	2019/06/21 14:13:29
Priority:	Normal
Type:	Note

Hi Curt –

Sorry for the delay – VHA clears the statement. Also adding Ndidi since she has queries on this as well.

Statement

(b5)

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Thanks,
Jill

From: Cashour, Curtis
Sent: Friday, June 21, 2019 1:55 PM
To: Snyder, Jill (b)(6) @va.gov>; Law, Cassandra M. (b)(6) @va.gov>; Llorente, Maria D. (b)(6) @va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; Beck, Lucille B. (b)(6) @va.gov>
Cc: Outlaw, William N. <(b)(6) @va.gov>; Valentino, Michael (VACO) (b)(6) @va.gov>; Wiechers, Ilse (b)(6) @va.gov>; Greilsamer, Alan (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) (b)(6) @va.gov>; Hastings, Patricia R. (b)(6) @va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Any update?

Curt Cashour
Press Secretary
Department of Veterans Affairs
(b)(6)
(b)(6) @va.gov
(b)(6)

From: Snyder, Jill
Sent: Friday, June 21, 2019 1:07 PM
To: Cashour, Curtis <(b)(6) @va.gov>; Law, Cassandra M. (b)(6) @va.gov>; Llorente, Maria D. (b)(6) @va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; Beck, Lucille B. (b)(6) @va.gov>

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Cc: Outlaw, William N. (b)(6) @va.gov>; Valentino, Michael (VACO) (b)(6) @va.gov>; Wiechers, Ilse (b)(6) @va.gov>; Greilsamer, Alan (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) (b)(6) @va.gov>; Hastings, Patricia R. (b)(6) @va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Hi Curt – can you please hold while I get 10B to sign off? I am walking up right now.

Thanks,
Jill

From: Cashour, Curtis
Sent: Friday, June 21, 2019 1:07 PM
To: Law, Cassandra M. (b)(6) @va.gov>; Llorente, Maria D. (b)(6) @va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; Beck, Lucille B. (b)(6) @va.gov>
Cc: Outlaw, William N. (b)(6) @va.gov>; Valentino, Michael (VACO) (b)(6) @va.gov>; Wiechers, Ilse (b)(6) @va.gov>; Snyder, Jill <(b)(6) @va.gov>; Greilsamer, Alan (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) (b)(6) @va.gov>; Hastings, Patricia R. <(b)(6) @va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

So I can release it to the media now?

Curt Cashour
Press Secretary
Department of Veterans Affairs
(b)(6)
(b)(6) @va.gov
(b)(6)

From: Law, Cassandra M.
Sent: Friday, June 21, 2019 1:06 PM
To: Cashour, Curtis <(b)(6) @va.gov>; Llorente, Maria D. (b)(6) @va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; Beck, Lucille B. <(b)(6) @va.gov>
Cc: Outlaw, William N. (b)(6) @va.gov>; Valentino, Michael (VACO) (b)(6) @va.gov>; Wiechers, Ilse <(b)(6) @va.gov>; Snyder, Jill (b)(6) @va.gov>; Greilsamer, Alan <(b)(6) @va.gov>; Zacher, Jennifer L. (PBM) (b)(6) @va.gov>; Hastings, Patricia R. (b)(6) @va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Hi Curt – this is cleared for 10P. Thank you, Cassie

From: Cashour, Curtis
Sent: Friday, June 21, 2019 1:05 PM
To: Llorente, Maria D. (b)(6) @va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Cc: Outlaw, William N. (b)(6) @va.gov>; Valentino, Michael (VACO) (b)(6) @va.gov>; Wiechers, Ilse (b)(6) @va.gov>; Snyder, Jill (b)(6) @va.gov>;

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Greilsamer, Alan (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) (b)(6) @va.gov>; Law, Cassandra M. <(b)(6) @va.gov>; Hastings, Patricia R. (b)(6) @va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

VHA - What is the ETA for final approval on this?

Curt Cashour
Press Secretary
Department of Veterans Affairs
(b)(6)
(b)(6)
(b)(6)

From: Llorente, Maria D.
Sent: Friday, June 21, 2019 12:37 PM
To: VHA 10P Actions <VHA10PActions@va.gov>
Cc: Outlaw, William N. (b)(6) @va.gov>; Valentino, Michael (VACO) (b)(6) @va.gov>; Wiechers, Ilse (b)(6) @va.gov>; Snyder, Jill (b)(6) @va.gov>; Greilsamer, Alan (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) (b)(6) @va.gov>; Cashour, Curtis (b)(6) @va.gov>; Law, Cassandra M. <(b)(6) @va.gov>; Hastings, Patricia R. (b)(6) @va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

This is cleared by 10P4. There is short time frame. Jill Snyder is the POC for VHA Comms. Now for 10P review/concurrence.

From: Outlaw, William N.
Sent: Friday, June 21, 2019 12:30 PM
To: Cashour, Curtis <(b)(6) @va.gov>; Valentino, Michael (VACO) (b)(6) @va.gov>; Wiechers, Ilse (b)(6) @va.gov>; Snyder, Jill (b)(6) @va.gov>
Cc: Greilsamer, Alan (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) (b)(6) @va.gov>; Llorente, Maria D. (b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Per Mike Valentino, Pharmacy Benefits is good with the statement but will send up through clearance channels.

From: Cashour, Curtis
Sent: Friday, June 21, 2019 12:24 PM
To: Valentino, Michael (VACO) (b)(6) @va.gov>; Wiechers, Ilse (b)(6) @va.gov>; Snyder, Jill (b)(6) @va.gov>
Cc: Outlaw, William N. (b)(6) @va.gov>; Greilsamer, Alan <(b)(6) @va.gov>; Zacher, Jennifer L. (PBM) (b)(6) @va.gov>; Llorente, Maria D. <(b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Thanks. Does VHA concur with the following?

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Curt Cashour
Press Secretary
Department of Veterans Affairs
(b)(6)
(b)(6) @va.gov
(b)(6)

From: Valentino, Michael (VACO)
Sent: Friday, June 21, 2019 12:17 PM
To: Wiechers, Ilse <(b)(6) @va.gov>; Snyder, Jill (b)(6) @va.gov>; Cashour, Curtis (b)(6) @va.gov>
Cc: Outlaw, William N. (b)(6) @va.gov>; Greilsamer, Alan <(b)(6) @va.gov>; Zacher, Jennifer L. (PBM) <(b)(6) @va.gov>; Llorente, Maria D. <(b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Dr. Llorente and I drafted a statement for the NYT inquiry and I believe it will be coming forward soon.

Here it is but please consider it DRAFT:

From: Wiechers, Ilse
Sent: Friday, June 21, 2019 12:07 PM
To: Snyder, Jill <(b)(6) @va.gov>; Valentino, Michael (VACO) (b)(6) @va.gov>; Cashour, Curtis <(b)(6) @va.gov>

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Cc: Outlaw, William N. (b)(6) @va.gov>; Greilsamer, Alan (b)(6) @va.gov>;
Zacher, Jennifer L. (PBM) (b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Adding Jen Zacher for coordination purposes.

From: Snyder, Jill
Sent: Friday, June 21, 2019 9:02 AM
To: Valentino, Michael (VACO) <(b)(6) @va.gov>; Wiechers, Ilse <(b)(6) @va.gov>;
Cashour, Curtis <(b)(6) @va.gov>
Cc: Outlaw, William N. (b)(6) @va.gov>; Greilsamer, Alan <(b)(6) @va.gov>;
Snyder, Jill <(b)(6) @va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Good afternoon Mike and Ilse,

I know you all are working on media responses regarding Ketamine, however we just received an email from the Boston Globe that the decision was made NOT to include it in the formulary. Please see email below and I am including Curt Cashour, VA Press Secretary, on this message to streamline responses.

Thank you,
Jill

From: Silverman, Ed <(b)(6) @statnews.com>
Sent: Friday, June 21, 2019 11:24 AM
To: VA Public Affairs <VAPublicAffairs@va.gov>
Subject: [EXTERNAL] question from a journalist

Hi ,

My name is Ed Silverman and I work for The Boston Globe's STAT News health site, where I track the pharmaceutical industry.

I understand a VA committee voted not to include a new Johnson&Johnson antidepressant spray drug called Spravato on its pharmacy list.

Can you please confirm and explain why the committee voted not to include it?

Thanks
ed silverman
(b)(6)
www.statnews.com/pharmalot/

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From: Snyder, Jill
Sent: Friday, June 21, 2019 9:59 AM
To: Cashour, Curtis <(b)(6) @va.gov>; Greilsamer, Alan (b)(6) @va.gov>
Cc: Eason, William J. (b)(6) @va.gov>; Screen, Gina <(b)(6) @va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Hi Curt –

I am following this in Alan's absence, program office is still working on the response, I will continue to follow up.

Thanks,
Jill

From: Cashour, Curtis
Sent: Friday, June 21, 2019 9:57 AM
To: Greilsamer, Alan <(b)(6) @va.gov>; Snyder, Jill <(b)(6) @va.gov>
Cc: Eason, William J. (b)(6) @va.gov>; Screen, Gina (b)(6) @va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Just following up here. Thanks.

From: Greilsamer, Alan
Sent: Thursday, June 20, 2019 3:34 PM
To: Cashour, Curtis (b)(6) @va.gov>
Cc: Eason, William J. (b)(6) @va.gov>; Screen, Gina <(b)(6) @va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

We will try to pin them down on a timeframe.

—
Alan Greilsamer
Director, Media Relations (10B2B)
Office of Communications
Veterans Health Administration
P: (b)(6)
E: (b)(6) @va.gov

From: Cashour, Curtis <(b)(6) @va.gov>
Date: Thursday, Jun 20, 2019, 3:18 PM
To: Greilsamer, Alan (b)(6) @va.gov>

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Cc: Eason, William J. (b)(6) @va.gov>, Screen, Gina (b)(6) @va.gov>, VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Is there an update here?

The original question was when will VA make a decision about putting spravato on the formulary.

Thanks,

Curt Cashour
Press Secretary
Department of Veterans Affairs
(b)(6)
(b)(6) @va.gov
(b)(6)

From: Greilsamer, Alan
Sent: Wednesday, June 19, 2019 9:05 AM
To: Cashour, Curtis <(b)(6) @va.gov>
Cc: Eason, William J. (b)(6) @va.gov>; Screen, Gina (b)(6) @va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

VHA clears

In March 2019, two weeks after the FDA approved intranasal esketamine for use in conjunction with an oral antidepressant for the treatment of treatment-resistant depression in adults, VA announced the treatment would be made available to Veterans based on their individual medical needs combined with providers' clinical assessments. VA is now preparing a thoughtful, step-wise approach to clinical implementation of esketamine that puts Veteran safety first and ensures close, careful monitoring of potential adverse events, including the risk of addiction. This reflects VA's commitment to seek new ways to provide the best health care available for our nation's Veterans.

Additional information

Steps VA has taken to date include:

- • * The first dose of intranasal esketamine was safely administered today, June 18, 2019, to a Veteran with treatment-resistant depression at the VA Boston Healthcare System.
- • * A standardized informed consent document and supporting patient education materials have been made available nationally through VHA's electronic signed consent platform.
- • * VHA established a national Esketamine Clinical Implementation Workgroup, which has representation from key VA Central Office stakeholder groups, facility leadership, and subject matter experts in ketamine and esketamine treatments for mental health disorders.
- • * VHA has launched the Esketamine Community of Practice, a virtual learning community that will combine regular teleconferences and a repository of resources to provide a forum for

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discussing progress in implementation and developing best practices while also ensuring clear communication across the organization.

- • * 13 sites have confirmed their participation as Early Adopters, and will work together supported by the Esketamine Community of Practice and the Esketamine Clinical Implementation Workgroup to implement clinical use of esketamine at their sites this summer and fall.

Ongoing next steps include:

- • * VA anticipates having final decisions about Pharmacy Benefits Management policies, including criteria for use, national protocol guidance, and formulary status by end of this week, pending ongoing deliberations of the Medical Advisory Panel and VISN Pharmacy Executive Committees.
- • * Development of a Medication Use Evaluation (MUE) which focuses on safety monitoring is underway, with anticipated implementation of the data entry portal in July 2019. The MUE will facilitate data reporting for the FDA REMS and will gather additional safety and monitoring data on all use of esketamine within VHA.

From: Cashour, Curtis
Sent: Tuesday, June 18, 2019 12:38 PM
To: Greilsamer, Alan (b)(6) @va.gov>; Screen, Gina(b)(6) @va.gov>
Cc: Eason, William J(b)(6) @va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Please let me know your recommended response to the below.

Thanks,

Curt Cashour
Press Secretary
Department of Veterans Affairs
(b)(6)
(b)(6) @va.gov
(b)(6)

From: Ben Carey (b)(6) @nytimes.com>
Sent: Tuesday, June 18, 2019 12:35 PM
To: Cashour, Curtis (b)(6) @va.gov>
Subject: Re: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Thanks Curt, please do. Main question for now is when is decision expected..? (i.e. how much time I got?)

Ben

Sent from my iPhone

AMERICAN OVERSIGHT

On Jun 18, 2019, at 12:22 PM, Cashour, Curtis (b)(6) @va.gov> wrote:

Will keep you posted. Thanks, Ben.

Curt Cashour
Press Secretary
Department of Veterans Affairs
(b)(6)
(b)(6) @va.gov
(b)(6)

From: Carey, Ben (b)(6) @nytimes.com>
Sent: Tuesday, June 18, 2019 11:36 AM
To: Cashour, Curtis (b)(6) @va.gov>
Subject: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Curt Cashour-

Hello from New York. It's Ben Carey emailing. I am a reporter in science at the NY Times, I cover psych topics. I have your email from Jennifer Steinhauer, NYT reporter in DC.

I would love to hear what/ when on the VA's expected decision this week whether to put Spravato on its formulary. Keep me in the loop on this, kindly, would be good to know when decision will be made, with some notice, and anything else VA puts out on this.

We'll likely cover decision either way.

Sincerely,

Ben Carey

Sender:	Snyder, Jill /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0B6E91EF72EE4A05ACC63873C64570E1-SNYDER, JIL (b)(6) @va.gov>
Recipient:	Cashour, Curtis /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dba510634baa46a085e28c62c254093f-Cashour, Cu (b)(6) @va.gov>; Law, Cassandra M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f888d507d6c54eb5a92fc44199eb5838-Law, Cassan (b)(6) @va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M (b)(6) @va.gov>; VHA 10P Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5098b521b1f34f8a97f74be24709d62f-VHA 10P Act <VHA10PActions@va.gov>; Beck, Lucille B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=845480228a8b43e7a5fef5716ded04c2-Beck, Lucil (b)(6) @va.gov>; Mojay, Ndidi /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35a1d15ff686495394e4380cf3c8eb63-Mojay, Ndid (b)(6) @va.gov>; Outlaw, William N. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3e1067978634fbf96a382bdcd5c1115-Outlaw, Wil

AMERICAN OVERSIGHT

	(b)(6) @va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b)(6) @va.gov>; Greilsamer, Alan /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fc02807af08443fbb5c68c590d58fa4b-Greilsamer, (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen (b)(6) @va.gov>; Hastings, Patricia R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a504fbfe766048a5a65461c45f28e9de-Hastings, P (b)(6) @va.gov>; VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>
Sent Date:	2019/06/21 14:13:27
Delivered Date:	2019/06/21 14:13:29

AMERICAN OVERSIGHT

From:	Law, Cassandra M. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F888D507D6C54EB5A92FC44199EB5838-LAW, CASSAN (b)(6) @va.gov>
To:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>
Subject:	FW: SVAC-Majority Inquiry for Info re: Esketamine
Date:	2019/06/21 15:21:32
Due Date:	2019/06/20 20:00:00
Priority:	Normal
Type:	Note

Cassandra M. Law

From: Law, Cassandra M. (b)(6) @va.gov>
Date: Friday, Jun 21, 2019, 3:21 PM
To: Graham, Christopher L. (b)(6) @va.gov>, Brooks, Aja (b)(6) @va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>, VHA 10P Actions <VHA10PActions@va.gov>, Llorente, Maria D. (b)(6) @va.gov>
Subject: RE: SVAC-Majority Inquiry for Info re: Esketamine

Thank you all. Aja - you can add one line at the beginning to address the specific language of your request, but the rest should remain the same as just cleared. Below is how it should read. This has been closely worked at both VHA and Department levels. Many thanks, Cassie

(b5)

From: Graham, Christopher L. (b)(6) @va.gov>
Date: Friday, Jun 21, 2019, 3:15 PM
To: Brooks, Aja (b)(6) @va.gov>

AMERICAN OVERSIGHT

Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>, VHA 10P Actions <VHA10PActions@va.gov>
Subject: RE: SVAC-Majority Inquiry for Info re: Esketamine

Aja,

please see the attached cleared earlier today, will this work?

Thanks,
Chris Graham, MHA
Health Systems Specialist
Department of Veterans Affairs
Office of the Deputy Under Secretary for Health for Policy and Services (10P)
Office: (b)(6)

From: Brooks, Aja
Sent: Friday, June 21, 2019 2:44 PM
To: VHA 10P Actions <VHA10PActions@va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Subject: FW: SVAC-Majority Inquiry for Info re: Esketamine
Importance: High

Adding 10P

From: Brooks, Aja
Sent: Friday, June 21, 2019 2:41 PM
To: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Cc: Michael Valentino (VACO) (b)(6) @va.gov) ; (b)(6) @va.gov>
Subject: FW: SVAC-Majority Inquiry for Info re: Esketamine
Importance: High

VHA 10P4 –

OCLA request a response on the inquiry regarding Spravato. Do we have any information we can share with the committee regarding this drug. Committee staff are under the assumption that this drug was rejected. Any previously cleared language would be much appreciated. We'd like to share something with them today, if possible.

v/r
AJ

From: Blair, Emily (Veterans Affairs) <(b)(6) @vetaff.senate.gov>
Sent: Friday, June 21, 2019 12:50 PM
To: Wilson, Joe (VHA) (b)(6) @va.gov>
Subject: [EXTERNAL] SVAC-Majority Inquiry for Info re: Esketamine

Hi Joe,

AMERICAN OVERSIGHT

I'm just reaching out to request info on the VA health oversight committee's rejection of Spravato/Esketamine, the ketamine-based drug used to treat treatment-resistant depression. I know the decision by the oversight committee was just made today, but any quick info you can provide on this today would be great.

Thank you!

Emily

Emily Blair
Professional Staff Member
U.S. Senate Committee on Veterans' Affairs
412 Russell Senate Office Building
Washington, DC 20510
(b)(6)

Sender:	Law, Cassandra M. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F888D507D6C54EB5A92FC44199EB5838-LAW, CASSAN *(b)(6)* @va.gov>
Recipient:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, *(b)(6)* @va.gov>
Sent Date:	2019/06/21 15:21:31
Delivered Date:	2019/06/21 15:21:32
Message Flags:	Unread

AMERICAN OVERSIGHT

From:	Valentino, Michael (VACO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO,>
To:	Brooks, Aja /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5c59e6730234420da11251416b699f1c-Brooks, Aja *(b)(6)* @va.gov>
CC:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer *(b)(6)* @va.gov>
Subject:	FW: SVAC-Majority Inquiry for Info re: Esketamine
Date:	2019/06/21 14:48:00
Priority:	Normal
Type:	Note

Courtesy copy.....hopefully the official cleared copy will be on its way soon.

Mike

From: Valentino, Michael (VACO)
Sent: Friday, June 21, 2019 2:48 PM
To: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Subject: RE: SVAC-Majority Inquiry for Info re: Esketamine

Draft response for review and consideration:



Mike

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From: Brooks, Aja
Sent: Friday, June 21, 2019 2:41 PM
To: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Cc: Valentino, Michael (VACO) <(b)(6) @va.gov>
Subject: FW: SVAC-Majority Inquiry for Info re: Esketamine
Importance: High

VHA 10P4 –

OCLA request a response on the inquiry regarding Spravato. Do we have any information we can share with the committee regarding this drug. Committee staff are under the assumption that this drug was rejected. Any previously cleared language would be much appreciated. We'd like to share something with them today, if possible.

v/r
AJ

From: Blair, Emily (Veterans Affairs) (b)(6) @vetaff.senate.gov>
Sent: Friday, June 21, 2019 12:50 PM
To: Wilson, Joe (VHA (b)(6) @va.gov>
Subject: [EXTERNAL] SVAC-Majority Inquiry for Info re: Esketamine

Hi Joe,

I'm just reaching out to request info on the VA health oversight committee's rejection of Spravato/Esketamine, the ketamine-based drug used to treat treatment-resistant depression. I know the decision by the oversight committee was just made today, but any quick info you can provide on this today would be great.

Thank you!

Emily

Emily Blair
Professional Staff Member
U.S. Senate Committee on Veterans' Affairs
412 Russell Senate Office Building
Washington, DC 20510
(b)(6)

Sender:	Valentino, Michael (VACO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO,>
Recipient:	Brooks, Aja /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5c59e6730234420da11251416b699f1c-Brooks, Aja (b)(6) @va.gov>;

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	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>
Sent Date:	2019/06/21 14:49:00
Delivered Date:	2019/06/21 14:48:00

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To:	Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M (b)(6) @va.gov>
Subject:	FW: SVAC-Majority Inquiry for Info re: Esketamine
Date:	2019/06/21 14:27:11
Priority:	Normal
Type:	Note

FYI.....

From: Valentino, Michael (VACO)
Sent: Friday, June 21, 2019 2:21 PM
To: Brooks, Aja (b)(6) @va.gov>; Emmendorfer, Thomas (PBM) (b)(6) @va.gov>
Subject: RE: SVAC-Majority Inquiry for Info re: Esketamine

It wasn't rejected AJ....it is available on a case-by-case basis.

We've drafted a response for media inquiries that could probably be used to answer this.

Could you please send this to 10P4 Actions for a response?

Mike

From: Brooks, Aja
Sent: Friday, June 21, 2019 1:55 PM
To: Emmendorfer, Thomas (PBM (b)(6) @va.gov>; Valentino, Michael (VACO) (b)(6) @va.gov>
Subject: FW: SVAC-Majority Inquiry for Info re: Esketamine

What's going on

From: Blair, Emily (Veterans Affairs) <(b)(6) @vetaff.senate.gov>
Sent: Friday, June 21, 2019 12:57 PM
To: Wilson, Joe (VHA) (b)(6) @va.gov>; Brooks, Aja <(b)(6) @va.gov>
Subject: [EXTERNAL] RE: SVAC-Majority Inquiry for Info re: Esketamine

Thank you, Joe.

Hi Aja—any info you could share on this today would be greatly appreciated!

Thanks all,

Emily

AMERICAN OVERSIGHT

From: Wilson, Joe (VHA) (b)(6) @va.gov>
Sent: Friday, June 21, 2019 12:53 PM
To: Blair, Emily (Veterans Affairs) <(b)(6) @vetaff.senate.gov>; Brooks, Aja (b)(6) @va.gov>
Cc: Wilson, Joe (VHA) (b)(6) @va.gov>
Subject: RE: SVAC-Majority Inquiry for Info re: Esketamine

Hi Emily,

Adding Aja Brooks as I was covering for her during her absence.

Regards,

Joe Wilson

From: Blair, Emily (Veterans Affairs) (b)(6) @vetaff.senate.gov>
Sent: Friday, June 21, 2019 12:50 PM
To: Wilson, Joe (VHA) (b)(6) @va.gov>
Subject: [EXTERNAL] SVAC-Majority Inquiry for Info re: Esketamine

Hi Joe,

I'm just reaching out to request info on the VA health oversight committee's rejection of Spravato/Esketamine, the ketamine-based drug used to treat treatment-resistant depression. I know the decision by the oversight committee was just made today, but any quick info you can provide on this today would be great.

Thank you!

Emily

Emily Blair
Professional Staff Member
U.S. Senate Committee on Veterans' Affairs
412 Russell Senate Office Building
Washington, DC 20510
(b)(6)

Recipient:	Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M (b)(6) @va.gov>
Sent Date:	2019/06/21 14:27:14
Delivered Date:	2019/06/21 14:27:11
Message Flags:	Unsent

AMERICAN OVERSIGHT

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From:	Llorente, Maria D. </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F5C91F577D894BD9A0F09305DB34DD4F-LLORENTE, M>
To:	Beck, Lucille B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=845480228a8b43e7a5fef5716ded04c2-Beck, Lucil (b)(6) @va.gov>
Subject:	FW: SVAC-Majority Inquiry for Info re: Esketamine
Date:	2019/06/21 16:23:00
Priority:	Normal
Type:	Note

Want to make sure you have info upon return.

From: Copeland, Brittany R.
Sent: Friday, June 21, 2019 3:55 PM
To: Brooks, Aja (b)(6) @va.gov>; Law, Cassandra M. (b)(6) @va.gov>; Graham, Christopher L. (b)(6) @va.gov>; VHA 10B <vha10b@va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; Llorente, Maria D. (b)(6) @va.gov>
Subject: RE: SVAC-Majority Inquiry for Info re: Esketamine

Good afternoon AJ,

The statement below is cleared.

Thank you!

Brittany R. Copeland, MHA
Health System Specialist
Office of the VHA Chief of Staff (10B)
810 Vermont Ave NW | Washington, DC 20420
o: (b)(6) | c: (b)(6)

From: Brooks, Aja
Sent: Friday, June 21, 2019 3:29 PM
To: Law, Cassandra M. (b)(6) @va.gov>; Graham, Christopher L. (b)(6) @va.gov>; VHA 10B <vha10b@va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; Llorente, Maria D. (b)(6) @va.gov>
Subject: RE: SVAC-Majority Inquiry for Info re: Esketamine

OCLA acknowledges receipt adding VHA 10B for clearance

From: Law, Cassandra M.
Sent: Friday, June 21, 2019 3:21 PM
To: Graham, Christopher L. (b)(6) @va.gov>; Brooks, Aja (b)(6) @va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>;

AMERICAN OVERSIGHT

Llorente, Maria D. <(b)(6) @va.gov>
Subject: RE: SVAC-Majority Inquiry for Info re: Esketamine

Thank you all. Aja - you can add one line at the beginning to address the specific language of your request, but the rest should remain the same as just cleared. Below is how it should read. This has been closely worked at both VHA and Department levels. Many thanks, Cassie

---



From: Graham, Christopher L. (b)(6) @va.gov>
Date: Friday, Jun 21, 2019, 3:15 PM
To: Brooks, Aja (b)(6) @va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>, VHA 10P Actions <VHA10PActions@va.gov>
Subject: RE: SVAC-Majority Inquiry for Info re: Esketamine

Aja,

please see the attached cleared earlier today, will this work?

Thanks,
Chris Graham, MHA
Health Systems Specialist
Department of Veterans Affairs
Office of the Deputy Under Secretary for Health for Policy and Services (10P)
Office: (b)(6)

From: Brooks, Aja
Sent: Friday, June 21, 2019 2:44 PM

AMERICAN OVERSIGHT

To: VHA 10P Actions <VHA10PActions@va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Subject: FW: SVAC-Majority Inquiry for Info re: Esketamine
Importance: High

Adding 10P

From: Brooks, Aja
Sent: Friday, June 21, 2019 2:41 PM
To: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Cc: Michael Valentino (VACO) (b)(6) @va.gov (b)(6) @va.gov>
Subject: FW: SVAC-Majority Inquiry for Info re: Esketamine
Importance: High

VHA 10P4 –

OCLA request a response on the inquiry regarding Spravato. Do we have any information we can share with the committee regarding this drug. Committee staff are under the assumption that this drug was rejected. Any previously cleared language would be much appreciated. We'd like to share something with them today, if possible.

v/r
AJ

From: Blair, Emily (Veterans Affairs) (b)(6) @vetaff.senate.gov>
Sent: Friday, June 21, 2019 12:50 PM
To: Wilson, Joe (VHA) (b)(6) @va.gov>
Subject: [EXTERNAL] SVAC-Majority Inquiry for Info re: Esketamine

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Thank you!

Emily

Emily Blair
Professional Staff Member
U.S. Senate Committee on Veterans' Affairs
412 Russell Senate Office Building
Washington, DC 20510
(b)(6)

AMERICAN OVERSIGHT

Sender:	Llorente, Maria D. </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F5C91F577D894BD9A0F09305DB34DD4F-LLORENTE, M>
Recipient:	Beck, Lucille B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=845480228a8b43e7a5fef5716ded04c2-Beck, Lucil (b)(6) @va.gov>
Sent Date:	2019/06/21 16:23:24
Delivered Date:	2019/06/21 16:23:00

AMERICAN OVERSIGHT

To:	Hastings, Patricia R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a504fbfe766048a5a65461c45f28e9de-Hastings, P (b)(6) @va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>
Subject:	FW: Successful first dose of esketamine in VHA
Date:	2019/06/18 12:00:54
Priority:	Normal
Type:	Note

Sent with BlackBerry Work
(www.blackberry.com)

From: Wiechers, Ilse (b)(6) @va.gov>
Date: Tuesday, Jun 18, 2019, 10:47 AM
To: VHA 10NC5 Action <VHA10NC5Action@va.gov>, Valentino, Michael (VACO) (b)(6) @va.gov>, Emmendorfer, Thomas (PBM) (b)(6) @va.gov>, Zacher, Jennifer L. (PBM) <(b)(6) @va.gov>, Boyd, Teresa D. <(b)(6) @va.gov>, Llorente, Maria D. (b)(6) @va.gov>
Cc: Dantzler, Anne (b)(6) @va.gov>, Todd, Catherine A. (b)(6) @va.gov>, Bradley, John (b)(6) @va.gov>, Festin, Fe Erlita <(b) (6) @va.gov>, Wiechers, Ilse (b)(6) @va.gov>, Houranieh, Antoun (b)(6) @va.gov>, Salow, Marci VHABHS (b)(6) @va.gov>, Charness, Michael <(b)(6) @va.gov>
Subject: Successful first dose of esketamine in VHA

Recipient:	Hastings, Patricia R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a504fbfe766048a5a65461c45f28e9de-Hastings, P (b)(6) @va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>
Sent Date:	2019/06/18 12:00:54
Message Flags:	Unsent

AMERICAN OVERSIGHT

From:	Emmendorfer, Thomas (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC96BB44E7AE2C94C43B55D094-EMMENDORFER>
To:	Zacher, Jennifer L. (PBM) /o=VA/ou=VISN 12/cn=RECIPIENTS/cn=VHANCHZACHEJ (b)(6) @va.gov>; Streit, Phillip P /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=acfac72743604e3b8e80a555ebba45df-Streit, Phi (b)(6) @va.gov>
Subject:	FW: Sprvato update....
Date:	2019/03/14 13:57:00
Priority:	Normal
Type:	Note

Here is what Ilse sent this morning for her draft 10N memo.

I am good with the ordering document as it is written....

From: Zacher, Jennifer L. (PBM)
Sent: Thursday, March 14, 2019 1:23 PM
To: Emmendorfer, Thomas (PBM) (b)(6) @va.gov>
Cc: Streit, Phillip P (b)(6) @va.gov>
Subject: FW: Sprvato update....

Hi Tom,
Please see draft that Phillip and I have collectively worked on. Let us know if you have any suggestions or edits.
Thanks,
JZ

Sender:	Emmendorfer, Thomas (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC96BB44E7AE2C94C43B55D094-EMMENDORFER>
Recipient:	Zacher, Jennifer L. (PBM) /o=VA/ou=VISN 12/cn=RECIPIENTS/cn=VHANCHZACHEJ (b)(6) @va.gov>; Streit, Phillip P /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=acfac72743604e3b8e80a555ebba45df-Streit, Phi (b)(6) @va.gov>
Sent Date:	2019/03/14 13:57:35
Delivered Date:	2019/03/14 13:57:00
Message Flags:	Unsent
From:	Wiechers, Ilse /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0C7B1428D9E4233A641F125C5B6FC4F-WIECHERS, I (b)(6) @va.gov>
To:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M (b)(6) @va.gov>
Subject:	RE: Spravato update
Date:	2019/03/14 10:25:18

AMERICAN OVERSIGHT

Priority:	Normal
Type:	Note

Good morning!

Here is the draft memo for Spravato. Please take a look and let me know what you think. The main unanswered question is what date should we put for when all facilities should be certified with the REMS?

Working on the informed consent language today.

Ilse

From: Wiechers, Ilse
Sent: Wednesday, March 13, 2019 12:32 PM
To: Emmendorfer, Thomas (PBM) <(b)(6) @va.gov>; Llorente, Maria D. (b)(6) @va.gov>
Subject: Spravato update

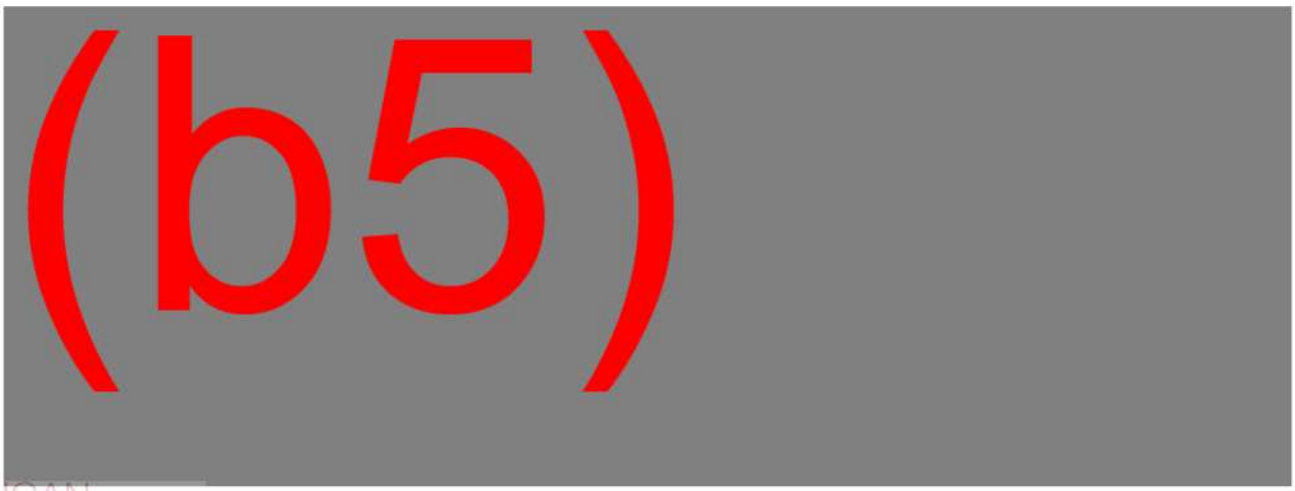
Tom & Maria –

I just sent the draft 10N memo to 10NC5 Action and to our SMEs for review and input. I've asked for feedback by tomorrow 10 AM, so I should have you a document to review by midday ET.

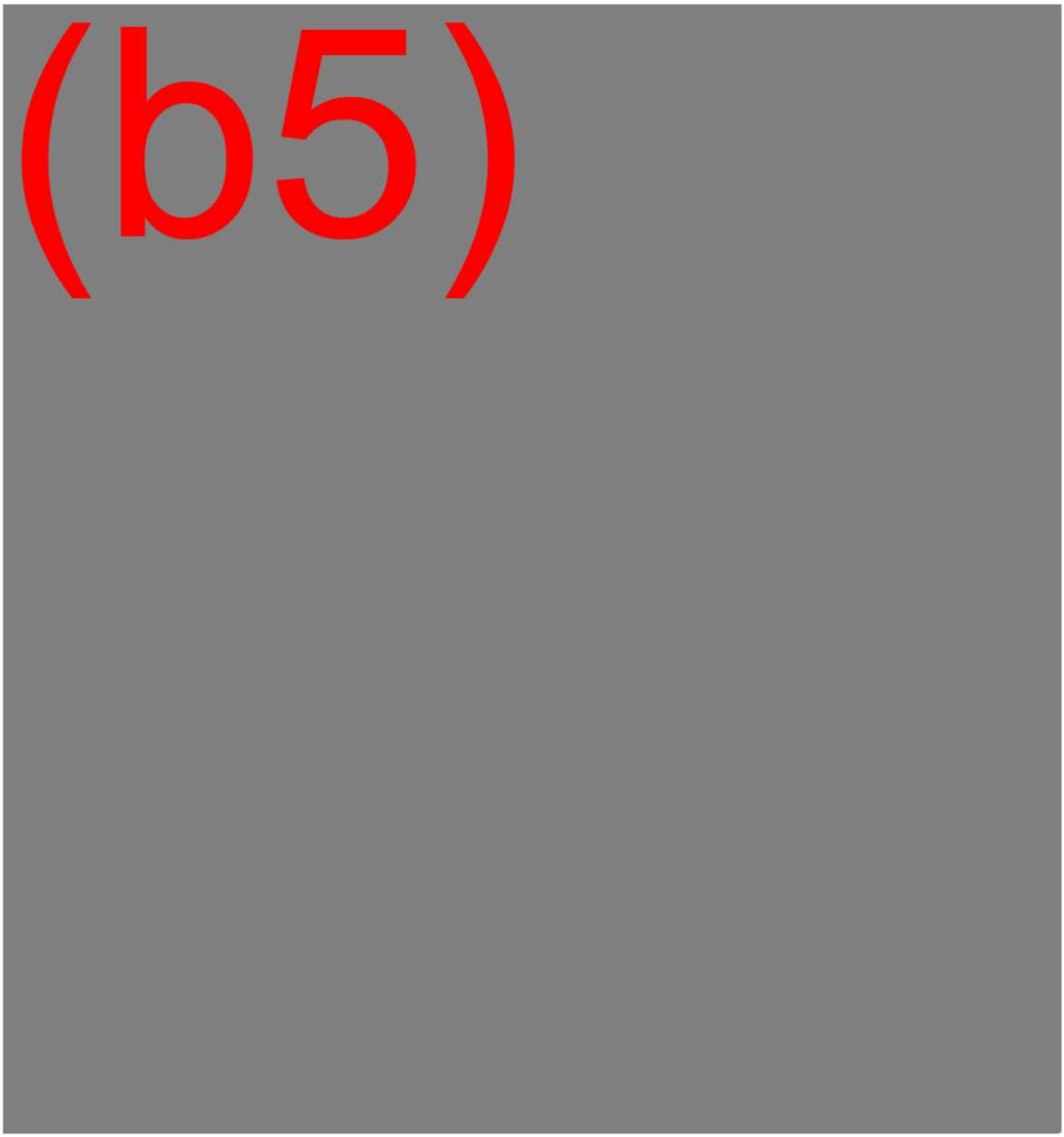
As a heads up, the pieces are coming together in my head right now as I've laid out in the notes below. I think this will be memo #1 of 2, with a second memo and further instruction to follow in ~ 2 weeks time. I'm awaiting input from OMHSP leadership to see what they think about how I've outlined things below (and in the memo draft), but wanted to keep you in the loop on my thought process.

Turning to informed consent this afternoon, more on that to follow.

Ilse
***



AMERICAN OVERSIGHT



***

Ilse R. Wiechers, MD, MPP, MHS
National Director, Psychotropic Drug Safety Initiative (PDSI)
Co-Director, Care for Patients with Complex Problems (CP)^2
Associate Director, Northeast Program Evaluation Center

AMERICAN OVERSIGHT

Office of Mental Health and Suicide Prevention (10NC5), Department of Veterans Affairs
Assistant Clinical Professor of Psychiatry, Yale University School of Medicine
cell (b)(6)
email: (b)(6) @va.gov | (b)(6)

Connect to:
PDSI Home
PDSI Management System
FAQs

Sender:	Wiechers, Ilse /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0C7B1428D9E4233A641F125C5B6FC4F-WIECHERS, I (b)(6) @va.gov>
Recipient:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M (b)(6) @va.gov>
Sent Date:	2019/03/14 10:25:09
Delivered Date:	2019/03/14 10:25:18

AMERICAN OVERSIGHT

AMERICAN OVERSIGHT

From:	Smith, Avery /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9471C2D02A8B472B8543E09CB140085F-SMITH, AVER (b)(6) @va.gov>
To:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>
Subject:	FW: Spravato/esketamine approval
Date:	2019/06/24 11:08:26
Due Date:	2019/06/23 20:00:00
Priority:	Normal
Type:	Note

Interesting this is waiting for you! Good Morning

From: Sandifer, Estella (Maria)
Sent: Monday, June 24, 2019 10:35 AM
To: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Cc: VHA 10P Actions <VHA10PActions@va.gov>
Subject: FW: Spravato/esketamine approval

10P4,

Please see the entire email and provide a response no later than 11:30 a.m., today.

Request:
We have received additional questions on Spravato/esketamine. Is it possible to receive responses by noon?

There are two new questions highlighted below. For everyone awareness I am copying the statement that was cleared last week.

V/r,

Maria Sandifer
Office of the Deputy Under Secretary for Health
for Policy and Services (10P)
Work ph: (202) 461-7413
Cell: (b)(6)
Email: (b)(6) @va.gov

From: Snyder, Jill
Sent: Monday, June 24, 2019 10:29 AM
To: VHA 10P Actions <VHA10PActions@va.gov>; Valentino, Michael (VACO) (b)(6) @va.gov>; Wiechers, Ilse (b)(6) @va.gov>

AMERICAN OVERSIGHT

Cc: VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: FW: Spravato/esketamine approval

Good morning,

We have received additional questions on Spravato/esketamine. Is it possible to receive responses by noon?

There are two new questions highlighted below. For everyone awareness I am copying the statement that was cleared last week.

After reviewing the available published evidence regarding the safety and effectiveness of esketamine (Spravato), a team of VA clinicians approved on June 20 the use of esketamine (Spravato) on a non-formulary basis. This process is similar to "prior authorization" formulary designations used in non-VA health care systems, and will enable VA psychiatrists to offer esketamine to patients when clinically indicated.

In addition, VA developed clinical and procedural guidance and other tools to promote thoughtful patient selection and safe administration practices, in keeping with the FDA-approved indications for esketamine use and safety requirements. These evidence-based processes will ensure the medication is prioritized for use in Veterans who have not previously responded to adequate trials of other available treatments for major depression.

VA will closely monitor the use of esketamine in Veterans to more fully understand its relative safety and effectiveness as compared to other available treatments. Based on this information, VA may revise its clinical guidance and formulary status if warranted.

This decision reflects VA's commitment to seek new ways to provide the best health care available for our nation's Veterans.

Thanks,
Jill

From: Abbie Bennett (b)(6)@connectingvets.com>
Sent: Monday, June 24, 2019 9:09 AM
To: VA Public Affairs <VAPublicAffairs@va.gov>
Subject: [EXTERNAL] Spravato/esketamine approval

Could I please get a statement ASAP on the VA's decision to approve Spravato/esketamine for use in VA medical centers ASAP?

I would also like the following information:

AMERICAN OVERSIGHT

1. What is the estimated cost to the VA for Spravato/esketamine prescription per veteran?

2. How will the VA monitor its use nationwide?

Abbie Bennett
Reporter
Connecting Vets
C (b)(6)
(b)(6)

Entercom | Washington D.C.
1015 Half Street, S.E., Suite 200
Washington, D.C. 20003
M: +(b)(6)
entercom.com

Sender:	Smith, Avery /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9471C2D02A8B472B8543E09CB140085F-SMITH, AVER (b)(6) va.gov>
Recipient:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>
Sent Date:	2019/06/24 11:08:25
Delivered Date:	2019/06/24 11:08:26

AMERICAN OVERSIGHT

From:	Smith, Avery /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9471C2D02A8B472B8543E09CB140085F-SMITH, AVER (b)(6) @va.gov>
To:	VHA 10P4P Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8dc3dab451414f59b9797e8ed199c1e8-VHA 10P4P A <vha10P4Paction@va.gov>
CC:	VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>
Subject:	FW: Spravato/esketamine approval
Date:	2019/06/24 10:36:47
Priority:	Normal
Type:	Note

10P4P,

Please review the request below and provide response to VHA 10P4 Action as soon as possible before 1130am today.

Thanks

Avery

From: Sandifer, Estella (Maria)
Sent: Monday, June 24, 2019 10:35 AM
To: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Cc: VHA 10P Actions <VHA10PActions@va.gov>
Subject: FW: Spravato/esketamine approval

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Maria Sandifer
Office of the Deputy Under Secretary for Health
for Policy and Services (10P)

AMERICAN OVERSIGHT

Work ph: (b)(6)
Cell: (b)(6)
Email: (b)(6) @va.gov

From: Snyder, Jill
Sent: Monday, June 24, 2019 10:29 AM
To: VHA 10P Actions <VHA10PActions@va.gov>; Valentino, Michael (VACO) (b)(6) @va.gov>; Wiechers, Ilse (b)(6) @va.gov>
Cc: VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: FW: Spravato/esketamine approval

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_____

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_____

Thanks,
Jill

From: Abbie Bennett (b)(6)@connectingvets.com>
Sent: Monday, June 24, 2019 9:09 AM

AMERICAN OVERSIGHT

To: VA Public Affairs <VAPublicAffairs@va.gov>
Subject: [EXTERNAL] Spravato/esketamine approval

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2. How will the VA monitor its use nationwide?

Abbie Bennett
Reporter
Connecting Vets
C (b)(6)
(b)(6)

Entercom | Washington D.C.
1015 Half Street, S.E., Suite 200
Washington. D.C. 20003
M: (b)(6)
entercom.com

Sender:	Smith, Avery /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9471C2D02A8B472B8543E09CB140085F-SMITH, AVER (b)(6) @va.gov>
Recipient:	VHA 10P4P Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8dc3dab451414f59b9797e8ed199c1e8-VHA 10P4P A <vha10P4Paction@va.gov>; VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>
Sent Date:	2019/06/24 10:36:46
Delivered Date:	2019/06/24 10:36:47

AMERICAN OVERSIGHT

From:	Emmendorfer, Thomas (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC96BB44E7AE2C94C43B55D094-EMMENDORFER (b)(6) @va.gov>
To:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>
Subject:	FW: Spravato Info
Date:	2019/08/23 11:25:28
Priority:	Normal
Type:	Note

37 Dose kits purchased at 5 VA medical facilities up thru 8/22/2019.

VA Medical Facilities

- • Nashville =4
- • Lom Linda =4
- • Albuquerque = 21
- • Fayetteville, AR =2
- • Boston = 6

From: Lenz, Sue (PBM)
Sent: Friday, August 23, 2019 9:50 AM
To: Nowak, John <(b)(6) @va.gov>
Subject: RE: Spravato Info

This is what I got

From: Nowak, John
Sent: Friday, August 23, 2019 9:45 AM
To: Emmendorfer, Thomas (PBM) (b)(6) @va.gov>
Cc: Lenz, Sue (PBM) (b)(6) @va.gov>
Subject: RE: Spravato Info

Sue/Tom

I just submitted to SMO for the last 24 months. I don't know how long the product has been on the market but will check for purchases in the ppv data to validate the SMO and to add if there are purchases going back further

---

From: Emmendorfer, Thomas (PBM)
Sent: Friday, August 23, 2019 9:11 AM
To: Lenz, Sue (PBM) (b)(6) @va.gov>; Nowak, John (b)(6) @va.gov>
Cc: Zacher, Jennifer L. (PBM) (b)(6) @va.gov>
Subject: FW: Spravato Info

AMERICAN OVERSIGHT

Sue/John,

Could one of you run the request below using the report functions in McKesson Connect so we have the most recent data?

Tom

From: Valentino, Michael (VACO)
Sent: Friday, August 23, 2019 10:07 AM
To: Emmendorfer, Thomas (PBM) (b)(6) @va.gov>
Subject: FW: Spravato Info

From: Valentino, Michael (VACO)
Sent: Thursday, August 22, 2019 1:32 PM
To: Zacher, Jennifer L. (PBM) (b)(6) @va.gov>
Subject: FW: Spravato Info

Hi Jenn,

Can you have someone run our PPV purchases and let me know how much VA facilities have purchased from the time it was available through whatever data we have now.

Should include the site name, how many units ordered and the cost.

Thanks!

Mike

From: Lieberman, Steven
Sent: Thursday, August 22, 2019 1:25 PM
To: Beck, Lucille B. (b)(6) @va.gov>; Stone, Richard A., MD <(b)(6) @va.gov>; Boyd, Teresa D. (b)(6) @va.gov>; Oshinski, Renee (b)(6) @va.gov>; Czarnecki, Tammy (b)(6) @va.gov>; Valentino, Michael (VACO) <(b)(6) @va.gov>
Cc: Jensen, Jon M. (b)(6) @va.gov>; Howard, Kristi <(b)(6) @va.gov>; Law, Cassandra M. (b)(6) @va.gov>
Subject: RE: Spravato Info

Thanks Lu. This is very helpful. Any word on amount purchased? Do we purchase it only when needed or do we have some on stock? Sorry if that is below and I missed it.

From: Beck, Lucille B.
Sent: Thursday, August 22, 2019 10:26 AM
To: Lieberman, Steven (b)(6) @va.gov>; Stone, Richard A., MD <(b)(6) @va.gov>; Boyd, Teresa D. <(b)(6) @va.gov>; Oshinski, Renee (b)(6) @va.gov>; Czarnecki, Tammy

AMERICAN OVERSIGHT

(b)(6) @va.gov>; Valentino, Michael (VACO) (b)(6) @va.gov>
Cc: Jensen, Jon M. <(b)(6) @va.gov>; Howard, Kristi (b)(6) @va.gov>; Law, Cassandra M. (b)(6) @va.gov>
Subject: FW: Spravato Info
Importance: High

Update from Pharmacy per our discussion this morning and the clips today.

From: Zacher, Jennifer L. (PBM)
Sent: Thursday, August 22, 2019 9:39 AM
To: Beck, Lucille B. (b)(6) @va.gov>
Cc: Valentino, Michael (VACO) (b)(6) @va.gov>; Wiechers, Ilse (b)(6) @va.gov>
Subject: Spravato Info
Importance: High

Hi Lu,
As per call with Mike this morning, here is a brief bullet list of all of the controls we put in place for Spravato:

- • March 5, 2019 – Spravato was approved by FDA
- • March 8, 2019 – Spravato was added to FSS contract for purchase by VA sites
- • March 11-12, 2019 – Product overview presented to internal clinical groups (CMOs, MH leads, VISN Pharmacist Executives)
- • March 15, 2019 – FAQ document distributed to the field
- • March 18, 2019 – Memo issued to field with instructions on how to obtain REMS certification as required by FDA
- • March 19, 2019 – Spravato became available in the U.S. pharmaceutical supply chain
- • May 13-15, 2019 – The Spravato drug monograph, draft criteria for use, and field comments were presented to both the VISN Pharmacist Executive Committee and the Medical Advisory Panel. Draft documents were developed in collaboration with the Office of Mental Health. After discussion, the issue was tabled until the June face to face committee meeting so that feedback from the VPE/MAP committee and field commenters could be incorporated.
- • June 12, 2019 – launched Esketamine Community of Practice monthly teleconference, open to anyone in VHA interested in learning about esketamine
- • June 20, 2019 – based on careful review of available evidence, the MAP/VPE committee voted to:
    - • Designate esketamine as a non-formulary drug which will be made available with an approved prospective review
    - • Approve evidence-based prescribing guidance
    - • Establish an ongoing clinical monitor to assess the drug's safety and effectiveness in the Veteran population
    - • Provide clear and consistent messaging to VA providers
- • July 1, 2019 – launched Esketamine Community of Practice SharePoint site, which serves as a repository of resources related to clinical use of esketamine within VHA

AMERICAN OVERSIGHT

- • July 15, 2019 –Date that the clinical monitor to assess Spravato's safety and effectiveness (aka MUET) went live

Here is the patient specific data from Ilse:

- • 3 patients to date at 2 sites
- • VA Boston began treatment of Patient #1 on June 18, 2019
- • VA New Mexico began treatment of Patient #2 on July 24, 2019 and Patient #3 on July 25, 2019
- • All three patients are continuing to receive treatments, no significant adverse events reported to date, tolerating treatment well

Please let us know if you need any additional information.
JZ

Jennifer L. Zacher, PharmD, BCPP
Associate Chief Consultant
VA Pharmacy Benefits Management Services
(b)(6)
(b)(6) @va.gov

Sender:	Emmendorfer, Thomas (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC96BB44E7AE2C94C43B55D094-EMMENDORFER (b)(6) @va.gov>
Recipient:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>
Sent Date:	2019/08/23 11:25:27
Delivered Date:	2019/08/23 11:25:28

AMERICAN OVERSIGHT

From:	Wiechers, Ilse /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0C7B1428D9E4233A641F125C5B6FC4F-WIECHERS, I (b)(6) @va.gov>
To:	VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>
Subject:	FW: Spravato Info
Date:	2019/08/22 10:50:16
Importance:	High
Priority:	Urgent
Type:	Note

FYSA

From: Zacher, Jennifer L. (PBM)
Sent: Thursday, August 22, 2019 6:39 AM
To: Beck, Lucille B. (b)(6) @va.gov>
Cc: Valentino, Michael (VACO) (b)(6) @va.gov>; Wiechers, Ilse <(b)(6) @va.gov>
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AMERICAN OVERSIGHT

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VA Pharmacy Benefits Management Services
(b)(6)
(b)(6) @va.gov

Sender:	Wiechers, Ilse /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0C7B1428D9E4233A641F125C5B6FC4F-WIECHERS, I (b)(6) @va.gov>
Recipient:	VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>
Sent Date:	2019/08/22 10:50:15
Delivered Date:	2019/08/22 10:50:16

AMERICAN OVERSIGHT

To:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>
Subject:	FW: Spravato Info
Date:	2019/08/23 11:23:28
Priority:	Normal
Type:	Note

37 Dose kits purchased at 5 VA medical facilities up thru 8/22/2019.

VA Medical Facilities

- • Nashville
- • Lom Linda
- • Albuque
- • Fayetteville, AR
- • Boston

From: Lenz, Sue (PBM)
Sent: Friday, August 23, 2019 9:50 AM
To: Nowak, John (b)(6) @va.gov>
Subject: RE: Spravato Info

This is what I got

From: Nowak, John
Sent: Friday, August 23, 2019 9:45 AM
To: Emmendorfer, Thomas (PBM)(b)(6) @va.gov>
Cc: Lenz, Sue (PBM) (b)(6) @va.gov>
Subject: RE: Spravato Info

Sue/Tom

I just submitted to SMO for the last 24 months. I don't know how long the product has been on the market but will check for purchases in the ppv data to validate the SMO and to add if there are purchases going back further

---

From: Emmendorfer, Thomas (PBM)
Sent: Friday, August 23, 2019 9:11 AM
To: Lenz, Sue (PBM)(b)(6) @va.gov>; Nowak, John (b)(6) @va.gov>
Cc: Zacher, Jennifer L. (PBM) (b)(6) @va.gov>
Subject: FW: Spravato Info

Sue/John,

AMERICAN OVERSIGHT

Could one of you run the request below using the report functions in McKesson Connect so we have the most recent data?

Tom

From: Valentino, Michael (VACO)
Sent: Friday, August 23, 2019 10:07 AM
To: Emmendorfer, Thomas (PBM) <(b)(6) @va.gov>
Subject: FW: Spravato Info

From: Valentino, Michael (VACO)
Sent: Thursday, August 22, 2019 1:32 PM
To: Zacher, Jennifer L. (PBM) (b)(6) @va.gov>
Subject: FW: Spravato Info

Hi Jenn,

Can you have someone run our PPV purchases and let me know how much VA facilities have purchased from the time it was available through whatever data we have now.

Should include the site name, how many units ordered and the cost.

Thanks!

Mike

From: Lieberman, Steven
Sent: Thursday, August 22, 2019 1:25 PM
To: Beck, Lucille B. (b)(6) @va.gov>; Stone, Richard A., MD (b)(6) @va.gov>; Boyd, Teresa D. <(b)(6) @va.gov>; Oshinski, Renee (b)(6) @va.gov>; Czarnecki, Tammy (b)(6) @va.gov>; Valentino, Michael (VACO) <(b)(6) @va.gov>
Cc: Jensen, Jon M (b)(6) @va.gov>; Howard, Kristi (b)(6) @va.gov>; Law, Cassandra M. (b)(6) @va.gov>
Subject: RE: Spravato Info

Thanks Lu. This is very helpful. Any word on amount purchased? Do we purchase it only when needed or do we have some on stock? Sorry if that is below and I missed it.

From: Beck, Lucille B.
Sent: Thursday, August 22, 2019 10:26 AM
To: Lieberman, Steven <(b)(6) @va.gov>; Stone, Richard A., MD (b)(6) @va.gov>; Boyd, Teresa D. <(b)(6) @va.gov>; Oshinski, Renee (b)(6) @va.gov>; Czarnecki, Tammy (b)(6) @va.gov>; Valentino, Michael (VACO) <(b)(6) @va.gov>
Cc: Jensen, Jon M. <(b)(6) @va.gov>; Howard, Kristi <(b)(6) @va.gov>; Law, Cassandra M. (b)(6) @va.gov>

AMERICAN OVERSIGHT

Subject: FW: Spravato Info
Importance: High

Update from Pharmacy per our discussion this morning and the clips today.

From: Zacher, Jennifer L. (PBM)
Sent: Thursday, August 22, 2019 9:39 AM
To: Beck, Lucille B. (b)(6) @va.gov>
Cc: Valentino, Michael (VACO) (b)(6) @va.gov>; Wiechers, Ilse (b)(6) @va.gov>
Subject: Spravato Info
Importance: High

Hi Lu,
As per call with Mike this morning, here is a brief bullet list of all of the controls we put in place for Spravato:

- • March 5, 2019 – Spravato was approved by FDA
- • March 8, 2019 – Spravato was added to FSS contract for purchase by VA sites
- • March 11-12, 2019 – Product overview presented to internal clinical groups (CMOs, MH leads, VISN Pharmacist Executives)
- • March 15, 2019 – FAQ document distributed to the field
- • March 18, 2019 – Memo issued to field with instructions on how to obtain REMS certification as required by FDA
- • March 19, 2019 – Spravato became available in the U.S. pharmaceutical supply chain
- • May 13-15, 2019 – The Spravato drug monograph, draft criteria for use, and field comments were presented to both the VISN Pharmacist Executive Committee and the Medical Advisory Panel. Draft documents were developed in collaboration with the Office of Mental Health. After discussion, the issue was tabled until the June face to face committee meeting so that feedback from the VPE/MAP committee and field commenters could be incorporated.
- • June 12, 2019 – launched Esketamine Community of Practice monthly teleconference, open to anyone in VHA interested in learning about esketamine
- • June 20, 2019 – based on careful review of available evidence, the MAP/VPE committee voted to:
    - • Designate esketamine as a non-formulary drug which will be made available with an approved prospective review
    - • Approve evidence-based prescribing guidance
    - • Establish an ongoing clinical monitor to assess the drug's safety and effectiveness in the Veteran population
    - • Provide clear and consistent messaging to VA providers
- • July 1, 2019 – launched Esketamine Community of Practice SharePoint site, which serves as a repository of resources related to clinical use of esketamine within VHA
- • July 15, 2019 –Date that the clinical monitor to assess Spravato's safety and effectiveness (aka MUET) went live

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Here is the patient specific data from Ilse:

- • 3 patients to date at 2 sites
- • VA Boston began treatment of Patient #1 on June 18, 2019
- • VA New Mexico began treatment of Patient #2 on July 24, 2019 and Patient #3 on July 25, 2019
- • All three patients are continuing to receive treatments, no significant adverse events reported to date, tolerating treatment well

Please let us know if you need any additional information.
JZ

Jennifer L. Zacher, PharmD, BCPP
Associate Chief Consultant
VA Pharmacy Benefits Management Services
(b)(6)
(b)(6) va.gov

Recipient:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>
Sent Date:	2019/08/23 11:23:33
Delivered Date:	2019/08/23 11:23:28
Message Flags:	Unread Unsent

AMERICAN OVERSIGHT

From:	Llorente, Maria D. </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F5C91F577D894BD9A0F09305DB34DD4F-LLORENTE, M>
To:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>
Subject:	FW: Spravato External Communication Draft
Date:	2019/03/11 12:09:00
Priority:	Normal
Type:	Note

Hi Tom. Made a few edits.

From: Emmendorfer, Thomas (PBM)
Sent: Monday, March 11, 2019 10:29 AM
To: Llorente, Maria D. (b)(6) @va.gov>
Cc: Wiechers, Ilse (b)(6) @va.gov>; Valentino, Michael (VACO) (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) (b)(6) @va.gov>
Subject: FW: Spravato External Communication Draft

Hi Maria,

The external communication is ready for your review.

We are working on finalizing the internal FAQ document.

Tom

From: Thomas Emmendorfer (b)(6) @va.gov>
Date: Friday, March 8, 2019 at 6:14 PM
To: Michael Valentino (b)(6) @va.gov>
Cc: "Wiechers, Ilse" (b)(6) @va.gov>, Jennifer Zacher (b)(6) @va.gov>
Subject: FW: Spravato External Communication Draft

Hi Mike,

The external communication document is ready for your review.

Isle,

(b5)

Jenn has made it clear to J&J that we need their educational materials as soon as possible.

Jenn,

AMERICAN OVERSIGHT

Can you make sure J&J includes educational materials that are listed in their REMS form below as one of their deliverables to us?

Thank you,

Tom

Sent with BlackBerry Work
(www.blackberry.com)

From: Wiechers, Ilse (b)(6) @va.gov>
Date: Friday, Mar 08, 2019, 5:35 PM
To: Emmendorfer, Thomas (PBM) <(b)(6) @va.gov>, Zacher, Jennifer L. (PBM) <(b)(6) @va.gov>
Subject: RE: Spravato External Communication Draft

Hi Tom &Jenn –

Attached are my edits to the external document.

(b5)

More to come on Monday after further discussion with folks in Ethics and OMHSP re informed consent.

Thanks,
Ilse

(b5)

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(b5)

From: Emmendorfer, Thomas (PBM)
Sent: Friday, March 08, 2019 12:28 PM
To: Wiechers, Ilse (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) (b)(6) @va.gov>
Subject: Re: Spravato External Communication Draft

Hi Ilse,

Here is our first draft on the External Communication for your review. (b5)
(b5)

Tom

From: "Wiechers, Ilse" (b)(6) @va.gov>
Date: Friday, March 8, 2019 at 3:03 PM
To: Jennifer Zacher (b)(6) @va.gov>
Cc: Thomas Emmendorfer <(b)(6) @va.gov>
Subject: RE: Spravato Internal Communication Draft

Got it – thanks. Keep me posted as more details are made clear in the coming days. I've started reading the documents they have made available on the Spravato REMS webpage to try to familiarize myself as well.

From: Zacher, Jennifer L. (PBM)
Sent: Friday, March 08, 2019 11:44 AM
To: Wiechers, Ilse (b)(6) @va.gov>
Cc: Emmendorfer, Thomas (PBM) (b)(6) @va.gov>
Subject: RE: Spravato Internal Communication Draft

Hi,
Based on how this REMS is written, I don't think so. Right now it looks like just the healthcare facility and the pharmacy needs to be "certified" in the system, and then we order from the wholesaler. It doesn't look to me like much clinical patient data needs to be reported, so we probably don't need that level of oversight. I will know more in the next day or two though, and I will keep you posted.
JZ

From: Wiechers, Ilse
Sent: Friday, March 08, 2019 1:41 PM
To: Zacher, Jennifer L. (PBM) (b)(6) @va.gov>

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Cc: Emmendorfer, Thomas (PBM) (b)(6) @va.gov>
Subject: RE: Spravato Internal Communication Draft

Thanks – will take a look shortly. I still haven't heard back from ethics, (b5)
(b5)

(b5)

Ilse

From: Zacher, Jennifer L. (PBM)
Sent: Friday, March 08, 2019 11:27 AM
To: Wiechers, Ilse <(b)(6) @va.gov>
Cc: Emmendorfer, Thomas (PBM) (b)(6) @va.gov>
Subject: Spravato Internal Communication Draft

Hi Ilse,
As per your conversation with Tom earlier, attached is a draft internal communication that we developed related to Spravato. Can you please review, add any edits you might have and then send back to us?
Thanks much!
Jennifer

Jennifer L. Zacher, PharmD, BCPP
Associate Chief Consultant
VA Pharmacy Benefits Management Services
(b)(6)
(b)(6) @va.gov

Sender:	Llorente, Maria D. </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F5C91F577D894BD9A0F09305DB34DD4F-LLORENTE, M>
Recipient:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>
Sent Date:	2019/03/11 12:09:23
Delivered Date:	2019/03/11 12:09:00

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(b5)

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From:	Smith, Avery /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9471C2D02A8B472B8543E09CB140085F-SMITH, AVER (b)(6) @va.gov>
To:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>
CC:	Smith, Avery /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9471c2d02a8b472b8543e09cb140085f-Smith, Aver (b)(6) @va.gov>
Subject:	FW: SMEs/Talking Points for Spravato® (esketamine)
Date:	2019/03/21 13:21:25
Due Date:	2019/03/20 20:00:00
Priority:	Normal
Type:	Note

Guys, I through up on this one, didn't get it to you, I asked for more time until 3pm. But please do what you can

Thanks

Avery

From: Sandifer, Estella (Maria)
Sent: Thursday, March 21, 2019 6:53 AM
To: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Cc: VHA 10P Actions <VHA10PActions@va.gov>
Subject: FW: SMEs/Talking Points for Spravato® (esketamine)

Good morning,

Please review the request below and submit your concurrence to **10P NLT 11 a.m., today.**

Request:
Will you look at the below request from OPIA and let us know if you concur on items 1 and 2.

Requesting responses by tomorrow (March 21) by noon ET.

V/r,

Maria Sandifer
Office of the Deputy Under Secretary for Health

AMERICAN OVERSIGHT

for Policy and Services (10P)
Work ph: (b)(6)
Cell: (b)(6)
Email: (b)(6) @va.gov

From: Greilsamer, Alan
Sent: Wednesday, March 20, 2019 6:18 PM
To: VHA 10P Actions <VHA10PActions@va.gov>; VHA 10N Action <VHA10NAction@va.gov>
Cc: VHA 10NC Action <vha10ncaction@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: FW: SMEs/Talking Points for Spravato® (esketamine)

10P, 10N,

Will you look at the below request from OPIA and let us know if you concur on items 1 and 2.

Requesting responses by tomorrow (March 21) by noon ET.

Thanks, Alan

From: Mojay, Ndidi (b)(6) @va.gov>
Date: Wednesday, Mar 20, 2019, 2:58 PM
To: Greilsamer, Alan (b)(6) @va.gov>
Cc: Carter, Susan (b)(6) @va.gov>, Noller, Randal (b)(6) @va.gov>, VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: RE: SMEs/Talking Points for Spravato® (esketamine)

Hi Alan,

Can you check with your folks? Is this accurate to say? Need this today.

1. • Do vets have any out of pocket costs associated with taking this drug?

(b5)

2. • And, any estimate of how many vets the VA expects will receive the drug, say over the next year or so?

(b5)

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(b5)

From: Greilsamer, Alan
Sent: Monday, March 18, 2019 4:21 PM
To: Mojay, Ndidi (b)(6) @va.gov>
Cc: Carter, Susan (b)(6) @va.gov>; Noller, Randal (b)(6) @va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: SMEs/Talking Points for Spravato® (esketamine)

Ndidi,

Dr. Ilse Wiechers, National Director, Psychotropic Drug Safety Initiative, is the SME for VHA Mental Health. We also will be providing an SME from Pharmacy. Additionally, Pharmacy will be providing answers to questions b and h.

Please let us know if you need anything else at this point.

Thank you, Alan

a. • What clinics currently utilize esketamine in other forms? How many Veterans are currently using it?

(b5)

b. • When/if will it be VA wide?

(b5)

c. • Talking points need to stress that administration needs to be in a medical setting?

(b5)

d. • What are the side effects? How long do you have to be on this treatment?

(b5)

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(b5)

How long do you have to be on this treatment

(b5)

e. • Can we add how quickly does it take to work and how long does it last.

(b5)

f. • What type of depression will this address?

(b5)

g. • What is the percentage of Veterans receiving VA health care who suffer from depression? What is the percentage who would benefit from this treatment?

(b5)

h. • How much does it cost?

(b5)

--
Alan Greilsamer
Director, Media Relations (10B2B)
Office of Communications

AMERICAN OVERSIGHT

Veterans Health Administration
P: (b)(6)
E: (b)(6) @va.gov

Sender:	Smith, Avery /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9471C2D02A8B472B8543E09CB140085F-SMITH, AVER (b)(6) @va.gov>
Recipient:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>; Smith, Avery /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9471c2d02a8b472b8543e09cb140085f-Smith, Aver (b)(6) @va.gov>
Sent Date:	2019/03/21 13:21:23
Delivered Date:	2019/03/21 13:21:25
Message Flags:	Unread

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From:	Gavin, Stacy /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4017313de0a84f8e8ceade280f77d235-Gavin, Stac (b)(6) @va.gov>
To:	VHA 10P4P Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8dc3dab451414f59b9797e8ed199c1e8-VHA 10P4P A <vha10P4Paction@va.gov>
CC:	VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b)(6) @va.gov>
Subject:	FW: SME Needed for Spravato® (esketamine)
Date:	2019/03/18 12:53:02
Importance:	High
Priority:	Urgent
Type:	Note

PBM,
Did you receive this (**due ASAP today**)? Ilse is actually out of the office, but is starting to draft a response now. I wanted to give you a heads up so you can be ready to edit/add to it, if you hadn't seen it yet.
If you want to provide a SME as well, that would be great.
Thanks.
Stacy

From: Davis, Lashelle (VHACO)
Sent: Monday, March 18, 2019 12:39 PM
To: VHA 10NC5 Action <VHA10NC5Action@va.gov>
Cc: VHA CO 10NC Front Office HSSs <VHACO10NCFOHSSs@va.gov>
Subject: FW: SME Needed for Spravato® (esketamine)
Importance: High
*****EXPEDITE ACTION ITEM*****
Please provide your response to the questions below ASAP, today.
Thank you,
Lashelle

From: Greilsamer, Alan
Sent: Monday, March 18, 2019 12:26 PM
To: VHA 10N Action <VHA10NAction@va.gov>
Cc: VHA 10NC Action <vha10ncaction@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: FW: SME Needed for Spravato® (esketamine)
Good morning 10N,
Apologies for this hot request. OPIA would like to get this information today as a press release on this topic is scheduled to go out later today/tomorrow at the latest.
Requests:

1. • By today ASAP please provide an SME(s) to be available for potential media interviews. Requesting name(s), title(s) and short bio (if available).

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2. • By today EOD, talking points about Spravato® (esketamine) and its benefits.
    a. • What clinics currently utilize esketamine in other forms? How many Veterans are currently using it?
    b. • When/if will it be VA wide?
    c. • Talking points need to stress that administration needs to be in a medical setting?
    d. • What are the side effects? How long do you have to be on this treatment?
    e. • Can we add how quickly does it take to work and how long does it last.
    f. • What type of depression will this address?
    g. • What is the percentage of Veterans receiving VA health care who suffer from depression? What is the percentage who would benefit from this treatment?
    h. • How much does it cost?

Thanks, Alan

From: Forte, Kimberly P.
Sent: Monday, March 18, 2019 12:17 PM
To: Greilsamer, Alan &lt*(b)(6)* @va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Cc: Smith, Monica (VACO) &lt *(b)(6)* @va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: RE: SME Needed for Spravato® (esketamine)

Good afternoon,
10P respectfully request this item be deferred to Office of Mental Health. They are the best to offer a SME and the experts given the direct communication to patients. PCS is happy to review and assist as needed.
v/r
Kimberly Forte'
Health Systems Specialist to the
Deputy Under Secretary for Health for Policy & Services
Office: *(b)(6)*
Fax: *(b)(6)*
True leaders don't create followers, they create more leaders!!!

From: Greilsamer, Alan
Sent: Monday, March 18, 2019 9:38 AM
To: VHA 10P Actions <VHA10PActions@va.gov>
Cc: Smith, Monica (VACO) <*(b)(6)* @va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: SME Needed for Spravato® (esketamine)

10P Action,
OPIA is moving forward with getting concurrence on the attached press release. Additionally, they want to start pitching the story on VA providing Spravato® (esketamine) to Veterans based on their individual medical needs combined with the provider's clinical assessment.

Requests:

1. • By today noon ET, please provide an SME(s) to be available for potential media interviews. Requesting name(s), title(s) and short bio (if available).

2. • By today EOD, talking points about Spravato® (esketamine) and its benefits.

Please let us know if you have any questions .

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Thanks, Alan
--
Alan Greilsamer
Director, Media Relations (10B2B)
Office of Communications
Veterans Health Administration
P:(b)(6)
E: (b)(6) @va.gov

Sender:	Gavin, Stacy /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4017313de0a84f8e8ceade280f77d235-Gavin, Stac <(b)(6) @va.gov>
Recipient:	VHA 10P4P Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8dc3dab451414f59b9797e8ed199c1e8-VHA 10P4P A <vha10P4Paction@va.gov>; VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b)(6) @va.gov>
Sent Date:	2019/03/18 12:53:00
Delivered Date:	2019/03/18 12:53:02
Message Flags:	Unread
From:	Paige, Paula /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=73F90D4A44054DEF820B9F343BFBF070-PAIGE, PAUL (b)(6) @va.gov>
To:	Ledesma, Mark P. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=acbc9290cfec4fff8651002b5b0330c5-Ledesma, Ma (b)(6) @va.gov>
CC:	Carter, Susan /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02cad1f13b7642b98bc94ac7edcb7f31-Carter, Sus (b)(6) @va.gov>; Noller, Randal /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=67341b1360c542238e428e0fc53d9d93-Noller, Ran (b)(6) @va.gov>; Christian, Tatjana /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=94a1231b7ae04216a5cdffef784c9b3b-Christian, (b)(6) @va.gov>; Greilsamer, Alan /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fc02807af08443fbb5c68c590d58fa4b-Greilsamer, (b)(6) @va.gov>; VHA CO 10B2B Media /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12e0caca48054b8da1e793651a89d81c-VHA CO 10B2 <VHACO10B2BMedia@va.gov>
Subject:	VA to make new nasal spray drug available for treatment-resistant depression_15MARCH2019 OCLA
Date:	2019/03/18 10:05:38
Priority:	Normal
Type:	Note

Mark,

Please see feedback from OCLA. OGC had no issues.

AMERICAN OVERSIGHT

Respectfully,
Paula A. Paige
Public Affairs Officer
Office of Media Relations, Office of Public and Intergovernmental Affairs
U.S. Department of Veterans Affairs
810 Vermont Ave. NW, Room 913
Washington, D.C. 20420
(b)(6) @va.gov
(b)(6) (work)
(b)(6) (cell)
www.vets.gov
VA on Facebook. Twitter. YouTube. Flickr. Blog

Sender:	Paige, Paula /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=73F90D4A44054DEF820B9F343BFBF070-PAIGE, PAUL (b)(6) @va.gov>
Recipient:	Ledesma, Mark P. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=acbc9290cfec4fff8651002b5b0330c5-Ledesma, Ma (b)(6) @va.gov>; Carter, Susan /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02cad1f13b7642b98bc94ac7edcb7f31-Carter, Sus (b)(6) @va.gov>; Noller, Randal /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=67341b1360c542238e428e0fc53d9d93-Noller, Ran (b)(6) @va.gov>; Christian, Tatjana /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=94a1231b7ae04216a5cdffef784c9b3b-Christian, (b)(6) @va.gov>; Greilsamer, Alan /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fc02807af08443fbb5c68c590d58fa4b-Greilsamer, (b)(6) @va.gov>; VHA CO 10B2B Media /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12e0caca48054b8da1e793651a89d81c-VHA CO 10B2 <VHACO10B2BMedia@va.gov>
Sent Date:	2019/03/18 10:05:36
Delivered Date:	2019/03/18 10:05:38

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From:	Valentino, Michael (VACO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO,>
To:	Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen (b)(6) @va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>
Subject:	FW: Request for a 15-min call with Dr. Stone on Tues, 8/27
Date:	2019/08/27 10:23:00
Priority:	Normal
Type:	Note

FYI.....

Mike

From: Valentino, Michael (VACO)
Sent: Tuesday, August 27, 2019 10:21 AM
To: Williams, Jessica D. (b)(6) @va.gov>; O'Toole, Thomas P. (b)(6) @va.gov>; Jensen, Jon M. (b)(6) @va.gov>
Cc: VHA USH Meeting Requests <VHAUSHMeetingRequests@va.gov>; Howard, Kristi (b)(6) @va.gov>; Adams, Jennifer L. (VHACO) (b)(6) @va.gov>; Katikos, Nicole (OGC) (b)(6) @va.gov>
Subject: RE: Request for a 15-min call with Dr. Stone on Tues, 8/27

Hi Jessica,

(b5)
[redacted]

I have to leave (b) (6) [redacted] at 3pm today and I have a few other things on my schedule. I'm available today from 10:30 to 11:30 1:00 to 1:30 and 2:00 to 3:00 if any of those times work for a call. If not, I can ask someone else from PBM to join the call.

Tom,

Here is some updated information (b5) [redacted]
(b5)

- • March 5, 2019 – Spravato was approved by FDA
- • March 8, 2019 – Spravato was added to FSS contract for purchase by VA sites
- • March 11-12, 2019 – Product overview presented to internal clinical groups (CMOs, MH leads, VISN Pharmacist Executives)

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- • March 15, 2019 – FAQ document distributed to the field
- • March 18, 2019 – Memo issued to field with instructions on how to obtain REMS certification as required by FDA
- • March 19, 2019 – Spravato became available in the U.S. pharmaceutical supply chain
- • May 13-15, 2019 – The Spravato drug monograph, draft criteria for use, and field comments were presented to both the VISN Pharmacist Executive Committee and the Medical Advisory Panel. Draft documents were developed in collaboration with the Office of Mental Health. After discussion, the issue was tabled until the June face to face committee meeting so that feedback from the VPE/MAP committee and field commenters could be incorporated.
- • June 12, 2019 – launched Esketamine Community of Practice monthly teleconference, open to anyone in VHA interested in learning about esketamine
- • June 20, 2019 – based on careful review of available evidence, the MAP/VPE committee voted to:
    - • Designate esketamine as a non-formulary drug which will be made available with an approved prospective review
    - • Approve evidence-based prescribing guidance
    - • Establish an ongoing clinical monitor to assess the drug's safety and effectiveness in the Veteran population
    - • Provide clear and consistent messaging to VA providers
- • July 1, 2019 – launched Esketamine Community of Practice SharePoint site, which serves as a repository of resources related to clinical use of esketamine within VHA
- • July 15, 2019 –Date that the clinical monitor to assess Spravato's safety and effectiveness (aka MUET) went live

Here is the patient specific data from Ilse:

- • 3 patients to date at 2 sites
- • VA Boston began treatment of Patient #1 on (b) (6) 2019
- • VA New Mexico began treatment of Patient #2 on (b) (6) 2019 and Patient #3 on (b) (6) 2019
- • All three patients are continuing to receive treatments, no significant adverse events reported to date, tolerating treatment well

37 Dose kits purchased at 5 VA medical facilities up thru 8/22/2019.

VA Medical Facilities

- • Nashville =4
- • Lom Linda =4
- • Albuquerque = 21
- • Fayetteville, AR =2

Boston = 6

Mike

From: Williams, Jessica D.
Sent: Tuesday, August 27, 2019 10:11 AM
To: Valentino, Michael (VACO) (b)(6) @va.gov>; O'Toole, Thomas P.

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<Thomas.O'Toole@va.gov>; Jensen, Jon M. (b)(6) @va.gov>
Cc: VHA USH Meeting Requests <VHAUSHMeetingRequests@va.gov>; Howard, Kristi (b)(6) @va.gov>; Adams, Jennifer L. (VHACO) (b)(6) @va.gov>; Katikos, Nicole (OGC) (b)(6) @va.gov>
Subject: RE: Request for a 15-min call with Dr. Stone on Tues, 8/27
Importance: High

Good Morning Dr. Valentino,

On behalf of Dr. Stone, would you mind joining this call along with Dr. O'Toole, to discuss Spravato with (b) (6) from Johnson &Johnson. Also, if you could provide any materials regarding Spravato, we would greatly appreciate it.

Once we receive confirmation of participation, I will follow up with Johnson &Johnson for an actual time. We thank you for your time and participation.

V/r
Jessica

From: Jensen, Jon M.
Sent: Tuesday, August 27, 2019 9:54 AM
To: O'Toole, Thomas P. <Thomas.O'Toole@va.gov>; Williams, Jessica D. (b)(6) @va.gov>; Adams, Jennifer L. (VHACO) (b)(6) @va.gov>; Katikos, Nicole (OGC) (b)(6) @va.gov>
Cc: VHA USH Meeting Requests <VHAUSHMeetingRequests@va.gov>; Howard, Kristi (b)(6) @va.gov>
Subject: RE: Request for a 15-min call with Dr. Stone on Tues, 8/27

Mike Valentino has updates on this

Jon M. Jensen
VHA Acting Deputy Chief of Staff
(b)(6)

Sent with BlackBerry Work
(www.blackberry.com)

From: O'Toole, Thomas P. (b)(6) @va.gov>
Date: Tuesday, Aug 27, 2019, 9:48 AM
To: Williams, Jessica D. <(b)(6) @va.gov>, Jensen, Jon M. (b)(6) @va.gov>, Adams, Jennifer L. (VHACO) (b)(6) @va.gov>, Katikos, Nicole (OGC) (b)(6) @va.gov>
Cc: VHA USH Meeting Requests <VHAUSHMeetingRequests@va.gov>, Howard, Kristi (b)(6) @va.gov>
Subject: RE: Request for a 15-min call with Dr. Stone on Tues, 8/27

I'm happy to field the call but not aware of any specifics to the topic (Spravato) - does Dave Carroll or someone from MH also need to be on the call (or in my place) or can anyone get me up to speed on either information to convey or messaging? I defer to your preference

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Thanks
Tom

From: Williams, Jessica D.
Sent: Tuesday, August 27, 2019 9:09 AM
To: O'Toole, Thomas P. (b)(6) @va.gov>; Jensen, Jon M. (b)(6) @va.gov>; Adams, Jennifer L. (VHACO) (b)(6) @va.gov>; Katikos, Nicole (OGC) <(b)(6) @va.gov>
Cc: VHA USH Meeting Requests <VHAUSHMeetingRequests@va.gov>; Howard, Kristi (b)(6) @va.gov>
Subject: RE: Request for a 15-min call with Dr. Stone on Tues, 8/27
Importance: High

Good Morning Dr. O' Toole,

On behalf of Dr. Stone, will you be able to take this call with (b) (6) from Johnson &Johnson, today.
Dr. Stone is on a site in West Virginia with poor connectivity.

V/r
Jessica

From: Jensen, Jon M.
Sent: Tuesday, August 27, 2019 8:55 AM
To: Williams, Jessica D. (b)(6) @va.gov>; Adams, Jennifer L. (VHACO) (b)(6) @va.gov>; Katikos, Nicole (OGC) (b)(6) @va.gov>
Cc: VHA USH Meeting Requests <VHAUSHMeetingRequests@va.gov>; Howard, Kristi (b)(6) @va.gov>
Subject: RE: Request for a 15-min call with Dr. Stone on Tues, 8/27

Won't be able to do it today we are in WV. And connectivity is spotty. The day tomorrow is fully booked. Both days are emergent issues that need his direct attention. Can you check with Tom O'Toole to see if he is spun up enough to take the call?

Jon M. Jensen
VHA Acting Deputy Chief of Staff
(b)(6)

Sent with BlackBerry Work
(www.blackberry.com)

From: Williams, Jessica D. (b)(6) @va.gov>
Date: Tuesday, Aug 27, 2019, 8:46 AM
To: Jensen, Jon M. (b)(6) @va.gov>, Adams, Jennifer L. (VHACO) (b)(6) @va.gov>, Katikos, Nicole (OGC) (b)(6) @va.gov>
Cc: VHA USH Meeting Requests <VHAUSHMeetingRequests@va.gov>, Howard, Kristi (b)(6) @va.gov>

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Subject: FW: Request for a 15-min call with Dr. Stone on Tues, 8/27

Morning Jon –

Dr. Stone needs to connect with (b) (6) from Johnson &Johnson for 15 minutes today, hopefully this afternoon. Just need a time that will work while you all are in the car. Advise please. Nicole will be reaching out to you as well.

V/r
Jessica

From: Williams, Jessica D.
Sent: Tuesday, August 27, 2019 8:34 AM
To: (b) (6) (b)(6) @its.jnj.com>
Cc: VHA USH Meeting Requests <VHAUSHMeetingRequests@va.gov>; Adams, Jennifer L. (VHACO) (b)(6) @va.gov>
Subject: RE: Request for a 15-min call with Dr. Stone on Tues, 8/27

Good Morning (b) (6)

Please let us verify Dr. Stone's calendar for the remainder of today. Dr. Stone has unexpected official travel for today. I will follow back up with you shortly. Thanks!

V/r
Jessica

From: (b) (6) (b)(6) @its.jnj.com>
Sent: Tuesday, August 27, 2019 8:28 AM
To: VHA USH Meeting Requests <VHAUSHMeetingRequests@va.gov>
Subject: [EXTERNAL] RE: Request for a 15-min call with Dr. Stone on Tues, 8/27
Importance: High

Good morning,

I am following up regarding this request for a call with Dr. Stone. I also left a voicemail message to follow up on this request as well.

Please let me know when Dr. Stone will be available to accommodate a 15-minute call with (b) (6) in follow up to a May 14th meeting regarding Spravato. The nature of this call is time sensitive, hence my follow-up.

Thank you,

(b) (6)
Janssen Pharmaceuticals, Inc. | 1125 Trenton-Harbourton Road | A1.300.19 | Titusville, NJ 08560
Office: (b)(6) | email: (b)(6)

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From: [redacted] [OMPUS]
Sent: Friday, August 23, 2019 1:45 PM
To: vhaushmeetingrequests@va.gov
Subject: Request for a 15-min call with Dr. Stone on Tues, 8/27

Hi Kristi (and team),

Thank you for taking my call and providing me with this e-mail address. As mentioned, [redacted] has requested a 15-minute call with Dr. Stone to follow up on a discussion that they had on May 14. [redacted] met with Dr. Stone regarding Spravato in May.

My contact information is below. I look forward to hearing back regarding Dr. Stone's availability.

Thank you... and Kristi, *(b)(6)*

[redacted]
Janssen Pharmaceuticals, Inc. | 1125 Trenton-Harbourton Road | A1.300.19 | Titusville, NJ 08560
Office: *(b)(6)* | email: *(b)(6)*

Sender:	Valentino, Michael (VACO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO,>
Recipient:	Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen *(b)(6)* @va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer *(b)(6)* @va.gov>
Sent Date:	2019/08/27 10:23:41
Delivered Date:	2019/08/27 10:23:00

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From:	Wiechers, Ilse /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0C7B1428D9E4233A641F125C5B6FC4F-WIECHERS, I (b)(6) @va.gov>
To:	VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>
Subject:	FW: QUERY: Ketamine-Spravato// VICE News // No Deadline - interview request
Date:	2019/08/21 12:20:57
Priority:	Normal
Type:	Note

FYI – movement afoot from VICE news about ketamine/esketamine.

From: Wiechers, Ilse
Sent: Wednesday, August 21, 2019 9:10 AM
To: Valentino, Michael (VACO) (b)(6) @va.gov>; Lahl, Dennis (b)(6) @va.gov>; VHA 10P4P Action <vha10P4Paction@va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>
Subject: RE: QUERY: Ketamine-Spravato// VICE News // No Deadline - interview request

Concur for 10NC5. Thanks for cc'ing me, Mike.

However, a note that further below in the thread there was reference to #(b5)

(b5)

Ilse

***

Ilse R. Wiechers, MD, MPP, MHS
National Director, Psychotropic Drug Safety Initiative (PDSI)
National Lead, Esketamine Clinical Implementation
Associate Director, Northeast Program Evaluation Center
Office of Mental Health and Suicide Prevention (10NC5), Department of Veterans Affairs
Assistant Clinical Professor of Psychiatry, Yale University School of Medicine
cell (b)(6)
email: (b)(6) @va.gov | (b)(6)

From: Valentino, Michael (VACO)
Sent: Wednesday, August 21, 2019 8:50 AM
To: Lahl, Dennis (b)(6) @va.gov>; VHA 10P4P Action <vha10P4Paction@va.gov>

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Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>; Wiechers, Ilse (b)(6) @va.gov>
Subject: RE: QUERY: Ketamine-Spravato// VICE News // No Deadline - interview request

Ok. I concur the statement is accurate

Sent with BlackBerry Work
(www.blackberry.com)

From: Lahl, Dennis (b)(6) @va.gov>
Date: Wednesday, Aug 21, 2019, 11:43 AM
To: Valentino, Michael (VACO) <(b)(6) @va.gov>, VHA 10P4P Action <vha10P4Paction@va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>, VHA 10P4 Communication Group <vha10p4comm@va.gov>, Wiechers, Ilse (b)(6) @va.gov>
Subject: RE: QUERY: Ketamine-Spravato// VICE News // No Deadline - interview request

Correct, VHA Communications called and I mentioned that to them "So we are not addressing the questions, just providing a statement" and I was told correct. I have a feeling this will most likely come back but will move the statement along as they requested. If approved. Thanks!

Dennis

Dennis Lahl FAC-P/PM
Office of the Assistant Deputy Under Secretary for Health for Patient Care Services (10P4)
VACO PCS IT/BCAG/ISO Liaison
TMS OPCS DM
ph: (b)(6)
fax: (b)(6)
Dennis Lahl

From: Valentino, Michael (VACO)
Sent: Wednesday, August 21, 2019 11:41 AM
To: Lahl, Dennis (b)(6) @va.gov>; VHA 10P4P Action <vha10P4Paction@va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; Wiechers, Ilse (b)(6) @va.gov>
Subject: RE: QUERY: Ketamine-Spravato// VICE News // No Deadline - interview request

The proposed response is factually correct but it does not address the specific questions the reporter asked.

Sent with BlackBerry Work
(www.blackberry.com)

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From: Lahl, Dennis (b)(6) @va.gov>
Date: Wednesday, Aug 21, 2019, 11:36 AM
To: VHA 10P4P Action <vha10P4Paction@va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>, VHA 10P4 Communication Group <vha10p4comm@va.gov>, VHA 10P Actions <VHA10PActions@va.gov>
Subject: FW: QUERY: Ketamine-Spravato// VICE News // No Deadline - interview request

10P4P Actions,

OPIA has sent the below statement for review and approval to an inquiry from HBO. Please note the **Deadline: 1:300pm Today.** Let me know if you have any questions or concerns. Thanks!

Dennis

Inquiry questions:

- • "The use of ketamine at VA isn't common. Veterans are paying out of pocket for this type of treatment outside of VA."
    - • What legislation allows VA to use ketamine in treatment?
    - • Is the San Francisco VA the only VA facility using ketamine?
    - • Are other VA medical centers being encouraged to use ketamine in treatment?
    - • What is the national policy for using ketamine to treat Veterans?
- • "Spravato (esketamine) is FDA approved, but hasn't been rolled out to all VA clinics."
    - • What is the hold up?
    - • What are the benefits of it?

OPIA response:

(b5)

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(b5)

Dennis

Dennis Lahl FAC-P/PM
Office of the Assistant Deputy Under Secretary for Health for Patient Care Services (10P4)
VACO PCS IT/BCAG/ISO Liaison
TMS OPCS DM
ph: *(b)(6)*
fax: *(b)(6)*
Dennis Lahl

From: Hammonds, Michele
Sent: Wednesday, August 21, 2019 11:28 AM
To: VHA 10P Actions <VHA10PActions@va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>
Cc: VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: FW: QUERY: Ketamine-Spravato// VICE News // No Deadline - interview request
Importance: High

10P for Mike and Tom in Pharmacy – This is a time sensitive Rachel Win, Producer/Editor, of Vice News about the controversial drug esketamine (Spravato)

Is the following response still accurate?

(b5)

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(b5)

Deadline: 2pm Today

Michele Hammonds
Office of Communications (10B2B)
(b)(6)

From: Mandreucci, Christina M.
Sent: Wednesday, August 21, 2019 11:12 AM
To: Piork, Steve (b)(6) @va.gov>; Ballesteros, Mark (b)(6) @va.gov>; McConnell, Dillon J. (b)(6) @va.gov>; Cashour, Curtis <(b)(6) @va.gov>; Carter, Susan (b)(6) @va.gov>
Cc: Hutton, James <(b)(6) @va.gov>; Thomas, Tom (b)(6) @va.gov>; Baxter, Jessica (b)(6) @va.gov>; Noller, Randal <(b)(6) @va.gov>; Mcgee, Damian J (b)(6) @va.gov>; Hammonds, Michele <(b)(6) @va.gov>; Screen, Gina (b)(6) @va.gov>
Subject: RE: QUERY: Ketamine-Spravato// VICE News // No Deadline - interview request

VHA, can you confirm?

From: Piork, Steve
Sent: Wednesday, August 21, 2019 9:02 AM
To: Mandreucci, Christina M. (b)(6) @va.gov>; Ballesteros, Mark (b)(6) @va.gov>; McConnell, Dillon J. <(b)(6) @va.gov>; Cashour, Curtis (b)(6) @va.gov>; Carter, Susan (b)(6) @va.gov>
Cc: Hutton, James <(b)(6) @va.gov>; Thomas, Tom (b)(6) @va.gov>; Baxter, Jessica (b)(6) @va.gov>; Noller, Randal (b)(6) @va.gov>; Mcgee, Damian J (b)(6) @va.gov>; Hammonds, Michele <(b)(6) @va.gov>; Screen, Gina (b)(6) @va.gov>
Subject: RE: QUERY: Ketamine-Spravato// VICE News // No Deadline - interview request

I believe so... VHA, please confirm.

Regards,

Steve H. Piork
Office of Public Affairs – New York
U.S. Department of Veterans Affairs
245 W Houston Street
New York, NY 10014
(b)(6) (office)
(b)(6) (cell)

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copying of this e-mail or the information herein by anyone other than the intended recipient is prohibited. If you have received this e-mail in error, please notify by reply e-mail and destroy the original message and all copies.

From: Mandreucci, Christina M. (b)(6) @va.gov>
Date: Wednesday, Aug 21, 2019, 8:54 AM
To: Piork, Steve <(b)(6) @va.gov>, Ballesteros, Mark (b)(6) @va.gov>, McConnell, Dillon J. (b)(6) @va.gov>, Cashour, Curtis (b)(6) @va.gov>, Carter, Susan <(b)(6) @va.gov>
Cc: Hutton, James <(b)(6) @va.gov>, Thomas, Tom <(b)(6) @va.gov>, Baxter, Jessica (b)(6) @va.gov>, Noller, Randal <(b)(6) @va.gov>, Mcgee, Damian J <(b)(6) @va.gov>, Hammonds, Michele <(b)(6) @va.gov>, Screen, Gina (b)(6) @va.gov>
Subject: RE: QUERY: Ketamine-Spravato// VICE News // No Deadline - interview request

Is the following response still accurate?

(b5)

From: Piork, Steve
Sent: Wednesday, August 21, 2019 8:45 AM
To: Ballesteros, Mark <(b)(6) @va.gov>; Mandreucci, Christina M. (b)(6) @va.gov>; McConnell, Dillon J. <(b)(6) @va.gov>; Cashour, Curtis (b)(6) @va.gov>; Carter, Susan (b)(6) @va.gov>
Cc: Hutton, James <(b)(6) @va.gov>; Thomas, Tom (b)(6) @va.gov>; Baxter, Jessica (b)(6) @va.gov>; Noller, Randal (b)(6) @va.gov>; Mcgee, Damian J <(b)(6) @va.gov>; Hammonds, Michele <(b)(6) @va.gov>; Screen, Gina (b)(6) @va.gov>
Subject: RE: QUERY: Ketamine-Spravato// VICE News // No Deadline - interview request

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Good morning.

The queries came from the Connecticut I-Team. I've also included the last follow up response that went out to the reporter.

Can we find out if we started to prescribe this drug in VA yet? If so, when did VA start?

Answer (b5)

How many veterans have been treated with Spravato since the VA started offering it?

Answer: (b5)

Regards,

Steve
NY OPA
o. (b)(6)
m. (b)(6)

Confidentiality Note: This e-mail is intended only for the person to whom it is addressed and may contain information that is privileged, confidential, or otherwise protected from disclosure. Dissemination, distribution, or copying of this e-mail or the information herein by anyone other than the intended recipient is prohibited. If you have received this e-mail in error, please notify by reply e-mail and destroy the original message and all copies.

From: Ballesteros, Mark
Sent: Wednesday, August 21, 2019 7:53 AM
To: Mandreucci, Christina M. (b)(6) @va.gov>; McConnell, Dillon J. (b)(6) @va.gov>; Cashour, Curtis <(b)(6) @va.gov>; Carter, Susan (b)(6) @va.gov>; Piork, Steve (b)(6) @va.gov>
Cc: Hutton, James (b)(6) @va.gov>; Thomas, Tom (b)(6) @va.gov>; Baxter, Jessica (b)(6) @va.gov>; Noller, Randal (b)(6) @va.gov>; Mcgee, Damian J (b)(6) @va.gov>; Hammonds, Michele (b)(6) @va.gov>; Screen, Gina (b)(6) @va.gov>
Subject: RE: QUERY: Ketamine-Spravato// VICE News // No Deadline - interview request

Adding Steve Piork from the NY team as he worked on a Spravato query last month.

I believe this was the approved response:

(b5)

AMERICAN OVERSIGHT



From: Mandreucci, Christina M.
Sent: Tuesday, August 20, 2019 8:31 PM
To: McConnell, Dillon J. (b)(6) @va.gov>; Cashour, Curtis (b)(6) @va.gov>; Carter, Susan (b)(6) @va.gov>
Cc: Hutton, James <(b)(6) @va.gov>; Ballesteros, Mark <(b)(6) @va.gov>; Thomas, Tom (b)(6) @va.gov>; Baxter, Jessica (b)(6) @va.gov>; Noller, Randal (b)(6) @va.gov>; Mcgee, Damian J <(b)(6) @va.gov>; Hammonds, Michele (b)(6) @va.gov>; Screen, Gina (b)(6) @va.gov>
Subject: RE: QUERY: Ketamine-Spravato// VICE News // No Deadline - interview request

Thanks, Dillon.

VHA — what do you recommend?

Sent with BlackBerry Work
(www.blackberry.com)

From: McConnell, Dillon J. (b)(6) @va.gov>
Date: Tuesday, Aug 20, 2019, 8:18 PM
To: Cashour, Curtis (b)(6) @va.gov>, Mandreucci, Christina M. (b)(6) @va.gov>, Carter, Susan (b)(6) @va.gov>

AMERICAN OVERSIGHT

Cc: Hutton, James (b)(6) @va.gov>, Ballesteros, Mark (b)(6) @va.gov>, Thomas, Tom (b)(6) @va.gov>, Baxter, Jessica (b)(6) @va.gov>, Noller, Randal (b)(6) @va.gov>, Mcgee, Damian J (b)(6) @va.gov>
Subject: QUERY: Ketamine-Spravato// VICE News // No Deadline - interview request

Good Evening Curt/Christine,

The San Francisco PAO received the following inquiry from VICE News requesting an interview RE: Ketamine. Reporter is also interested in Spravto and why VA hasn't been prescribing the drug to veterans. Since the request is national in scope from a national outlet, we recommend OMR handle but let us know how you'd like to proceed. Thanks!

QUERY:
Outlet: VICE News, airs weekly on HBO.
Subject: Ketamine-Spravato interview request
Reporter: Rachel Win, Producer/Editor,
Phone: (b)(6)
Email: (b)(6) @vice.com
Deadline: No Deadline
Summary of request: Rachel Win with VICE News is requesting a background interview with Dr. Tobias Marton to discuss the use of ketamine and Spravato to treat depression and PTSD in Veterans at the SFVAMC. However, her questions are about national VA policy.

Questions:

- • "The use of ketamine at VA isn't common. Veterans are paying out of pocket for this type of treatment outside of VA."
    - • What legislation allows VA to use ketamine in treatment?
    - • Is the San Francisco VA the only VA facility using ketamine?
    - • Are other VA medical centers being encouraged to use ketamine in treatment?
    - • What is the national policy for using ketamine to treat Veterans?
- • "Spravato (esketamine) is FDA approved, but hasn't been rolled out to all VA clinics."
    - • What is the hold up?
    - • What are the benefits of it?

Thanks,
Dillon

cid:image002.gif@01D3FF1B.AEBB0B90
Dillon McConnell
Public Affairs Specialist
Los Angeles Regional Office of Public Affairs*
Office of Public and Intergovernmental Affairs (OPIA)

AMERICAN OVERSIGHT

Department of Veterans Affairs
* Region includes: AK, CA, HI, ID, NV, OR, WA
Ph: (b)(6) | Email (b)(6) @va.gov

Sender:	Wiechers, Ilse /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0C7B1428D9E4233A641F125C5B6FC4F-WIECHERS, I (b)(6) @va.gov>
Recipient:	VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>
Sent Date:	2019/08/21 12:20:55
Delivered Date:	2019/08/21 12:20:57

AMERICAN OVERSIGHT

From:	Gavin, Stacy /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4017313DE0A84F8E8CEADE280F77D235-GAVIN, STAC (b)(6) @va.gov>
To:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b)(6) @va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b)(6) @va.gov>; Drexler, Karen MD (Atlanta) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c456a9bf391415bb4bdb9b6f88bdf45-Drexler, Ka (b)(6) @va.gov>
Subject:	FW: News release prenotification: VA to make new nasal spray drug available for treatment-resistant depression
Date:	2019/03/19 14:26:28
Priority:	Normal
Type:	Note

FYI

From: Dudley, Tracy
Sent: Tuesday, March 19, 2019 2:11 PM
To: VHA 10NC5 Action <VHA10NC5Action@va.gov>
Cc: VHA CO 10NC Front Office HSSs <VHACO10NCFOHSSs@va.gov>
Subject: FW: News release prenotification: VA to make new nasal spray drug available for treatment-resistant depression

FYSA – This press release will be going out today at 3 p.m. ET.

Thank You!
Tracy

Tracy L. Dudley
Health System Specialist
ADUSH for Clinical Operations (10NC)
(b)(6) (Direct)
(b)(6) (iPhone)

From: Greilsamer, Alan
Sent: Tuesday, March 19, 2019 2:06 PM
To: VHA 10P Actions <VHA10PActions@va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>; VHA 10N Action <VHA10NAction@va.gov>; VHA 10NC Action <vha10ncaction@va.gov>; Wiechers, Ilse (b)(6) @va.gov>
Cc: VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: FW: News release prenotification: VA to make new nasal spray drug available for treatment-resistant depression

AMERICAN OVERSIGHT

FYSA – This press release will be going out today at 3 p.m. ET.

From: Christian, Tatjana
Sent: Tuesday, March 19, 2019 1:56 PM
Subject: News release prenotification: VA to make new nasal spray drug available for treatment-resistant depression

Good afternoon,

This news release, attached and cut and pasted below, is scheduled to go out at 3 p.m. today, March 19, and will be posted on VA's news releases webpage.

Please make appropriate notifications.

++++++++++++++++++++

FOR IMMEDIATE RELEASE
March 19, 2019

VA to make new nasal spray drug available for treatment-resistant depression

WASHINGTON — Today the U.S. Department of Veterans Affairs (VA) announced its health care providers will now be able to offer the newly approved Spravato naval spray for treatment-resistant depression.

The treatment will be made available to Veterans based on their individual medical needs combined with providers' clinical assessments.

The move follows the March 5 Food and Drug Administration (FDA) approval of Spravato (esketamine) nasal spray. Spravato was approved for use in conjunction with an oral antidepressant for the treatment of treatment-resistant depression in adults.

"We're pleased to be able to expand options for Veterans with depression who have not responded to other treatments," said VA Secretary Robert Wilkie. "It reflects our commitment to seek new ways to provide the best health care available for our nation's Veterans."

Spravato will be available through a restricted distribution system under an FDA-approved Risk Evaluation and Mitigation Strategy (REMS). The purpose of the REMS is to mitigate the risks of serious adverse outcomes and the potential abuse and misuse of Spravato.

AMERICAN OVERSIGHT

VA health care providers will monitor Veterans for serious adverse outcomes, such as sedation and difficulty with attention, judgment and thinking (dissociation), abuse and misuse, worsening of depression and suicidal thoughts and behaviors.

Veterans will self-administer Spravato nasal spray under the direct observation of a health care provider in a certified medical facility, and then must be monitored by a health care provider for at least two hours after receiving their dose. Spravato cannot be dispensed directly to Veterans for use at home.

For additional information on access to Mental Health Support for Veterans, visit VA Mental Health. Veterans in immediate crisis may call the Veterans Crisis Line at 800-273-8255 and press 1, text to 838255 or chat online at Veterans Crisis Line.

###

Sender:	Gavin, Stacy /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4017313DE0A84F8E8CEADE280F77D235-GAVIN, STAC *(b)(6)* @va.gov>
Recipient:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I *(b)(6)* @va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer *(b)(6)* @va.gov>; Drexler, Karen MD (Atlanta) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c456a9bf391415bb4bdb9b6f88bdf45-Drexler, Ka *(b)(6)* @va.gov>
Sent Date:	2019/03/19 14:26:25
Delivered Date:	2019/03/19 14:26:28

AMERICAN OVERSIGHT

From:	Smith, Monica (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=511ea9e77a234375a91a7b34ce23719d-Smith, Moni (b)(6) @va.gov>
To:	Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da (b)(6) @va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M (b)(6) @va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b)(6) @va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>; Law, Cassandra M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f888d507d6c54eb5a92fc44199eb5838-Law, Cassan (b)(6) @va.gov>; Beck, Lucille B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=845480228a8b43e7a5fef5716ded04c2-Beck, Lucil (b)(6) @va.gov>
CC:	VHA 10P4 Communication Group /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4ba2ff9b4604547be7834a71415253c-VHA 10P4 Co <vha10p4comm@va.gov>
Subject:	FW: News release prenotification: VA to make new nasal spray drug available for treatment-resistant depression
Date:	2019/03/19 14:02:43
Priority:	Normal
Type:	Note

Good day, everyone - FYI – this is going out at 3 p.m. today.

From: Christian, Tatjana
Sent: Tuesday, March 19, 2019 1:56 PM
Subject: News release prenotification: VA to make new nasal spray drug available for treatment-resistant depression

Good afternoon,

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Please make appropriate notifications.

++++++++++++++++++++

FOR IMMEDIATE RELEASE

March 19, 2019

VA to make new nasal spray drug available for treatment-resistant depression

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The treatment will be made available to Veterans based on their individual medical needs combined with providers’ clinical assessments.

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The move follows the March 5 Food and Drug Administration (FDA) approval of Spravato (esketamine) nasal spray. Spravato was approved for use in conjunction with an oral antidepressant for the treatment of treatment-resistant depression in adults. “We’re pleased to be able to expand options for Veterans with depression who have not responded to other treatments,” said VA Secretary Robert Wilkie. “It reflects our commitment to seek new ways to provide the best health care available for our nation’s Veterans.”

Spravato will be available through a restricted distribution system under an FDA-approved Risk Evaluation and Mitigation Strategy (REMS). The purpose of the REMS is to mitigate the risks of serious adverse outcomes and the potential abuse and misuse of Spravato.

VA health care providers will monitor Veterans for serious adverse outcomes, such as sedation and difficulty with attention, judgment and thinking (dissociation), abuse and misuse, worsening of depression and suicidal thoughts and behaviors.

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For additional information on access to Mental Health Support for Veterans, visit VA Mental Health. Veterans in immediate crisis may call the Veterans Crisis Line at 800-273-8255 and press 1, text to 838255 or chat online at Veterans Crisis Line.

###

Sender:	Smith, Monica (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=511ea9e77a234375a91a7b34ce23719d-Smith, Moni (b)(6) @va.gov>
Recipient:	Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da (b)(6) @va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M (b)(6) @va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b)(6) @va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>; Law, Cassandra M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f888d507d6c54eb5a92fc44199eb5838-Law, Cassan (b)(6) @va.gov>; Beck, Lucille B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=845480228a8b43e7a5fef5716ded04c2-Beck, Lucil (b)(6) @va.gov>; VHA 10P4 Communication Group /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4ba2ff9b4604547be7834a71415253c-VHA 10P4 Co <vha10p4comm@va.gov>
Sent Date:	2019/03/19 14:02:41
Delivered Date:	2019/03/19 14:02:43

AMERICAN OVERSIGHT

From:	Wiechers, Ilse /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0C7B1428D9E4233A641F125C5B6FC4F-WIECHERS, I (b)(6) @va.gov>
To:	Smith, Clifford A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b729882079394f37af66f66722f99400-Smith, Clif (b)(6) @va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da (b)(6) @va.gov>
CC:	McGuire, Marsden H. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29e9d648c29f4885828c10446fdd7379-McGuire, Ma (b)(6) @va.gov>; Pomerantz, Andrew /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29a9288df9a34e84bddfd00cde79f11b-Pomerantz, (b)(6) @va.gov>
Subject:	FW: need input on language for national consult for community care TRD referral (ECT/rTMS/ketamine/Spravato)
Date:	2019/08/22 15:30:09
Priority:	Normal
Type:	Note

Dave &Cliff –

(b5)

Thanks,
Ilse

From: Wiechers, Ilse
Sent: Thursday, August 22, 2019 12:26 PM
To: McGuire, Marsden H. (b)(6) @va.gov>; Katz, Ira R. (b)(6) @va.gov>; Pomerantz, Andrew (b)(6) @va.gov>; Drexler, Karen MD (Atlanta) (b)(6) @va.gov>; Fuller, Matthew A. (PBM) (b)(6) @va.gov>; Cunningham, Fran (b)(6) @va.gov>; Czekanski, Elizabeth R (b)(6) @va.gov>; Myrick, Donald L. (Hugh) (b)(6) @va.gov>; Krystal, John (b)(6) @va.gov>; Shiroma, Paulo R. (b)(6) @va.gov>; Yoon, Gihyun (b)(6) @va.gov>; Mohamed, Somaia (b)(6) @va.gov>; Ranganathan, Mohini (b)(6) @va.gov>; Mathew, Sanjay (HOU) (b)(6) @va.gov>; Wells, Daina L. (b)(6) @va.gov>; 'Paul E. Holtzheimer' (b)(6) @hitchcock.org>; Hauser, Peter (b)(6) @va.gov>; Yesavage, Jerome (b)(6) @va.gov>; 'Jerome A Yesavage' (b)(6) @stanford.edu>; Martis, Brian (b)(6) @va.gov>
Cc: Zacher, Jennifer L. (PBM) (b)(6) @va.gov>
Subject: need input on language for national consult for community care TRD referral (ECT/rTMS/ketamine/Spravato)

AMERICAN OVERSIGHT

Hi everyone –

I am working on creation of a national consult order that would facilitate referral to care in the community for our newly developed Treatment Resistant Depression (TRD) Standard Episode of Care (SEOC). The TRD SEOC includes language that provides 6 months of care related to TRD and has been designed to cover ECT, rTMS, and "medications administered in a healthcare clinical setting" – i.e. IV ketamine and Spravato. This will allow us to ensure tracking and proper referral to community providers who actually have the ability to provide the desired treatment.

I would greatly appreciate your input on the language for this consult by next Wednesday, August 28th. Take a look at the draft language below(b5)

(b5)

Happy to set up a call to discuss briefly with individuals or a larger group, as people are interested, please just let me know.

Once we finalize language, I will work with the Community Care team to ensure we get this deployed nationally. Updates on that process to follow.

Thanks,
Ilse



AMERICAN OVERSIGHT

Other questions???

***

Ilse R. Wiechers, MD, MPP, MHS
National Director, Psychotropic Drug Safety Initiative (PDSI)
National Lead, Esketamine Clinical Implementation
Associate Director, Northeast Program Evaluation Center
Office of Mental Health and Suicide Prevention (10NC5), Department of Veterans Affairs
Assistant Clinical Professor of Psychiatry, Yale University School of Medicine
cell (b)(6)
email (b)(6) @va.gov | (b)(6)

Sender:	Wiechers, Ilse /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0C7B1428D9E4233A641F125C5B6FC4F-WIECHERS, I (b)(6) @va.gov>
Recipient:	Smith, Clifford A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b729882079394f37af66f66722f99400-Smith, Clif (b)(6) @va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da (b)(6) @va.gov>; McGuire, Marsden H. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29e9d648c29f4885828c10446fdd7379-McGuire, Ma (b)(6) @va.gov>; Pomerantz, Andrew /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29a9288df9a34e84bddfd00cde79f11b-Pomerantz, (b)(6) @va.gov>
Sent Date:	2019/08/22 15:30:08
Delivered Date:	2019/08/22 15:30:09

AMERICAN OVERSIGHT

To:	Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M (b)(6) @va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b)(6) @va.gov>; Boyd, Teresa D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6886a7d555a43e0bee23c1e40e1c234-Boyd, Teres (b)(6) @va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da (b)(6) @va.gov>
Subject:	FW: Nasal spray depression drug may be riskier than first thought
Date:	2019/06/12 09:44:56
Priority:	Normal
Type:	Note

FYI....

The VISN 1 Pharmacist Executive sent an excerpt from an NBC article on Spravato.

From: Emmendorfer, Thomas (PBM)
Sent: Tuesday, June 11, 2019 4:31 PM
To: Valentino, Michael (VACO) (b)(6) @va.gov>; Narayana, Sampath (VISN1) (b)(6) @va.gov>
Cc: Zacher, Jennifer L. (PBM) (b)(6) @va.gov>; Fuller, Matthew A. (PBM) (b)(6) @va.gov>
Subject: RE: Nasal spray depression drug may be riskier than first thought

I google Sam's title and found the article. Published 7 hours ago.

https://www.nbcnews.com/health/health-news/caution-urged-over-use-fast-acting-version-ketamine-depression-n1016176

From: Valentino, Michael (VACO)
Sent: Tuesday, June 11, 2019 4:23 PM
To: Narayana, Sampath (VISN1) (b)(6) @va.gov>
Cc: Emmendorfer, Thomas (PBM) (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) (b)(6) @va.gov>; Fuller, Matthew A. (PBM) (b)(6) @va.gov>
Subject: RE: Nasal spray depression drug may be riskier than first thought

Hi Sam,

Was this a published article?

AMERICAN OVERSIGHT

Sent with BlackBerry Work
(www.blackberry.com)

From: Narayana, Sampath (VISN1) (b)(6) @va.gov>
Date: Tuesday, Jun 11, 2019, 3:29 PM
To: VHAPBM VPE Formulary Committee <VPEFormularyCommittee@va.gov>
Subject: RE: Nasal spray depression drug may be riskier than first thought

From: Narayana, Sampath (VISN1)
Sent: Tuesday, June 11, 2019 3:27 PM
To: VISN 1 Chiefs of Pharmacy <PharChiefs@med.va.gov>
Subject: Nasal spray depression drug may be riskier than first thought

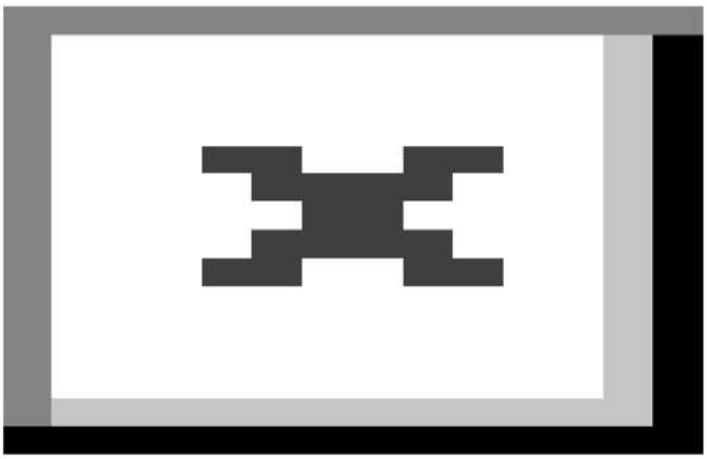
Esketamine's trajectory to approval shows — step by step — how drugmakers can take advantage of shortcuts in the FDA process with the agency's blessing and maneuver through safety and efficacy reviews to bring a lucrative drug to market.

Step 1: In late 2013, Janssen got the FDA to designate esketamine a "breakthrough therapy" because it showed the potential to reverse depression rapidly — a holy grail for suicidal patients, such as those in an emergency room. That potential was based on a two-day study during which 30 patients were given esketamine intravenously. "Breakthrough therapy" status puts drugs on a fast track to approval, with more frequent input from the FDA.

Step 2: But discussions between regulators and drug manufacturers can affect the amount and quality of evidence required by the agency. In the case of Spravato, they involved questions like, how many drugs must fail before a patient's depression is considered intractable or "treatment-resistant"? And how many successful clinical trials are necessary for FDA approval?

Step 3: Any prior agreements can leave the FDA's expert advisory committees hamstrung in reaching a verdict. Fiedorowicz abstained on Spravato because, though he considered Janssen's study design flawed, the FDA had approved it.

AMERICAN OVERSIGHT



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Sent Date:	2019/06/12 09:46:24
Delivered Date:	2019/06/12 09:44:56
Message Flags:	Unread Unsent

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From:	Neff, Melissa VHAV10 /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2531B80E4493471AA43935843C7EFC6C-NEFF, MELIS (b)(6) @va.gov>
To:	VHAPBM VPE Formulary Committee /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fcba1f4b52e048838d3053091f54eb4e-VHAPBH VPE <VPEFormularyCommttee@va.gov>
Subject:	FW: Memorandum: Certification with SPRAVATO™ Risk Evaluation and Mitigation Strategy (REMS) from Office of the DUSHOM
Date:	2019/03/18 17:11:41
Priority:	Normal
Type:	Note

Got this thru the back door.
M

Melissa G Neff PharmD 6 σ BB

VISN 10 Pharmacy Executive
Serving Indiana, Michigan, and Ohio
11500 Northlake Drive, Suite 200
Cincinnati, OH 45249

From: Office of the DUSHOM Communications
Sent: Monday, March 18, 2019 2:15 PM
To: VHA VISN Directors <VHAVISNDirectors@va.gov>; VHACLE BVAC Group <VHACLEBVACGroup@va.gov>
Cc: VHA VISN Admin Reps <VHAVISNAdminReps@va.gov>; VHA 10NC Action <vha10ncaction@va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>; Wiechers, Ilse <(b)(6) @va.gov>; VHA CO 10N Support Staff <VHACO10NSS@va.gov>; McCarthy, Brian (b)(6) @va.gov>
Subject: Memorandum: Certification with SPRAVATO™ Risk Evaluation and Mitigation Strategy (REMS)

Good Afternoon,

Please see the attached memorandum "Certification with SPRAVATO™ Risk Evaluation and Mitigation Strategy (REMS)."

1. The purpose of this memorandum and its attachments is to outline the procedures for the use of Spravato® (eskatamine) nasal spray which was approved by the Food and Drug Administration (FDA) on March 5, 2019, to be used in conjunction with an oral antidepressant, for the treatment of depression in adults who have tried other antidepressant medicines but have not benefited from them (see Attachment A for Esketamine Frequently Asked Questions).

2. Because of the risk of serious adverse outcomes resulting from sedation and dissociation caused by Spravato® administration, and the potential for abuse and misuse of the drug, it is only available through a restricted distribution system, under an FDA approved Risk Evaluation and Mitigation Strategy (REMS). Please

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see and follow instructions in Attachment B for REMS Healthcare Setting Certification Guidance.

3. All medical centers must become a Spravato® REMS certified Healthcare Setting and certified Pharmacy. *Within 30 days of this memorandum*, facilities should report completion of REMS Healthcare Setting certification to their VISN Chief Mental Health Officer, who should then report VISN-wide REMS certification by email to Dr. Ilse Wiechers at(b) (6) @va.gov.

4. There are resource requirements that facilities must plan to accommodate. Spravato® is intended for patient self-administration under the direct observation of a healthcare provider, and patients are required to be monitored by a healthcare provider for at least 2 hours after Spravato® administration. Spravato® must never be dispensed directly to a patient for home use.

5. • No special privileges are required to prescribe Spravato®.

6. Once educational materials from the manufacturer of Spravato® are made available to VA to review, the review and use of those materials will be consistent with VHA Directive, 1108.10, Promotion of Drugs and Drug-Related Supplies By Pharmaceutical Company Representatives (PCR) located at: https://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=6435.

7. Please contact Ilse Wiechers, MD, Office of Mental Health and Suicide Prevention at *(b)(6)* @va.gov with any questions related to this request.

Renee Oshinski

Attachments

Sender:	Neff, Melissa VHAV10 /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2531B80E4493471AA43935843C7EFC6C-NEFF, MELIS *(b)(6)* @va.gov>
Recipient:	VHAPBM VPE Formulary Committee /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fcba1f4b52e048838d3053091f54eb4e-VHAPBH VPE <VPEFormularyCommttee@va.gov>
Sent Date:	2019/03/18 17:11:38
Delivered Date:	2019/03/18 17:11:41

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From:	Carroll, David (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=95E14EBD3B6745C8952A823B04DABFF5-CARROLL, DA (b)(6) @va.gov>
To:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b)(6) @va.gov>; VHA 10P4P Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8dc3dab451414f59b9797e8ed199c1e8-VHA 10P4P A <vha10P4Paction@va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M (b)(6) @va.gov>; Smith, Monica (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=511ea9e77a234375a91a7b34ce23719d-Smith, Moni (b)(6) @va.gov>
CC:	VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>
Subject:	FW: Memorandum: Certification with SPRAVATO™ Risk Evaluation and Mitigation Strategy (REMS)
Date:	2019/03/18 14:35:10
Priority:	Normal
Type:	Note

FYI – the memo was distributed by 10N

From: Office of the DUSHOM Communications
Sent: Monday, March 18, 2019 2:15 PM
To: VHA VISN Directors <VHAVISNDirectors@va.gov>; VHACLE BVAC Group <VHACLEBVACGroup@va.gov>
Cc: VHA VISN Admin Reps <VHAVISNAdminReps@va.gov>; VHA 10NC Action <vha10ncaction@va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>; Wiechers, Ilse (b)(6) @va.gov>; VHA CO 10N Support Staff <VHACO10NSS@va.gov>; McCarthy, Brian (b)(6) @va.gov>
Subject: Memorandum: Certification with SPRAVATO™ Risk Evaluation and Mitigation Strategy (REMS)

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misuse of the drug, it is only available through a restricted distribution system, under an FDA approved Risk Evaluation and Mitigation Strategy (REMS). Please see and follow instructions in Attachment B for REMS Healthcare Setting Certification Guidance.

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7. Please contact Ilse Wiechers, MD, Office of Mental Health and Suicide Prevention a(b) (6) @va.gov with any questions related to this request.

Renee Oshinski

Attachments

Sender:	Carroll, David (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=95E14EBD3B6745C8952A823B04DABFF5-CARROLL, DA (b)(6) @va.gov>
Recipient:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b)(6) @va.gov>; VHA 10P4P Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8dc3dab451414f59b9797e8ed199c1e8-VHA 10P4P A <vha10P4Paction@va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M (b)(6) @va.gov>; Smith, Monica (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=511ea9e77a234375a91a7b34ce23719d-Smith, Moni

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	(b)(6) @va.gov>; VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>
Sent Date:	2019/03/18 14:35:06
Delivered Date:	2019/03/18 14:35:10

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From:	Dudley, Tracy /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2BEF1C88D64447BC9087572C951D0CB1-DUDLEY, TRA (b)(6) @va.gov>
To:	Cunningham, Kristin /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=751e0c41ec7842bf9f125e521c2210d0-Cunningham, (b)(6) @va.gov>; RICKS, TARA /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=78f7ce01f841454d809345d1c1d98483-RICKS, TARA (b)(6) @va.gov>
CC:	Diamond, Sue OSI /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dbe74b578de4d2b83334f00cc6bed3c-Diamond, Su (b)(6) @va.gov>; Pedene, Paula L. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0915253a9464acd9130816941bc7f5b-Pedene, Pau (b)(6) @va.gov>; Greilsamer, Alan /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fc02807af08443fbb5c68c590d58fa4b-Greilsamer, (b)(6) @va.gov>; MISSION ACT Action Items /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f18bef245b8744b9a8d49d03a22c192d-MISSION ACT <MISSIONACTActionItems@va.gov>; VHA 10NC Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aeebc70340b3476a87b15fbe600f1888-VHA 10NC Ac <vha10ncaction@va.gov>; VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>; VHA MISSION Act Core Team /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3edfe913aa924e36a5c97be6976f7304-VHA MISSION <VHAMISSIONActCoreTeam@va.gov>
Subject:	FW: Leadership Requesting: Talking Points and Data Need for VA Mental Health Clinicians on Stellate Ganglion Block Procedure
Date:	2019/06/20 15:21:33
Priority:	Normal
Type:	Note

Good Afternoon

On behalf of 10NC, Dr Sherrie Schuldheis clears the response from 10NC5.

Thank You!
Tracy

Tracy L. Dudley

Health System Specialist
ADUSH for Clinical Operations (10NC)
(b)(6) (Direct)
(b)(6) (iPhone)

From: Schuldheis, Sherrie L, Ph.D
Sent: Thursday, June 20, 2019 3:16 PM

AMERICAN OVERSIGHT

To: Dudley, Tracy (b)(6) @va.gov>; VHA 10NC Clearance <VHA10NCClearance2@va.gov>
Subject: RE: Leadership Requesting: Talking Points and Data Need for VA Mental Health Clinicians on Stellate Ganglion Block Procedure

10NC clears

Sherrie Schuldheis, PhD, RN, CENP
Special Assistant, ADUSH Clinical Operations
VHA 10NC
810 Vermont NW
Washington, DC 20420
202.345.1579 (cell)
(b)(6) @va.gov

From: Gavin, Stacy
Sent: Thursday, June 20, 2019 2:57 PM
To: VHA CO 10NC Front Office HSSs <VHACO10NCFOHSSs@va.gov>
Cc: VHA 10NC5 Action <VHA10NC5Action@va.gov>; Schnurr, Paula P. (b)(6) @va.gov>; Holtzheimer, Paul (b)(6) @va.gov>
Subject: FW: Leadership Requesting: Talking Points and Data Need for VA Mental Health Clinicians on Stellate Ganglion Block Procedure

Good afternoon,

With apologies for the delay, please see the talking points below:

10NC5 Response:



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From: RICKS, TARA
Sent: Thursday, June 20, 2019 10:21 AM
To: Cunningham, Kristin <(b)(6) @va.gov>; Diamond, Sue OSI (b)(6) @va.gov>; Poff, Susan (b)(6) @va.gov>; Pedene, Paula L. (b)(6) @va.gov>; Burden, Rachael (b)(6) @va.gov>; VACO 80E1 <(b)(6) @mail.va.gov>; Greilsamer, Alan (b)(6) @va.gov>; Small, Stephanie T. (b)(6) @va.gov>; Eason, William J. <(b)(6) @va.gov>; Ackerman, William <(b)(6) @va.gov>; Andringa, Elizabeth D. (b)(6) @va.gov>; Baum, Robert <(b)(6) @va.gov>; Bennett, Jennifer (Jenna) <(b)(6) @va.gov>; Boyd, Teresa D. (b)(6) @va.gov>; Bucsko, Daniel <(b)(6) @va.gov>; Chesney, Colin <(b)(6) @va.gov>; Davidson, Benjamin C. (ERPi) <(b)(6) @va.gov>; Diamond, Sue OSI <(b)(6) @va.gov>; Goldsberry, Wilmya <(b)(6) @va.gov>; Gore, Ohm J. (Booz Allen Hamilton) (b)(6) @va.gov>; Gramlick, Debbie (b)(6) @va.gov>; Greenstone, Clinton (b)(6) @va.gov>; Hayes, Terrence (b)(6) @va.gov>; Heard, Maureen (b)(6) @va.gov>; Jaastad, Derrick (b)(6) @va.gov>; Jenkins, Matthew A <(b)(6) @va.gov>; Kelley, Kimberly (b)(6) @va.gov>; MacDonald, Jennifer E. (Physician) <(b)(6) @va.gov>; Oshinski, Renee (b)(6) @va.gov>; Paige, Paula (b)(6) @va.gov>; Roberts, Kirsten L. (ERPI) <(b)(6) @va.gov>; Scanlon, Aimee B. (b)(6) @va.gov>; Sommers, Evelyn <(b)(6) @va.gov>; Subbu, Sankalpa <(b)(6) @va.gov>; VHA 10D Action <VHA10DAction@va.gov>; VHA 10N Action <VHA10NAction@va.gov>; VHA 10NG Action

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<VHA10NGAction@va.gov>; VHA Healthcare Operations Center <VHAHOC@va.gov>; Warner, Debra L. (b)(6) @va.gov>; White, Crystal M. <(b)(6) @va.gov>; Williams, Joseph A (OSI) (b)(6) @va.gov>; Smith, Clifford A. (b)(6) @va.gov>; Carroll, David (VACO) (b)(6) @va.gov>; Daniels, Lindsay (b)(6) @va.gov>; Gavin, Stacy (b)(6) @va.gov>; McGuire, Marsden H. <(b)(6) @va.gov>; Miller, Matthew (VCL Director) (b)(6) @va.gov>; Pollack, Stacey <(b)(6) @va.gov>; Pomerantz, Andrew (b)(6) @va.gov>; Smith, Clifford A. <(b)(6) @va.gov>; Strmiska, Jon G. (b)(6) @va.gov>
Cc: Ackerman, William (b)(6) @va.gov>; Andringa, Elizabeth D. (b)(6) @va.gov>; Bagchi, Kaushiki M. (APTIVE Resources LLC) <(b)(6) @va.gov>; Boccia, Alexis L (b)(6) @va.gov>; Galagaza, Geraldine (b)(6) @va.gov>; Heard, Maureen (b)(6) @va.gov>; Kelley, Kimberly (b)(6) @va.gov>; Parker, Ginger (b)(6) @va.gov>; Pedene, Paula L. <(b)(6) @va.gov>; Screen, Gina (b)(6) @va.gov>; Seekins, DeAnne <(b)(6) @va.gov>; Hutchins, Anne C SAMVAMC (b)(6) @va.gov>; Buyck, David W SAMVAMC <(b)(6) @va.gov>
Subject: RE: Leadership Requesting: Talking Points and Data Need for VA Mental Health Clinicians on Stellate Ganglion Block Procedure

Thank you Ms. Cunningham. We will await guidance.

Adding my ND, COS, and Mental Health Chief since the visibility of this request is moving beyond the public affairs arena.

From: Cunningham, Kristin
Sent: Thursday, June 20, 2019 10:17 AM
To: RICKS, TARA (b)(6) @va.gov>; Diamond, Sue OSI <(b)(6) @va.gov>; Poff, Susan (b)(6) @va.gov>; Pedene, Paula L. (b)(6) @va.gov>; Burden, Rachael (b)(6) @va.gov>; VACO 80E1 <vaco80e1@mail.va.gov>; Greilsamer, Alan (b)(6) @va.gov>; Small, Stephanie T. <(b)(6) @va.gov>; Eason, William J. (b)(6) @va.gov>; VHA MISSION Act Core Team <VHAMISSIONActCoreTeam@va.gov>; Smith, Clifford A. <(b)(6) @va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>
Cc: Ackerman, William (b)(6) @va.gov>; Andringa, Elizabeth D. (b)(6) @va.gov>; Bagchi, Kaushiki M. (APTIVE Resources LLC) <(b)(6) @va.gov>; Boccia, Alexis L <(b)(6) @va.gov>; Galagaza, Geraldine <(b)(6) @va.gov>; Heard, Maureen <(b)(6) @va.gov>; Kelley, Kimberly <(b)(6) @va.gov>; Parker, Ginger (b)(6) @va.gov>; Pedene, Paula L. (b)(6) @va.gov>; Screen, Gina (b)(6) @va.gov>; Cunningham, Kristin (b)(6) @va.gov>
Subject: RE: Leadership Requesting: Talking Points and Data Need for VA Mental Health Clinicians on Stellate Ganglion Block Procedure

Adding Dr Smith and 10NC5 action. They are working on guidance for the SGB.

Kristin J. Cunningham, PMP
Executive Officer to the Deputy Under Secretary
for Health for Community Care
Office of Community Care

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P – (b)(6)
C – (b)(6)
Email: (b)(6) @va.gov

From: RICKS, TARA
Sent: Thursday, June 20, 2019 10:15 AM
To: Diamond, Sue OSI (b)(6) @va.gov>; Poff, Susan (b)(6) @va.gov>; Pedene, Paula L. (b)(6) @va.gov>; Burden, Rachael (b)(6) @va.gov>; VACO 80E1 <vaco80e1@mail.va.gov>; Greilsamer, Alan (b)(6) @va.gov>; Small, Stephanie T. (b)(6) @va.gov>; Eason, William J. (b)(6) @va.gov>; VHA MISSION Act Core Team <VHAMISSIONActCoreTeam@va.gov>
Cc: Ackerman, William (b)(6) @va.gov>; Andringa, Elizabeth D. (b)(6) @va.gov>; Bagchi, Kaushiki M. (APTIVE Resources LLC) (b)(6) @va.gov>; Boccia, Alexis L (b)(6) @va.gov>; Galagaza, Geraldine (b)(6) @va.gov>; Heard, Maureen (b)(6) @va.gov>; Kelley, Kimberly (b)(6) @va.gov>; Parker, Ginger (b)(6) @va.gov>; Pedene, Paula L. (b)(6) @va.gov>; Screen, Gina (b)(6) @va.gov>
Subject: RE: Leadership Requesting: Talking Points and Data Need for VA Mental Health Clinicians on Stellate Ganglion Block Procedure

Thank you Ms. Diamond.

From: Diamond, Sue OSI
Sent: Thursday, June 20, 2019 10:07 AM
To: RICKS, TARA (b)(6) @va.gov>; Poff, Susan (b)(6) @va.gov>; Pedene, Paula L. (b)(6) @va.gov>; Burden, Rachael (b)(6) @va.gov>; VACO 80E1 <vaco80e1@mail.va.gov>; Greilsamer, Alan (b)(6) @va.gov>; Small, Stephanie T. (b)(6) @va.gov>; Eason, William J. (b)(6) @va.gov>; VHA MISSION Act Core Team <VHAMISSIONActCoreTeam@va.gov>
Cc: Ackerman, William (b)(6) @va.gov>; Andringa, Elizabeth D. (b)(6) @va.gov>; Bagchi, Kaushiki M. (APTIVE Resources LLC) (b)(6) @va.gov>; Boccia, Alexis L (b)(6) @va.gov>; Galagaza, Geraldine (b)(6) @va.gov>; Heard, Maureen (b)(6) @va.gov>; Kelley, Kimberly (b)(6) @va.gov>; Parker, Ginger (b)(6) @va.gov>; Pedene, Paula L. (b)(6) @va.gov>; Screen, Gina (b)(6) @va.gov>
Subject: RE: Leadership Requesting: Talking Points and Data Need for VA Mental Health Clinicians on Stellate Ganglion Block Procedure

Adding the MISSION Act Core Team to assist with getting you a response.

From: RICKS, TARA
Sent: Thursday, June 20, 2019 10:01 AM
To: Poff, Susan (b)(6) @va.gov>; Pedene, Paula L. (b)(6) @va.gov>; Burden, Rachael (b)(6) @va.gov>; VACO 80E1 <vaco80e1@mail.va.gov>; Greilsamer, Alan (b)(6) @va.gov>; Small, Stephanie T. (b)(6) @va.gov>; Eason, William J. (b)(6) @va.gov>
Cc: Ackerman, William (b)(6) @va.gov>; Andringa, Elizabeth D.

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(b)(6) @va.gov>; Bagchi, Kaushiki M. (APTIVE Resources LLC) <(b)(6) @va.gov>; Boccia, Alexis L <(b)(6) @va.gov>; Diamond, Sue OSI <(b)(6) @va.gov>; Galagaza, Geraldine <(b)(6) @va.gov>; Heard, Maureen <(b)(6) @va.gov>; Kelley, Kimberly (b)(6) @va.gov>; Parker, Ginger <(b)(6) @va.gov>; Pedene, Paula L. (b)(6) @va.gov>; Screen, Gina (b)(6) @va.gov>

Subject: Leadership Requesting: Talking Points and Data Need for VA Mental Health Clinicians on Stellate Ganglion Block Procedure

Importance: High

Good morning everyone,

I wasn't sure who would be the best POC for this request – so I am emailing everyone.

VISN 6 is experiencing a significant up-tick in service request from Veterans regarding the stellate ganglion block procedure, to include request to use 'Mission Act resources' if the facility doesn't offer the procedure.

Our VISN COS and VISN Mental Health Chief understand that a lot of these request are being driven by the 60 minutes segment, and that this story offered our Veterans and family members hope that relief is on the way for their persisting nightmares, anger, and fear (PTSD). Veterans are now actively calling their mental health doctors wanting this procedure within our region – and our doctors don't know what to say or how to move forward with these requests. Our clinicians are wanting specific guidance **before** Veterans go out on their own and get this procedure that VA considers 'experimental.'

In addition to SGB, Leadership would also like talking points for Spravato after the results of today's national formulary meeting. The focus of these talking points would be for our mental health doctors and what they should tell patients.

Links to the story's for quick reference.

1. • The stellate ganglion block procedure LINK
2. • Spravato (Ketamine-like drug) LINK

Just to reiterate this is not a request for media talking points. This is a request for talking points for our mental health teams to communicate with patients. Leadership is concerned if we do not get ahead of this it will ulitmately turn into an access or care issue especially for the health and well-being of our Veterans receiving mental health and suicide prevention services.

Thank you in advance.

Tara Ricks-Edger
Director of Communications
VISN 6 – U.S. Department of Veterans Affairs

"It is not the critic who counts; not the man who points out how the strong man stumbles, or where the doer of deeds could have done them better. The credit belongs to the man who is actually in the arena...who strives valiantly; who errs, who comes short again and again, because there is no effort without error and shortcoming; but who does actually strive to do the deeds; who knows great enthusiasms, the great devotions; who spends himself in a worthy cause; who at the best knows in the end the triumph of high achievement, and who at the worst, if he

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fails, at least fails while daring greatly, so that his place shall never be with those cold and timid souls who neither know victory nor defeat." - Theodore Roosevelt

Sender:	Dudley, Tracy /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2BEF1C88D64447BC9087572C951D0CB1-DUDLEY, TRA (b)(6) @va.gov>
Recipient:	Cunningham, Kristin /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=751e0c41ec7842bf9f125e521c2210d0-Cunningham, (b)(6) @va.gov>; RICKS, TARA /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=78f7ce01f841454d809345d1c1d98483-RICKS, TARA (b)(6) @va.gov>; Diamond, Sue OSI /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dbe74b578de4d2b83334f00cc6bed3c-Diamond, Su (b)(6) @va.gov>; Pedene, Paula L. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0915253a9464acd9130816941bc7f5b-Pedene, Pau (b)(6) @va.gov>; Greilsamer, Alan /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fc02807af08443fbb5c68c590d58fa4b-Greilsamer, (b)(6) @va.gov>; MISSION ACT Action Items /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f18bef245b8744b9a8d49d03a22c192d-MISSION ACT <MISSIONACTActionItems@va.gov>; VHA 10NC Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aeebc70340b3476a87b15fbe600f1888-VHA 10NC Ac <vha10ncaction@va.gov>; VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>; VHA MISSION Act Core Team /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3edfe913aa924e36a5c97be6976f7304-VHA MISSION <VHAMISSIONActCoreTeam@va.gov>
Sent Date:	2019/06/20 15:21:30
Delivered Date:	2019/06/20 15:21:33

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From:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>
To:	Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen (b)(6) @va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>
Subject:	FW: J&J updates
Date:	2019/03/12 16:13:33
Priority:	Normal
Type:	Note

Just finished our 3pm call with Maria and Ilse. Ilse is going to send out an e-mail summarizing her next steps with estimated timelines…but here are the main bullet points that I have from the call:

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From: Streit, Phillip P
Sent: Tuesday, March 12, 2019 11:18 AM
To: Zacher, Jennifer L. (PBM) <(b)(6) @va.gov>; Emmendorfer, Thomas (PBM) <(b)(6) @va.gov>
Subject: RE: J&J updates

Tom,
The pharmacy enrollment form is attached. I also included the ordering summary. I didn’t mention in the summary that the pharmacy enrollment is not operational on the website as this must be pending as they have the link on their site https://www.spravatorems.com/pharmacies. Either way, the printed form can be downloaded there as well.
Phillip

AMERICAN OVERSIGHT

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Sent: Tuesday, March 12, 2019 8:03 AM
To: Emmendorfer, Thomas (PBM) <(b)(6) @va.gov>
Cc: Streit, Phillip P <(b)(6) @va.gov>
Subject: RE: J&J updates

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JZ

From: Emmendorfer, Thomas (PBM)
Sent: Tuesday, March 12, 2019 10:01 AM
To: Zacher, Jennifer L. (PBM) &lt(b)(6) @va.gov>
Subject: J&J updates

Hi Jenn,

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Tom

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Delivered Date:	2019/03/12 16:13:33

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AMERICAN OVERSIGHT

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Sent Date:	2019/03/12 16:13:31
Delivered Date:	2019/03/12 16:13:33
Message Flags:	Unread

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SPRAVATO™ REMS
Pharmacy Enrollment Form

SPRAVATO™ is only available through the SPRAVATO™ REMS (Risk Evaluation and Mitigation Strategy). Only Pharmacies and Healthcare Settings that are certified in the SPRAVATO™ REMS can receive SPRAVATO™.

To become a SPRAVATO™ REMS certified Pharmacy, enroll by following these 3 steps:

STEP 1: REVIEW	STEP 2: COMPLETE AND SIGN	STEP 3: SUBMIT
➤ Designate an Authorized Representative ➤ Authorized Representative review the following: • Prescribing Information • Fact Sheet • Medication Guide • Instruction for Use	➤ The Authorized Representative must complete the *Pharmacy Enrollment Form* ➤ If the Authorized Representative changes, the new Authorized Representative must complete and sign a new *Pharmacy Enrollment Form*	➤ Submit the *Pharmacy Enrollment Form* either: • Online at www.SPRAVATOrems.com. or • Print and fax completed form to 1-877-778-0091

** Indicates Required Field*

Pharmacy Information

Name of Pharmacy*:		
Pharmacy Address 1*:	Address Line 2:	
City*:	State*:	ZIP*:
DEA License Number* (On file with distributor account):		DEA Expiration Date* (MM/DD/YYYY):

Pharmacy Type*:(select all that apply) ☐ Clinic ☐ Hospital ☐ Inpatient ☐ Long-term care ☐ Mental Health Facility ☐ Outpatient ☐ Specialty ☐ Other _____

Your pharmacy information will be shared with Janssen's patient support and distribution partners, to allow your pharmacy to purchase product.

Pharmacy Shipping Address, if different than above

Pharmacy Address: (address must match the DEA address associated with your Pharmacy's DEA number)		Address Line 2:
City:	State:	ZIP:

Pharmacy Authorized Representative Information

First Name*:		Last Name*:	Title*:
Telephone Number*:	EXT:	Fax*:	Email Address*:

Alternate Contact

First Name:		Last Name:
Phone Number:	EXT:	Fax:

Pharmacy Authorized Representative Agreement

I am the Authorized Representative designated by my pharmacy to oversee implementation and coordinate the activities of the SPRAVATO™ REMS. By signing this form, I agree, on behalf of myself and pharmacy, to comply with the following requirements:

I will:

- Enroll in the SPRAVATO™ REMS by completing this *Pharmacy Enrollment Form* and submitting this form to the SPRAVATO™ REMS.
- Train all relevant staff involved in dispensing SPRAVATO™ on the following:
  - SPRAVATO™ can only be dispensed to a certified healthcare setting.
  - SPRAVATO™ must never be dispensed directly to a patient for home use.
- Establish processes and procedures to verify that a healthcare setting is certified before dispensing SPRAVATO™
- Before dispensing SPRAVATO™, verify the healthcare setting is certified using the established processes and procedures.
- Not distribute, transfer, loan or sell SPRAVATO™ except to certified dispensers.
- Maintain records documenting staff's completion of training.
- Maintain records that all REMS processes and procedures are in place and are being followed.
- Maintain records of all shipments of SPRAVATO™ received and dispensing information including patient name, dose, number of devices and date dispensed.
- Comply with audits carried out by Janssen Pharmaceuticals, Inc. or third party acting on behalf of Janssen Pharmaceuticals, Inc. to ensure that all processes and procedures are in place and are being followed.

Authorized Representative Signature*:	**Date*:**

Healthcare providers should report suspected adverse events or product quality complaints associated with SPRAVATO™ to Janssen at 1-800-JANSSEN (1-800-526-7736) or the FDA at 1-800-FDA-1088 or online at www.fda.gov/medwatch.

Phone: 1-855-382-6022 **www.SPRAVATOrems.com** **Fax: 1-877-778-0091**

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© Janssen Pharmaceuticals, Inc. 2019 03/19 1

To:	Zacher, Jennifer L. (PBM) /o=VA/ou=VISN 12/cn=RECIPIENTS/cn=VHANCHZACHEJ (b)(6) @va.gov>; Valentino, Michael (VACO) ((b)(6) @va.gov) /o=VA/ou=VA Martinsburg/cn=Recipients/cn=vhacoValenM (b)(6) @va.gov>
Subject:	FW: J&J updates
Date:	2019/03/12 16:09:27
Priority:	Normal
Type:	Note

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Sent Date:	2019/03/12 16:09:31
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Message Flags:	Unread Unsent

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To:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>
Subject:	FW: J&J Prices Ketamine-Like Depression Treatment at $590-$885 for Two Doses
Date:	2019/03/08 15:47:01
Priority:	Normal
Type:	Note

(b) (6)

From: Crismon, M L [mailto:(b)(6)
Sent: Friday, March 08, 2019 2:40 PM
To: list@cpnp.org
Subject: [EXTERNAL] J&J Prices Ketamine-Like Depression Treatment at $590-$885 for Two Doses

J&J Prices Ketamine-Like Depression Treatment at $590-$885 for Two Doses

By Reuters Staff
March 07, 2019

https://img.medscapestatic.com/publication/logo-reutersprofessional.gif?interpolation=lanczos-none&resize=*:85

- Added to Email Alerts

(Reuters) - Johnson &Johnson said on Wednesday its nasal spray depression treatment, called Spravato, will be priced at $590 for a 56 mg dose and $885 for 84 mg.
During the induction phase of the therapy, which lasts for a month, patients will be treated twice a week with either dose, resulting in a wholesale

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acquisition cost or list price in the range of $4,720 to $6,785, Janssen spokesman Greg Panico said in an email statement.
Subsequent maintenance doses will be provided either once a week or every two weeks, adding up to monthly costs ranging from $2,360 to $3,540.
The list price of a drug is not necessarily what patients actually pay. Out-of-pocket costs vary based on an individual's healthcare plans and the duration of treatment.
J&J's Spravato, which is chemically similar to commonly-abused ketamine, was approved by the U.S. Food and Drug Administration on Tuesday, making it the first new depression treatment in more than 30 years.
Reuters Health Information © 2019

M. Lynn Crismon, Pharm.D.
Dean
James T. Doluisio Regents Chair and Behren's Centennial Professor



2409 University Ave. MC #A1900
Austin, TX 78712
Ph: (b)(6)
FAX: (b)(6)
e-mail: (b)(6)
Website: www.utexas.edu/pharmacy

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Sent Date:	2019/03/08 15:47:00
Delivered Date:	2019/03/08 15:47:01

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From:	Franklin, Keita /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=15EA4A5623C141D0A1D02611F7E975CD-FRANKLIN, K (b)(6) @va.gov>
To:	(b) (6) (b)(6)
CC:	Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da (b)(6) @va.gov>
Subject:	FW: J&J Media Statement 5PM 6/12
Date:	2019/06/12 16:43:03
Priority:	Normal
Type:	Note

Courtney – Dave rallied the troops on this and we have a bit more feedback. See note below!

From: Wiechers, Ilse
Sent: Wednesday, June 12, 2019 3:31 PM
To: Carroll, David (VACO) (b)(6) @va.gov>; Valentino, Michael (VACO) (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) (b)(6) @va.gov>; Fuller, Matthew A. (PBM) (b)(6) @va.gov>; Boyd, Teresa D. (b)(6) @va.gov>; Bernstein, Alan (b)(6) @va.gov>; Screen, Gina (b)(6) @va.gov>; Lieberman, Steven (b)(6) @va.gov>; Jensen, Jon M. (b)(6) @va.gov>; Franklin, Keita (b)(6) @va.gov>
Subject: RE: J&J Media Statement 5PM 6/12

(b) (6)

Partnership with the VA

- • Throughout the partnership with the VA on this public education campaign and beyond, we have strictly complied with the laws in place that govern partnerships across industry and government related to ethics and conflicts of interest.

Ilse

From: Carroll, David (VACO)
Sent: Wednesday, June 12, 2019 12:17 PM
To: Wiechers, Ilse <(b)(6) @va.gov>; Valentino, Michael (VACO) (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) <(b)(6) @va.gov>; Fuller, Matthew A. (PBM) (b)(6) @va.gov>; Boyd, Teresa D. (b)(6) @va.gov>; Wiechers, Ilse (b)(6) @va.gov>; Bernstein, Alan (b)(6) @va.gov>; Screen, Gina (b)(6) @va.gov>; Lieberman, Steven <(b)(6) @va.gov>; Jensen, Jon M. (b)(6) @va.gov>; Franklin, Keita <(b)(6) @va.gov>

AMERICAN OVERSIGHT

Subject: J&J Media Statement 5PM 6/12
Importance: High

Dr. Franklin received the attached Media Response that J&J is making to the media today (5PM). They asked for any concerns from VA. Although there may not be anything technically wrong (e.g., VA does have a MOA with J&J), the MOA has nothing to do directly with Spravato or it development or use. No directly association is stated, but it could be implied. Adding Dr. Wiechers and other leaders involved in our implementation of Spravato for their guidance on a response.

From: Wiechers, Ilse
Sent: Wednesday, June 12, 2019 2:24 AM
To: Carroll, David (VACO) <(b)(6) @va.gov>; Valentino, Michael (VACO) <(b)(6) @va.gov>; Zacher, Jennifer L. (PBM) <(b)(6) @va.gov>; Fuller, Matthew A. (PBM) (b)(6) @va.gov>; Boyd, Teresa D. <(b)(6) @va.gov>
Subject: Esketamine Community of Practice call tomorrow @ 2 pm ET

Hi everyone –

A quick reminder of the call in information for those able to join tomorrow. Please use the MODERATOR code listed below, as I anticipate we may need to mute the audience due to large number of participants.

Matthew – I will turn it over to you for slides 18-19 on updates re PBM policies. Please feel free to edit those slides if you like and send me revised slides tomorrow by 1 pm ET.

Join Skype Meeting (Trouble Joining? Try Skype Web App)
Join audio by VANTS at 1-800-767-1750, moderator 13331#

Thanks,
Ilse

***

Ilse R. Wiechers, MD, MPP, MHS
National Director, Psychotropic Drug Safety Initiative (PDSI)
Associate Director, Northeast Program Evaluation Center
Office of Mental Health and Suicide Prevention (10NC5), Department of Veterans Affairs
Assistant Clinical Professor of Psychiatry, Yale University School of Medicine
cell (b)(6)
email: (b)(6) @va.gov | (b)(6)

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Recipient:	(b) (6) its.jnj.com>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group

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	(FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da (b)(6) @va.gov>
Sent Date:	2019/06/12 16:43:02
Delivered Date:	2019/06/12 16:43:03

AMERICAN OVERSIGHT

From:	Wiechers, Ilse /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0C7B1428D9E4233A641F125C5B6FC4F-WIECHERS, I (b)(6) @va.gov>
To:	VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>
Subject:	FW: Intranasal esketamine draft guidelines
Date:	2019/03/06 19:23:03
Priority:	Normal
Type:	Note

FYI from earlier today from Durham.

Sent with BlackBerry Work
(www.blackberry.com)

From: Leinbach, Jonathan E DURVAMC (b)(6) @va.gov>
Date: Wednesday, Mar 06, 2019, 12:30 PM
To: Wiechers, Ilse (b)(6) @va.gov>, Mankad, Mehul V. DURVAMC (b)(6) @va.gov>
Cc: Kahlon, Christie H. (b)(6) @va.gov>
Subject: RE: Intranasal esketamine draft guidelines

Thank you, Ilse. Interesting times. Jonathan

Sent with BlackBerry Work
(www.blackberry.com)

From: Wiechers, Ilse (b)(6) @va.gov>
Date: Wednesday, Mar 06, 2019, 3:24 PM
To: Mankad, Mehul V. DURVAMC (b)(6) @va.gov>
Cc: Leinbach, Jonathan E DURVAMC (b)(6) @va.gov>, Kahlon, Christie H. (b)(6) @va.gov>
Subject: RE: Intranasal esketamine draft guidelines

Mehul –

I was following the intranasal esketamine approval closely as well, and you are right, questions will start coming from patients and others soon. Currently we do not have anything drafted re intranasal, but I will start working with PBM and OMHSP to address this.

As for APA, I will indeed be there! (b) (6)

Best,
Ilse

AMERICAN OVERSIGHT

From: Mankad, Mehul V. DURVAMC
Sent: Wednesday, March 06, 2019 11:13 AM
To: Wiechers, Ilse (b)(6) @va.gov>
Cc: Leinbach, Jonathan E DURVAMC (b)(6) @va.gov>; Kahlon, Christie H. (b)(6) @va.gov>
Subject: Intranasal esketamine draft guidelines

Hi Ilse,

We were wondering if VACO has any draft guidelines for the use of intranasal esketamine. It's a matter of time before the requests start coming in from patients and providers for this newly FDA-approved agent. We have seen the draft guidelines on intravenous ketamine for psychiatric disorders and had an opportunity to comment on those when they were being developed.

I'm including our ACOS/MH and psych clinical pharmacy specialist on this email.

(b) (6)

(b) (6)

Regards,

Mehul Mankad, MD
Chief of Psychiatry
Chief of Acute Care Division
Durham VA HCS

Sender:	Wiechers, Ilse /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0C7B1428D9E4233A641F125C5B6FC4F-WIECHERS, I (b)(6) @va.gov>
Recipient:	VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>
Sent Date:	2019/03/06 19:23:02
Delivered Date:	2019/03/06 19:23:03

AMERICAN OVERSIGHT

From:	Llorente, Maria D. </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F5C91F577D894BD9A0F09305DB34DD4F-LLORENTE, M>
To:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>
Subject:	FW: iMedConsent - intranasal esketamine
Date:	2019/03/08 14:28:00
Priority:	Normal
Type:	Note

FYI

From: Sharpe, Virginia A.
Sent: Friday, March 8, 2019 2:28 PM
To: Llorente, Maria D. (b)(6) @va.gov>; Tompkins, Paul A. (b)(6) @va.gov>
Subject: RE: iMedConsent - intranasal esketamine

Thank you, I've received the email from Ilse and will cc you on the reply.
Ashby

From: Llorente, Maria D.
Sent: Friday, March 08, 2019 2:26 PM
To: Sharpe, Virginia A. (b)(6) @va.gov>; Tompkins, Paul A. (b)(6) @va.gov>
Subject: RE: iMedConsent - intranasal esketamine

Thank you very much. Tom Emmendorfer reached out to mental health program office re the ketamine informed consent and Ilse Wiechers was going to be reaching out to you. I will forward this to the group to assure communication. Thank you again for raising this question this morning.
Maria Llorente

From: Sharpe, Virginia A.
Sent: Friday, March 8, 2019 2:17 PM
To: Llorente, Maria D. (b)(6) @va.gov>; Tompkins, Paul A. (b)(6) @va.gov>
Subject: iMedConsent - intranasal esketamine

Hi Maria – Great to meet you this morning. I wanted you to have my contact info and also provide you with information about the process to develop a consent form for intranasal esketamine. I'm adding Paul Tompkins from my office in case he has more to add.
Paul Dr. Llorente is here on detail to PCS from the DCVA.
Ashby

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Here's the information about the risk threshold for treatments and procedures requiring signature informed consent:

VHA Handbook 1004.01, Informed Consent for Clinical Treatments and Procedures, dated August 14, 2009 (Revised May 22, 2017).

(2) **Treatments and Procedures That Require Signature Consent.** Prior to undertaking certain treatments and procedures, the practitioner must document the informed consent process in detail (as specified in subpars. 13c(2)(a) and 13c(2)(b)) and obtain the patient's signature on a VA authorized consent form.
(a) The patient's signature consent must be obtained for treatments and procedures that:
1. Can be reasonably expected to produce significant pain or discomfort to the patient;
2. Can be reasonably expected to produce pain or discomfort to the patient that is substantial enough to require sedation, anesthesia, or narcotic analgesia;
3. Can be reasonably considered to have a significant risk of complication or morbidity;
4. Require injections of any substance into a joint space or body cavity (excluding the intravascular space); or
5. Are listed in Appendix A.

Here's the info. about the process for consent form development. 10NC and PCS have process in place to manage SME input.

VHA Handbook 1004.05, iMedConsent™, dated December 10, 2014.

10. CONTACTS:
b. **Clinical Content Concerns and Requests.**
(1) Concerns related to the clinical content in the iMedConsent™ program and requests for new content need to be reviewed and approved by the relevant Specialty Chief and submitted to the vendor using email (content@dialogmedical.com). Submission must include the name of the document (or proposed name if new content is being requested), the specialty (or proposed specialty), and a description of the concern or new content request.

(2) The vendor, Dialog Medical, evaluates content requests on a 90-day timeframe (estimated) to determine whether content modification or new content is needed. Dialog Medical provides a summary of actions taken in response to any field request to Patient Care Services for review.

(3) Patient Care Services, in conjunction with designated operational policy offices under the Deputy Under Secretary for Health for Operations and Management, is responsible for ensuring that consent form content is consistent with VHA policy and practice.

++++++++++++++

Virginia Ashby Sharpe, Ph.D.
Acting Executive Director
National Center for Ethics in Health Care
Veterans Health Administration 10E1E
810 Vermont Ave. NW, Washington, DC 20420 (mail)
811 Vermont Ave. NW, Washington, DC 20420 #624 (physical)
office landline: *(b)(6)*

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mobile: (b)(6)
fax: 202-632-8456
(b)(6) @va.gov
intranet: http://vaww.ethics.va.gov/
internet: http://www.ethics.va.gov/

Sender:	Llorente, Maria D. </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F5C91F577D894BD9A0F09305DB34DD4F-LLORENTE, M>
Recipient:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>
Sent Date:	2019/03/08 14:28:16
Delivered Date:	2019/03/08 14:28:00

AMERICAN OVERSIGHT

From:	Stone, Richard A., MD /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BD16619615D64ADEA22E45E63FF6462A-STONE, RICH (b)(6) @va.gov>
SentVia:	Emmendorfer, Thomas (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC96BB44E7AE2C94C43B55D094-EMMENDORFER>
To:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>
Subject:	FW: HHS Nasal Spray
Date:	2019/03/07 14:26:29
Start Date:	2019/03/07 09:00:00
End Date:	2019/03/07 09:30:00
Priority:	Normal
Type:	Schedule.Meeting.Request
Location:	VACO 800

Sender:	Stone, Richard A., MD /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BD16619615D64ADEA22E45E63FF6462A-STONE, RICH (b)(6) @va.gov>; Emmendorfer, Thomas (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC96BB44E7AE2C94C43B55D094-EMMENDORFER>
Recipient:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>
Sent Date:	2019/03/07 14:26:27
Delivered Date:	2019/03/07 14:26:29

AMERICAN OVERSIGHT

From:	Stone, Richard A., MD /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BD16619615D64ADEA22E45E63FF6462A-STONE, RICH (b)(6) @va.gov>
SentVia:	Emmendorfer, Thomas (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC96BB44E7AE2C94C43B55D094-EMMENDORFER (b)(6) @va.gov>
To:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>
Subject:	FW: HHS Nasal Spray
Date:	2019/03/07 14:26:30
Start Date:	2019/03/07 09:00:00
End Date:	2019/03/07 09:30:00
Priority:	Normal
Type:	Schedule.Meeting.Request
Location:	VACO 800

Sender:	Stone, Richard A., MD /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BD16619615D64ADEA22E45E63FF6462A-STONE, RICH (b)(6) @va.gov>; Emmendorfer, Thomas (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC96BB44E7AE2C94C43B55D094-EMMENDORFER (b)(6) @va.gov>
Recipient:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>
Sent Date:	2019/03/07 14:26:27
Delivered Date:	2019/03/07 14:26:30

AMERICAN OVERSIGHT

From:	Stone, Richard A., MD /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BD16619615D64ADEA22E45E63FF6462A-STONE, RICH (b)(6) @va.gov>
To:	Stone, Richard A., MD /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bd16619615d64adea22e45e63ff6462a-Stone, Rich (b)(6) @va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>; Beck, Lucille B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=845480228a8b43e7a5fef5716ded04c2-Beck, Lucil (b)(6) @va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>; Jensen, Jon M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddeb735ace76400db5c3f10603188a14-Jensen, Jon (b)(6) @va.gov>
Subject:	FW: HHS Nasal Spray
Date:	2019/03/07 14:26:30
Start Date:	2019/03/07 09:00:00
End Date:	2019/03/07 09:30:00
Priority:	Normal
Type:	Appointment
Location:	VACO 800

Sender:	Stone, Richard A., MD /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BD16619615D64ADEA22E45E63FF6462A-STONE, RICH (b)(6) @va.gov>
Recipient:	Stone, Richard A., MD /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bd16619615d64adea22e45e63ff6462a-Stone, Rich (b)(6) @va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>; Beck, Lucille B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=845480228a8b43e7a5fef5716ded04c2-Beck, Lucil (b)(6) @va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>; Jensen, Jon M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddeb735ace76400db5c3f10603188a14-Jensen, Jon (b)(6) @va.gov>
Sent Date:	2019/03/07 14:26:30

AMERICAN OVERSIGHT

From:	Smith, Monica (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=511EA9E77A234375A91A7B34CE23719D-SMITH, MONI (b)(6) @va.gov>
To:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da (b)(6) @va.gov>
Subject:	FW: HHS bought a nasal spray for depression - DRAFT News Release - REVISED
Date:	2019/03/13 13:18:56
Priority:	Normal
Type:	Note

See below. What can you give me for FAQs or talking points on this topic?

From: Greilsamer, Alan
Sent: Wednesday, March 13, 2019 1:18 PM
To: Smith, Monica (VACO) (b)(6) @va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

(b5) [redacted]

From: Smith, Monica (VACO)
Sent: Wednesday, March 13, 2019 1:17 PM
To: Greilsamer, Alan (b)(6) @va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Thank you, Alan. Also, Gina had asked for FAQs. (b5) [redacted]

From: Greilsamer, Alan
Sent: Wednesday, March 13, 2019 1:16 PM
To: Smith, Monica (VACO) (b)(6) @va.gov>; Screen, Gina (b)(6) @va.gov>; Ledesma, Mark P. (b)(6) @va.gov>
Cc: Emmendorfer, Thomas (PBM) (b)(6) @va.gov>; Carroll, David (VACO) (b)(6) @va.gov>; Valentino, Michael (VACO) (b)(6) @va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Monica – It is being worked. We will keep you updated on our progress. Thanks, Alan

---

From: Smith, Monica (VACO)
Sent: Wednesday, March 13, 2019 12:50 PM
To: Screen. Gina (b)(6) @va.gov>; Greilsamer, Alan (b)(6) @va.gov>; Ledesma, Mark P. (b)(6) @va.gov>
Cc: Emmendorfer, Thomas (PBM) (b)(6) @va.gov>; Carroll, David (VACO)

AMERICAN OVERSIGHT

(b)(6) @va.gov>; Valentino, Michael (VACO) (b)(6) @va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Hi there – checking in on status. VHA wants to get this out ASAP. Since FDA released last week and there is WH interest, can you expedite review?

From: Smith, Monica (VACO)
Sent: Tuesday, March 12, 2019 4:16 PM
To: Screen, Gina (b)(6) @va.gov>; Greilsamer, Alan (b)(6) @va.gov>; Ledesma, Mark P. (b)(6) @va.gov>
Cc: Emmendorfer, Thomas (PBM) (b)(6) @va.gov>; Carroll, David (VACO) (b)(6) @va.gov>; Valentino, Michael (VACO) (b)(6) @va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Gina, Mark, Alan – please see the revised draft version of the press release. FAQs are being worked and will be sent asap. Pharmacy and Mental Health SMEs are on the email in case there are questions.

From: Smith, Monica (VACO)
Sent: Tuesday, March 12, 2019 12:10 PM
To: Screen, Gina (b)(6) @va.gov>; Greilsamer, Alan (b)(6) @va.gov>; Ledesma, Mark P. (b)(6) @va.gov>
Cc: Outlaw. William N. <(b)(6) @va.gov>; Emmendorfer, Thomas (PBM) (b)(6) @va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

Agreed. I had a lot of questions when Tom and I were reviewing the draft. We will get with Pharmacy and Mental Health to develop.

From: Screen, Gina
Sent: Tuesday, March 12, 2019 10:24 AM
To: Smith, Monica (VACO) (b)(6) @va.gov>; Greilsamer, Alan <(b)(6) @va.gov>; Ledesma, Mark P. (b)(6) @va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

I think we also need a few faq's about this... I'm sure a lot of people will have questions...

From: Smith, Monica (VACO)
Sent: Tuesday, March 12, 2019 10:22 AM
To: Greilsamer, Alan <(b)(6) @va.gov>; Ledesma, Mark P. (b)(6) @va.gov>; Screen, Gina <(b)(6) @va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; Llorente, Maria D. (b)(6) @va.gov>; Valentino, Michael (VACO) <(b)(6) @va.gov>; Emmendorfer, Thomas (PBM) (b)(6) @va.gov>; Carroll, David (VACO) (b)(6) @va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>; Law, Cassandra M. <(b)(6) @va.gov>; VHA

AMERICAN OVERSIGHT

10P Actions <VHA10PActions@va.gov>; Beck, Lucille B. (b)(6) @va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

VHA Comms:
As you may have seen in the news last week, there is a new drug coming on the market to treat depression. VA will offer this to Veterans. Please see attached draft press release for your expedited review. Our Pharmacy SMEs (Tom Emmendorfer and Mike Valentino) are on the cc: line to address any questions. I also understand there is internal communication in draft for communication to the field.

Bottom Line Up Front:
Spravato® will be available for VA providers to prescribe to Veterans based on their clinical assessment and the individual medical needs.

Background Information:

- • The Food and Drug Administration (FDA) approved Spravato® on March 5, 2019.
- • VA Pharmacy Benefits Management (PBM) Services has developed a national protocol for the use of intravenous ketamine in treatment resistant depression and severe suicidal ideation which was published in December 2017.

Sender:	Smith, Monica (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=511EA9E77A234375A91A7B34CE23719D-SMITH, MONI (b)(6) @va.gov>
Recipient:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da (b)(6) @va.gov>
Sent Date:	2019/03/13 13:18:54
Delivered Date:	2019/03/13 13:18:56

AMERICAN OVERSIGHT

From:	Wiechers, Ilse /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0C7B1428D9E4233A641F125C5B6FC4F-WIECHERS, I (b)(6) @va.gov>
To:	VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>
Subject:	FW: HHS bought a nasal spray for depression - DRAFT News Release - REVISED
Date:	2019/03/13 16:38:36
Priority:	Normal
Type:	Note

FYI

From: Emmendorfer, Thomas (PBM)
Sent: Wednesday, March 13, 2019 1:09 PM
To: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Cc: Wiechers, Ilse <(b)(6) @va.gov>; Valentino, Michael (VACO) (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) <(b)(6) @va.gov>; Smith, Monica (VACO) (b)(6) @va.gov>
Subject: FW: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

10P4P clears the attached internal communication Frequently Asked Question (FAQ) document for Spravato® and the COMMS plan.

NOTE: The draft FAQ and COMMS plan will need to be cleared to the individuals on the e-mail below.

Below are the parts of the COMMS plan that has already been executed:

- • Key leadership Spravato® (Esketamine) Nasal Inhalation Presentations
  - • Patient Care Services Chief Consultant Meeting: Monday, March 11, 2019
  - • Veterans Integrated Service Network (VISN) Chief Medical Officer (CMO) Meeting: Monday, March 11, 2019
  - • VISN Mental Health Leads Meeting: Monday, March 11, 2019
  - • VISN Pharmacist Executive (VPE) Committee Meeting: Tuesday, March 12, 2019

Below are the parts of the COMMS plan that will be executed after the FAQ is cleared

- • Pharmacy Benefits Management (PBM) Services and the Office of Mental Health and Suicide Prevention (OMHSP) will use listservs for broad distribution of the internal FAQs.

From: Smith, Monica (VACO)
Sent: Wednesday, March 13, 2019 3:01 PM
To: Ledesma, Mark P. (b)(6) @va.gov>; Greilsamer, Alan <(b)(6) @va.gov>; Screen, Gina <(b)(6) @va.gov>
Cc: Emmendorfer, Thomas (PBM) <(b)(6) @va.gov>; Carroll, David (VACO) (b)(6) @va.gov>; Valentino, Michael (VACO) <(b)(6) @va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

AMERICAN OVERSIGHT

Thanks. Tom and Dave – please let Mark know what the internal plans are.

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Sent: Wednesday, March 13, 2019 3:00 PM
To: Smith, Monica (VACO) (b)(6) @va.gov>; Greilsamer, Alan (b)(6) @va.gov>; Screen, Gina (b)(6) @va.gov>
Cc: Emmendorfer, Thomas (PBM) (b)(6) @va.gov>; Carroll, David (VACO) (b)(6) @va.gov>; Valentino, Michael (VACO) (b)(6) @va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; Ledesma, Mark P. (b)(6) @va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

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They want to make sure that we have an internal comms plan in place to help answer questions from providers and Veterans before they clear the release.

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Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Hi Monica,

AMERICAN OVERSIGHT

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Monica – It is being worked. We will keep you updated on our progress. Thanks, Alan

---

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Gina, Mark, Alan – please see the revised draft version of the press release. FAQs are being worked and will be sent asap. Pharmacy and Mental Health SMEs are on the email in case there are questions.

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To: Screen, Gina (b)(6) @va.gov>; Greilsamer, Alan <(b)(6) @va.gov>; Ledesma, Mark P. (b)(6) @va.gov>
Cc: Outlaw, William N. (b)(6) @va.gov>; Emmendorfer, Thomas (PBM) (b)(6) @va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

AMERICAN OVERSIGHT

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To: Smith, Monica (VACO) (b)(6) @va.gov>; Greilsamer, Alan <(b)(6) @va.gov>; Ledesma, Mark P. (b)(6) @va.gov>
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To: Greilsamer, Alan (b)(6) @va.gov>; Ledesma, Mark P. <(b)(6) @va.gov>; Screen, Gina (b)(6) @va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; Llorente, Maria D.(b)(6) @va.gov>; Valentino, Michael (VACO) (b)(6) @va.gov>; Emmendorfer, Thomas (PBM) (b)(6) @va.gov>; Carroll, David (VACO) <(b)(6) @va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>; Law, Cassandra M. <(b)(6) @va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; Beck, Lucille B. (b)(6) @va.gov>
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VHA Comms:
As you may have seen in the news last week, there is a new drug coming on the market to treat depression. VA will offer this to Veterans. Please see attached draft press release for your expedited review. Our Pharmacy SMEs (Tom Emmendorfer and Mike Valentino) are on the cc: line to address any questions. I also understand there is internal communication in draft for communication to the field.

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Spravato® will be available for VA providers to prescribe to Veterans based on their clinical assessment and the individual medical needs.

Background Information:

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- • VA Pharmacy Benefits Management (PBM) Services has developed a national protocol for the use of intravenous ketamine in treatment resistant depression and severe suicidal ideation which was published in December 2017.

Sender:	Wiechers, Ilse /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0C7B1428D9E4233A641F125C5B6FC4F-WIECHERS, I (b)(6) @va.gov>
Recipient:	VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>
Sent Date:	2019/03/13 16:38:34
Delivered Date:	2019/03/13 16:38:36

AMERICAN OVERSIGHT

From:	Emmendorfer, Thomas (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC96BB44E7AE2C94C43B55D094-EMMENDORFER (b)(6) @va.gov>
To:	Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen (b)(6) @va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b)(6) @va.gov>
Subject:	FW: HHS bought a nasal spray for depression - DRAFT News Release - REVISED
Date:	2019/03/13 18:57:59
Priority:	Normal
Type:	Note

FYI...
Jenn,
Please have Lucy use this version to build the header ect...
There were two minor edits made.
Thank you,
Tom

Sent with BlackBerry Work
(www.blackberry.com)

From: Smith, Monica (VACO) (b)(6) @va.gov>
Date: Wednesday, Mar 13, 2019, 5:20 PM
To: Ledesma, Mark P. (b)(6) @va.gov>, Greilsamer, Alan (b)(6) @va.gov>, Screen, Gina (b)(6) @va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>, Emmendorfer, Thomas (PBM) (b)(6) @va.gov>
Subject: FW: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

See attached cleared by 10P4 Acting ADUSH.

From: Llorente, Maria D. (b)(6) @va.gov>
Date: Wednesday, Mar 13, 2019, 5:09 PM
To: Emmendorfer, Thomas (PBM) <(b)(6) @va.gov>
Cc: Wiechers, Ilse (b)(6) @va.gov>, Valentino, Michael (VACO) (b)(6) @va.gov>, Smith, Monica (VACO) (b)(6) @va.gov>
Subject: FW: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

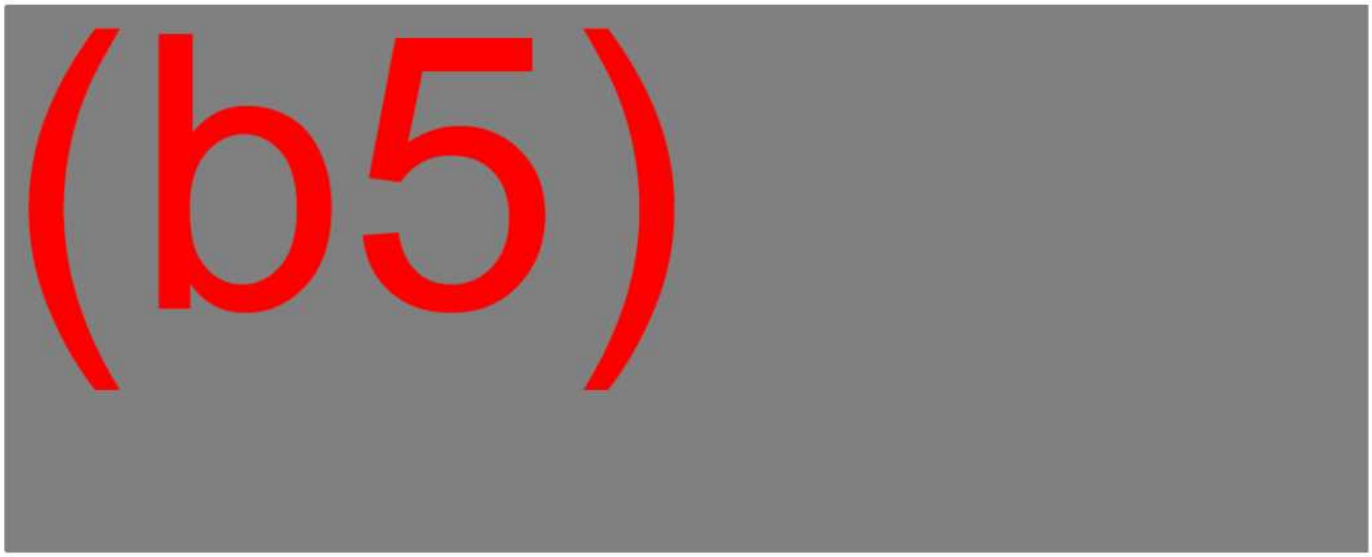
A very minor edit. Otherwise, looks good.
Maria

AMERICAN OVERSIGHT

From: Emmendorfer, Thomas (PBM)
Sent: Wednesday, March 13, 2019 3:37 PM
To: Wiechers, Ilse (b)(6) @va.gov>
Cc: Llorente, Maria D. <(b)(6) @va.gov>; Valentino, Michael (VACO) (b)(6) @va.gov>; Smith, Monica (VACO) (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) (b)(6) @va.gov>
Subject: FW: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Ilse,
By chance, do you know if Spravato® has been discussed on any Mental Health leadership calls yet? If so, could you please add to the list below? Also, make sure you agree with my COMMS plan that needs to be executed yet.

DRAFT message to 10P4 Actions:



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To: Ledesma, Mark P. <(b)(6) @va.gov>; Greilsamer, Alan (b)(6) @va.gov>; Screen, Gina (b)(6) @va.gov>
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AMERICAN OVERSIGHT

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Sent Date:	2019/03/13 18:57:58
Delivered Date:	2019/03/13 18:57:59

AMERICAN OVERSIGHT

Message Flags:	Unread

AMERICAN OVERSIGHT

From:	Emmendorfer, Thomas (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC96BB44E7AE2C94C43B55D094-EMMENDORFER (b)(6) @va.gov>
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CC:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>
Subject:	FW: HHS bought a nasal spray for depression - DRAFT News Release - REVISED
Date:	2019/03/14 15:59:27
Priority:	Normal
Type:	Note

FYI...

As soon as you review and I get the green light. I will respond saying "Yes and the FAQ will be sent out internally tomorrow."

From: Ledesma, Mark P.
Sent: Thursday, March 14, 2019 3:44 PM
To: Smith, Monica (VACO) (b)(6) @va.gov>; Emmendorfer, Thomas (PBM) (b)(6) @va.gov>
Cc: Ledesma, Mark P. (b)(6) @va.gov>; Ledesma, Mark P. (b)(6) @va.gov>
Subject: FW: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Monica, Tom,

Could you please help answer Krystal's question?

Regards,
Mark

From: Toles, Krystal M.
Sent: Thursday, March 14, 2019 3:36 PM
To: Ledesma, Mark P. (b)(6) @va.gov>; Yang, Robert B. (b)(6) @va.gov>
Cc: VHA 10B <vha10b@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Mark,

Is an internal message to the field also pending?

From: Ledesma, Mark P.
Sent: Thursday, March 14, 2019 1:22 PM

AMERICAN OVERSIGHT

To: Yang, Robert B. (b)(6) @va.gov>
Cc: VHA 10B <vha10b@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>; Toles, Krystal M. (b)(6) @va.gov>; Ledesma, Mark P. (b)(6) @va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Hi Robert,

I'm resubmitting the nasal spray news release on behalf of 10P for review/conncurence.

I have also attached the internal communication Frequently Asked Question (FAQ) document for Spravato® for review/concurrence.

Below are the parts of the internal comms plan that has already been executed:

- • Key leadership Spravato® (Esketamine) Nasal Inhalation Presentations
  - • Patient Care Services Chief Consultant Meeting: Monday, March 11, 2019
  - • Veterans Integrated Service Network (VISN) Chief Medical Officer (CMO) Meeting: Monday, March 11, 2019
  - • VISN Pharmacist Executive (VPE) Committee Meeting: Tuesday, March 12, 2019

Below are the parts of the comms plan that will be executed after the FAQ is cleared

- • Pharmacy Benefits Management (PBM) Services and the Office of Mental Health and Suicide Prevention (OMHSP) will use listservs for broad distribution of the internal FAQs.

Please let me know if you have questions. Thanks.

Regards,
Mark

From: Yang, Robert B.
Sent: Wednesday, March 13, 2019 4:38 PM
To: Ledesma, Mark P. (b)(6) @va.gov>
Cc: VHA 10B <vha10b@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>; Toles, Krystal M. (b)(6) @va.gov>
Subject: FW: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Hello Mark,

The press release is unable to be cleared at this time. Please see highlighted below for feedback.

Thanks,

Robert B Yang
Health System Specialist
Office of the VHA Chief of the Staff (10B)
810 Vermont Ave NW
Washington DC 20420

AMERICAN OVERSIGHT

Office: (b)(6)
Cell: (b)(6)
(b)(6) @va.gov

From: Toles, Krystal M.
Sent: Wednesday, March 13, 2019 4:14 PM
To: Yang, Robert B. <(b)(6) @va.gov>
Cc: VHA 10B <vha10b@va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Thanks for your review, Robert.

(b5)

From: Ledesma, Mark P.
Sent: Wednesday, March 13, 2019 1:22 PM
To: VHA 10B <vha10b@va.gov>
Cc: VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>; Ledesma, Mark P. (b)(6) @va.gov>
Subject: FW: HHS bought a nasal spray for depression - DRAFT News Release - REVISED
Importance: High

Good afternoon, 10B.

We have an **urgent request for review/concurrence** of the attached news release. 10P wants to get this out ASAP – since FDA released last week and there is WH interest.

Please let me know if you have questions. Thank you.

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Cc: Emmendorfer, Thomas (PBM) (b)(6) @va.gov>; Carroll, David (VACO) (b)(6) @va.gov>; Valentino, Michael (VACO) (b)(6) @va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

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AMERICAN OVERSIGHT

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Recipient:	Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen

AMERICAN OVERSIGHT

	(b)(6) va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>
Sent Date:	2019/03/14 15:59:26
Delivered Date:	2019/03/14 15:59:27

AMERICAN OVERSIGHT

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To:	Zacher, Jennifer L. (PBM) /o=VA/ou=VISN 12/cn=RECIPIENTS/cn=VHANCHZACHEJ (b)(6) @va.gov>
Subject:	FW: HHS bought a nasal spray for depression - DRAFT News Release - REVISED
Date:	2019/03/14 13:44:00
Priority:	Normal
Type:	Note

(b5)

From: Emmendorfer, Thomas (PBM)
Sent: Thursday, March 14, 2019 10:19 AM
To: Szudarski, Lucy (PBM) (b)(6) @va.gov>
Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

Hi Lucy,

Thank you for doing this! Could you use this version of the Esketamine Frequently Asked Question document?

(b5)

Tom

From: Szudarski, Lucy (PBM)
Sent: Thursday, March 14, 2019 9:13 AM
To: Emmendorfer, Thomas (PBM) (b)(6) @va.gov>
Subject: FW: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

AMERICAN OVERSIGHT

Hi Tom,
Here it is on our PBM letterhead, I was able to fit it on two pages. I hope this is what you wanted, let me know if this is ok.
Thanks,
Lucy

From: Emmendorfer, Thomas (PBM)
Sent: Wednesday, March 13, 2019 5:58 PM
To: Zacher, Jennifer L. (PBM) (b)(6) @va.gov>; Valentino, Michael (VACO) (b)(6) @va.gov>; Wiechers, Ilse (b)(6) @va.gov>
Subject: FW: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

FYI...

Jenn,

Please have Lucy use this version to build the header ect...

There were two minor edits made.

Thank you,

Tom

Sent with BlackBerry Work
(www.blackberry.com)

From: Smith, Monica (VACO) (b)(6) @va.gov>
Date: Wednesday, Mar 13, 2019, 5:20 PM
To: Ledesma, Mark P. <(b)(6) @va.gov>, Greilsamer, Alan (b)(6) @va.gov>, Screen, Gina (b)(6) @va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>, Emmendorfer, Thomas (PBM) (b)(6) @va.gov>
Subject: FW: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

See attached cleared by 10P4 Acting ADUSH.

From: Llorente, Maria D. (b)(6) @va.gov>
Date: Wednesday, Mar 13, 2019, 5:09 PM
To: Emmendorfer, Thomas (PBM) <(b)(6) @va.gov>
Cc: Wiechers, Ilse (b)(6) @va.gov>, Valentino, Michael (VACO) (b)(6) @va.gov>, Smith, Monica (VACO) (b)(6) @va.gov>
Subject: FW: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

A very minor edit. Otherwise, looks good.
Maria

AMERICAN OVERSIGHT

From: Emmendorfer, Thomas (PBM)
Sent: Wednesday, March 13, 2019 3:37 PM
To: Wiechers, Ilse <(b)(6) @va.gov>
Cc: Llorente, Maria D. <(b)(6) @va.gov>; Valentino, Michael (VACO) <(b)(6) @va.gov>; Smith, Monica (VACO) (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) (b)(6) @va.gov>
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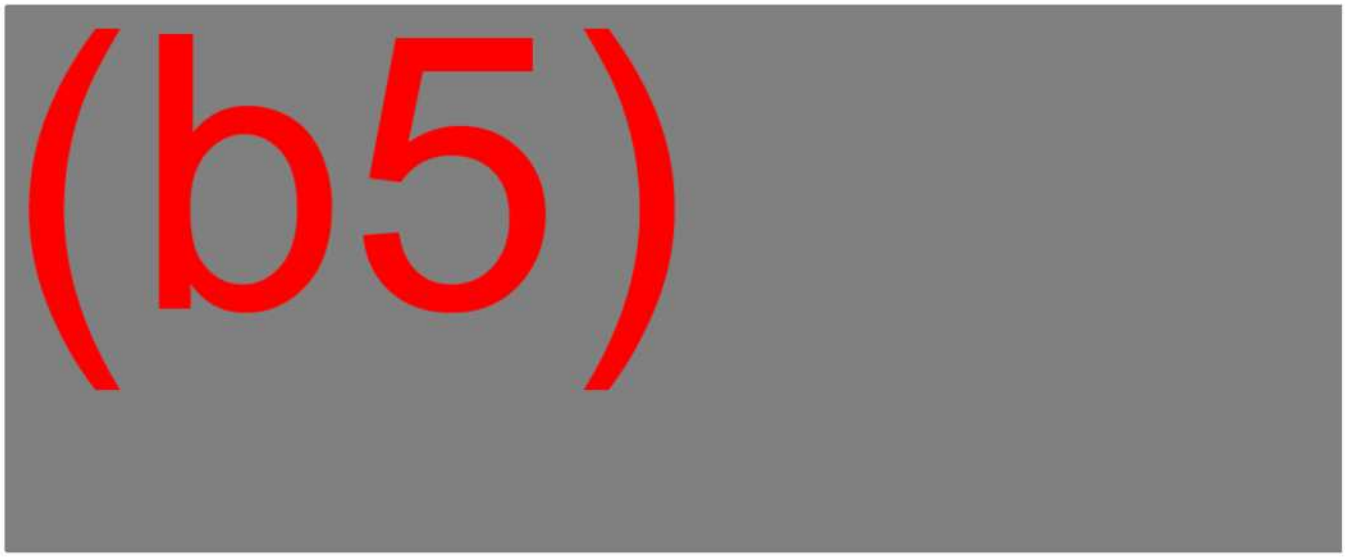
Ilse,
By chance, do you know if Spravato® has been discussed on any Mental Health leadership calls yet? If so, could you please add to the list below? Also, make sure you agree with my COMMS plan that needs to be executed yet.

DRAFT message to 10P4 Actions:



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AMERICAN OVERSIGHT

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Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release - REVISED

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AMERICAN OVERSIGHT

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Monica – It is being worked. We will keep you updated on our progress. Thanks, Alan

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Recipient:	Zacher, Jennifer L. (PBM) /o=VA/ou=VISN 12/cn=RECIPIENTS/cn=VHANCHZACHEJ (b)(6) @va.gov>
Sent Date:	2019/03/14 13:44:45
Delivered Date:	2019/03/14 13:44:00
Message Flags:	Unsent

AMERICAN OVERSIGHT

To:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b)(6) @va.gov>
CC:	Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M (b)(6) @va.gov>; Valentino, Michael (VACO) (Michael.Valentino@va.gov) /o=VA/ou=VA Martinsburg/cn=Recipients/cn=vhacoValenM <(b)(6) @va.gov>; Smith, Monica (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=511ea9e77a234375a91a7b34ce23719d-Smith, Moni (b)(6) @va.gov>; Meyer, Laurence /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=56f0ba2c110d4e60863b66f9728f669d-Meyer, Laur (b)(6) @va.gov>; Denietolis, Angela L. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b51b87cff64f4354b78eb943f97b47f3-Denietolis, (b)(6) @va.gov>; Wilson, Miyako /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4cef274e43b04f318944b3eaa3f2dc00-Wilson, Miy (b)(6) @va.gov>
Subject:	FW: HHS bought a nasal spray for depression - DRAFT News Release - REVISED
Date:	2019/03/13 15:26:12
Priority:	Normal
Type:	Note

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Subject: RE: HHS bought a nasal spray for depression - DRAFT News Release

VHA Comms:
As you may have seen in the news last week, there is a new drug coming on the market to treat depression. VA will offer this to Veterans. Please see attached draft press release for your expedited review. Our Pharmacy SMEs (Tom Emmendorfer and Mike Valentino) are on the cc: line to address any questions. I also understand there is internal communication in draft for communication to the field.

Bottom Line Up Front:
Spravato® will be available for VA providers to prescribe to Veterans based on their clinical assessment and the individual medical needs.

Background Information:

- • The Food and Drug Administration (FDA) approved Spravato® on March 5, 2019.
- • VA Pharmacy Benefits Management (PBM) Services has developed a national protocol for the use of intravenous ketamine in treatment resistant depression and severe suicidal ideation which was published in December 2017.

Recipient:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b)(6) @va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M (b)(6) @va.gov>; Valentino, Michael (VACO) (b)(6) @va.gov) /o=VA/ou=VA Martinsburg/cn=Recipients/cn=vhacoValenM <(b)(6) @va.gov>; Smith, Monica (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=511ea9e77a234375a91a7b34ce23719d-Smith, Moni (b)(6) @va.gov>;

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	Meyer, Laurence /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=56f0ba2c110d4e60863b66f9728f669d-Meyer, Laur (b)(6) @va.gov>; Denietolis, Angela L. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b51b87cff64f4354b78eb943f97b47f3-Denietolis, (b)(6) @va.gov>; Wilson, Miyako /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4cef274e43b04f318944b3eaa3f2dc00-Wilson, Miy (b)(6) @va.gov>
Sent Date:	2019/03/13 15:26:15
Delivered Date:	2019/03/13 15:26:12
Message Flags:	Unread Unsent

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To:	Valentino, Michael (VACO) (b)(6) @va.gov) /o=VA/ou=VA Martinsburg/cn=Recipients/cn=vnacovalenm (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) /o=VA/ou=VISN 12/cn=RECIPIENTS/cn=VHANCHZACHEJ (b)(6) @va.gov>
Subject:	FW: HHS bought a nasal spray for depression
Date:	2019/03/08 07:42:09
Priority:	Normal
Type:	Note

Hi Mike,

JuestIn case there are any questions from Dr. Stone about Spravato. Quick summary of points:

- • J&J CEO stated the product will commercially launch by 3/18/2019 (from Jon J.) in case it comes up
- • From Briefing yesterday, Dr. Stone asked about adding to contract. Thanks to Jenn giving me a quick refresher course I was able to state it takes 30 days of commercial sales to establish nFAMP.
- • Explained Formulary review and adding a drug to contract are separate.
- • FY15—Mental Health survey—8 site self-reported the use of ketamine for MH condition
- • 2019 survey—MH hopes to have information about Ketamine later this month (# of sites and estimated # of patients)

From: Wiechers, Ilse
Sent: Thursday, March 07, 2019 10:04 AM
To: Emmendorfer, Thomas (PBM) (b)(6) @va.gov>; Carroll, David (VACO) (b)(6) @va.gov>
Cc: Valentino, Michael (VACO) (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) (b)(6) @va.gov>; Llorente, Maria D. (b)(6) @va.gov>; Law, Cassandra M. (b)(6) @va.gov>
Subject: RE: HHS bought a nasal spray for depression

Yes – self reported data from the field.

Attached is a copy of the full Somatic Treatment Field Assessment – ketamine for MH is section III.

From: Emmendorfer, Thomas (PBM)
Sent: Thursday, March 07, 2019 7:00 AM
To: Wiechers, Ilse <(b)(6) @va.gov>; Carroll, David (VACO) <(b)(6) @va.gov>
Cc: Valentino, Michael (VACO) <(b)(6) @va.gov>; Zacher, Jennifer L. (PBM) (b)(6) @va.gov>; Llorente, Maria D. <(b)(6) @va.gov>; Law, Cassandra M. (b)(6) @va.gov>
Subject: Re: HHS bought a nasal spray for depression

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Hi Ilse,

Thank you very much for the information below!

Will the updated data also include any info on number of Veterans that have received ketamine for treatment of MH conditions?

Tom

From: "Wiechers, Ilse" (b)(6) @va.gov>
Date: Thursday, March 7, 2019 at 9:55 AM
To: "Carroll, David (VACO)" (b)(6) @va.gov>, Thomas Emmendorfer (b)(6) @va.gov>
Cc: Michael Valentino <(b)(6) @va.gov>, Jennifer Zacher (b)(6) @va.gov>, "Llorente, Maria D." (b)(6) @va.gov>, "Law, Cassandra M." (b)(6) @va.gov>
Subject: RE: HHS bought a nasal spray for depression

Below are the sites reporting use in FY15 from the assessment we did of the field back in fall 2016. The 2019 assessment went to the field in Feb and we are working to gather the final data from sites now. Hope to have updated data about sites using IV ketamine for treatment of MH conditions sometime later this month.

1-(689) VA Connecticut HCS, CT
18-(501) New Mexico HCS
23-(618) Minneapolis, MN
1-(523) VA Boston HCS, MA
6-(659) Salisbury, NC
12-(607) Madison, WI
16-(580) Houston, TX
21-(662) San Francisco, CA

Best,
Ilse

From: Carroll, David (VACO)
Sent: Thursday, March 07, 2019 6:39 AM
To: Emmendorfer, Thomas (PBM) (b)(6) @va.gov>; Wiechers, Ilse (b)(6) @va.gov>
Cc: Valentino, Michael (VACO) (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) (b)(6) @va.gov>; Llorente, Maria D. (b)(6) @va.gov>; Law, Cassandra M. (b)(6) @va.gov>
Subject: RE: HHS bought a nasal spray for depression

I do not. Ilse may have a list or can otherwise find out.

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From: Emmendorfer, Thomas (PBM)
Sent: Thursday, March 7, 2019 9:25 AM
To: Carroll, David (VACO) (b)(6) @va.gov>
Cc: Valentino, Michael (VACO) (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) (b)(6) @va.gov>; Llorente, Maria D. (b)(6) @va.gov>; Law, Cassandra M. (b)(6) @va.gov>
Subject: Re: HHS bought a nasal spray for depression

Hi Dave,

The briefing went very well. By chance, do you have a list of known VA medical facilities that are using intravenous ketamine for the treatment of refractory depression?

Thank you,

Tom

From: Thomas Emmendorfer <(b)(6) @va.gov>
Date: Thursday, March 7, 2019 at 7:45 AM
To: Jon Jensen (b)(6) @va.gov>
Cc: Michael Valentino <(b)(6) @va.gov>, "Carroll, David (VACO)" (b)(6) @va.gov>, "Beck, Lucille B." <(b)(6) @va.gov>, "Howard, Kristi" (b)(6) @va.gov>, Jennifer Zacher (b)(6) @va.gov>, "Llorente, Maria D." (b)(6) @va.gov>, "Law, Cassandra M." (b)(6) @va.gov>
Subject: Re: HHS bought a nasal spray for depression

Will do.

From: Jon Jensen <(b)(6) @va.gov>
Date: Thursday, March 7, 2019 at 7:41 AM
To: Thomas Emmendorfer <(b)(6) @va.gov>
Cc: Michael Valentino <(b)(6) @va.gov>, "Carroll, David (VACO)" (b)(6) @va.gov>, "Beck, Lucille B." (b)(6) @va.gov>, "Howard, Kristi" <(b)(6) @va.gov>, Jennifer Zacher (b)(6) @va.gov>, "Llorente, Maria D." (b)(6) @va.gov>, "Law, Cassandra M." (b)(6) @va.gov>
Subject: RE: HHS bought a nasal spray for depression

Tom, can you come to Morning Report today to discuss? Starts at 9:30.

From: Emmendorfer, Thomas (PBM)
Sent: Wednesday, March 06, 2019 10:15 PM
To: Jensen, Jon M. <(b)(6) @va.gov>
Cc: Valentino, Michael (VACO) (b)(6) @va.gov>; Carroll, David (VACO) (b)(6) @va.gov>; Beck, Lucille B. (b)(6) @va.gov>; Howard, Kristi (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) (b)(6) @va.gov>; Llorente, Maria D. <(b)(6) @va.gov>; Law,

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Cassandra M. <(b)(6) @va.gov>
Subject: RE: HHS bought a nasal spray for depression

Hi Jon,

I hope all is going well. Below is the information that Jenn, Mike, and I pulled together for you. Let us know if you need anything else.

Tom

Bottom Line Up Front:
Spravato® will be available to VA providers to administer to Veterans based on their clinical assessment and the individual medical needs of our nation's Veterans.

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- • Spravato's® chemical name is esketamine which is a S(+) enantiomer, a slightly different version of ketamine, and provides similar therapeutic effects to ketamine.
- • Intravenous ketamine has been used for several years in the United States for treatment refractory depression based on the body of medical evidence published in the literature.
- • Intravenous ketamine is FDA approved as an anesthetic agent for diagnostic and surgical procedures that do not require skeletal muscle relaxation and has been used for several decades.
- • Intravenous ketamine has been used for several years in the United States for treatment resistant depression and intractable neuropathic pain based on the body of medical evidence published in the literature.
- • VA Pharmacy Benefits Management (PBM) Services has developed a national protocol for the use of intravenous ketamine in treatment resistant depression and severe suicidal ideation which was published in December 2017 (attached).
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- • The patient self-administers Spravato® nasal spray under the supervision of a health care provider in a certified doctor's office or clinic, and the spray cannot be taken home.
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- • Because of the risk of sedation and dissociation, patients must be monitored by a health care provider for at least two hours after receiving their Spravato® dose.

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From: Jensen, Jon M.
Sent: Wednesday, March 06, 2019 7:50 PM
To: Emmendorfer, Thomas (PBM) <(b)(6) @va.gov>; Valentino, Michael (VACO) <(b)(6) @va.gov>; Carroll, David (VACO) <(b)(6) @va.gov>; Beck, Lucille B. <(b)(6) @va.gov>; Howard, Kristi <(b)(6) @va.gov>; Zacher, Jennifer L. (PBM) <(b)(6) @va.gov>
Subject: RE: HHS bought a nasal spray for depression

Thanks Tom!

Jon Jensen
VHA Acting Deputy Chief of Staff
W: (b)(6)
C: (b)(6)

From: Emmendorfer, Thomas (PBM) <(b)(6) @va.gov>
Date: Wednesday, Mar 06, 2019, 7:49 PM
To: Jensen, Jon M. <(b)(6) @va.gov>, Valentino, Michael (VACO) <(b)(6) @va.gov>, Carroll, David (VACO) <(b)(6) @va.gov>, Beck, Lucille B. <(b)(6) @va.gov>, Howard, Kristi <(b)(6) @va.gov>, Zacher, Jennifer L. (PBM) <(b)(6) @va.gov>
Subject: RE: HHS bought a nasal spray for depression

Hi Jon,

We will work on it and get a response back.

Tom

Sent with BlackBerry Work
(www.blackberry.com)

From: Jensen, Jon M. <(b)(6) @va.gov>
Date: Wednesday, Mar 06, 2019, 7:34 PM
To: Valentino, Michael (VACO) <(b)(6) @va.gov>, Carroll, David (VACO <(b)(6) @va.gov>, Beck, Lucille B. <(b)(6) @va.gov>, Howard, Kristi <(b)(6) @va.gov>, Emmendorfer, Thomas (PBM) <(b)(6) @va.gov>, Zacher, Jennifer L. (PBM) <(b)(6) @va.gov>
Subject: RE: HHS bought a nasal spray for depression

Adding Jennifer

Jon Jensen
VHA Acting Deputy Chief of Staff
W: (b)(6)
C: (b)(6)

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From: Jensen, Jon M. <(b)(6) @va.gov>
Date: Wednesday, Mar 06, 2019, 7:27 PM
To: Valentino, Michael (VACO) <(b)(6) @va.gov>, Carroll, David (VACO) (b)(6) @va.gov>, Beck, Lucille B. <(b)(6) @va.gov>, Howard, Kristi <(b)(6) @va.gov>, Emmendorfer, Thomas (PBM) (b)(6) @va.gov>
Subject: RE: HHS bought a nasal spray for depression

Just spoke to Dr Stone. We need to get something a little earlier than 10. As soon as you can would be fantastic.
Secva has asked for an update.

Jon Jensen
VHA Acting Deputy Chief of Staff
W (b)(6)
C (b)(6)

From: Jensen, Jon M. (b)(6) @va.gov>
Date: Wednesday, Mar 06, 2019, 5:40 PM
To: Valentino, Michael (VACO) <(b)(6) @va.gov>, Carroll, David (VACO) (b)(6) @va.gov>, Beck, Lucille B (b)(6) @va.gov>, Howard, Kristi <(b)(6) @va.gov>, Emmendorfer, Thomas (PBM) (b)(6) @va.gov>
Subject: HHS bought a nasal spray for depression

Good evening, need some information on a nasal spray used for depression? POTUS heard HHS recently purchased and he felt it would be great for us. That's all I got. Can you pull info on what it would be, if we purchase currently, if we are looking into it etc. would sure appreciate anything you could provide by 10am.

Jon Jensen
VHA Acting Deputy Chief of Staff
W: (b)(6)
C: (b)(6)

Recipient:	Valentino, Michael (VACO) (b)(6) @va.gov) /o=VA/ou=VA Martinsburg/cn=Recipients/cn=vhacoValenM (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) /o=VA/ou=VISN 12/cn=RECIPIENTS/cn=VHANCHZACHEJ (b)(6) @va.gov>
Sent Date:	2019/03/08 07:42:14
Delivered Date:	2019/03/08 07:42:09
Message Flags:	Unread Unsent

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To:	Valentino, Michael (VACO) /o=VA/ou=VA Martinsburg/cn=Recipients/cn=vhacoValenM (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) /o=VA/ou=VISN 12/cn=RECIPIENTS/cn=VHANCHZACHEJ (b)(6) @va.gov>
Subject:	FW: HHS bought a nasal spray for depression
Date:	2019/03/06 21:55:08
Priority:	Normal
Type:	Note

Edits in red below for your review....

(b5)

From: Emmendorfer, Thomas (PBM)
Sent: Wednesday, March 06, 2019 9:06 PM
To: Zacher, Jennifer L. (PBM) (b)(6) @va.gov>; Valentino, Michael (VACO) (b)(6) @va.gov) (b)(6) @va.gov>
Subject: FW: HHS bought a nasal spray for depression

I called Jon and the SecVA and maybe Dr. Stone have a meeting at White House tomorrow and Trump wants to meet with President of Johnson and Johnson. I told him we could give a very high level talking point and some background bullet points.

Jenn and I pulled the Background Info bullet points from the FDA Immediate Release on the approval: https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm632761.htm

(b5)

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From: Jensen, Jon M.
Sent: Wednesday, March 06, 2019 7:50 PM
To: Emmendorfer, Thomas (PBM) (b)(6) @va.gov>; Valentino, Michael (VACO) (b)(6) @va.gov>; Carroll, David (VACO) (b)(6) @va.gov>; Beck, Lucille B. (b)(6) @va.gov>; Howard, Kristi (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) (b)(6) @va.gov>
Subject: RE: HHS bought a nasal spray for depression

Thanks Tom!

Jon Jensen
VHA Acting Deputy Chief of Staff
W: (b)(6)
C: (b)(6)

From: Emmendorfer, Thomas (PBM) (b)(6) @va.gov>
Date: Wednesday, Mar 06, 2019, 7:49 PM
To: Jensen, Jon M. (b)(6) @va.gov>, Valentino, Michael (VACO) (b)(6) @va.gov>, Carroll, David (VACO) (b)(6) @va.gov>, Beck, Lucille B (b)(6) @va.gov>, Howard, Kristi (b)(6) @va.gov>, Zacher, Jennifer L. (PBM) (b)(6) @va.gov>
Subject: RE: HHS bought a nasal spray for depression

Hi Jon,

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(www.blackberry.com)

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Date: Wednesday, Mar 06, 2019, 7:34 PM
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Subject: RE: HHS bought a nasal spray for depression

Adding Jennifer

Jon Jensen
VHA Acting Deputy Chief of Staff
W:(b)(6)
C:(b)(6)

From: Jensen, Jon M. <(b)(6) @va.gov>
Date: Wednesday, Mar 06, 2019, 7:27 PM
To: Valentino, Michael (VACO) <(b)(6) @va.gov>, Carroll, David (VACO) (b)(6) @va.gov>, Beck, Lucille B. (b)(6) @va.gov>, Howard, Kristi <(b)(6) @va.gov>, Emmendorfer, Thomas (PBM) (b)(6) @va.gov>
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Jon Jensen
VHA Acting Deputy Chief of Staff
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Date: Wednesday, Mar 06, 2019, 5:40 PM
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Subject: HHS bought a nasal spray for depression

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VHA Acting Deputy Chief of Staff
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Recipient:	Valentino, Michael (VACO) ((b)(6) @va.gov) /o=VA/ou=VA Martinsburg/cn=Recipients/cn=vhacoValenM <(b)(6) @va.gov>; Zacher, Jennifer L. (PBM) /o=VA/ou=VISN 12/cn=RECIPIENTS/cn=VHANCHZACHEJ (b)(6) @va.gov>
Sent Date:	2019/05/02 04:09:18
Delivered Date:	2019/03/06 21:55:08
Message Flags:	Unread Unsent

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From:	Emmendorfer, Thomas (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC96BB44E7AE2C94C43B55D094-EMMENDORFER (b)(6) @va.gov>
To:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen (b)(6) @va.gov>
Subject:	FW: HHS bought a nasal spray for depression
Date:	2019/03/07 08:35:53
Priority:	Normal
Type:	Note

I am going to brief Maria quick, but below are answers to questions

---

From: "Beck, Lucille B." (b)(6) @va.gov>
Date: Thursday, March 7, 2019 at 8:05 AM
To: Jon Jensen (b)(6) @va.gov>, Thomas Emmendorfer (b)(6) @va.gov>
Cc: Michael Valentino <(b)(6) @va.gov>, "Carroll, David (VACO)" (b)(6) @va.gov>, "Howard, Kristi" (b)(6) @va.gov>, Jennifer Zacher (b)(6) @va.gov>, "Llorente, Maria D." (b)(6) @va.gov>, "Law, Cassandra M." (b)(6) @va.gov>
Subject: RE: HHS bought a nasal spray for depression

Questions being asked?

So, will it be available in VA? Yes (is our BLUF)

Is it now? No, I called REMS 1-800 program no firm launch date yet—however, may be towards end of month

What training is needed to implement? I printed off Healthcare setting, patient, pharmacy, enrollment forms as well as patient monitoring form.

I can describe our process in general that we work with companies with REMS (e.g. we typically get them to remove providing patient specific info. Ect…)

Lucille B. Beck, Ph.D.
Deputy Under Secretary for Health
for Policy and Services (10P)
VA Central Office
Phone (b)(6)

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Cell : (b)(6)

Sent with BlackBerry Work
(www.blackberry.com).

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Date: Thursday, Mar 07, 2019, 7:41 AM
To: Emmendorfer, Thomas (PBM) <(b)(6) @va.gov>
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Subject: RE: HHS bought a nasal spray for depression

Thanks Tom!

Jon Jensen
VHA Acting Deputy Chief of Staff
W: (b)(6)
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AMERICAN OVERSIGHT

Hi Jon,

We will work on it and get a response back.

Tom

Sent with BlackBerry Work
(www.blackberry.com)

From: Jensen, Jon M. (b)(6) @va.gov>
Date: Wednesday, Mar 06, 2019, 7:34 PM
To: Valentino, Michael (VACO) (b)(6) @va.gov>, Carroll, David (VACO) (b)(6) @va.gov>, Beck, Lucille B. (b)(6) @va.gov>, Howard, Kristi (b)(6) @va.gov>, Emmendorfer, Thomas (PBM) (b)(6) @va.gov>, Zacher, Jennifer L. (PBM) (b)(6) @va.gov>
Subject: RE: HHS bought a nasal spray for depression

Adding Jennifer

Jon Jensen
VHA Acting Deputy Chief of Staff
W: (b)(6)
C: (b)(6)

From: Jensen, Jon M. (b)(6) @va.gov>
Date: Wednesday, Mar 06, 2019, 7:27 PM
To: Valentino, Michael (VACO) (b)(6) @va.gov>, Carroll, David (VACO) (b)(6) @va.gov>, Beck, Lucille B. (b)(6) @va.gov>, Howard, Kristi (b)(6) @va.gov>, Emmendorfer, Thomas (PBM) (b)(6) @va.gov>
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Secva has asked for an update.

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VHA Acting Deputy Chief of Staff
W: (b)(6)
C: (b)(6)

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Date: Wednesday, Mar 06, 2019, 5:40 PM
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W (b)(6)
C (b)(6)

Sender:	Emmendorfer, Thomas (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC96BB44E7AE2C94C43B55D094-EMMENDORFER (b)(6) @va.gov>
Recipient:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen (b)(6) @va.gov>
Sent Date:	2019/03/07 08:35:51
Delivered Date:	2019/03/07 08:35:53

AMERICAN OVERSIGHT

From:	Emmendorfer, Thomas (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC96BB44E7AE2C94C43B55D094-EMMENDORFER (b)(6) @va.gov>
To:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>
Subject:	FW: HHS bought a nasal spray for depression
Date:	2019/03/08 18:21:37
Priority:	Normal
Type:	Note

Intravenous ketamine guidance attached

Sent with BlackBerry Work
(www.blackberry.com)

From: Emmendorfer, Thomas (PBM) (b)(6) @va.gov>
Date: Wednesday, Mar 06, 2019, 10:14 PM
To: Jensen, Jon M. (b)(6) @va.gov>
Cc: Valentino, Michael (VACO) <(b)(6) @va.gov>, Carroll, David (VACO) <(b)(6) @va.gov>, Beck, Lucille B. <(b)(6) @va.gov>, Howard, Kristi (b)(6) @va.gov>, Zacher, Jennifer L. (PBM) <(b)(6) @va.gov>, Llorente, Maria D. (b)(6) @va.gov>, Law, Cassandra M. <(b)(6) @va.gov>
Subject: RE: HHS bought a nasal spray for depression

Hi Jon,

I hope all is going well. Below is the information that Jenn, Mike, and I pulled together for you. Let us know if you need anything else.

Tom

Bottom Line Up Front:
Spravato® will be available to VA providers to administer to Veterans based on their clinical assessment and the individual medical needs of our nation's Veterans.

Background Information:

- • The Food and Drug Administration (FDA) approved Spravato® on March 5, 2019.
- • Spravato's® chemical name is esketamine which is a S(+) enantiomer, a slightly different version of ketamine, and provides similar therapeutic effects to ketamine.
- • Intravenous ketamine has been used for several years in the United States for treatment refractory depression based on the body of medical evidence published in the literature.
- • Intravenous ketamine is FDA approved as an anesthetic agent for diagnostic and surgical procedures that do not require skeletal muscle relaxation and has been used for several decades.

AMERICAN OVERSIGHT

- • Intravenous ketamine has been used for several years in the United States for treatment resistant depression and intractable neuropathic pain based on the body of medical evidence published in the literature.
- • VA Pharmacy Benefits Management (PBM) Services has developed a national protocol for the use of intravenous ketamine in treatment resistant depression and severe suicidal ideation which was published in December 2017 (attached).
- • VA PBM developed Guidance on Off Label Prescribing of drugs in August 2013 and the national protocol for the use of intravenous ketamine is consistent with this guidance (attached).
- • Spravato® is a Schedule III Controlled Substance and cannot be dispensed as an outpatient prescription for a patient to take home.
- • The patient self-administers Spravato® nasal spray under the supervision of a health care provider in a certified doctor's office or clinic, and the spray cannot be taken home.
- • Unlike ketamine which VA medical facilities can purchase unrestricted through the pharmaceutical prime vendor with next day delivery, Spravato® is only available through a restricted distribution system, under an FDA approved Risk Evaluation and Mitigation Strategy (REMS).
- • Spravato® must be administered in a certified medical office where the health care provider can monitor the patient.
- • Spravato® labeling contains a Boxed Warning that cautions that patients are at risk for sedation and difficulty with attention, judgment and thinking (dissociation), abuse and misuse, and suicidal thoughts and behaviors after administration of the drug.
- • Because of the risk of sedation and dissociation, patients must be monitored by a health care provider for at least two hours after receiving their Spravato® dose.

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Sent: Wednesday, March 06, 2019 7:50 PM
To: Emmendorfer, Thomas (PBM) (b)(6) @va.gov>; Valentino, Michael (VACO) (b)(6) @va.gov>; Carroll, David (VACO) (b)(6) @va.gov>; Beck, Lucille B. (b)(6) @va.gov>; Howard, Kristi (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) (b)(6) @va.gov>
Subject: RE: HHS bought a nasal spray for depression

Thanks Tom!

Jon Jensen
VHA Acting Deputy Chief of Staff
W (b)(6)
C: (b)(6)

From: Emmendorfer, Thomas (PBM) <(b)(6) @va.gov>
Date: Wednesday, Mar 06, 2019, 7:49 PM

AMERICAN OVERSIGHT

To: Jensen, Jon M. <(b)(6) @va.gov>, Valentino, Michael (VACO) <(b)(6) @va.gov>, Carroll, David (VACO) <(b)(6) @va.gov>, Beck, Lucille B. <(b)(6) @va.gov>, Howard, Kristi (b)(6) @va.gov>, Zacher, Jennifer L. (PBM) (b)(6) @va.gov>
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Adding Jennifer

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VHA Acting Deputy Chief of Staff
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Sent Date:	2019/03/08 18:21:36
Delivered Date:	2019/03/08 18:21:37

AMERICAN OVERSIGHT

From:	Emmendorfer, Thomas (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC96BB44E7AE2C94C43B55D094-EMMENDORFER (b)(6) @va.gov>
To:	Outlaw, William N. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3e1067978634fbf96a382bdcd5c1115-Outlaw, Wil (b)(6) @va.gov>
Subject:	FW: HHS bought a nasal spray for depression
Date:	2019/03/11 15:37:30
Priority:	Normal
Type:	Note

FYI...

From: "Llorente, Maria D." (b)(6) @va.gov>
Date: Monday, March 11, 2019 at 3:25 PM
To: Thomas Emmendorfer <(b)(6) @va.gov>, "Outlaw, William N." (b)(6) @va.gov>, "Wiechers, Ilse" (b)(6) @va.gov>
Subject: FW: HHS bought a nasal spray for depression

I have no edits. Concur.

From: Emmendorfer, Thomas (PBM)
Sent: Monday, March 11, 2019 3:21 PM
To: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Cc: Llorente, Maria D. (b)(6) @va.gov>; Outlaw, William N. (b)(6) @va.gov>; Carroll, David (VACO) (b)(6) @va.gov>; Wiechers, Ilse (b)(6) @va.gov>
Subject: FW: HHS bought a nasal spray for depression

The attached external press release has been developed in coordination with 10P4P and 10NC5. We left a place holder in for a potential quote from Dr. Stone.

Request clearance to 10P for review.

From: Thomas Emmendorfer (b)(6) @va.gov>
Date: Thursday, March 7, 2019 at 7:45 AM
To: Jon Jensen (b)(6) @va.gov>
Cc: Michael Valentino <(b)(6) @va.gov>, "Carroll, David (VACO)" (b)(6) @va.gov>, "Beck, Lucille B." (b)(6) @va.gov>, "Howard, Kristi" (b)(6) @va.gov>, Jennifer Zacher (b)(6) @va.gov>, "Llorente, Maria D." (b)(6) @va.gov>, "Law, Cassandra M." <(b)(6) @va.gov>
Subject: Re: HHS bought a nasal spray for depression

Will do.

AMERICAN OVERSIGHT

From: Jon Jensen <(b)(6) @va.gov>
Date: Thursday, March 7, 2019 at 7:41 AM
To: Thomas Emmendorfer <(b)(6) @va.gov>
Cc: Michael Valentino (b)(6) @va.gov>, "Carroll, David (VACO)" (b)(6) @va.gov>, "Beck, Lucille B." (b)(6) @va.gov>, "Howard, Kristi" (b)(6) @va.gov>, Jennifer Zacher (b)(6) @va.gov>, "Llorente, Maria D." (b)(6) @va.gov>, "Law, Cassandra M." <(b)(6) @va.gov>
Subject: RE: HHS bought a nasal spray for depression

Tom, can you come to Morning Report today to discuss? Starts at 9:30.

From: Emmendorfer, Thomas (PBM)
Sent: Wednesday, March 06, 2019 10:15 PM
To: Jensen, Jon M. (b)(6) @va.gov>
Cc: Valentino, Michael (VACO) (b)(6) @va.gov>; Carroll, David (VACO) (b)(6) @va.gov>; Beck, Lucille B. <(b)(6) @va.gov>; Howard, Kristi (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) <(b)(6) @va.gov>; Llorente, Maria D. (b)(6) @va.gov>; Law, Cassandra M. (b)(6) @va.gov>
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Recipient:	Outlaw, William N. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3e1067978634fbf96a382bdcd5c1115-Outlaw, Wil (b)(6) @va.gov>
Sent Date:	2019/03/11 15:37:31
Delivered Date:	2019/03/11 15:37:30

AMERICAN OVERSIGHT

To:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b)(6) @va.gov>; McGuire, Marsden H. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29e9d648c29f4885828c10446fdd7379-McGuire, Ma (b)(6) @va.gov>; Pomerantz, Andrew /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29a9288df9a34e84bddfd00cde79f11b-Pomerantz, (b)(6) @va.gov>; Katz, Ira R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=65f4e28aa7574641932c29fed7c0b4b8-Katz, Ira R (b)(6) @va.gov>
CC:	VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>
Subject:	FW: HHS bought a nasal spray for depression
Date:	2019/03/07 05:41:48
Priority:	Normal
Type:	Note

Sent with BlackBerry Work
(www.blackberry.com)

From: Law, Cassandra M. (b)(6) @va.gov>
Date: Thursday, Mar 07, 2019, 4:50 AM
To: Emmendorfer, Thomas (PBM) <(b)(6) @va.gov>, Jensen, Jon M. (b)(6) @va.gov>
Cc: Valentino, Michael (VACO) (b)(6) @va.gov>, Carroll, David (VACO) (b)(6) @va.gov>, Beck, Lucille B. (b)(6) @va.gov>, Howard, Kristi (b)(6) @va.gov>, Zacher, Jennifer L. (PBM) <(b)(6) @va.gov>, Llorente, Maria D. (b)(6) @va.gov>
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Sent Date:	2019/03/07 05:41:48
Message Flags:	Unsent

AMERICAN OVERSIGHT

From:	Carroll, David (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=95E14EBD3B6745C8952A823B04DABFF5-CARROLL, DA <(b)(6) @va.gov>
To:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b)(6) @va.gov>; McGuire, Marsden H. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29e9d648c29f4885828c10446fdd7379-McGuire, Ma <(b)(6) @va.gov>; Pomerantz, Andrew /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29a9288df9a34e84bddfd00cde79f11b-Pomerantz, (b)(6) @va.gov>; Katz, Ira R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=65f4e28aa7574641932c29fed7c0b4b8-Katz, Ira R (b)(6) @va.gov>
CC:	VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>
Subject:	FW: HHS bought a nasal spray for depression
Date:	2019/03/07 05:42:52
Priority:	Normal
Type:	Note

FYI - see info below from Pharmacy.

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Subject: RE: HHS bought a nasal spray for depression

Good morning. Thank you very much for the great work and organization last night.
Jon, please let us know if any additional information is needed for either Dr. Stone or SECVA.

Thank you, Cassie

From: Emmendorfer, Thomas (PBM) (b)(6) @va.gov>
Date: Wednesday, Mar 06, 2019, 10:14 PM
To: Jensen, Jon M. <(b)(6) @va.gov>
Cc: Valentino, Michael (VACO) <(b)(6) @va.gov>, Carroll, David (VACO) (b)(6) @va.gov>, Beck, Lucille B. <(b)(6) @va.gov>, Howard, Kristi (b)(6) @va.gov>, Zacher, Jennifer L. (PBM) <(b)(6) @va.gov>, Llorente, Maria D. (b)(6) @va.gov>, Law, Cassandra M. <(b)(6) @va.gov>
Subject: RE: HHS bought a nasal spray for depression

AMERICAN OVERSIGHT

Hi Jon,

I hope all is going well. Below is the information that Jenn, Mike, and I pulled together for you. Let us know if you need anything else.

Tom

-

Bottom Line Up Front:

Spravato® will be available to VA providers to administer to Veterans based on their clinical assessment and the individual medical needs of our nation's Veterans.

Background Information:

- • The Food and Drug Administration (FDA) approved Spravato® on March 5, 2019.
- • Spravato's® chemical name is esketamine which is a S(+) enantiomer, a slightly different version of ketamine, and provides similar therapeutic effects to ketamine.
- • Intravenous ketamine has been used for several years in the United States for treatment refractory depression based on the body of medical evidence published in the literature.
- • Intravenous ketamine is FDA approved as an anesthetic agent for diagnostic and surgical procedures that do not require skeletal muscle relaxation and has been used for several decades.
- • Intravenous ketamine has been used for several years in the United States for treatment resistant depression and intractable neuropathic pain based on the body of medical evidence published in the literature.
- • VA Pharmacy Benefits Management (PBM) Services has developed a national protocol for the use of intravenous ketamine in treatment resistant depression and severe suicidal ideation which was published in December 2017 (attached).
- • VA PBM developed Guidance on Off Label Prescribing of drugs in August 2013 and the national protocol for the use of intravenous ketamine is consistent with this guidance (attached).
- • Spravato® is a Schedule III Controlled Substance and cannot be dispensed as an outpatient prescription for a patient to take home.
- • The patient self-administers Spravato® nasal spray under the supervision of a health care provider in a certified doctor's office or clinic, and the spray cannot be taken home.
- • Unlike ketamine which VA medical facilities can purchase unrestricted through the pharmaceutical prime vendor with next day delivery, Spravato® is only available through a restricted distribution system, under an FDA approved Risk Evaluation and Mitigation Strategy (REMS).
- • Spravato® must be administered in a certified medical office where the health care provider can monitor the patient.
- • Spravato® labeling contains a Boxed Warning that cautions that patients are at risk for sedation and difficulty with attention, judgment and thinking (dissociation), abuse and misuse, and suicidal thoughts and behaviors after administration of the drug.
- • Because of the risk of sedation and dissociation, patients must be monitored by a health care provider for at least two hours after receiving their Spravato® dose.

AMERICAN OVERSIGHT

From: Jensen, Jon M.
Sent: Wednesday, March 06, 2019 7:50 PM
To: Emmendorfer, Thomas (PBM) <(b) (6) @va.gov>; Valentino, Michael (VACO) (b) (6) @va.gov>; Carroll, David (VACO) <(b) (6) @va.gov>; Beck, Lucille B. <(b) (6) @va.gov>; Howard, Kristi (b) (6) @va.gov>; Zacher, Jennifer L. (PBM) (b) (6) @va.gov>
Subject: RE: HHS bought a nasal spray for depression

Thanks Tom!

Jon Jensen
VHA Acting Deputy Chief of Staff
W:
C:(b) (6)

From: Emmendorfer, Thomas (PBM) *(b)(6)* @va.gov>
Date: Wednesday, Mar 06, 2019, 7:49 PM
To: Jensen, Jon M. <*(b)(6)* @va.gov>, Valentino, Michael (VACO) *(b)(6)* @va.gov>, Carroll, David (VACO) *(b)(6)* @va.gov>, Beck, Lucille B. *(b)(6)* @va.gov>, Howard, Kristi *(b)(6)* @va.gov>, Zacher, Jennifer L. (PBM) <*(b)(6)* @va.gov>
Subject: RE: HHS bought a nasal spray for depression

Hi Jon,

We will work on it and get a response back.

Tom

Sent with BlackBerry Work
(www.blackberry.com)

From: Jensen, Jon M. <*(b)(6)* @va.gov>
Date: Wednesday, Mar 06, 2019, 7:34 PM
To: Valentino, Michael (VACO) <*(b)(6)* @va.gov>, Carroll, David (VACO) *(b)(6)* @va.gov>, Beck, Lucille B. <*(b)(6)* @va.gov>, Howard, Kristi *(b)(6)* @va.gov>, Emmendorfer, Thomas (PBM) <*(b)(6)* @va.gov>, Zacher, Jennifer L. (PBM) *(b)(6)* @va.gov>
Subject: RE: HHS bought a nasal spray for depression

Adding Jennifer

Jon Jensen
VHA Acting Deputy Chief of Staff
W:*(b)(6)*

AMERICAN OVERSIGHT

C: (b)(6)

From: Jensen, Jon M. (b)(6) @va.gov>
Date: Wednesday, Mar 06, 2019, 7:27 PM
To: Valentino, Michael (VACO) <(b)(6) @va.gov>, Carroll, David (VACO) (b)(6) @va.gov>, Beck, Lucille B. (b)(6) @va.gov>, Howard, Kristi <(b)(6) @va.gov>, Emmendorfer, Thomas (PBM) (b)(6) @va.gov>
Subject: RE: HHS bought a nasal spray for depression

Just spoke to Dr Stone. We need to get something a little earlier than 10. As soon as you can would be fantastic.
Secva has asked for an update.

Jon Jensen
VHA Acting Deputy Chief of Staff
W: (b)(6)
C: (b)(6)

From: Jensen, Jon M. (b)(6) @va.gov>
Date: Wednesday, Mar 06, 2019, 5:40 PM
To: Valentino, Michael (VACO) (b)(6) @va.gov>, Carroll, David (VACO) (b)(6) @va.gov>, Beck, Lucille B. (b)(6) @va.gov>, Howard, Kristi <(b)(6) @va.gov>, Emmendorfer, Thomas (PBM) (b)(6) @va.gov>
Subject: HHS bought a nasal spray for depression

Good evening, need some information on a nasal spray used for depression? POTUS heard HHS recently purchased and he felt it would be great for us. That's all I got. Can you pull info on what it would be, if we purchase currently, if we are looking into it etc. would sure appreciate anything you could provide by 10am.

Jon Jensen
VHA Acting Deputy Chief of Staff
W: (b)(6)
C: (b)(6)

Sender:	Carroll, David (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=95E14EBD3B6745C8952A823B04DABFF5-CARROLL, DA (b)(6) @va.gov>
Recipient:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b)(6) @va.gov>; McGuire, Marsden H. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29e9d648c29f4885828c10446fdd7379-McGuire, Ma

AMERICAN OVERSIGHT

	.(b)(6) @va.gov>; Pomerantz, Andrew /c=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29a9288df9a34e84bddfd00cde79f11b-Pomerantz, (b)(6) @va.gov>; Katz, Ira R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=65f4e28aa7574641932c29fed7c0b4b8-Katz, Ira R (b)(6) @va.gov>; VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>
Sent Date:	2019/03/07 05:42:50
Delivered Date:	2019/03/07 05:42:52

AMERICAN OVERSIGHT

From:	Llorente, Maria D. </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F5C91F577D894BD9A0F09305DB34DD4F-LLORENTE, M>
To:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>
Subject:	FW: Group just voted to change ketamine to match Esketamine
Date:	2019/06/20 16:17:52
Priority:	Normal
Type:	Note

FYI

Sent with BlackBerry Work
(www.blackberry.com)

From: Wiechers, Ilse (b)(6) @va.gov>
Date: Thursday, Jun 20, 2019, 1:47 PM
To: Llorente, Maria D. (b)(6) @va.gov>
Subject: RE: Group just voted to change ketamine to match Esketamine

Noted, and reasonable. Considering an existing evidence-based treatment for TRD prior to moving to esketamine or ketamine is totally reasonable. That said, not all patients are going to be willing to try ECT, but I think having that discussion with them should be part of a process of walking through treatment steps.

From: Llorente, Maria D.
Sent: Thursday, June 20, 2019 11:44 AM
To: Wiechers, Ilse (b)(6) @va.gov>
Subject: Group just voted to change ketamine to match Esketamine

Just as an FYI

Sent with BlackBerry Work
(www.blackberry.com)

Sender:	Llorente, Maria D. </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F5C91F577D894BD9A0F09305DB34DD4F-LLORENTE, M>
Recipient:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>
Sent Date:	2019/06/20 16:17:51
Delivered Date:	2019/06/20 16:17:52

AMERICAN OVERSIGHT

From:	Emmendorfer, Amanda (CMOP) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E7CED4955BBA46A7BFCB92540F89A12E-EMMENDORFER (b)(6) @va.gov>
To:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>
Subject:	FW: Frequently Asked Questions (FAQ): Esketamine (Spravato®)
Date:	2019/03/15 14:19:59
Importance:	High
Priority:	Urgent
Type:	Note

Thumbs up Dr. Emmendorfer!!

From: Sales, Marie
Sent: Friday, March 15, 2019 1:55 PM
To: VHAPBM MAP Committee <pbm.map@med.va.gov>; VHAPBM VISN Pharmacist Executives <VISNPharmacyExecs@va.gov>; VHAPBM Pharmacy Chiefs <PharmacyChiefs@va.gov>; VHAPBM PMO <PMO@va.gov>
Subject: Frequently Asked Questions (FAQ): Esketamine (Spravato®)
Importance: High

Attached is the **Frequently Asked Questions (FAQ)** sheet addressing the newly FDA-approved **esketamine (Spravato®)** nasal spray for treatment-resistant depression published by the VA Pharmacy Benefits Management Services and Office of Mental Health and Suicide Prevention. This FAQ sheet accompanies VA's News Release and will also be available online at the following link https://vaww.cmopnational.va.gov/cmop/pbm/default.aspx (pending posting).

The purpose of this FAQ sheet is to:

- • Disseminate new drug information to the provider-level regarding esketamine (Spravato®)
- • Provide answers on availability and accessibility of esketamine (Spravato®) within VA

Sender:	Emmendorfer, Amanda (CMOP) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E7CED4955BBA46A7BFCB92540F89A12E-EMMENDORFER (b)(6) @va.gov>
Recipient:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>
Sent Date:	2019/03/15 14:19:57
Delivered Date:	2019/03/15 14:19:59

AMERICAN OVERSIGHT

From:	Bartch, Chantelle /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B9BA056376BD41A49C4EBAE378E14FFE-BARTCH, CHA (b)(6) @va.gov>
To:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>
Subject:	FW: Follow Up: HHS Nasal Spray
Date:	2019/03/08 07:23:26
Priority:	Normal
Type:	Note

Hi Tom,

Don't think this is a proper slide deck format. Can you help put this in the proper format pls?

From: Kraemer, John E
Sent: Thursday, March 7, 2019 4:48 PM
To: VHA 10P4 PCS Clearance <VHA10P4PCSClearance@va.gov>
Subject: FW: Follow Up: HHS Nasal Spray

For clearance.

Request
Follow up from Thursday's morning meeting.

Response
Attachment. For review and clearance for an 8:30am meeting tomorrow morning.

From: Valentino, Michael (VACO)
Sent: Thursday, March 07, 2019 4:40 PM
To: VHA 10P4 Actions <VHA10P4Actions@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Cc: Llorente, Maria D. (b)(6) @va.gov>; Beck, Lucille B. (b)(6) @va.gov>; Emmendorfer, Thomas (PBM) (b)(6) @va.gov>
Subject: RE: Follow Up: HHS Nasal Spray

For review and clearance for an 8:30am meeting tomorrow morning

-----Original Appointment-----
From: Howard, Kristi **On Behalf Of** Stone, Richard A., MD
Sent: Thursday, March 07, 2019 2:35 PM
To: Llorente, Maria D.; Beck, Lucille B.; Emmendorfer, Thomas (PBM); Jensen, Jon M.; Valentino, Michael (VACO); Connell, Lawrence B.
Subject: Follow Up: HHS Nasal Spray
When: Friday, March 08, 2019 8:30 AM-9:00 AM (UTC-05:00) Eastern Time (US &Canada).
Where: VACO 802 or VANTS 1-800-767-1750 A/C 22021

AMERICAN OVERSIGHT

Follow up from Thursday's morning meeting.

Sender:	Bartch, Chantelle /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B9BA056376BD41A49C4EBAE378E14FFE-BARTCH, CHA *(b)(6)* @va.gov>
Recipient:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer *(b)(6)* @va.gov>
Sent Date:	2019/03/08 07:23:24
Delivered Date:	2019/03/08 07:23:26

AMERICAN OVERSIGHT

From:	Emmendorfer, Thomas (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC96BB44E7AE2C94C43B55D094-EMMENDORFER>
To:	Bartch, Chantelle /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b9ba056376bd41a49c4ebae378e14ffe-Bartch, Cha (b)(6) @va.gov>
Subject:	FW: Follow Up: HHS Nasal Spray
Date:	2019/03/08 07:25:32
Priority:	Normal
Type:	Note

Sent with BlackBerry Work
(www.blackberry.com)

From: Valentino, Michael (VACO) (b)(6) @va.gov>
Date: Thursday, Mar 07, 2019, 5:22 PM
To: Pfeffer, Debora (b)(6) @va.gov>, Howard, Kristi <(b)(6) @va.gov>
Cc: Llorente, Maria D. <(b)(6) @va.gov>, Beck, Lucille B. (b)(6) @va.gov>, Emmendorfer, Thomas (PBM) (b)(6) @va.gov>, Jensen, Jon M. <(b)(6) @va.gov>, Connell, Lawrence B. <(b)(6) @va.gov>
Subject: RE: Follow Up: HHS Nasal Spray

Fixed a minor typo in this version

From: Pfeffer, Debora
Sent: Thursday, March 07, 2019 4:07 PM
To: Howard, Kristi (b)(6) @va.gov>
Cc: Llorente, Maria D. <(b)(6) @va.gov>; Beck, Lucille B. (b)(6) @va.gov>; Emmendorfer, Thomas (PBM) <(b)(6) @va.gov>; Jensen, Jon M. (b)(6) @va.gov>; Valentino, Michael (VACO) <(b)(6) @va.gov>; Connell, Lawrence B. (b)(6) @va.gov>; Pfeffer, Debora (b)(6) @va.gov>
Subject: FW: Follow Up: HHS Nasal Spray

Good afternoon Kristi

Please see the attached slide presentation that will be utilized at the 0830 meeting tomorrow (Friday, 8 March).

Thank you so much
Deb

-----Original Appointment-----
From: Howard, Kristi **On Behalf Of** Stone, Richard A., MD
Sent: Thursday, March 07, 2019 2:35 PM

AMERICAN OVERSIGHT

To: Llorente, Maria D.; Beck, Lucille B.; Emmendorfer, Thomas (PBM); Jensen, Jon M.; Valentino, Michael (VACO); Connell, Lawrence B.
Subject: Follow Up: HHS Nasal Spray
When: Friday, March 08, 2019 8:30 AM-9:00 AM (UTC-05:00) Eastern Time (US &Canada).
Where: VACO 802 or VANTS 1-800-767-1750 A/C 22021

Follow up from Thursday's morning meeting.

Sender:	Emmendorfer, Thomas (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC96BB44E7AE2C94C43B55D094-EMMENDORFER>
Recipient:	Bartch, Chantelle /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b9ba056376bd41a49c4ebae378e14ffe-Bartch, Cha (b)(6) @va.gov>
Sent Date:	2019/03/08 07:25:32

AMERICAN OVERSIGHT

From:	Valentino, Michael (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO, (b)(6) @va.gov>
SentVia:	Microsoft Outlook /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=MICROSOFTEXCHANGE329E71EC88AE4615BBC36AB6CE41109EFDAAD960 <MicrosoftExchange329e71ec88ae4615bbc36ab6ce41109e@DVAGOV.onmicrosoft.com>
To:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b)(6) @va.gov>
Subject:	FW: Esketamine Community of Practice
Date:	2019/06/25 11:15:27
Start Date:	2019/06/12 14:00:00
End Date:	2019/06/12 15:00:00
Priority:	Normal
Type:	Schedule.Meeting.Resp.Tent
Location:	Skype for online meeting VANTS for audio at 1-800767-1750, 45914#

Sent by Microsoft Exchange Server

Sender:	Valentino, Michael (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO, (b)(6) @va.gov>; Microsoft Outlook /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=MICROSOFTEXCHANGE329E71EC88AE4615BBC36AB6CE41109EFDAAD960 <MicrosoftExchange329e71ec88ae4615bbc36ab6ce41109e@DVAGOV.onmicrosoft.com>
Recipient:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b)(6) @va.gov>
Sent Date:	2019/06/25 11:15:27

AMERICAN OVERSIGHT

From:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino (b)(6) @va.gov>
SentVia:	Microsoft Outlook /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=MICROSOFTEXCHANGE329E71EC88AE4615BBC36AB6CE41109EFDAAD960 <MicrosoftExchange329e71ec88ae4615bbc36ab6ce41109e@DVAGOV.onmicrosoft.com>
To:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b)(6) @va.gov>
Subject:	FW: Esketamine Community of Practice
Date:	2019/08/28 17:15:25
Start Date:	2019/06/12 14:00:00
End Date:	2019/06/12 15:00:00
Priority:	Normal
Type:	Schedule.Meeting.Resp.Tent
Location:	Skype for online meeting VANTS for audio at 1-800767-1750, 45914#

Sent by Microsoft Exchange Server

Sender:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>; Microsoft Outlook /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=MICROSOFTEXCHANGE329E71EC88AE4615BBC36AB6CE41109EFDAAD960 <MicrosoftExchange329e71ec88ae4615bbc36ab6ce41109e@DVAGOV.onmicrosoft.com>
Recipient:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b)(6) @va.gov>
Sent Date:	2019/08/28 17:15:25

AMERICAN OVERSIGHT

From:	Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd /O=FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=182805D689894DA4B2D00810DA5E305C-STEWART, KA (b)(6) @va.gov>
To:	VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>
CC:	VHA CO 10NC Front Office HSSs /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcf91f73967a49c287d8747b7aee675e-VHA CO 10NC <VHACO10NCFOHSSs@va.gov>
Subject:	FW: esketamine briefing slides for clearance to present at ORD meeting
Date:	2019/08/23 16:01:31
Priority:	Normal
Type:	Note

Good Afternoon 10NC5,

On behalf of 10N/10NC, Dr. Thomas O'Toole clears your attached slide deck.

Thank you,

Katie Stewart, MSW, LCSW
Health Systems Specialist
Office of the ADUSH for Clinical Operations (10NC)
(b)(6) (office)
(b)(6) (cell)

From: O'Toole, Thomas P.
Sent: Friday, August 23, 2019 3:45 PM
To: Butler, Dakota <(b)(6) @va.gov>; VHA 10NC Clearance <VHA10NCClearance2@va.gov>
Subject: RE: esketamine briefing slides for clearance to present at ORD meeting

10NC clears

From: Butler, Dakota
Sent: Friday, August 23, 2019 2:19 PM
To: VHA 10NC Clearance <VHA10NCClearance2@va.gov>
Subject: FW: esketamine briefing slides for clearance to present at ORD meeting

Good afternoon 10NC Leadership,

The attached slide deck has been reviewed and is ready for clearance.

Please note the Esketamine Clinical Implementation for presentation at the upcoming VA ORD Esketamine Study Planning Meeting There will likely be some participants present who are not VA employees and the presentation is on Monday, September 9th.

AMERICAN OVERSIGHT

Thank You,

Dakota Butler
Veterans Health Administration
ADUSH for Clinical Operations(10NC)
(b)(6) @va.gov
Tel: (b)(6)
Mobile: (b)(6)

From: Strmiska, Jon G.
Sent: Friday, August 23, 2019 2:10 PM
To: VHA CO 10NC Front Office HSSs <VHACO10NCFOHSSs@va.gov>
Cc: VHA 10NC5 Action <VHA10NC5Action@va.gov>; Wiechers, Ilse (b)(6) @va.gov>
Subject: esketamine briefing slides for clearance to present at ORD meeting

10NC,

Cleared by Drs. McGuire and Smith.

Please clear the attached slide deck on the Esketamine Clinical Implementation for presentation at the upcoming VA ORD Esketamine Study Planning Meeting. We are making efforts to coordinate and collaborate between clinical implementation and research implementation of esketamine. There will likely be some participants present who are not VA employees.

The presentation is on Monday, September 9th.

Jon G. Strmiska
Manager, Business Operations
Office of Mental Health Services and
Suicide Prevention (10NC5)
Phone: (b)(6)
FAX: 202.495.5933

INTEGRITY COMMITMENT ADVOCACY RESPECT EXCELLENCE

Sender:	Stewart, Katharine E. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=182805D689894DA4B2D00810DA5E305C-STEWART, KA (b)(6) @va.gov>
Recipient:	VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>;

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	VHA CO 10NC Front Office HSSs /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcf91f73967a49c287d8747b7aee675e-VHA CO 10NC <VHACO10NCFOHSSs@va.gov>
Sent Date:	2019/08/23 16:01:29
Delivered Date:	2019/08/23 16:01:31
Message Flags:	Unread

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(b5)

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To:	VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>
CC:	VHA 10NC Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aeebc70340b3476a87b15fbe600f1888-VHA 10NC Ac <vha10ncaction@va.gov>; VHA CO 10N Support Staff /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=49641c3663c04aa58d87f8b7fa6dd515-VHA CO 10N <VHACO10NSS@va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b)(6) @va.gov>
Subject:	FW: esketamine briefing slides for clearance to present at ORD meeting
Date:	2019/08/23 14:35:28
Priority:	Normal
Type:	Note

Good Afternoon

On behalf of 10NC, Christine Croteau clears the attachment.

Thank You!
Tracy

Tracy L. Dudley
Health System Specialist
ADUSH for Clinical Operations (10NC)
Office: (b)(6)
Mobile: (b)(6)
(b)(6) @va.gov

*Integrity, **C**ommitment, **A**dvocacy, **R**espect, **E**xcellence - **I CARE***

From: Croteau, Christine
Sent: Friday, August 23, 2019 2:29 PM
To: Butler, Dakota (b)(6) @va.gov>; VHA 10NC Clearance <VHA10NCClearance2@va.gov>
Subject: RE: esketamine briefing slides for clearance to present at ORD meeting

10NC clears

From: Strmiska, Jon G.
Sent: Friday, August 23, 2019 2:10 PM
To: VHA CO 10NC Front Office HSSs <VHACO10NCFOHSSs@va.gov>

AMERICAN OVERSIGHT

Cc: VHA 10NC5 Action <VHA10NC5Action@va.gov>; Wiechers, Ilse (b)(6) @va.gov>
Subject: esketamine briefing slides for clearance to present at ORD meeting

10NC,

Cleared by Drs. McGuire and Smith.

Please clear the attached slide deck on the Esketamine Clinical Implementation for presentation at the upcoming VA ORD Esketamine Study Planning Meeting. We are making efforts to coordinate and collaborate between clinical implementation and research implementation of esketamine. There will likely be some participants present who are not VA employees.

The presentation is on Monday, September 9th.

Jon G. Strmiska
Manager, Business Operations
Office of Mental Health Services and
Suicide Prevention (10NC5)
Phone: (b)(6)
FAX: 202.495.5933

INTEGRITY COMMITMENT ADVOCACY RESPECT EXCELLENCE

Sender:	Dudley, Tracy /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2BEF1C88D64447BC9087572C951D0CB1-DUDLEY, TRA (b)(6) @va.gov>
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Subject:	FW: esketamine briefing slides for clearance to present at ORD meeting
Date:	2019/08/23 16:00:57
Priority:	Normal
Type:	Note

Good afternoon,

On behalf of 10NC, Dr. Thomas O'Toole clears the attached slide deck.

Thank You,

Dakota Butler
Veterans Health Administration
ADUSH for Clinical Operations(10NC)
(b)(6) @va.gov
Tel: (b)(6)
Mobile: (b)(6)

From: O'Toole, Thomas P.
Sent: Friday, August 23, 2019 3:45 PM
To: Butler, Dakota (b)(6) @va.gov>; VHA 10NC Clearance <VHA10NCClearance2@va.gov>
Subject: RE: esketamine briefing slides for clearance to present at ORD meeting

10NC clears

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From: Strmiska, Jon G.
Sent: Friday, August 23, 2019 2:10 PM
To: VHA CO 10NC Front Office HSSs <VHACO10NCFOHSSs@va.gov>
Cc: VHA 10NC5 Action <VHA10NC5Action@va.gov>; Wiechers, Ilse <(b)(6) @va.gov>
Subject: esketamine briefing slides for clearance to present at ORD meeting

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Jon G. Strmiska
Manager, Business Operations
Office of Mental Health Services and
Suicide Prevention (10NC5)
Phone:(b)(6)
FAX: 202.495.5933

INTEGRITY COMMITMENT ADVOCACY RESPECT EXCELLENCE

Sender:	Butler, Dakota /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=67CD7A5F80CC4F168E96DC3C57BDB810-BUTLER, DAK (b)(6) @va.gov>
Recipient:	VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>; VHA 10N Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d5efbba2df804a3a8f191ebd6f6062d4-VHA 10N Act <VHA10NAction@va.gov>; VHA CO 10N Support Staff /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=49641c3663c04aa58d87f8b7fa6dd515-VHA CO 10N <VHACO10NSS@va.gov>
Sent Date:	2019/08/23 16:00:54
Delivered Date:	2019/08/23 16:00:57

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From:	Lowe, Joette /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2cda61a196f849548a246b80455099d9-Lowe, Joett (b)(6) @va.gov>
To:	VHAPBM VPE Formulary Committee /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fcba1f4b52e048838d3053091f54eb4e-VHAPBH VPE <VPEFormularyCommttee@va.gov>
Subject:	FW: Esketamine
Date:	2019/03/21 09:14:01
Priority:	Normal
Type:	Note

Just FYI on feedback from the MH side of the issue.

Joette S. Lowe, PharmD
VISN 7 Pharmacy Executive (VPE)
3701 Loop Road East
Tuscaloosa, AL 35404
(b)(6)

Suicide Prevention is Everyone’s Business. *#BeThere.*



cid:image009.jpg@01D328A1.8C7B68A0

From: Myrick, Donald L. (Hugh)
Sent: Wednesday, March 20, 2019 12:31 PM
To: Lowe, Joette <(b)(6) @va.gov>
Subject: FW: Esketamine

Just FYI.

Hugh Myrick, MD
ACOS, Mental Health Service Line
Ralph H. Johnson VAMC
Director, Addiction Sciences Division
Director, Military Sciences Division
MUSC, Charleston SC

Suicide Prevention is Everyone’s Business. *#BeThere.*



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From: Myrick, Donald L. (Hugh)
Sent: Wednesday, March 20, 2019 1:22 PM
To: Landreth, Edward S. <(b)(6) @va.gov>; Magnes, N. Sarah <(b)(6) @va.gov>; Cohen, Jay L. <(b)(6) @va.gov>; Holliday, Steve <(b)(6) @va.gov>; VHACLE BVAC Group <VHACLEBVACGroup@va.gov>
Subject: RE: Esketamine

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(b) (6)

Hugh Myrick, MD
ACOS, Mental Health Service Line
Ralph H. Johnson VAMC
Director, Addiction Sciences Division
Director, Military Sciences Division
MUSC, Charleston SC
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From: Landreth, Edward S.
Sent: Wednesday, March 20, 2019 12:54 PM
To: Magnes, N. Sarah <(b)(6) @va.gov>; Cohen, Jay L. <(b)(6) @va.gov>; Holliday, Steve <(b)(6) @va.gov>; VHACLE BVAC Group <VHACLEBVACGroup@va.gov>
Subject: RE: Esketamine
Consider it done.

From: Magnes, N. Sarah
Sent: Wednesday, March 20, 2019 11:54 AM
To: Cohen, Jay L. <(b)(6) @va.gov>; Holliday, Steve <(b)(6) @va.gov>; VHACLE BVAC Group <VHACLEBVACGroup@va.gov>
Subject: RE: Esketamine
I’d like to suggest that we discuss further on both our Monday calls.
Thanks!
Sarah Magnes, PhD, LCSW, BCD
Chief Mental Health Officer
VISN 7 Southeast Network
Office: (b)(6)
Cell (b)(6)



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From: Cohen, Jay L.
Sent: Wednesday, March 20, 2019 11:54 AM
To: Holliday. Steve <(b)(6) @va.gov>; Magnes, N. Sarah <(b)(6) @va.gov>; VHACLE BVAC Group <VHACLEBVACGroup@va.gov>
Subject: RE: Esketamine

Same in V23…not sure the point of the memo and the requirement to get registered within 30 days when much of the details hadn’t been worked out…

Jay L. Cohen, Ph.D.
Interim Chief Mental Health Officer
VA Midwest Healthcare Network—VISN 23
(b)(6) @va.gov
(b)(6)

From: Holliday, Steve
Sent: Wednesday, March 20, 2019 11:48 AM
To: Magnes, N. Sarah <(b)(6) @va.gov>; VHACLE BVAC Group <VHACLEBVACGroup@va.gov>
Subject: RE: Esketamine

There were similar concerns expressed on our VISN 17 PDSI Work Group call this morning. I told them to wait until VACO rolls out the materials and training materials. That is, we are NOT providing it now and won’t until these things happen.
Steve

From: Magnes, N. Sarah
Sent: Wednesday, March 20, 2019 10:45 AM
To: VHACLE BVAC Group <VHACLEBVACGroup@va.gov>
Subject: Esketamine

Good Morning,
I was wondering if anyone else has had strong pushback from pharmacy and the field on this? When the Somatic Treatment Survey came out, none of our facilities expressed an interest in providing Ketamine treatment. Besides the fast turnaround, the VISN Pharmacy Exec expressed the following concerns –



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(b5)

Thanks, Sarah

Sarah Magnes, PhD, LCSW, BCD
Chief Mental Health Officer
VISN 7 Southeast Network
Office: (b)(6)
Cell: (b)(6)



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Recipient:	VHAPBM VPE Formulary Committee /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fcba1f4b52e048838d3053091f54eb4e-VHAPBH VPE <VPEFormularyCommttee@va.gov>
Sent Date:	2019/03/21 09:13:57
Delivered Date:	2019/03/21 09:14:01

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From:	Valentino, Michael (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO, (b)(6) @va.gov>
To:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b)(6) @va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M (b)(6) @va.gov>
Subject:	FW: Esketamine
Date:	2019/03/21 09:38:07
Priority:	Normal
Type:	Note

Just an example FYI.....have had a few reports of pushback from the field....

Sent with BlackBerry Work
(www.blackberry.com)

From: Lowe, Joette (b)(6) @va.gov>
Date: Thursday, Mar 21, 2019, 9:14 AM
To: VHAPBM VPE Formulary Committee <VPEFormularyCommittee@va.gov>
Subject: FW: Esketamine

Just FYI on feedback from the MH side of the issue.

Joette S. Lowe, PharmD
VISN 7 Pharmacy Executive (VPE)
3701 Loop Road East
Tuscaloosa, AL 35404
(b)(6)
Suicide Prevention is Everyone's Business. *#BeThere.*



cid:image009.jpg@01D328A1.8C7B68A0

From: Myrick, Donald L. (Hugh)
Sent: Wednesday, March 20, 2019 12:31 PM
To: Lowe, Joette (b)(6) @va.gov>
Subject: FW: Esketamine

Just FYI.

Hugh Myrick, MD
ACOS, Mental Health Service Line

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Ralph H. Johnson VAMC
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To: Landreth, Edward S. (b)(6) @va.gov>; Magnes, N. Sarah (b)(6) @va.gov>; Cohen, Jay L. (b)(6) @va.gov>; Holliday, Steve <(b)(6) @va.gov>; VHACLE BVAC Group <VHACLEBVACGroup@va.gov>
Subject: RE: Esketamine

(b) (6)

Hugh Myrick, MD
ACOS, Mental Health Service Line
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Chief Mental Health Officer
VISN 7 Southeast Network
Office: (b)(6)
Cell: (b)(6)



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Sent: Wednesday, March 20, 2019 11:54 AM
To: Holliday, Steve <(b)(6) @va.gov>; Magnes, N. Sarah <(b)(6) @va.gov>; VHACLE BVAC Group <VHACLEBVACGroup@va.gov>
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Jay L. Cohen, Ph.D.
Interim Chief Mental Health Officer
VA Midwest Healthcare Network—VISN 23
(b)(6) @va.gov
(b)(6)

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From: Holliday, Steve
Sent: Wednesday, March 20, 2019 11:48 AM
To: Magnes, N. Sarah (b)(6) @va.gov>; VHACLE BVAC Group <VHACLEBVACGroup@va.gov>
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Chief Mental Health Officer
VISN 7 Southeast Network
Office: (b)(6)
Cell: (b)(6)

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Recipient:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b)(6) @va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M (b)(6) @va.gov>
Sent Date:	2019/03/21 09:38:04
Delivered Date:	2019/03/21 09:38:07

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FDA Briefing Document

Psychopharmacologic Drugs Advisory Committee (PDAC) and Drug Safety and Risk Management (DSaRM) Advisory Committee Meeting

February 12, 2019

Agenda Topic: The committees will discuss the efficacy, safety, and risk-benefit profile of New Drug Application (NDA) 211243, esketamine 28 mg single-use nasal spray device, submitted by Janssen Pharmaceuticals, Inc., for the treatment of treatment-resistant depression

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VA-19-1109-B-001842

The attached package contains background information prepared by the Food and Drug Administration (FDA) for the panel members of the advisory committee. The FDA background package often contains assessments and/or conclusions and recommendations written by individual FDA reviewers. Such conclusions and recommendations do not necessarily represent the final position of the individual reviewers, nor do they necessarily represent the final position of the Review Division or Office. We have brought New Drug Application 211243, esketamine for the treatment of treatment-resistant depression to this Advisory Committee to gain the Committee's insights and opinions, and the background package may not include all issues relevant to the final regulatory recommendation and instead is intended to focus on issues identified by the Agency for discussion by the advisory committee. The FDA will not issue a final determination on the issues at hand until input from the advisory committee process has been considered and all reviews have been finalized. The final determination may be affected by issues not discussed at the advisory committee meeting.

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VA-19-1109-B-001843

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1. DIVISION DIRECTOR MEMORANDUM

M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: January 28, 2019

FROM: Tiffany R. Farchione, M.D.
Acting Director
Division of Psychiatry Products, HFD-130

TO: Members of the Psychopharmacologic Drugs Advisory Committee (PDAC) and Drug Safety and Risk Management (DSARM) Advisory Committee

SUBJECT: February 12, 2019 Meeting of the PDAC and DSaRM

Introduction:

This single-day combined meeting of the Psychopharmacologic Drugs Advisory Committee (PDAC) and the Drug Safety and Risk Management (DSaRM) Advisory Committee will focus on a number of issues critical to the Center for Drug Evaluation and Research (CDER) in evaluating a pending New Drug Application (NDA) for a drug-device combination of esketamine for intranasal administration to be used for the treatment of treatment-resistant depression (TRD). The combination product consists of a single-use nasal spray device that administers two sprays per device, each spray containing 14 mg of esketamine HCL. Thus, each device contains 28 mg of esketamine HCL.

For regulatory purposes, FDA considers patients to have TRD if they have Major Depressive Disorder (MDD) and, despite at least two trials of antidepressant treatment given at adequate doses for an adequate duration in the current episode, they have not responded to treatment. To date, only one medication has been approved for the treatment of TRD—a fixed-dose combination of fluoxetine (a selective serotonin reuptake inhibitor) and olanzapine (an atypical antipsychotic).

The esketamine development program received a Breakthrough Therapy Designation (BTD) in November 2013. The decision was based on preliminary evidence of efficacy from Study 2001, a phase 2a study exploring the effect of intravenous (IV) esketamine in patients with inadequate

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response to antidepressants (referred to as "TRD," although the definition in Study 2001 did not require failure of trials of two antidepressant drugs in the current episode), suggesting the potential for a rapid (within 24 hours) onset of effect, which was viewed as a potential substantial improvement over existing therapy for TRD, a serious or life-threatening condition.

Study 2001 also informed dose selection for a subsequent fixed-dose, dose-finding study of intranasal (IN) esketamine (Study 2003). A second study using IV dosing (Study 2002) suggested that once-weekly administration may not be sufficient to maintain antidepressant effect, thus informing the dosing frequency for subsequent studies. In Study 2003, the Applicant investigated IN esketamine doses from 14 to 84 mg in patients ages 18 to < 65 years with TRD. The results of Study 2003 suggested a dose-response relationship for esketamine; therefore, the Applicant selected the 56- and 84-mg doses for further development in phase 3. An additional study of esketamine 84 mg in patients with MDD deemed to be at imminent risk of suicide (Study SUI2001) may be viewed as supportive given that the population is similar (severe MDD, though treatment resistance was not required). Data from Study SUI2001 were included in this application to provide support for the claim that esketamine acts rapidly to reduce depressive symptoms; the primary efficacy endpoint in Study SUI2001 was change from baseline (CFB) to 4 hours post-dose on the Montgomery Asberg Depression Rating Scale (MADRS). In Study SUI2001, patients who received esketamine 84 mg experienced statistically significantly greater symptom improvement as measured by the MADRS at both 4 and 24 hours post-dose. Patients continued double-blind treatment with either twice weekly esketamine 84 mg or placebo, together with an oral antidepressant, for a total of four weeks; however, there was no statistical difference between the two treatment groups at the end of the study.

In addition to the four phase 2 studies described above, the Applicant has conducted five phase 3 studies in support of the TRD development program for esketamine. The phase 3 studies include two short-term, double-blind, placebo-controlled studies—one fixed-dose and one flexible-dose—in adult patients younger than 65 years of age; one short-term, double-blind, placebo-controlled, flexible-dose study in geriatric patients ≥ 65 years of age; one randomized withdrawal design study; and one long-term, open-label safety study. Patients in all of these studies had failed at least two prior antidepressant trials and, at study entry, had more severe symptoms on average than patients entering antidepressant trials for previously approved drugs. Thus, rather than randomizing severely ill patients to placebo alone, each study involved the addition of a new antidepressant at the same time that either esketamine or placebo was initiated, ensuring that all patients were receiving some form of active treatment.

Because of the purported rapid action of esketamine, it seemed feasible to start all patients on a new antidepressant without compromising the ability to detect a treatment effect in the esketamine treatment group. Given that approved antidepressants typically take 6 to 8 weeks to exert their full effect, if an effect was observed as early as 24 hours post-dose and was maintained throughout the treatment period, that would support esketamine's effectiveness. This is an important distinction as one considers whether, if approved, this drug would be indicated for the treatment of TRD or as an adjunct to treatment with an oral antidepressant.

The evidence in support of esketamine's effectiveness derives primarily from two positive phase 3 trials—the flexible-dose trial in adults younger than 65 years of age and the randomized

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withdrawal study. In the fixed-dose study of adults younger than 65 years of age, the prespecified analysis plan dictated that efficacy of the 84-mg dose would be evaluated first, followed by evaluation of the 56-mg dose. However, the 84-mg dose did not separate from placebo and the testing sequence ended there. The geriatric study included flexible doses ranging from 28 to 84 mg; the effect of esketamine in the combined dose group was not statistically superior to placebo (1-sided $p = 0.029$).

For most approved antidepressants, the evidence of effectiveness comes from at least two positive adequate and well-controlled short-term trials, with additional maintenance data provided via a randomized withdrawal trial conducted as a post-marketing commitment. In this application, there is only one positive short-term trial. The second positive trial is the randomized withdrawal study. The Division of Psychiatry Products has not previously considered a randomized withdrawal trial as one of the two adequate and well-controlled trials comprising substantial evidence of effectiveness, but it is not unreasonable to do so. It is important to note that the population randomized to continue drug or switch to placebo in a randomized withdrawal study is an enriched population—these are individuals who have already tolerated the drug and have already experienced clinical benefit from treatment with the drug. Whether and how these details would be reflected in labeling has not yet been determined.

The safety of esketamine was evaluated in the short-term double-blind trials relative to placebo and in a single long-term, open-label study. Because esketamine is the S-enantiomer of ketamine, special attention was paid to known adverse events associated with ketamine use as intended and with ketamine misuse and abuse. Sedation, dissociation, cognitive impairment, and suicidal ideation and behavior were treated as adverse events of special interest; thus, the clinical studies included specific assessments for these events.

The adverse events of greatest concern in the clinical development program were sedation, dissociation, and increases in blood pressure. Most of these events occurred within the first 2 hours following drug administration. FDA is proposing a Risk Evaluation and Mitigation Strategy (REMS) to assure safe use of esketamine. Among the key elements of the proposed REMS, esketamine administration would occur only in certain healthcare settings where the patient could be monitored for 2 hours after administration, the drug would not be dispensed directly to patients, and patients would be enrolled in a registry to better characterize the risks associated with esketamine administration.

The Agency is seeking input from the Committees on the following questions:

1. Has the Applicant provided substantial evidence of the effectiveness of esketamine for the treatment of treatment-resistant depression?

2. Has the applicant adequately characterized the safety profile of esketamine for the treatment of treatment-resistant depression?

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3. Given the effectiveness and safety of esketamine and the FDA's proposed risk evaluation and mitigation strategy (REMS), do the benefits outweigh the risks of esketamine for the treatment of treatment-resistant depression?

4. Discuss whether the FDA's proposed REMS would assure safe use of esketamine and what additional safeguards would be needed, if any.

5. Are additional data needed pre- or post-approval to address outstanding issues? Discuss whether such data should be required prior to approval.

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2. Purpose

The purpose of this Advisory Committee meeting is to obtain input from the committee on whether data provided by the applicant support a favorable benefit-risk profile of esketamine to support approval.

3. Treatment of Treatment-Resistant Depression

Major depressive disorder (MDD) is a serious and life-threatening condition with high rates of individual and society-level morbidity, and a chronic disease course. Over 16 million people in the United States[1] and over 300 million people worldwide[2] have depression. Patients with MDD may be unable to work, maintain relationships, attend to self-care, and in the most severe cases may become hospitalized or attempt or commit suicide. MDD is considered the leading cause of disability worldwide and also is associated with increased mortality rates (at a median rate of 10 years of life lost)[3]. About 30 to 40% of patients with MDD fail to respond to first-line treatments including oral antidepressant medications of all classes (selective serotonin reuptake inhibitors (SSRIs), serotonin-norepinephrine reuptake inhibitors (SNRIs), tricyclic antidepressants (TCAs), etc.) and/or psychotherapy[4]. In addition, the onset of treatment response for these modalities, even when effective, often takes at least four weeks, leading to greater suffering, expense, and risk.

Patients who have failed at least two trials of antidepressant treatment generally comprise the population with treatment-resistant depression (TRD). During an externally-led Patient-Focused Drug Development Meeting held on November 16, 2018, feedback from patient representatives noted a variety of concerns including inadequate or incomplete treatment responses, the need for multiple drug trials, and the side effects of existing MDD treatments[5]. Relative to other patients with MDD, patients with TRD can incur even more severe morbidity, with higher rates of hospitalization, suicidal ideation and behavior, and medical complications. The urgent need for a rapid-acting, safe, and effective way to interrupt a severe major depressive episode, and to prevent future episodes, remains a major concern; TRD treatments remain an unmet medical need.

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[1] https://www.nimh.nih.gov/health/statistics/major-depression.shtml Accessed December 11, 2018.

[2] World Health Organization. Depression and other common mental disorders. Global health estimates. (Geneva:World Health Organization; 2017.)

[3] Walker ER, McGee RE, Druss BG. Mortality in mental disorders and global disease burden implications: a systematic review and meta-analysis. *JAMA Psychiatry*. 2015;72:334-341.

[4] Rush AJ, Trivedi MH, Wisniewski SR, et al. Acute and longer-term outcomes in depressed outpatients requiring one or several treatment steps: a STAR*D report. *Am J Psychiatry*. 2006;163:1905-1917.

[5] https://secure2.convio.net/dabsa/site/SPageServer/;jsessionid=00000000.app268b?NONCE_TOKEN=68B6AC0BF8CA6ED6EA73E7D0B6B258A9&NONCE_TOKEN=8E5900F85A7E46F4D8095EE821724DA1&pagename=FDA_videos Accessed January 9, 2019.

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Standard of care measures for TRD include switching to a different antidepressant (of either the same or a different class), adding an adjunctive treatment to an ongoing antidepressant (typically a drug with a different mechanism of action), adding or switching psychotherapy, or referral for a procedure such as electroconvulsive therapy (ECT) or transcranial magnetic stimulation (TMS)[6].

The available treatments for TRD are limited. Only one medication is currently FDA-approved for TRD. The only other FDA-approved interventions for TRD are device-related and are reviewed by the Center for Devices and Radiological Health (CDRH). Some of these treatments are associated with significant adverse reactions and interventional concerns (such as use of general anesthesia, seizure induction, and memory loss with ECT; or surgical intervention and infection risk with vagus nerve stimulator (VNS) implantation). Other issues include inconvenient daily office visits (such as with TMS).

[6] https://www.uptodate.com/contents/unipolar-depression-in-adults-treatment-of-resistant-depression Accessed December 11, 2018.

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Table 1: Summary of FDA-Approved Products for Treatment of TRD

Product(s) Name	Relevant Indication	Year of Approval	Route and Frequency of Administration	Efficacy Information	Important Safety and Tolerability Issues	Regulatory Authority
FDA Approved Treatments Combine by Pharmacologic Class, if relevant						
Symbyax (Fluoxetine plus Olanzapine)	TRD	2003	Oral daily	MADRS Total Score Change from Baseline of -16 vs. olanzapine -12 and placebo -10 for Study 1, -18 vs. -14 and -9 for Study 2	Olanzapine is an antipsychotic associated with weight gain, hyperglycemia, and extrapyramidal symptoms/ akathisia	CDER
ECT	TRD (associated with either MDD or Bipolar Disorder)	1976 (most recent update 2018)	Bitemporal or unilateral temporal; up to 3 times a week for 6 to 10 treatments initially	Not available; approval based on various studies from research literature.	Memory concerns, use of general anesthesia	CDRH
TMS	TRD (patients who failed only 1 anti-depressant)	2008	Transcranial; up to daily for 4 to 6 weeks initially (20 to 30 sessions)	MADRS Total Score Change from Baseline of -6 at Week 4 and Week 6 active TMS vs. -4 at Week 4 and Week 6 sham TMS. Approval based on post-hoc analysis and responder/remission rates.	No major safety issues, limited long-term safety data	CDRH
VNS	TRD	2005	Once (surgical implant)	12-week sham placebo-controlled study not statistically significant. Approval was based on long-term open-label HAM-D responder data (30% response in 1 year versus 13% treatment as usual). 12-week open-label pilot study showed 34% MADRS responders.	Surgical intervention risks (allergies, infection, etc.)	CDRH

There are several other FDA-approved drugs for the separate indication of adjunctive treatment for partial response in MDD: quetiapine XR, aripiprazole, and brexpiprazole. From a regulatory standpoint, the adjunctive treatment indication applies to patients who have insufficient but partial response to their current oral antidepressant and may benefit from add-on treatment. This population is usually less severely ill than for the TRD population; these patients are frequently on their first antidepressant and adjunctive

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treatment trials have lower depression scale cutoff scores for study entry than TRD trials. See Section 6.1 for further explanation of our regulatory definition of TRD.

Additional off-label pharmacological interventions for TRD include ketamine, and augmentation with other antidepressants or antipsychotics, lithium, thyroid hormone, buspirone, and other drugs.

4. Product Under Review

The product under review is a drug-device combination of esketamine for intranasal (IN) administration. The esketamine drug product is a clear and colorless solution of esketamine HCl in water at a concentration of 161.4 mg/mL and an esketamine base equivalent concentration of 140 mg/mL. The pharmaceutical form proposed for marketing is a nasal spray solution with one presentation: a 28-mg unit-dose nasal spray device.

Esketamine is the S-enantiomer of ketamine, a N-methyl-D-aspartate glutamate (NMDA) receptor antagonist that enhances glutamine release in the brain. The FDA previously approved ketamine (under NDA 16812 as Ketalar) for use as a rapid-acting general anesthetic in February 1970, administered in solution form for use either intravenously (IV) or intramuscularly (IM). Esketamine has not been FDA-approved for any indication, although it has been approved for use as an anesthetic in Europe and South America, administered via IV or IM routes. Esketamine has greater affinity for the NMDA receptor and greater dopamine transporter inhibition than the R-enantiomer or racemic ketamine. Esketamine is a more potent anesthetic than racemic ketamine but has a more rapid metabolism.

No regulatory agencies have approved ketamine or esketamine for any psychiatric indication worldwide. Researchers have studied ketamine in recent years for use in MDD and several other psychiatric indications; ketamine is being prescribed and administered off-label for those indications.

Under this NDA, the Applicant proposes esketamine nasal spray for intranasal use for the treatment of TRD. After mutual agreement between FDA and the Applicant, TRD has been defined (from a regulatory standpoint) as a lack of clinically meaningful improvement in depressive symptoms after treatment with at least two different oral antidepressant medications as monotherapy, taken at adequate doses for adequate duration (at least 6 weeks) for their current episode of depression. The previous oral antidepressants could be from the same or different drug classes, which could include SSRIs, SNRIs, tricyclic antidepressants (TCAs), monoamine oxidase inhibitors (MAOIs), or any other oral antidepressants. (See Section 6.1 for more details.)

The Applicant proposes that esketamine be administered intranasally twice a week for an initial 4 weeks in addition to a newly initiated oral antidepressant. The proposed initial adult esketamine dose is 28 to 56 mg at each administration; it can be titrated to 84 mg by

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Week 2. The Applicant proposes continuation of treatment on a weekly basis for an additional 4 weeks, and then weekly or every other week during an ongoing maintenance phase.

5. Regulatory Background

- May 8, 2012, Pre-IND Meeting: FDA and the Applicant discussed nonclinical and clinical pharmacology study requirements, including carcinogenicity studies, repeat Olney lesion studies, and comparison studies to ketamine. The clinical reviewer discussed the regulatory definition of TRD (failure of treatment of at least two different antidepressant classes; this requirement later was modified in March 2014 to any two antidepressants), and the acceptability of the proposed phase 2 dose frequency and phase 3 study designs. The Applicant agreed to modify the proposed parallel-group phase 3 studies to incorporate a longer acute treatment period of at least four weeks to assess for persistence of effect; FDA and the Applicant agreed on the use of the Montgomery-Asberg Depression Rating Scale (MADRS) as the assessment scale during the studies to be measured at each timepoint. They also agreed upon other scales for adverse event (AE) assessment (Clinician Administered Dissociative States Scale (CADSS), Brief Psychiatric Rating Scale (BPRS), Massachusetts General Hospital-Cognitive and Physical Functioning Questionnaire (MGH-CPFQ) (later switched to Cogstate in April 2014)). FDA required abuse potential assessment studies and PDAC review.

- November 7, 2013: FDA granted Breakthrough Therapy Designation (BTD) status to the esketamine for TRD development program. TRD is a serious condition with an unmet clinical need for additional treatments, and phase 2 esketamine studies provided sufficient preliminary evidence of efficacy to grant BTD status.

- March 13, 2014, and May 6, 2014, BTD Advice Meetings: The Applicant and FDA agreed upon the regulatory definition of TRD for this program (failure of treatment of at least two different antidepressants of the same or different classes, given at an adequate dose and duration); determination that TRD criteria were met was to include retrospective determination of prior treatment failures if validated via scales and prior records (e.g., pharmacy, medical). FDA did not agree that an adjunctive treatment design (add-on to existing antidepressant) would merit a TRD treatment indication because adding a medication to a failed treatment in TRD was not sound clinical practice. Studies would start all participants on a new antidepressant in the acute phase, and – in addition – randomize subjects to esketamine or placebo, a so-called "add-on" design.

  FDA also requested a maintenance-of-effect study; the Applicant then proposed a randomized withdrawal design. FDA emphasized the use of centralized, blinded, remote raters in all phase 3 studies. FDA requested the use of active intranasal placebo but later agreed not to require it (accepting inactive intranasal placebo instead) if the Applicant instituted all blinding precautions for on-site staff. FDA also

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recommended a severe renal impairment study. The Applicant inquired whether they could file their application with only acute efficacy data, provided that they had sufficient safety data to fulfill ICH E1 criteria; the Agency did not agree, noting that we viewed this product very differently from previously approved oral antidepressants and would require maintenance data at the time of filing. FDA agreed that including at least 30% US subjects in phase 3 pivotal studies would allow for adequate representation relevant to our treatment population.

- June 5, 2014, BTD Advice Meeting: The Applicant and FDA discussed Chemistry, Manufacturing, and Controls (CMC) and abuse liability study requirements. FDA requested a phase 1 abuse liability study.

- June 18, 2014, Nonclinical Meeting: FDA and the Applicant discussed Olney lesion study (neurotoxicity) specifications for nonclinical requirements. FDA required a 14-day repeat-dose neurotoxicity rat study with post-dosing histological assessment to rule out vacuolization prior to phase 3 initiation.

- September 12, 2014, BTD Advice Meeting: FDA and the Applicant agreed to the proposed phase 3 short-term study and maintenance designs, with one short-term study being a flexible-dose study. FDA agreed that the maintenance study could be used as one of two positive studies to support a marketing application, along with a short-term fixed-dose study with statistically very persuasive results (later switched to any short-term study in March 2018, see below).

- December 8, 2014, End-of-Phase 2 Meeting: FDA and the Applicant agreed upon doses of 56 mg and 84 mg esketamine for the phase 3 studies. Patients with cardiovascular and cerebrovascular risk factors were to be excluded because of the risk for hypertension (HTN) with esketamine, and blood pressure (BP) was to be monitored pre- and post-dose. FDA agreed that the Applicant's nonclinical study program proposal for esketamine in combination with specific bridging studies to ketamine would be sufficient for NDA submission.

- June 24, 2015, Guidance Meeting: FDA's nonclinical team requested an additional acute neurotoxicity rat study due to concerns about NMDA antagonist class-related drug issues. The nonclinical team agreed the study could be conducted in parallel with phase 3 human studies.

- March 1, 2016, BTD Advice Meeting: FDA and the Applicant agreed on defining the important secondary endpoint of Onset of Clinical Response as the point at which a ≥50% improvement (instead of score ≤19) in MADRS total score was achieved, with sustained response at each subsequent timepoint (with one permitted excursion) for the phase 3 short-term studies. FDA also agreed to the proposed additional secondary endpoint of Sheehan Disability Scale (SDS) total score for potential inclusion in the label.

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- March 14, 2018, Pre-NDA Meeting: FDA agreed that the completed (to-date) phase 3 studies (3001, 3002, 3003, 3004, and 3005) were adequate to support filing of an NDA for review, and that phase 2 studies and studies conducted under a separate IND for a related indication would also be taken into consideration during our review. The Applicant was to provide demographic-based exploratory efficacy analyses for the pooled phase 3 short-term studies, 3001 and 3002. FDA requested a list of safety preferred terms in advance for review and agreement (which was provided April 18, 2018).

- June 28, 2018, Second Pre-NDA Meeting: FDA encouraged the Applicant to submit a proposed REMS with the NDA. FDA agreed to inclusion of bridging nonclinical studies with ketamine from Javelin in the submitted NDA.

6. Effectiveness of Esketamine for Treatment of Treatment-Resistant Depression

6.1. Phase 3 Study Design

There were four phase 3 randomized controlled trials conducted and submitted under NDA 211243. Three of them (3001, 3002, 3005) were of similar short-term parallel-group design, and one (3003) was a randomized withdrawal maintenance-of-effect design. In two studies (one parallel-group study and the randomized withdrawal study), esketamine was statistically superior to placebo on the study's primary efficacy endpoint; in the other two short-term parallel group studies, esketamine was not. All studies were international, with about a third of patients in the United States. The majority of subjects in all the studies were women in their 40s and 50s, white, with higher body mass index (BMI >24). Depending on the study, around 33 to 40% of enrolled subjects had failed three or more antidepressant (AD) treatments by the start of screening, and 12 to 17% had failed at least four.

The primary outcome measure used for the studies was the Montgomery-Asberg Depression Rating Scale (MADRS). The MADRS is a 10-item instrument with total score ranging from 0 to 60. A higher MADRS score indicates more severe depression. The 10 items are: sadness, apparent sadness, inner tension, reduced sleep, reduced appetite, concentration difficulties, lassitude, inability to feel, pessimistic thoughts, and suicidal thoughts. To decrease the introduction of bias, all MADRS score evaluations were performed by independent, remote (via telephone), blinded raters. Scales were administered on study visit days prior to intranasal esketamine (or placebo) dosing and with a few exceptions (shorter-term secondary endpoints) were meant to assess symptoms over the previous 7 days.

Baseline mean MADRS total scores for Studies 3001, 3002, and 3003 ranged from 37 to 38 (and for the geriatric Study 3005, the mean was 35). These baseline mean scores are higher than those in phase 3 studies for previously FDA-approved antidepressants and adjunctive treatment medications for depression (mean MADRS total scores ranged from

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28 to 36; the baseline MADRS means in Symbyax clinical trials ranged from 28 to 30) and indicate greater illness severity for the treatment population in the esketamine phase 3 studies than is typical for MDD development programs.

All the studies compared IN esketamine and IN placebo (with an added embittering agent as a blinding mechanism) each added to one of four newly initiated oral antidepressants (duloxetine, venlafaxine XR, escitalopram, or sertraline), each dosed daily beginning at the start of the treatment phase (except for duloxetine which stayed at the same dose, all were titrated to therapeutic doses over the course of the next 1 to 2 weeks). For the first 4 weeks of treatment (which encompassed the double-blind phase of the parallel-group studies), the nasal spray was administered twice weekly. For the maintenance-of-effect Study 3003 and for long-term open-label safety studies, the nasal spray was administered weekly for the next 4 weeks post-induction phase, then either weekly or every other week for ongoing maintenance.

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Table 2: Esketamine Phase 3 Randomized Double-Blind Active-Controlled Studies

Study	Design	Arms	Dosing	Duration	Primary Endpoint	Patients Enrolled	Population
TRD3002 (TRANSFORM-2)	Parallel-Group	Flexible-Dose Esketamine (56 or 84 mg) vs. Placebo, + Oral AD both arms	Twice Weekly IN (Oral AD Daily)	4-week treatment phase, 24-week follow-up or TRD3003	Change from Baseline (CFB) in MADRS Total Score at Week 4	224 total (114 on ESK + oral AD; 110 on placebo + oral AD)	Adults (18 to 64 years) with TRD
TRD3003 (SUSTAIN-1)	Randomized Withdrawal	Flexible or Fixed-Dose Esketamine (56 or 84 mg) vs. Placebo, + Oral AD all arms	Twice Weekly IN during 4-week phase, then weekly for next 4 weeks, then weekly or every other week per response (Oral AD Daily)	4-week treatment initiated during open-label direct-entry phase or during 3001 or 3002. Then 12-week open-label optimization phase. Then ongoing maintenance phase post- randomization.	Time to relapse during maintenance phase for stable remitters	705 total (437 direct entry + 268 from 3001 or 3002); 176 during maintenance phase (90 on ESK + oral AD; 86 on placebo +oral AD).	Adults (18 to 64 years) with TRD
TRD3001 (TRANSFORM-1)	Parallel-Group	Fixed-Dose Esketamine (56 or 84 mg) vs. Placebo, + Oral AD all arms	Twice Weekly IN (Oral AD Daily)	4-week treatment phase, 24-week follow-up or TRD3003	Change from Baseline (CFB) in MADRS Total Score at Week 4	344 total (115 on ESK 56 mg + oral AD; 116 on ESK 84 mg + oral AD; 113 on placebo + oral AD)	Adults (18 to 64 years) with TRD
TRD3005 (TRANSFORM-3)	Parallel-Group	Flexible-Dose Esketamine (28 or 56 or 84 mg) vs. Placebo, + Oral AD both arms	Twice Weekly IN (Oral AD Daily)	4-week treatment phase, 24-week follow-up or TRD3004 (long-term safety study)	Change from Baseline (CFB) in MADRS Total Score at Week 4	137 total (72 on ESK + oral AD; 65 on placebo + oral AD)	Geriatric (65 years and older) with TRD

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Key inclusion criteria mainly involved the definition of TRD for subjects. TRD diagnostic criteria for the phase 3 studies are derived from both regulatory definitions (from FDA and EMA) and established research criteria (including those derived from the STAR*D trials). The following inclusion criteria are quoted from pages 24 to 25 of the Applicant's Clinical Overview from their NDA application:

> Subjects were required to meet Diagnostic and Statistical Manual of Mental Disorders – Fifth Edition (DSM-5) diagnostic criteria for recurrent MDD or single-episode MDD (duration ≥2 years) without psychotic features, which was verified by the structured Mini International Neuropsychiatric Interview (MINI). Subjects must have been experiencing moderate to severe depressive symptomatology, as defined by a minimum total score on the investigator-rated Inventory of Depressive Symptomatology-Clinician rated, 30-item (ICD-C30) (≥34 for TRD3001 and TRD3002; ≥31 for TRD3005), and have a MADRS total score of ≥28 for TRD3001 and TRD3002 and ≥24 for TRD3005 based on assessment by a remote, independent rater at Weeks 1, 2, and 4 of the screening/ observational phase. In addition to assessing severity of depression, the qualitative and quantitative interview conducted by a remote rater, independent from the site, during screening assessed the diagnosis of depression and nonresponse to prior ADs to ensure appropriate subject selection for the studies.
>
> In all controlled phase 3 studies, **treatment resistance** was defined in accordance with the regulatory definition, i.e., a lack of clinically meaningful improvement (defined for phase 3 studies as **≤25%**) in the current episode of depression after treatment with at least 2 different antidepressant (AD) agents prescribed in adequate dosages for an adequate duration (defined for phase 3 studies as at least 6 weeks). Subjects in the phase 3 short-term DB studies were required to have demonstrated nonresponse to at least 2 different oral ADs, with nonresponse to 1 AD demonstrated prospectively prior to randomization. The Massachusetts General Hospital – Antidepressant Treatment Response Questionnaire (MGH-ATRQ), a reliable, and validated scale to determine treatment resistance in MDD, was used to document oral AD use and response (medication, dose, duration of treatment) in the current depression episode. Finally, written documentation of the MDD diagnosis and prior AD use from medical/pharmacy records was obtained.
>
> 1. Retrospective assessment of prior AD nonresponse in current episode of depression: all subjects in the phase 3 short-term studies were required to have had documented nonresponse (≤25% improvement per clinical judgment) to at least 1 oral AD treatment taken for the current episode of depression prior to the initial screening visit, at adequate dosage and for an adequate duration, as assessed on the MGH-ATRQ and confirmed by structured interview and documented records.
>
> 2. Prospective assessment of AD nonresponse: at the initial screening visit, subjects must have been receiving treatment for the current depression episode with a different oral AD for at least 2 weeks at or above the minimum therapeutic dose (per MGH-ATRQ). This drug was continued prospectively for 4 weeks during the screening/prospective observational phase. Only subjects who demonstrated (prospectively) nonresponse to the current oral AD after at least 6 weeks (≤25% improvement on MADRS total score from Week 1 to 4, together with a MADRS total score of ≥28 on Week 2 and Week 4 [≥24 for elderly subjects in TRD3005]), were eligible for randomization. Medication adherence was documented on the Patient Adherence Questionnaire during the screening/prospective observational phase to ensure that subjects took at least a minimum therapeutic dose of the current oral AD.

Of note, a protocol amendment for all the studies clarified the screening criteria for non-response in the current episode; subjects who had started their second antidepressant just before the

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screening phase had to have been taking it for at least 2 weeks at or above the therapeutic dose (for those on TCAs, verified by blood level) and continuously adherent (could not miss more than 4 days) during screening before they could be designated as non-responders. They would have to continue this second antidepressant at or above the minimum therapeutic dose during the screening phase.

Key exclusion criteria included:

- Previous history of non-response to ketamine or esketamine, or to all of the oral AD options for the induction phase, or to ECT (at least 7 treatments)
- History of VNS or deep brain stimulation in current episode of depression
- History of psychotic disorder (including MDD with psychotic symptoms), bipolar disorder, obsessive-compulsive disorder, intellectual disability, autism, cluster B personality disorder
- History of moderate or severe substance or alcohol use disorder within the 6 months before screening (and/or positive drug screen, unless due to prescribed medication that can be discontinued at least 1 week or 5 half-lives before treatment phase or cannabis use that is negative as of Day 1 of treatment phase)
- History of homicidal ideation/intent
- History of suicidal ideation/intent within the 6 months prior to screening as noted via positive answers to Items 4 or 5 on the C-SSRS, or during screening
- History of suicidal behavior in the year before screening, or during screening
- QT prolongation ≥450 msec during screening ECG or other significant arrhythmias
- Other major medical conditions including coronary artery disease

6.2. Phase 3 Efficacy Results

The two studies in which esketamine led to statistically significantly greater improvement in depressive symptoms than placebo will be described first, followed by a description of the other two studies. None of the results on the prespecified key secondary endpoints (only designated in Studies 3001 and 3002) were statistically significant after controlling for type I error based on the prespecified statistical analysis plan. Other secondary endpoints were evaluated without controlling for multiplicity. However, the primary endpoints (and most secondary endpoints) were *numerically* better for esketamine groups compared to placebo.

There were no clear subgroup efficacy trends. The United States subgroups in all studies generally aligned with the primary efficacy results, indicating generalizability of the overall results to the U.S. population.

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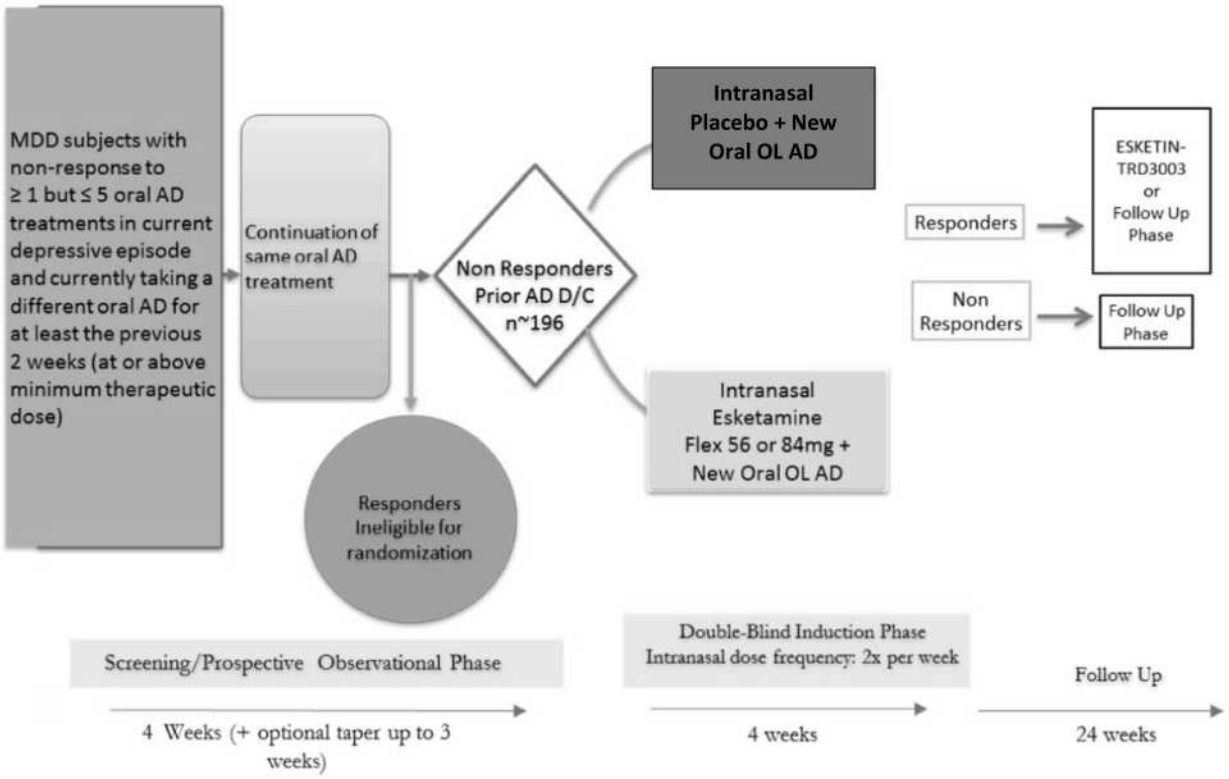
6.2.1. Study 3002 (TRANSFORM-2)

Study 3002 was a flexible-dose, randomized, parallel-group trial comparing IN esketamine and IN placebo each added to newly initiated oral antidepressant treatment. All esketamine subjects initially received a 56-mg dose and then could be titrated to 84 mg at the next dose, based on investigator discretion with regard to efficacy and tolerability. (Subjects in the placebo arm would follow the same procedure with the corresponding placebo dose.)

Figure 1: Study 3002 Study Design Schematic



Source: Adapted from Study 3002 CSR

About 40% of subjects in this study were from the U.S., with the rest from Europe. The distribution of demographic characteristics was generally similar for the two treatment groups. The placebo group was heavier (mean weight 82.7 kg±19.5 vs 79.3 kg±20.1 in esketamine) and older (mean age 46.4 years±11.1 vs 44.9 years±12.6 in esketamine) and had more individuals with comorbid HTN (25% vs 16% in esketamine). Baseline illness severity was also comparable between treatment groups (although lifetime suicidal behavior was higher in the placebo arm (13%) than the esketamine arm (8%)). About 2/3 of subjects in the esketamine arm ultimately received 84 mg twice weekly; 1/3 received 56 mg twice weekly. More patients dropped out of the esketamine arm (14%) compared to the placebo arm (10%).

Subjects in the esketamine treatment group experienced statistically significantly greater improvement in depressive symptoms, as measured by the CFB to endpoint in the MADRS, than patients in the placebo group (Table 3). On the MADRS, the mean difference between

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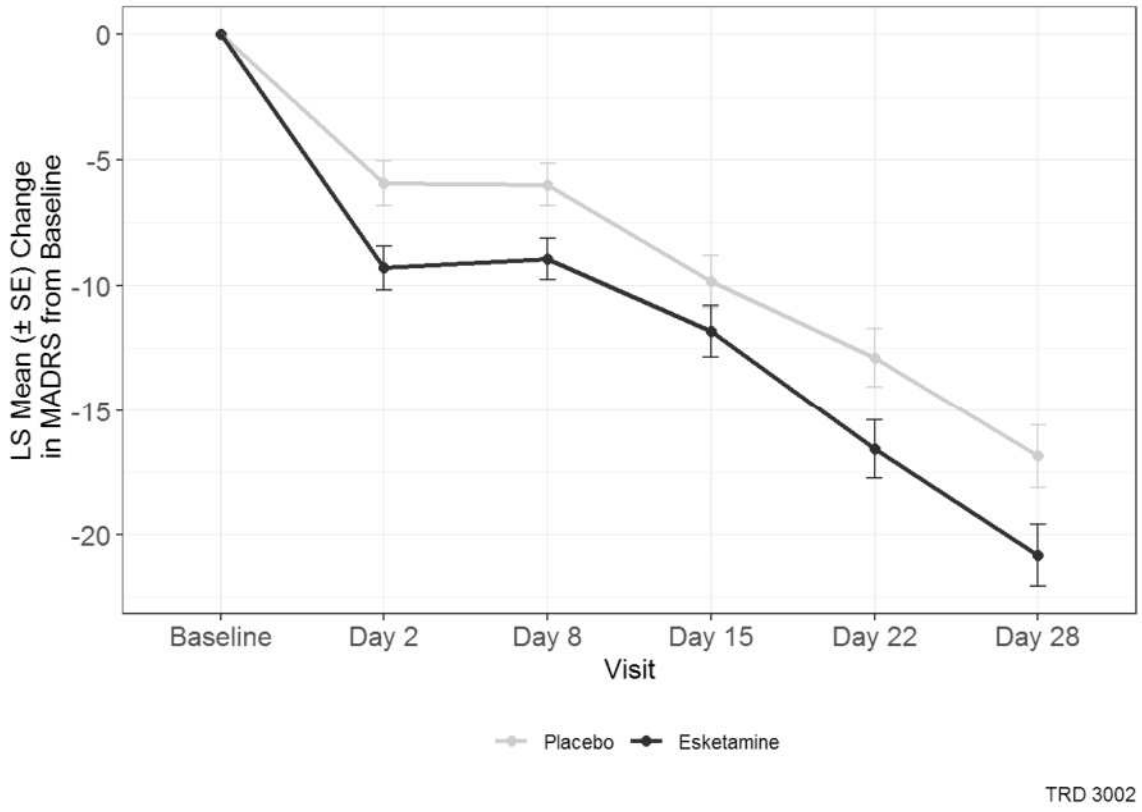
esketamine and placebo (Figure 2) was statistically significant at most time points throughout the 28 days of double-blind treatment (except Day 15).

Table 3: Study 3002 Primary Endpoint MADRS Total Score CFB at Day 28 Using MMRM (Full Analysis Population)

Treatment Arm	N	Baseline MADRS Total Score (SD)	LS Mean Change from Baseline (SE) at Week 4	LS Mean Difference from Placebo (SE) at Week 4	1-Sided *p*-value <0.025
Placebo + Oral AD	109	37.3 (5.7)	-15.8 (1.2)	--	--
Esketamine + Oral AD	114	37.0 (5.7)	-19.8 (1.3)	-4.0 (1.7)	**0.010**

Source: Study 3002 Clinical Study Report (CSR)

Figure 2: Study 3002 Primary Endpoint MADRS Total Score CFB at Day 28 Using MMRM (Full Analysis Population)



Source: Andrew Potter PhD, Statistical Reviewer

6.2.2. Study 3003 (SUSTAIN-1)

Subjects enrolled in this study came from either direct entry (following an open-label esketamine treatment protocol) or from Studies 3001 or 3002. All subjects who experienced ≥50% reduction from baseline in MADRS total score by the end of acute 4-week treatment were eligible to enter

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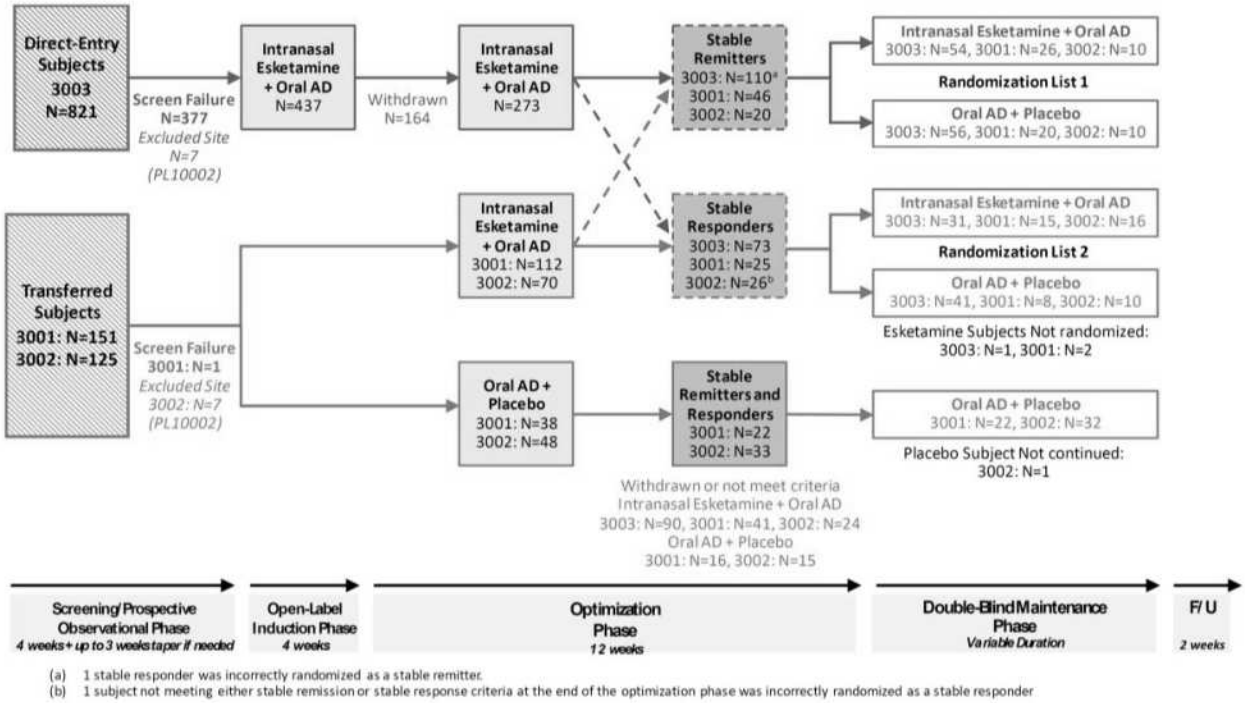
the optimization phase, where they received at least 12 weeks of open-label esketamine treatment with oral antidepressant ongoing. (Responder subjects who had originally been randomized to placebo during acute treatment in Studies 3001 or 3002 remained blinded to their original treatment but were not included in the final efficacy analysis populations. They all received IN placebo during the withdrawal phase.)

Figure 3: Study 3003 Patient Flowchart



(a) 1 stable responder was incorrectly randomized as a stable remitter.
(b) 1 subject not meeting either stable remission or stable response criteria at the end of the optimization phase was incorrectly randomized as a stable responder

Source: Study 3003 CSR

After completion of the optimization phase, in order to be randomized and enter the maintenance phase of Study 3003, subjects had to meet criteria for either stable remission or stable response:

- Stable Remission: MADRS total score ≤12 for at least 3 of the last 4 weeks of the optimization phase, with one excursion of a MADRS total score >12 or one missing MADRS assessments permitted at optimization week 13 or 14 only

- Stable Response: ≥50% reduction in MADRS total score from baseline (Day 1 of induction phase prior to first IN dose) in each of the last 2 weeks of the optimization phase, but without meeting criteria for stable remission.

Stable remitters were to comprise the analysis population for the primary efficacy endpoint, and stable responders were to comprise the analysis population for the secondary endpoint. Relapse during the maintenance phase was defined as a MADRS total score ≥22 for two consecutive assessments and/or undergoing hospitalization or another serious clinical event (as adjudicated by investigators). An interim analysis determined the number of relapses required to end the

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study (at least 59 total relapses). The maintenance period lasted for at least 500 days (3 patients continuing for at least 500 days).

Baseline demographic and psychiatric characteristics were generally similar across treatment groups for stable remitters. Most stable remitter subjects were from Europe (58%) with about 23% US representation (30% North American). One concern in this study was that one site in Poland drives the overall study result due to a 100% rate of placebo arm relapses (16 out of 16 subjects on placebo versus 2 out of 9 on esketamine) in both stable remitters and stable responders.

There was a statistically significant difference in time to relapse of depression favoring those subjects randomized to continue esketamine versus those who were switched to placebo (with oral antidepressant ongoing in both arms) in the stable remitters group. The secondary endpoint of time to relapse in the stable responders group was also statistically significant.

The result tables indicate the number of patients who had relapsed by the end of the study when the total number of observed events was large enough for the study to have a 90% power of detecting a hazard ratio of 0.493 comparing esketamine to placebo. A pre-planned interim analysis (IA), conducted after 31 relapses, determined that the final analysis should occur after at least 59 relapses were observed.

Table 4: Study 3003 Primary Efficacy Endpoint of Time to Relapse in Stable Remitters

	Esketamine + Oral AD	**Placebo + Oral AD**
Number Assessed	90	86
Number Censored (No Relapse)	66 (73%)	47 (55%)
Number of Relapses	24 (27%)	39 (45%)
Time to Relapse (Days)		
25% percentile (95% CI)	153 (105 to 225)	33 (22 to 48)
Median (95% CI)	NE	273 (97 to NE)
Hazard Ratio (HR) (95% CI)	0.49 (0.3 to 0.8)	--
2-sided p-value (<0.05)	**0.003**	--

Source: Study 3003 CSR, NE=not estimable

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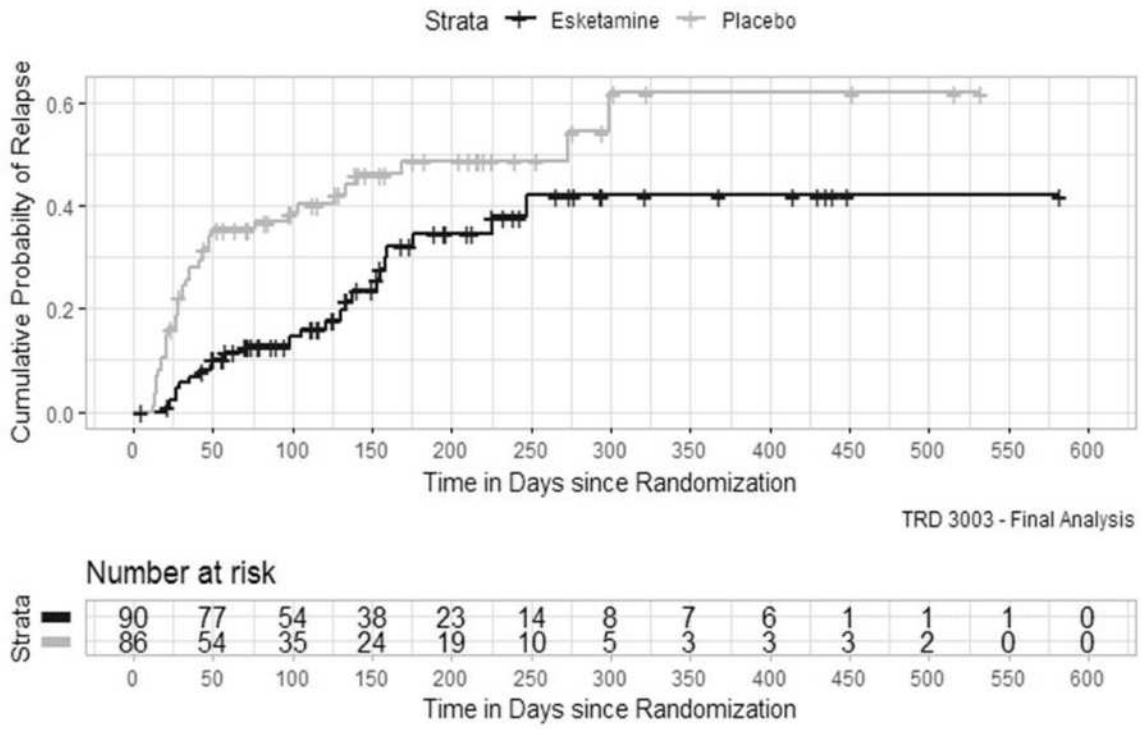
Figure 4: Study 3003 Primary Efficacy Endpoint of Time to Relapse in Stable Remitters



Source: Andrew Potter, PhD, Statistical Reviewer

Table 5: Study 3003 Secondary Efficacy Endpoint of Time to Relapse in Stable Responders

	Esketamine + Oral AD	**Placebo + Oral AD**
Number Assessed	62	59
Number Censored	46 (74%)	25 (42%)
Number of Relapses	16 (26%)	34 (58%)
Time to Relapse (Days)		
25% percentile (95% CI)	217 (56 to 635)	24 (17 to 46)
Median (95% CI)	635 (264 to 635)	88 (46 to 196)
Hazard Ratio (HR) (95% CI)	0.30 (0.16 to 0.55)	--
2-sided p-value (<0.05)	**<0.001**	--

Source: Study 3003 CSR, NE=not estimable

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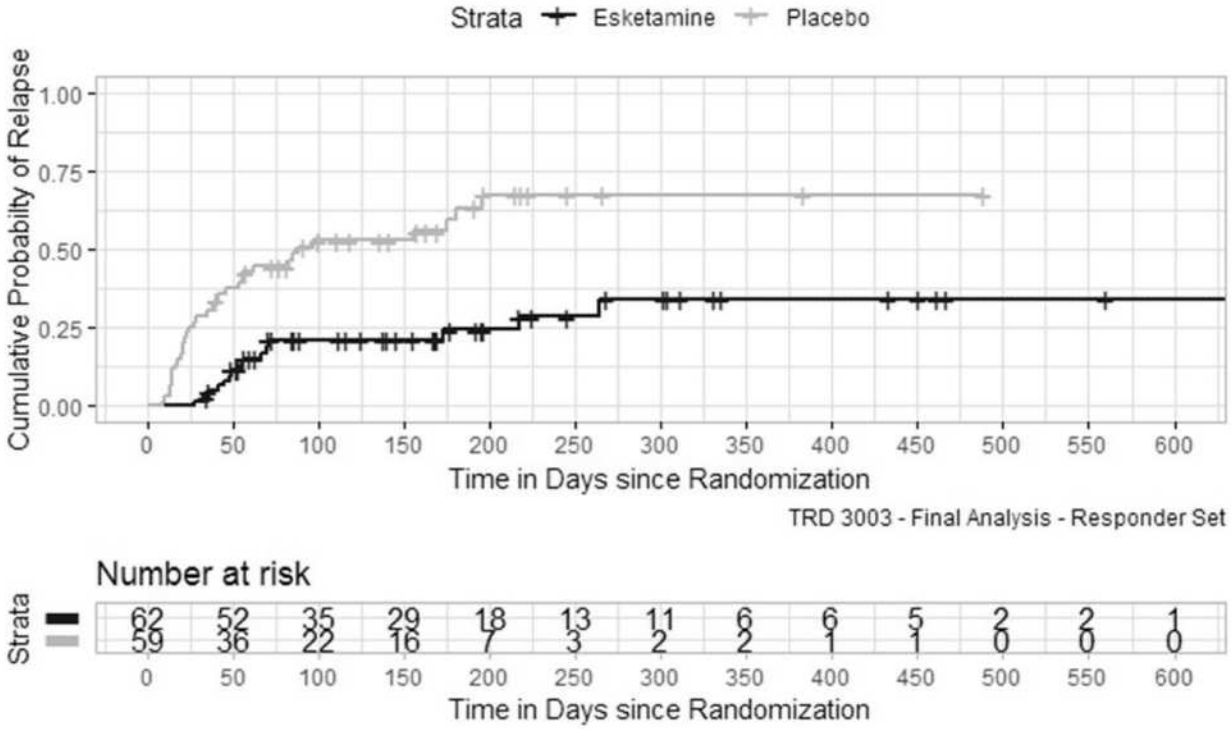
Figure 5: Study 3003 Secondary Efficacy Endpoint of Time to Relapse in Stable Responders



Source: Andrew Potter, PhD, Statistical Reviewer

Most of the differentiation between relapse on placebo versus esketamine (with oral antidepressant still ongoing in both arms) for the primary endpoint occurred within the first 2 to 4 weeks after randomization. Typically, in other maintenance-of-effect studies for MDD, relapses on drug versus placebo differentiate at a slower rate, beginning at about a month post-randomization according to an FDA meta-analysis[7]. Although the faster rate of relapse in this study may reflect the greater illness severity and fragility of a TRD population, there is some concern that it could reflect functional unblinding, with subjects realizing they are no longer on esketamine after switching to placebo. (The rapid deterioration on placebo is perhaps also surprising, as one might expect some protective effect from the ongoing oral antidepressant.) As compared to oral antidepressants, esketamine has noted immediate effects such as dissociation (for a majority of subjects, with rates as high as 75%) and sedation upon dosing, that do not dissipate with time according to the safety data reviewed. Subjects who have all been exposed to open-label esketamine for at least 16 weeks may be able to notice the difference soon after being switched to placebo. Acute esketamine withdrawal is likely not a factor, as dosing is infrequent during the maintenance phase.

[7] Borges, S, et al. "Review of Maintenance Trials for Major Depressive Disorder: A 25-Year Perspective from the US Food and Drug Administration." *J Clin Psychiatry* 2014;75(3):205-214.

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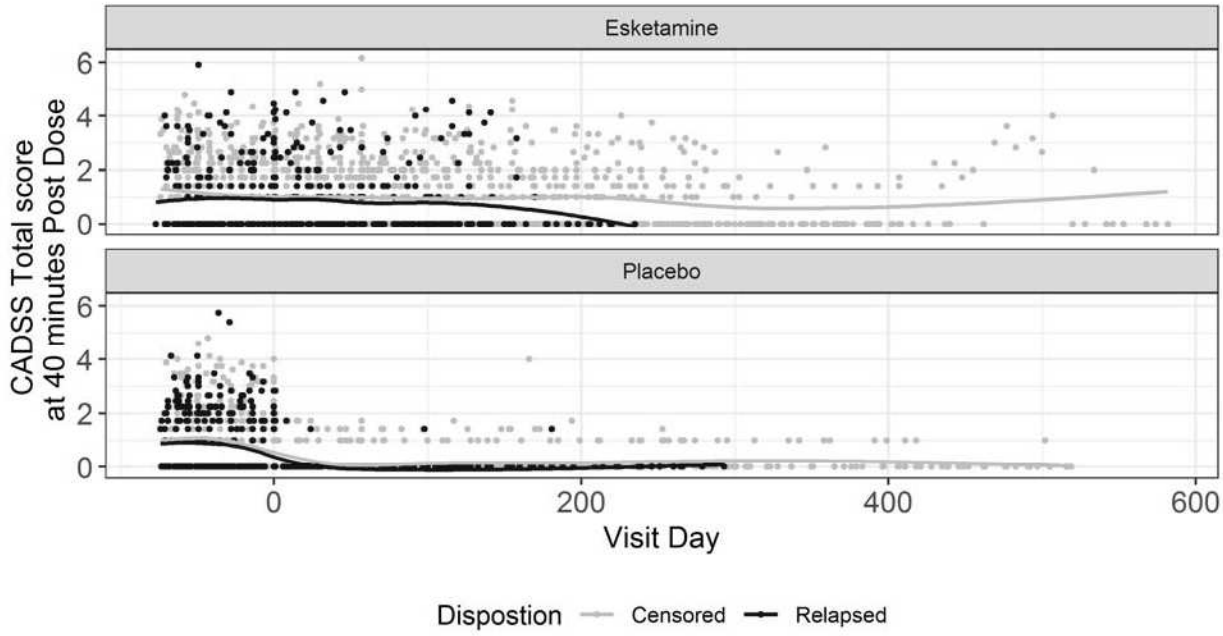
VA-19-1109-B-001868

The Applicant conducted an analysis indicating that only a few subjects reported significant changes in dissociation and sedation scale scores before and after randomization; censoring those subjects did not change the overall efficacy result.

FDA conducted further exploratory analysis of both the dissociation symptom trajectories and their association to the time to relapse of depression. The Applicant measured dissociative symptoms using the Clinician-Administered Dissociative States Scale (CADSS). In Figure 6, CADSS scores decline rapidly in the placebo arm when patients are randomized to stopping esketamine. FDA used a joint model of both CADSS score trajectories and time to depression relapse. This analysis found that both esketamine treatment (HR = 0.45, p = 0.0032) and CADSS score (HR = 0.63 per unit increase in square root CADSS, p = 0.0448) are associated with time to relapse of depression.

Figure 6 Treatment Arm Average CADSS score Trajectories Stratified by Relapse Status (TRD3003: FAS - Remitter Set)



Source: Andrew Potter, PhD, Statistical Reviewer

The presence of an association between dissociation and time to relapse introduces the possibility of alternative interpretations of the esketamine to placebo hazard ratio. Potential interpretations include:

- Despite the association of dissociative symptoms with increasing time to relapse, this unblinding does not change the evidence that esketamine delays time to depression relapse.
- The efficacy of esketamine in delaying time to relapse depends on the subject feeling some dissociative symptoms. The subject may worsen either due to suspecting they are no longer

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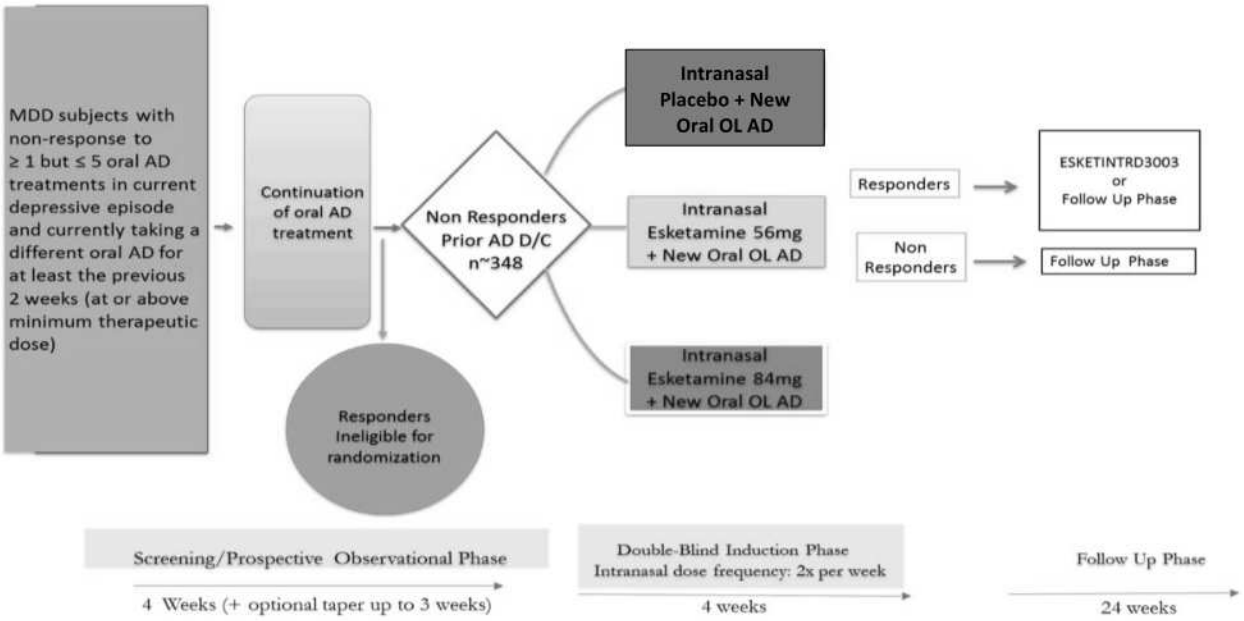
taking active drug, or because there is some primary antidepressant effect from or association with dissociation.

FDA's exploratory analysis cannot distinguish between these possibilities. It is thus possible, but not conclusive, that functional unblinding has partially impacted this study's results.

6.2.3. Study 3001 (TRANSFORM-1)

This study was a **fixed-dose** randomized parallel-group active-controlled trial. Based on the prespecified statistical plan, esketamine did not separate from placebo.

Figure 7 Study 3001 Study Design Schematic



Source: Adapted from Study 3001 CSR

Baseline demographic characteristics were generally similar across treatment arms for this study. About 40% of subjects were from the U.S., and approximately 70% were women. Baseline psychiatric characteristics were also generally similar; however, there was a higher percentage of subjects in the esketamine 84-mg arm with a history of failing three or more antidepressants (48%, 30%, and 41% in the esketamine 84-mg, esketamine 56-mg, and placebo arms, respectively).

The prespecified statistical analysis plan employed a fixed-sequence testing procedure to control the Type-I error rate. The esketamine 84-mg arm was prespecified as the first group to be tested, as it was the higher dose. Because the change from baseline on MADRS was not significantly different between the 84-mg treatment group and the placebo group, the testing sequence stopped here, and the 56-mg treatment group could not be formally analyzed. In an analysis that would be considered exploratory, subjects in the esketamine 56-mg arm did experience greater improvement in depressive symptoms as measured by the MADRS than patients in the placebo

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group. Of note, the least square mean difference between the esketamine 56-mg group and the placebo group is comparable to estimated treatment effects in other successful phase 3 studies. The nominally statistically significant ($p = 0.0114$) 56-mg dose arm in TRD3001 could be considered supportive evidence of effectiveness for the 56-mg dose, although this study was not positive based on the prespecified analysis plan.

Given that the esketamine 84-mg arm did not show superior efficacy over the lower dose, another concern is that we may not have sufficient evidence to say that there is a therapeutic dose response for the higher dose, relative to its higher rate of adverse events. This larger study's results did not confirm the dose-response relationship observed in the phase 2 Study 2003. Study 2003 compared esketamine 28 mg, 56 mg, and 84 mg to placebo (with a background oral antidepressant either ongoing or not). At 8 days post-dose, the placebo adjusted change from baseline in MADRS score was -4.2 (95% CI: -7.67, -0.79), -6.0 (95% CI: -9.71, -2.88), and -9.0 (95% CI: -12.53, -5.52) for 28 mg, 56 mg, and 84 mg esketamine respectively. (See Section 6.3.1 for more details.)

Table 6: Study 3001 Primary Endpoint MADRS Total Score CFB at Day 28 Using MMRM (Full Analysis Population)

Treatment Arm	**N**	**Baseline MADRS Total Score (SD)**	**LS Mean Change from Baseline (95% CI) at Week 4**	**LS Mean Difference from Placebo (95% CI) at Week 4**	**1-Sided *p*-value <0.025**
Placebo+Oral AD	113	37.5 (6.2)	-14.9 (-17.4 to -12.4)	--	--
Esketamine 56 mg+Oral AD	115	37.4 (4.8)	-18.9 (-21.4 to -16.4)	-4.1 (-7.7 to -0.5)	*0.013*
Esketamine 84 mg+Oral AD	114	37.8 (5.6)	-18.2 (-20.9 to -15.6)	-3.2 (-6.9 to +0.5)	0.044

Source: Study 3001 CSR and Andrew Potter, PhD, Statistical Reviewer

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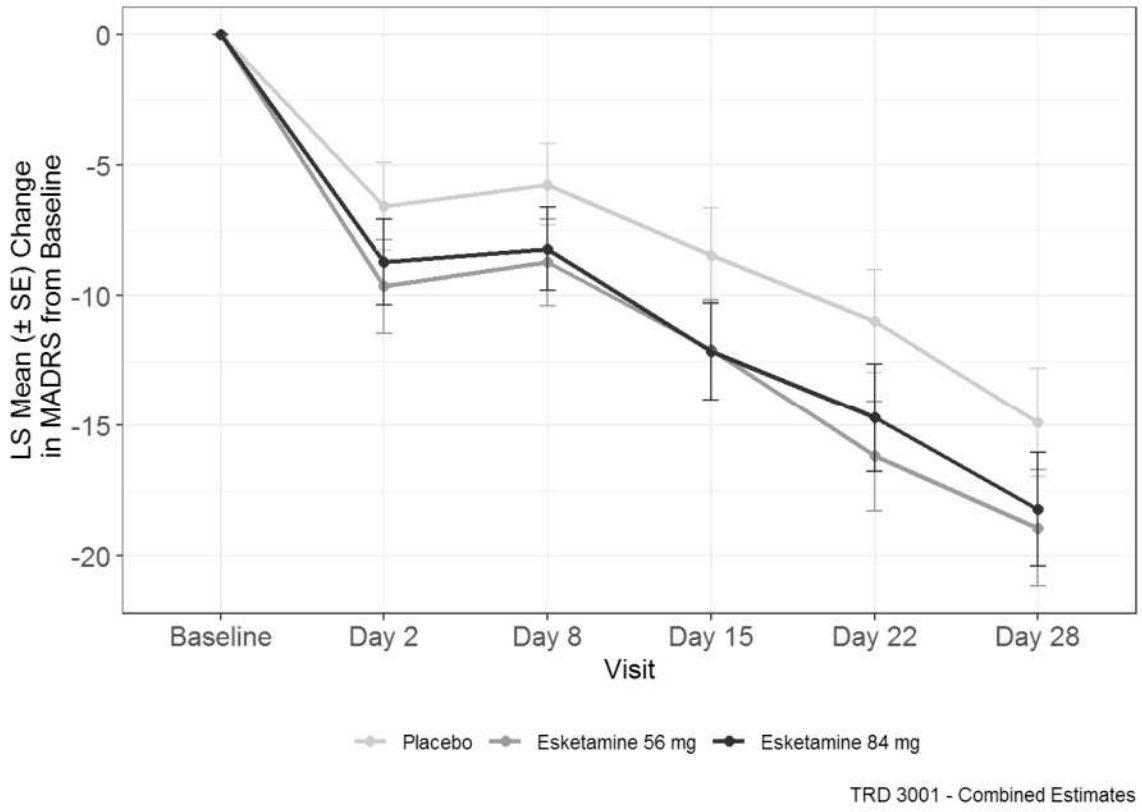
Figure 8: Study 3001 Primary Endpoint MADRS Total Score CFB at Day 28 Using MMRM (Full Analysis Population)



Source: Andrew Potter, PhD, Statistical Reviewer

6.2.4. Study 3005 (TRANSFORM-3)

This **geriatric** study used flexible dosing from 28 to 84 mg for the esketamine arm. Based on the prespecified statistical analysis plan, esketamine did not separate from placebo.

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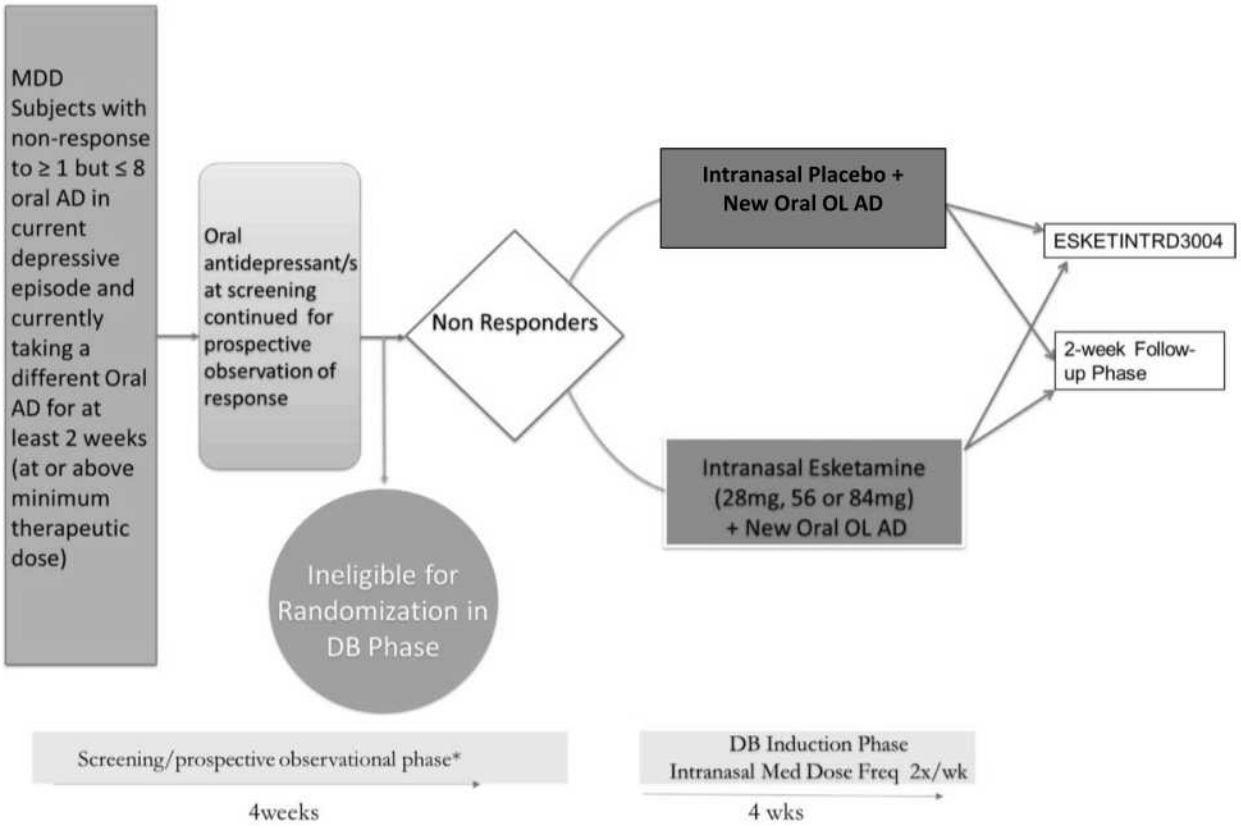
Figure 9 Study 3005 Design Schematic



Source: Adapted from Study 3005 CSR

The TRD inclusion cutoff scores for this study were slightly lower than those used for the non-geriatric adult phase 3 studies. The baseline demographic and psychiatric characteristics were generally similar across treatment groups, with about 51% U.S. representation. Unlike the previous studies, the mean age was 70 years, and the majority of subjects in this study were initiated on an SSRI (56%) instead of an SNRI for their oral antidepressant. A higher number of patients had a previous diagnosis of hypertension (47%), as expected for an older population. About 2/3 of subjects in the esketamine arm received 84 mg doses and 1/3 were on 56 mg.

The difference between the esketamine plus oral antidepressant group and the placebo plus oral antidepressant group was not statistically significant on the primary efficacy endpoint of change from baseline at Day 28 on the MADRS total score. Aside from not reaching statistical significance, this study has additional data integrity concerns given the unusual response curve shift at Day 28 (when a nearly significant effect emerged after a finding of no difference at all for the first 3 weeks, when an effect in other studies was present on Day 2), discrepancies between the locked datasets and reported protocol violations, and the inclusion of outliers with missing data. Study 3005 does not appear to be supportive of an esketamine effect.

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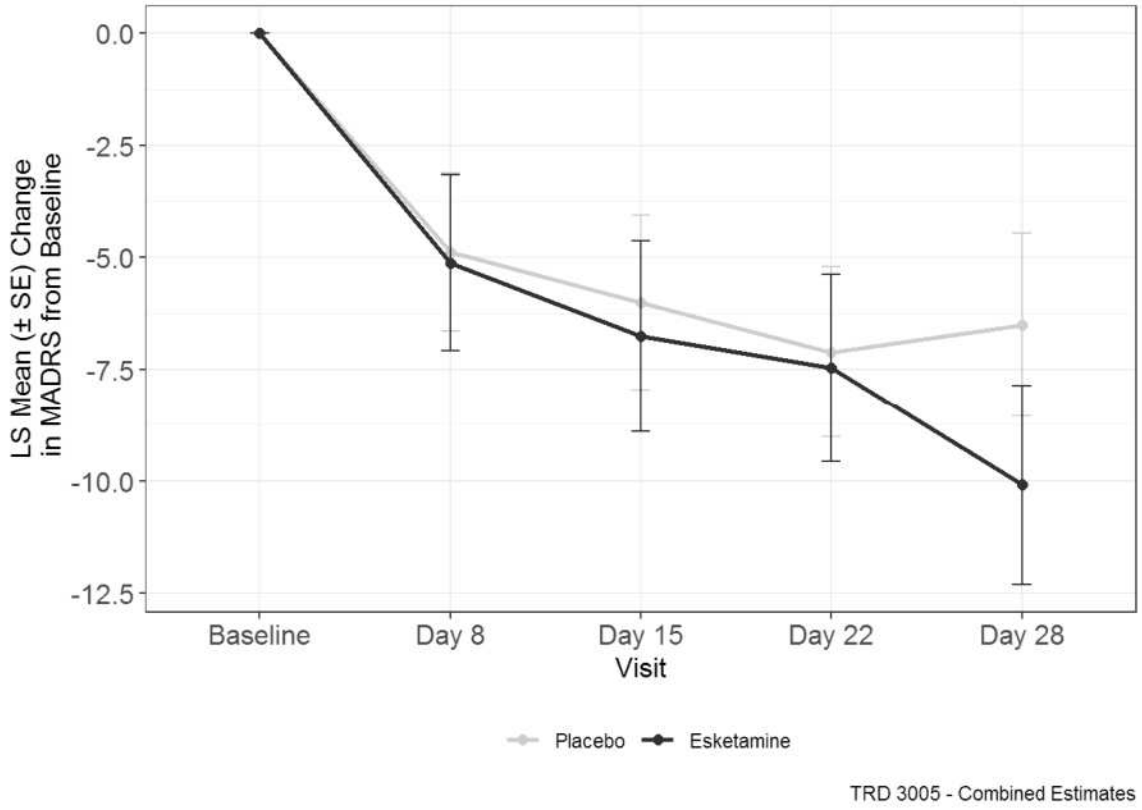
Table 7: Study 3005 Primary Endpoint MADRS Total Score Change from Baseline at Day 28 Using MMRM (Full Analysis Population)

Treatment Arm	N	Baseline MADRS Total Score (SD)	LS Mean Change from Baseline (95% CI) at Week 4	LS Mean Difference from Placebo (95% CI) at Week 4	1-Sided *p*-value <0.025
Placebo + Oral AD	65	34.8 (6.4)	-6.5 (-9.4 to -3.6)	--	--
Esketamine + Oral AD	72	35.5 (5.9)	-10.1 (-13.1 to -7.1)	-3.6 (-7.2 to 0.07)	0.029

Source: Study 3005 CSR and Andrew Potter, PhD, Statistical Reviewer

Figure 10: Study 3005 Primary Endpoint MADRS Total Score CFB at Day 28 Using MMRM (Full Analysis Population)



Source: Andrew Potter, PhD, Statistical Reviewer

6.2.5. Secondary Efficacy Endpoints and Other Results of Note

- Although no secondary endpoints in the phase 3 parallel-group studies met criteria for statistical significance, all were numerically better in the esketamine group than in the placebo group, and several reached nominal statistical significance. The only secondary endpoint that was consistently in the nominally significant range for *p*-values across the

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phase 3 parallel-group studies was the PHQ-9, a self-reported measure. The PHQ-9 is a self-reported depression symptom scale which provides confirmatory support for the MADRS.

Table 8: Esketamine Secondary Efficacy Endpoints

Study	**3001**			**3002**		**3005**	
	ESK 56 mg + Oral AD	ESK 84 mg + Oral AD	Placebo + Oral AD	ESK + Oral AD	Placebo + Oral AD	ESK + Oral AD	Placebo + Oral AD
MADRS Sustained Response Day 2+	10%	9%	2%	8% p=0.161*	5%	n/a	n/a
SDS	-2.5	-2.2	n/a	-4.0	n/a	-4.6	n/a
PHQ-9	-2.3	-2.2	n/a	-2.4	n/a	-2.8	n/a
MADRS Responders at Day 28	54%	53%	39%	69%	52%	27%	13%
MADRS Remitters at Day 28	36%	39%	31%	53%	31%	18%	7%
MADRS Sustained Response Day 8+	13%	11%	4%	11%	6%	n/a	n/a
GAD-7	-1.5	-1.4	n/a	-1.0	n/a	n/a	n/a
EQ-5D-5L CFB Mean Sum Score**	-19.0	-19.4	-14.6	-23.2	-17.1	-6.6	-1.6

*This was the only secondary endpoint that could be formally tested due to a fixed testing sequence. All the other secondary endpoints either could not be formally tested due to a previously statistically insignificant endpoint in the fixed testing sequence or were not controlled for multiplicity. p-value is one-sided.
**Scores are mean change from baseline only (SDS, PHQ-9, GAD-7 are mean change from baseline difference from placebo)
Source: CSRs from Studies 3001, 3002, 3005

- Key Secondary Endpoints for Studies 3001 and 3002: The following three outcome measures were prespecified as key secondary endpoints in the two adult (non-geriatric) phase 3 parallel-group studies:

    1. MADRS Sustained Response Starting Day 2 (Total Score Change from Baseline ≥50% response at Day 2, maintained through Day 28 with no worse than 25% response and one excursion allowed)

    2. Sheehan Disability Scale (SDS) total score change from baseline at Day 28

    3. PHQ-9 total score change from baseline at Day 28

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These endpoints were to be tested in a fixed sequence approach to adjust for multiplicity and type I error, if the primary endpoint was statistically significant.

For Study 3002, the primary endpoint was significant, so the first key secondary endpoint could be tested. However, that endpoint (MADRS Sustained Response Starting Day 2) was not statistically significant (see Table 7), and therefore, the subsequent key secondaries could not be formally tested for statistical significance. Both of the two subsequent key secondaries (SDS and PHQ-9) would have met nominal significance and showed numerical improvement in the esketamine group versus placebo for their respective endpoints. The SDS and PHQ-9 results here would provide supportive evidence of a greater trend towards efficacy in functional improvement and improvement in self-reported depression symptoms on IN esketamine versus IN placebo, plus an oral antidepressant, by Day 28.

For Study 3001, as the primary endpoint was not found to be significant, the key secondaries could not be formally tested. On an exploratory basis, the first key secondary (MADRS Sustained Response Starting Day 2) would have been nominally significant only for the esketamine 56-mg dose arm, and for both dose arms on the PHQ-9.

- Remission (MADRS ≤12) and Responder (≥50% MADRS Reduction from Baseline) Rates: Both percentage rates are numerically better for esketamine arms versus placebo arms in all phase 3 parallel-group studies. (The groups were not statistically compared.) This trend may indicate a clinically relevant subgroup of TRD patients who show marked clinical benefit from esketamine greater than placebo, with oral antidepressant ongoing in all arms. Also, the numerical Day 28 changes from baseline in mean total MADRS score for the esketamine groups in Studies 3001 and 3002 are consistent with the responder definition of *≥50% MADRS reduction from baseline.*

- Distribution of Response: MADRS mean total score distributions showed a trend towards greater change from baseline values for esketamine treatment groups compared to placebo for the parallel-group phase 3 studies. Again, this result seems to indicate at least a subgroup of TRD patients who show potential strong clinical benefit on esketamine compared to placebo, with oral AD ongoing.

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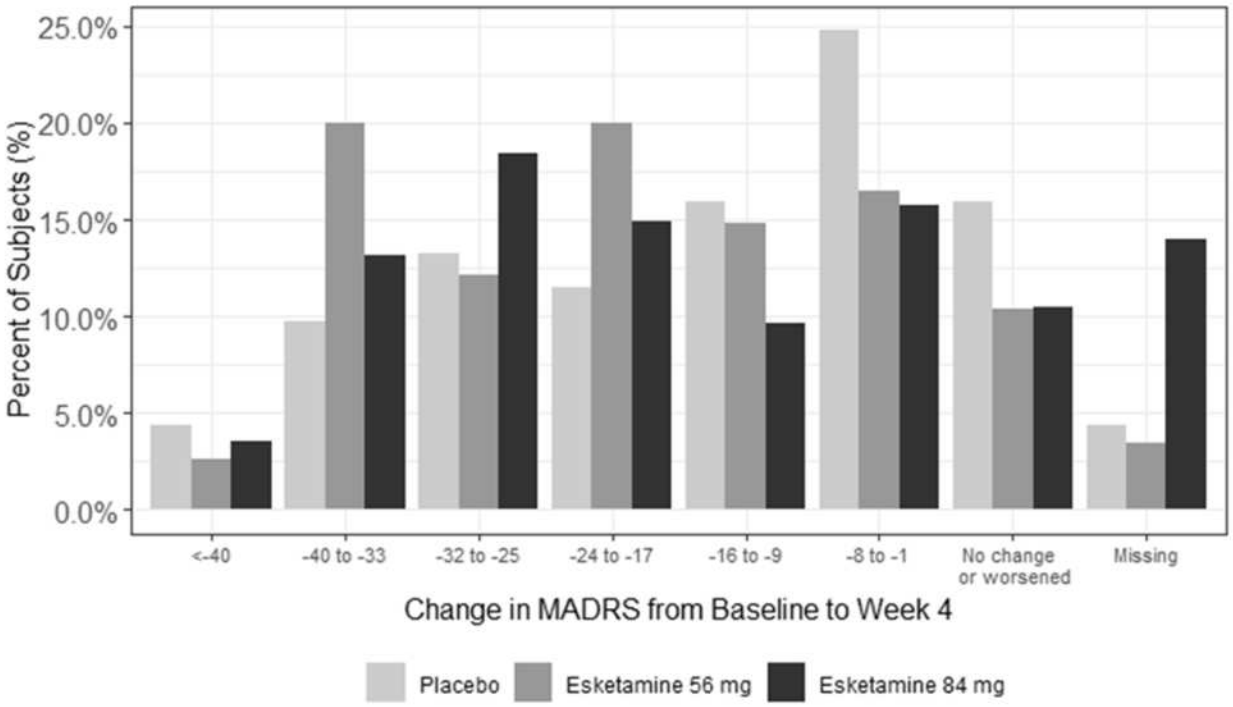
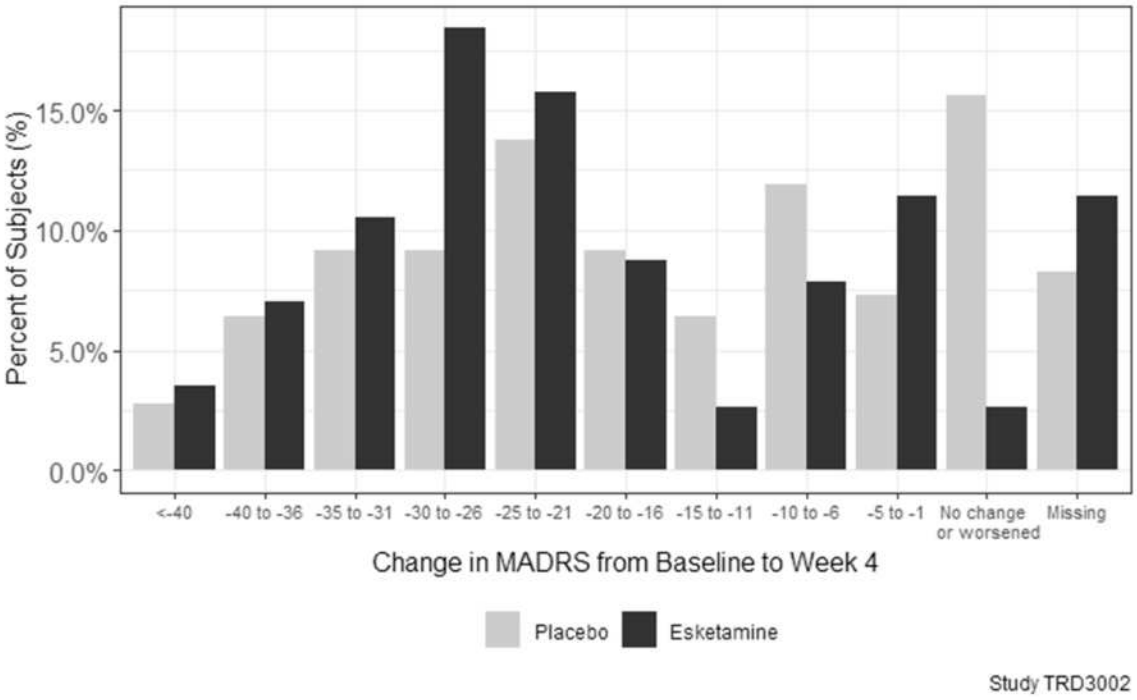
Figure 11: Study 3001 Distribution of Response on MADRS Total Score at Week 4



Source: Andrew Potter PhD, Statistical Reviewer

Figure 12: Study 3002 Distribution of Response on MADRS Total Score at Week 4



Source: Andrew Potter PhD, Statistical Reviewer

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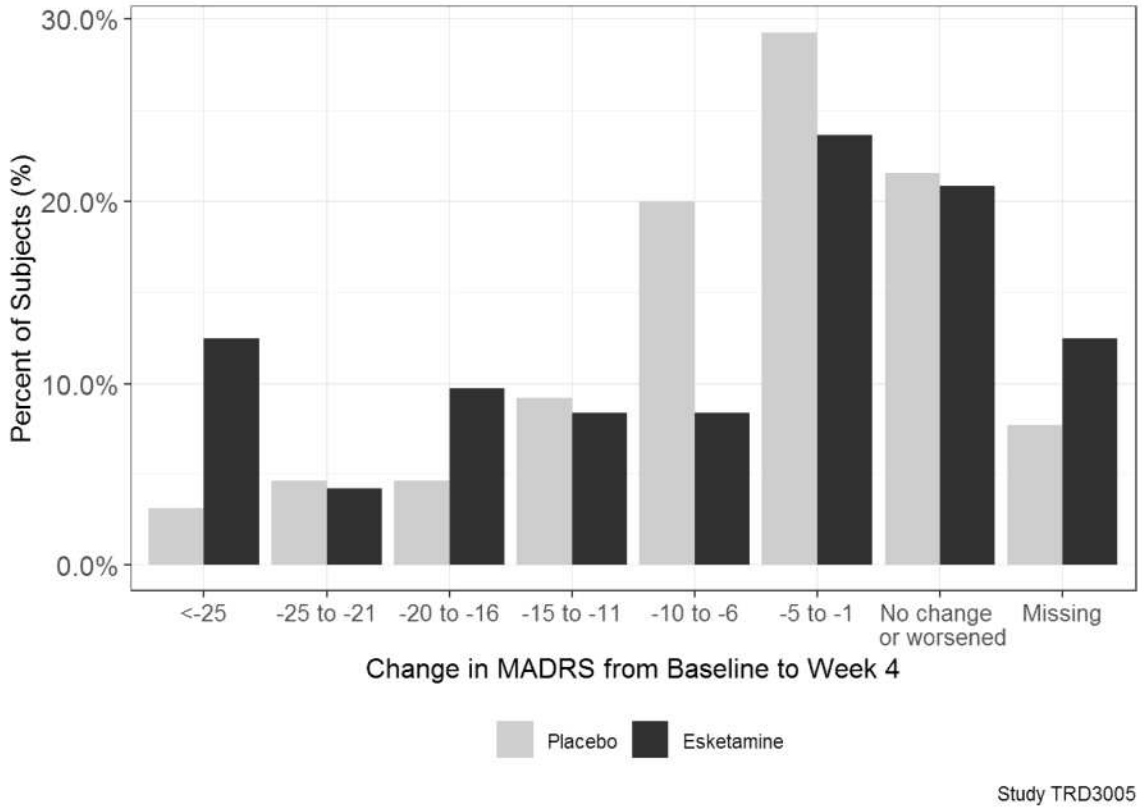
Figure 13: Study 3005 Distribution of Response on MADRS Total Score at Week 4



Source: Andrew Potter PhD, Statistical Reviewer

- Average Change from Baseline in MADRS Scores: To the extent that one can compare differences across trials, changes from baseline in MADRS mean total scores in the esketamine phase 3 parallel-group studies were comparable to the changes in previously approved antidepressants and adjunctive therapies. These changes are occurring in a treatment population with greater illness severity as based on higher mean baseline MADRS total scores and number of failed antidepressants.

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Table 9: MADRS Score Change from Baseline for Prior Approved Antidepressants

Indication	Antidepressant	MADRS LS Mean CFB at Primary Endpoint Range	MADRS LS Mean CFB Difference from Placebo/Active Control	Baseline MADRS Score
MDD	Vortioxetine	-13 to -20	-2.8 to -7.1	31 to 34
	Vilazodone	-9.7 to -13	-2.5 to -3.2	31 to 32
	Levomilnacipran	-14 to -17	-1.3 to -4.9	30 to 36
Adjunctive MDD	Aripiprazole	-8.5 to -8.8	-2.8 to -3.0	31 to 32
	Brexpiprazole	-7.7 to -8.5	-1.3 to -3.1	33 to 35
	Quetiapine XR	-14 to -17	-1.6 to -4.1	28 to 32
TRD	Olanzapine + Fluoxetine (fixed-dose combination)	-8.6 to -14	n/a	23 to 30
	Fluoxetine (vs. Olanzapine + Fluoxetine)	-1.2 to -11	-1.4 to -12	"
	Olanzapine (vs. Olanzapine + Fluoxetine)	-2.8 to -10	-0.8 to -11	"
	Esketamine	**-10.1 to -20.8**	**-3.2 to -4.1**	**37 to 38 adult, 35 geriatric**

Source: DPP Antidepressant Study Database from Previously Approved NDAs

6.3. Relevant Phase 2 Efficacy Results

6.3.1. Study 2003 (SYNAPSE)

Study 2003 was a fixed-dose study intended to help identify which dose(s) to carry forward to phase 3 studies. This phase 2 randomized, placebo-controlled, sequential parallel comparison design (SPCD), dose-response study consisted of two panels (A and B) and two 1-week double-blind treatment periods (1 and 2) for each panel. Panel A studied 28-, 56-, and 84-mg doses of esketamine and Panel B studied 14- and 56-mg doses. Background oral antidepressant treatment may or may not have been ongoing from previous treatment. The primary efficacy endpoint was the difference between IN esketamine and placebo for change from baseline in the MADRS total score for the combined double-blind treatment periods. The Applicant also analyzed pairwise comparisons of each esketamine dose versus placebo for dose response using a two different weighted combination tests based on estimates and standard errors from an ANCOVA model. The Applicant tested six hypotheses at an alpha of 0.1 that correspond to three pairwise esketamine – placebo comparisons where the test statistics were calculated two different ways. The Applicant did not prespecify any procedure for controlling the Type I error rate across these hypotheses. In addition, multiple, exploratory, dose-response analyses including MCP-mod were

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conducted without pre-specifying any method to control the Type-I error rate over these analyses.

Patient were randomized to treatment (IN esketamine or placebo) at the beginning of Period 1. Placebo non-responders were re-randomized to treatment in Period 2. Panels A and B were analyzed separately for efficacy. Panel A randomized 67 subjects in the US and Belgium, and Panel B randomized 41 subjects in Japan. Baseline demographic characteristics were generally similar to the phase 3 studies, although the baseline MADRS mean total scores were lower (less severe) at 34.1 in Panel A and 28.3 in Panel B.

Results: For Panel A, there was a statistically significant difference in mean MADRS total score in all esketamine dose groups versus placebo for Periods 1 and 2 combined on ANCOVA (LOCF) analysis. In addition, all esketamine doses were statistically significantly better than placebo in Period 1 but not Period 2. However, multiplicity adjustment was not considered for these exploratory analyses.

Table 10 MADRS Total Score: Change from Baseline to End Point ANCOVA LOCF Analysis; Double-Blind Phase, Panel A, Periods 1, 2, and Combined

Period		Placebo	Esketamine 28 mg	Esketamine 56 mg	Esketamine 84 mg
1	N	33	11	11	12
	LS Mean (SE)	-4.9 (1.74)	-9.8 (2.72)	-12.4 (2.66)	-15.3 (2.56)
	Mean diff Placebo (SE)	--	-5.0 (2.99)	-7.6 (2.90)	-10.5 (2.79)
	One-sided p-value < 0.025	--	0.051	0.006	<0.001
2	N	6	8	9	5
	LS Mean (SE)	-4.5 (2.92)	-7.6 (2.49)	-8.9 (2.51)	-11.4 (2.68)
	Mean diff Placebo (SE)	--	-3.1 (2.99)	-4.4 (3.06)	-6.9 (3.41)
	One-sided p-value < 0.025	--	0.152	0.083	0.028
Combined	Mean diff Placebo (SE)	--	-4.2 (2.1)	-6.3 (2.1)	-9.0 (2.1)
	90% CI	--	-7.7 to -0.8	-9.7 to -2.9	-12.5 to -5.5
	One-sided p-value < 0.025	--	0.021	0.001	<0.001

Source: Applicant's Advisory Committee Briefing Document

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Due to a failed consistency test between Periods 1 and 2, the combined analysis was not performed for Panel B. The individual period results showed no clear efficacy trends. The Applicant did not report detailed results.

Study 2003's results suggest a dose response where higher doses have superior efficacy; however, Study 2003 has limited applicability as a pivotal study to claim this dose response, and Study 3001 did not confirm this dose response. The Applicant analyzed multiple dose-response models and chose the model most supportive of the claimed dose response. Study 2003 differs from the phase 3 studies in its lack of consistency for background oral antidepressants, its smaller sample size, the use of SPCD that might not be valid depending on whether the required statistical assumptions are met, and its shorter treatment period.

In addition, Study 2003 may not have met the prespecified assumptions for the validity of either of the SPCD combination tests conducted. However, the Period 1 results suggest increasing antidepressant efficacy without the requirement of the SPCD assumptions, for Panel A only.

6.3.2. Study SUI2001

Study SUI2001 was a phase 2 double-blind randomized placebo-controlled study to evaluate the efficacy and safety of IN esketamine for the rapid reduction of symptoms of MDD including suicidal ideation, in subjects at imminent risk of suicide (under a separate Investigational New Drug application). The study was conducted at ten US sites. The primary endpoint was the efficacy of IN esketamine 84 mg versus placebo as measured by mean change from baseline on the MADRS total score at 4 hours post-dose on Day 1, with secondary endpoints looking at other timepoints (24 hours post-dose (Day 2), Day 25 (end of double-blind treatment), and Day 81 (end of follow-up treatment)).

There were 68 subjects randomized to treatment after presenting to an emergency room (ER) for treatment of MDD and imminent suicidal risk. Subjects were screened for official study entry within 24 to 48 hours of receiving an initial IN dose in the ER on Day 1 of double-blind treatment (and subsequently being admitted to an inpatient psychiatric unit). After study entry, subjects were still to receive standard of care treatment for MDD and suicidal risk, including at least 5 days of hospitalization and initiation, continuation, or augmentation of oral antidepressants.

Subjects were to continue blinded treatment until Day 25, followed by a 56-day follow-up phase (Day 26 to Day 81). Subjects were randomized in a 1:1 ratio to either 84 mg IN esketamine or IN placebo, to be dosed twice weekly for 4 weeks.

Oral antidepressants were to be continued throughout the double-blind treatment phase at the same dose after reaching therapeutic range. Efficacy and safety rating assessments were to be conducted separately to improve blinding.

Results: There were 66 subjects (35 on esketamine, 31 on placebo) who received at least one dose of study medication and comprised the intent-to-treat (ITT) population. There were 49

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completers (27 on esketamine, 22 on placebo). The majority of the 19 subjects who discontinued the study early were due to adverse events and lack of efficacy.

The majority of subjects were female (65%), with a mean age of 35.8 years (55% of subjects were under age 35). The mean MADRS score was 38.6 (SD 6.53). All had answered "yes" to having current suicidal ideation with intent on Question B5 of the Mini-International Neuropsychiatric Interview (MINI). These demographics reflect a severely ill study population, comparable to the one studied in the TRD adult phase 3 trials.

The efficacy results on the MADRS show numerical improvement at all timepoints on esketamine compared to placebo, although there was no statistically significant difference between treatment groups at Day 25.

Table 11 Study SUI2001 MADRS Mean Total Score Change from Baseline

	Day 1	Day 2	Day 25
Esketamine (SD)	-13.4 (9.0)	-19.3 (12.0)	-26.4 (14.5)
Placebo (SD)	-9.1 (8.4)	-12.8 (9.8)	-23.0 (10.8)
LS Mean Difference (SE)	-5.3 (2.1)	-7.2 (2.9)	-4.5 (3.1)
2-sided *p*-value <0.05	**0.015**	**0.015**	0.159

Source: Study SUI2001 CSR

The percentage of responders and remitters was also numerically higher at all timepoints in the esketamine group versus the placebo group (including at Day 81). At Day 25, 83% in the esketamine group were responders versus 63% on placebo. For remitters, 67% were on esketamine versus 50% on placebo.

Overall, although the sample size is small, and the background oral antidepressant was not as consistently controlled as in the phase 3 studies, this study is of interest as a parallel-group designed study in a population with significant MDD illness severity and clinical morbidity. The study presents supportive evidence consistent with most of the prior TRD esketamine study results.

7. Safety of Esketamine for the Treatment of TRD

7.1. Overarching Safety Issues

The review team identified sedation, dissociation, and increased blood pressure as the primary safety concerns related to this product. Cognitive function impairment, liver injury, and interstitial or ulcerative cystitis have been reported in post marketing data for ketamine. In the esketamine clinical program, there was no evidence of a higher rate of cognitive impairment or liver injury with esketamine relative to placebo. There were no reported cases of ulcerative or

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interstitial cystitis, but esketamine-treated patients had a higher incidence of lower urinary tract adverse events.

Randomization for Study 3001 included two esketamine arms. Therefore, the randomization ratio was 2:1 esketamine + oral AD: placebo + oral AD. Studies 3002 and 3005 had esketamine arms with flexible dosing (which had 1:1 randomization ratios). Data are presented separately for the 56- and 84-mg fixed doses for Study 3001; the flexible dosages of 28, 56, 84 mg are combined for Studies 3002 and 3005.

7.2. Deaths, Serious Adverse Events, Adverse Events Leading to Study Withdrawal

7.2.1. Deaths

There were six deaths in the esketamine for treatment-resistant depression development program as of January 8, 2019, all in esketamine-treated subjects. Three of these deaths were by suicide—two well after the patient's last dose of esketamine (12 and 20 days), and one 4 days after the patient's last dose of esketamine. The patients who committed suicide 12 and 4 days after their last dose both appeared to be improving based on their MADRS scores (from baseline of 27 to 9, and 41 to 25, respectively). The patient who committed suicide 20 days after his last dose was experiencing worsening symptoms (from MADRS 7, 13 days prior to death to MADRS 21, 6 days prior to death. The patient who committed suicide 4 days after last dose was enrolled in an ongoing study; that patient's Columbia Suicide Severity Rating Scale (C-SSRS) score was not available. The other two patients had scores of 0, both at baseline and at the visit prior to their deaths. Given the small number of cases, the severity of the patients' underlying illness, and the lack of a consistent pattern among these cases, it is difficult to consider these deaths as drug-related.

Of the remaining three cases, one involved a motorcycle accident 26 hours after the patient's last dose of esketamine. Given the timing of sedation-related adverse events in the clinical development program and the data from the driving studies, it seems unlikely that esketamine played a role in this accident. Another death occurred in a 60-year-old male patient with a history of hypertension and obesity who died suddenly on study day 113. At his last study visit 5 days prior to death, his blood pressure, heart rate, and pulse oximetry were all within normal limits before and after receiving esketamine. It seems unlikely that this death was drug-related. The last death was a 74-year-old woman with history of hypertension and hyperlipidemia who died of myocardial infarction 6 days after last dose of esketamine. Esketamine-induced increases in blood pressure normally last for less than 4 hours post-dose; therefore, the myocardial infarction is not likely related to elevated blood pressure.

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7.2.2. Serious Adverse Events

More serious adverse events (SAEs) were reported in subjects treated with esketamine than placebo.

Table 12: SAEs in Studies 3001, 3002, and 3005

	3001		3002		3005	
	Placebo	ESK	Placebo	ESK	Placebo	ESK
N. of subjects	113	231	109	115	65	72
Depression	1	6	0	0	0	1
Suicidal ideation	1	4	0	0	0	0
Road traffic accident/Death	0	0	0	1	0	0
Dizziness/Fall/Hip fracture	0	0	0	0	0	1
Cerebral hemorrhage	0	0	0	1	0	0
Headache	0	1	0	0	0	0
Blood pressure increased	0	0	0	0	0	1

Source: Qi Chen, MD, MPH, Safety Reviewer

SAEs of depression and suicidal ideation were reported with higher incidence in subjects treated with esketamine than placebo in Study 3001, but not in Studies 3002 or 3005. There was no obvious difference between the esketamine and placebo groups with respect to other SAEs.

7.2.3. Adverse Events Leading to Study Withdrawal

There were more adverse events leading to study withdrawal in esketamine groups than placebo groups in Studies 3001, 3002, and 3005. However, very few cases of each AE were reported. Most adverse events were reported only once and only in one study. Blood pressure increase, depression, and nausea were reported twice in one study, all in esketamine groups, which is consistent with the common adverse events profile.

7.3. Adverse Events

The most commonly reported adverse events were dissociation, dizziness/vertigo, nausea/vomiting, sedation, paresthesia, hypoaesthesia, blood pressure increase in Studies 3001, 3002, and 3005. The distribution of adverse events was similar between age groups. However, the common AEs in esketamine groups were less frequently reported in subjects ≥65 years old than in subjects < 65 year old. Adverse events occurring in greater than two percent of esketamine-treated subjects and at least twice as frequently as in placebo-treated subjects <65 years-old, and in subjects ≥ 65 years-old are presented in Tables 13 and 14, respectively.

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Table 13: Adverse Events ≥ 2% and ≥ Twice the Rate of Placebo by Treatment Group in Studies 3001 and 3002 (subjects < 65 years old)

Adverse Events	3001			3002	
	Placebo	Esketamine 56 mg	Esketamine 84 mg	Placebo	Esketamine
	N=113 n (%)	N=115 n (%)	N=116 n (%)	N=109 n (%)	N=115 n (%)
Dissociation	22 (19.5%)	53 (46.1%)	54 (46.6%)	20 (18.3%)	60 (52.2%)
Dizziness	11 (9.7%)	38 (33.0%)	32 (27.6%)	7 (6.4%)	32 (27.8%)
Nausea	12 (10.6%)	32 (27.8%)	37 (31.9%)	7 (6.4%)	31 (27.0%)
Sedation	13 (11.5%)	29 (25.2%)	29 (25.0%)	9 (8.3%)	22 (19.1%)
Vertigo	2 (1.8%)	24 (20.9%)	24 (20.7%)	4 (3.7%)	30 (26.1%)
Paraesthesia	3 (2.7%)	19 (16.5%)	11 (9.5%)	1 (0.9%)	14 (12.2%)
Hypoaesthesia oral	2 (1.8%)	16 (13.9%)	12 (10.3%)	1 (0.9%)	9 (7.8%)
Hypoaesthesia	2 (1.8%)	14 (12.2%)	17 (14.7%)	1 (0.9%)	8 (7.0%)
Blood pressure increased	5 (4.4%)	11 (9.6%)	14 (12.1%)	1 (0.9%)	12 (10.4%)
Vomiting	2 (1.8%)	7 (6.1%)	14 (12.1%)	2 (1.8%)	11 (9.6%)
Tachycardia	1 (0.9%)	2 (1.7%)	3 (2.6%)	0	0

Source: Qi Chen, MD, MPH, Safety Reviewer

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Table 14: Adverse Events ≥ 2% and ≥ Twice the Rate of Placebo by Treatment Group in Study 3005 (subjects ≥ 65 years old)

Adverse Events	Placebo N=65 n (%)	Esketamine N=72 n (%)
Dizziness	5 (7.7%)	17 (23.6%)
Dissociation	6 (9.2%)	15 (20.8%)
Nausea	3 (4.6%)	13 (18.1%)
Headache	2 (3.1%)	10 (13.9%)
Blood pressure increased	4 (6.2%)	10 (13.9%)
Vertigo	2 (3.1%)	8 (11.1%)
Hypoaesthesia oral	0 (0%)	5 (6.9%)
Vomiting	1 (3.1%)	5 (6.9%)
Hypoaesthesia	1 (1.5%)	4 (5.6%)
Diarrhoea	1 (1.5%)	3 (4.2%)
Hyperhidrosis	1 (1.5%)	3 (4.2%)
Nasal mucosal disorder	1 (1.5%)	3 (4.2%)
Nasal discomfort	0 (0%)	2 (2.8%)
Cough	0 (0%)	2 (2.8%)

Source: Qi Chen, MD, MPH, Safety Reviewer

Adverse events of lower urinary tract symptoms were 6 to 10% in esketamine groups compared to 1 to 3% in placebo in studies 3001 and 3002 (subjects < 65 years old), and 7% in esketamine vs. 4% in placebo in Study 3005 (subjects ≥ 65 years old). However, no cases of interstitial cystitis or ulcerative cystitis were identified during the clinical trials. Given that ketamine is associated with interstitial and ulcerative cystitis (observed in individuals who abuse ketamine), cystitis-related adverse events will likely be described in the Warnings and Precautions section of labeling if this product is approved.

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Table 15: Cystitis-related Adverse Events by Treatment Group in Studies 3001, 3002, and 3005

Study	3001			3002		3005	
Treatment	Placebo	ESK 56 mg	ESK 84 mg	Placebo	ESK 56 to 84 mg	Placebo	ESK 28 to 84 mg
N	113	115	116	109	115	65	72
Lower Urinary Tract AEs	3 (2.7%)	10 (8.7%)	5 (4.3%)	1 (0.9%)	11 (9.6%)	5 (7.7%)	6 (8.3%)
Urinary discomfort/pain	0	1	1	0	7	4	1
Cystitis/UTI	2	3	1	1	2	1	6
Micturition urgency	0	1	2	0	0	0	0
Pollakiuria/Nocturia	1	6	3	0	4	0	1
Sediment/Odour abnormal	0	0	1	0	0	0	0

**Symptoms of cystitis could be misreported as UTI due to similar clinical symptoms*
Source: Qi Chen, MD, MPH, Safety Reviewer

The most commonly reported lower urinary tract adverse events in subjects treated with esketamine were urinary frequency and dysuria.

Most (67%) of the lower urinary tract AEs were mild and resolved without intervention or esketamine dose reduction. Only two (0.04%) of the reported lower urinary tract AEs were considered severe—both were cases of urinary frequency, both occurred in the esketamine group. Only one lower urinary tract AE (a case of urinary tract infection) resulted in esketamine interruption. No dose effect was observed on the severity of the urinary AEs. 76% of the AEs were resolved or resolving at the subject's last assessment. No dose effect was observed on the outcome of the AEs.

Attempts to identify interstitial or ulcerative cystitis could be confounded by urinary tract infection symptoms in AE reports. However, notably higher incidences of urinary frequency and dysuria may indicate adverse effects on the bladder. In long-term observational Study 3004, lower urinary tract AEs were reported in 137 (19%) subjects, most of which (90%) were resolved at the subject's last assessment. The cumulative prevalence of subjects with lower urinary tract AEs in study 3004 was 7 subjects per thousand esketamine treatments compared to 11 per thousand treatments in short term Studies 3001, 3002, and 3005. The observed cumulative prevalence with placebo in the short-term studies was 4 per thousand treatments. On the other hand, esketamine was administered less frequently (weekly or twice weekly for 4 to 8 weeks, then every other week) in Study 3004 as compared to twice weekly in Studies 3001, 3002, and 3005. The longer duration between esketamine use may help the urinary tract to recover from any adverse effects of esketamine. Without a comparison arm, it is difficult to conclude whether esketamine treatment results in long-term adverse effects on the urinary tract.

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7.4. Laboratory Studies, Electrocardiograms (ECGs), and Vital Signs

7.4.1. Laboratory Studies

Esketamine treatment had little apparent effect on laboratory studies. Notably, esketamine was not found to produce clinically meaningful changes in liver enzymes or bilirubin. There was no increase in abnormalities in urinalysis relative to placebo.

7.4.2. ECGs

In a thorough QT study, intranasal esketamine treatment (84 mg dosage) was associated with a maximum heart-rate-adjusted reduction in QT interval relative to placebo of about 6 milliseconds at maximum effect, returning to baseline in 3 to 4 hours, a change that was not deemed to be clinically meaningful. No effects on PR or QRS intervals were found.

7.4.3. Vital Signs

7.4.3.1. Blood Pressure

The rate of potentially clinically important systolic blood pressure (SBP) increases (to ≥180 mmHg with increase of ≥20 mmHg) or diastolic blood pressure (DBP) increase (to ≥105 mmHg with increase ≥15 mmHg) was higher in the esketamine group than in the placebo group. (Table 17)

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Table 16: Post-dose Highest Blood Pressure Changes in Esketamine- and Placebo-treated Patients in Studies 3001, 3002, and 3005

Study	3001			3002		3005	
Treatment	Placebo	ESK 56 mg	ESK 84 mg	Placebo	ESK 56 to 84 mg	Placebo	ESK 28 to 84 mg
N	113	116	115	109	115	65	72
SBP (mmHg)							
Mean change ± SD	12 ± 10	20 ± 14	20 ± 13	9 ± 8	18 ± 12	15 ± 11	23 ± 16
SBP ≥180 and increase ≥ 20 n (%)	0	6 (5.2%)	2 (1.7%)	0	1 (0.9%)	1 (1.6%)	2 (2.8%)
DBP (mmHg)							
Change mean ± SD	10 ± 8	15 ± 8	14 ± 8	7 ± 5	12 ± 8	10 ± 7	12 ± 7
DBP ≥ 105 and increase ≥ 15 n (%)	2 (1.8%)	8 (7.0%)	10 (8.7%)	0	10(8.8%)	1(1.6%)	0

Source: Qi Chen, MD, MPH, Safety Reviewer

Adult subjects 18 to ≤ 65 years of age experienced greater mean increases in SBP and DBP in esketamine-treated subjects compared to placebo, and more subjects experienced potentially clinically meaningful increases of SBP to ≥180 mmHg (and change ≥ 20 mmHg) and DBP ≥ 105 mmHg (and change ≥ 15 mmHg). A similar pattern was not observed in subjects ≥ 65 years of age in Study 3005. The observed changes in blood pressure generally resolved in less than four hours without clinical intervention.

Table 17: Visits with Highest BP Measured at 1.5 hour and SBP Increase ≥10 or DBP ≥5

Study		3001		3002		3005	
Treatment		Placebo	ESK 56 to 84 mg	Placebo	ESK 56 to 84 mg	Placebo	ESK 28 to 84 mg
N (% of visits)	SBP	83 (9%)	177 (10%)	63 (8%)	79 (9%)	79 (16%)	102 (19%)
	DBP	1 (0.1%)	3 (0.2%)	0	0	1 (0.2%)	0

Source: Qi Chen, MD, MPH, Safety Reviewer

Usually the highest SBP was observed at 40 minutes. In about 10 to 20% of visits, the highest observed SBP increase of at least 10 mmHg was at 1.5 hours post dose. Clinical pharmacology data from Study 1013 also showed blood pressure effects last for about 4 hours and are likely

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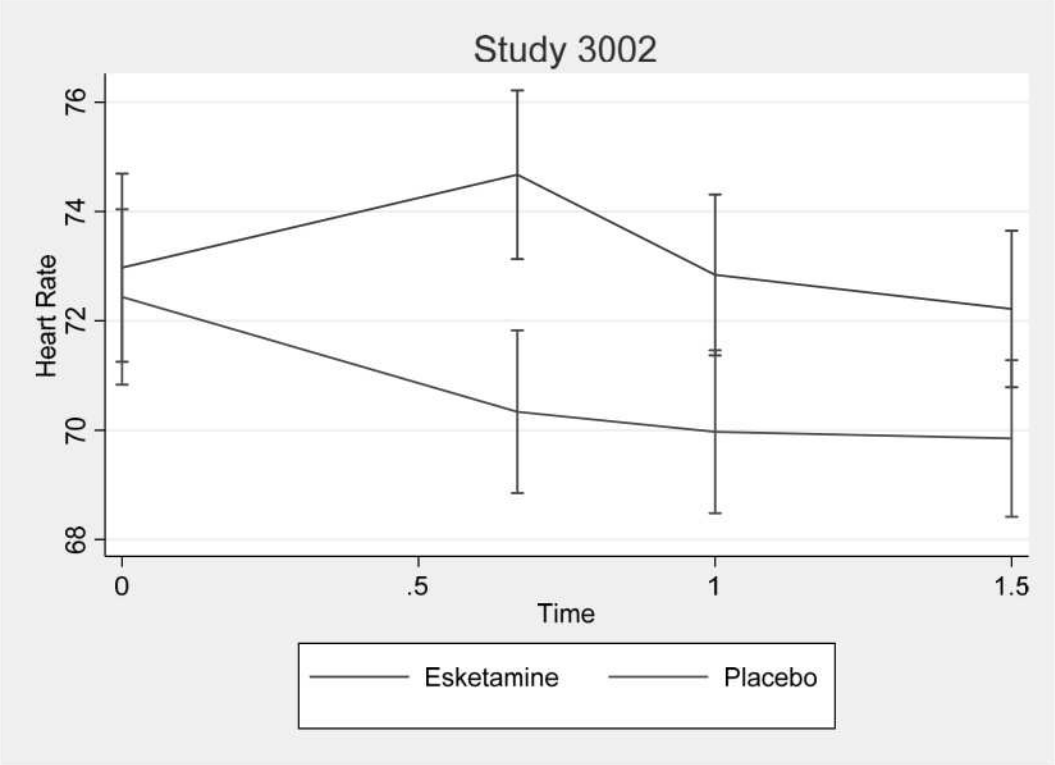
related to esketamine plasma levels. Longer post-dose observation would be needed to capture the full profile of esketamine-induced blood pressure increase.

7.4.3.2. Heart Rate

In most phase 1 and 2 studies, esketamine treatment was associated with increases in heart rate. This effect was not observed in Studies 3001 and 3005. In Study 3002, an increase in heart rate relative to placebo (random effects mean 4.7 bpm) was observed at 40 minutes (Figure 9). Given that the time pattern of heart rate changes seen in Study 3002 and phase 1 and 2 studies matched the time pattern of changes in blood pressure and the esketamine pharmacokinetic profile, it is likely that esketamine does cause an increase in heart rate in some patients, despite the absence of this observation in Studies 3001 and 3005.

Figure 14: Changes in Heart Rate in Study 3002



Source: Marc Stone, MD, Deputy Director of Safety

7.5. Other Adverse Events of Special Interest

7.5.1. Sedation

Sedation was evaluated using Modified Observer's Alertness/Sedation scale (MOAA/S) at pre-dose, and post-dose 15, 30, 45, 60, 75, and 90 minutes. On this scale, 0 represents a patient response only to painful stimulus, 1 is patient response only after painful stimulus, and 2 corresponds to response only after mild prodding or shaking. The data describing esketamine's sedative effects are presented in following table, lower score indicating worse sedation.

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Table 18: Number of Subjects Who Experienced Sedation at Least Once in Studies 3001, 3002, and 3005

Study	3001			3002		3005	
Treatment	Placebo	Esketamine 56 mg	84 mg	Placebo	Esketamine 56 to 84 mg	Placebo	Esketamine 28 to 84 mg
N	112	114		107	114	63	72
All sedation (score 0-4)							
n (%)	12 (10.7%)	57 (50.0%)	69 (60.5%)	11 (10.3%)	66 (57.9%)	12 (19.0%)	35 (48.6%)
Severe sedation (score 0-2)							
n	0	3	3	0	1	0	0

Source: Qi Chen, MD, MPH, Safety Reviewer

There was a substantially higher incidence of sedation in esketamine-treated patients (49 to 61%) than in placebo-treated patients (10% to 19%). In Study 3001, the sedation incidence was slightly higher in the esketamine 84-mg group than in the esketamine 56-mg group. The post-dose times at which sedation began, reached peak severity, and resolved in Studies 3001, 3002, 3003, and 3005 are presented in Figures 15 and 16.

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Figure 15: Sedation – Onset, Peak and Resolution time by Percentage of Study Population in Esketamine-treated Subjects <65 years-old in Studies 3001, 3002 and 3003

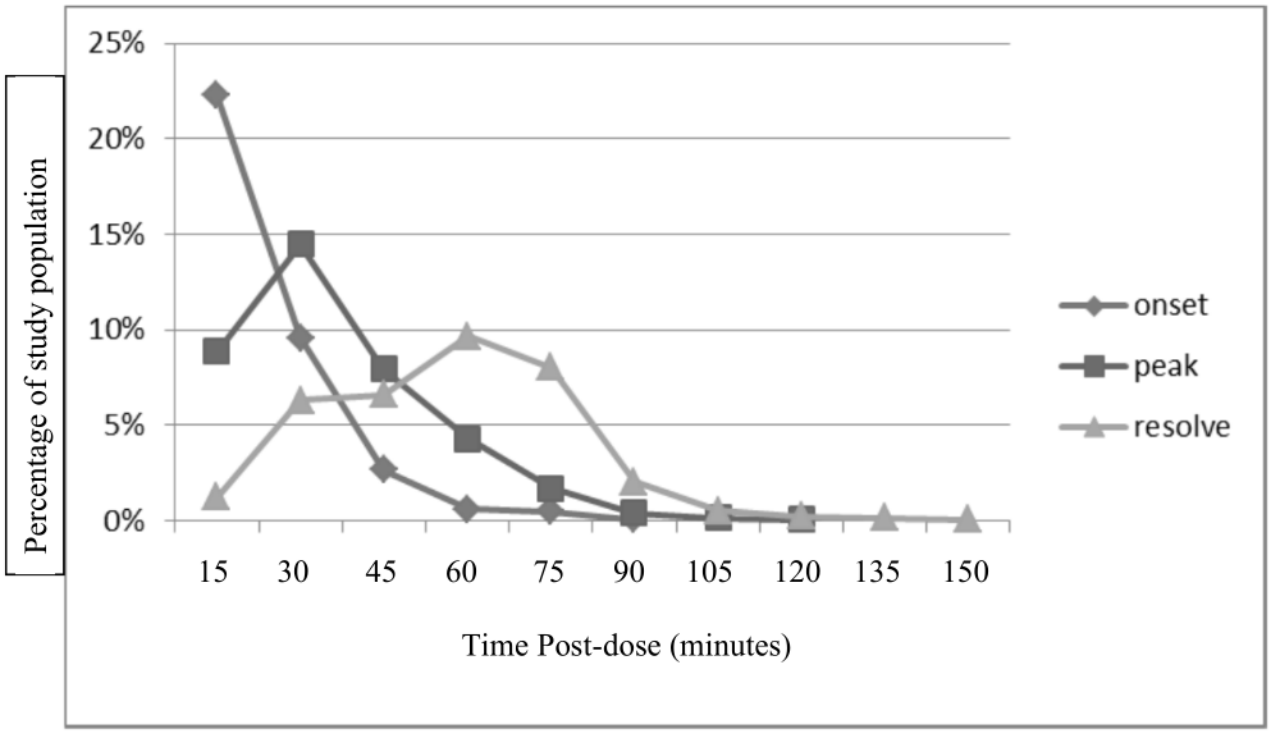

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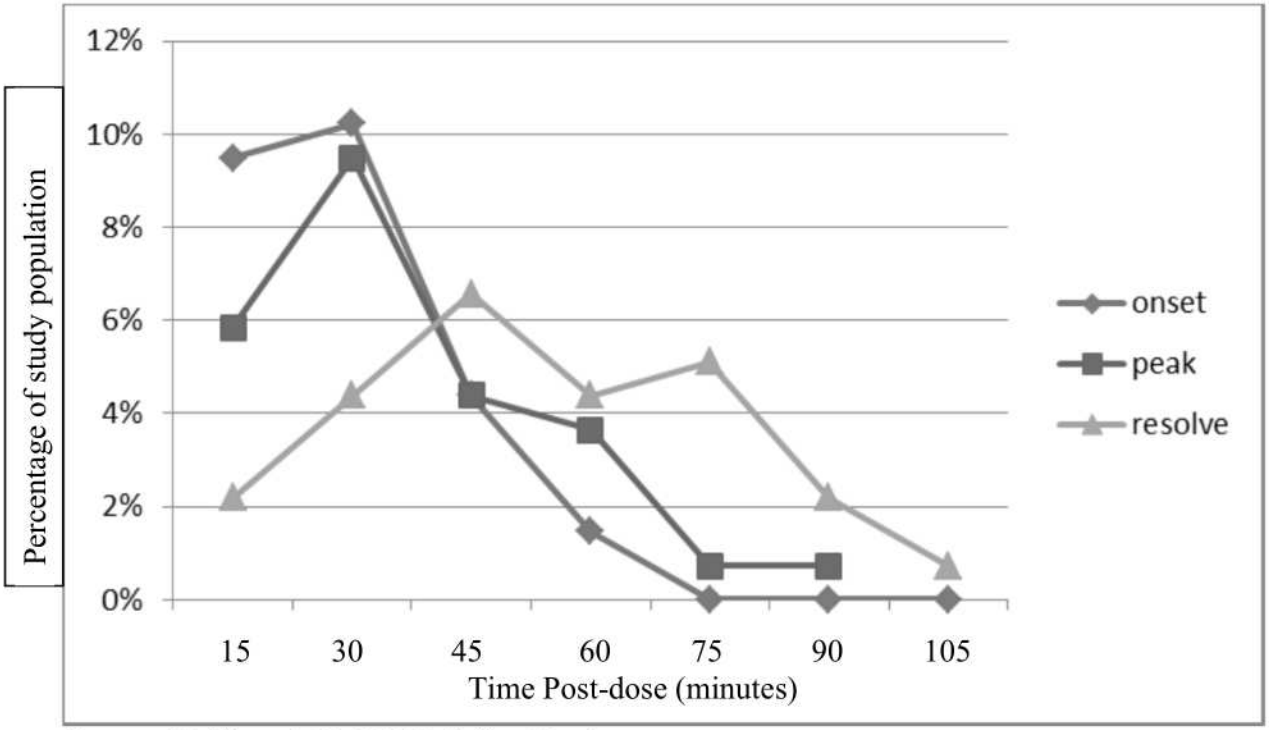
Figure 16: Sedation – Onset, Peak and Resolution Time by Percentage of Study Population in Esketamine-treated Subjects ≥ 65 years old in Study 3005



Source: Qi Chen, MD, MPH, Safety Reviewer

In subjects < 65 years old who developed sedation after esketamine use, the majority experienced sedation onset at 15 minutes, peak at 30 minutes, and resolution at 60 minutes. The latest onset, peak and resolution times were 90, 120, and 210 minutes, respectively. In subjects ≥ 65 years old who developed sedation after esketamine use, the majority experienced sedation onset and peak at 30 minutes, and resolution at 45 minutes. The latest onset, peak, and resolution times were 75, 90, and 105 minutes, respectively.

The latest onset time of any sedation among all subjects in Studies 3001, 3002, 3003, and 3005 was 90 minutes post-dose. Compared to subjects < 65 years old, sedation was not as severe in subjects ≥65 years old (minimum score=3) and was shorter in duration.

There were 24 subjects in whom severe sedation (MOAA/S score 0 to 2) occurred, with some subjects experiencing severe sedation on more than one visit (reports spanned 37 visits). All of the visits with severe sedation were after esketamine use and in subjects <65 years old.

In Studies 3001, 3002, 3003, and 3005, there were two subjects who experienced loss of consciousness (LOC) with MOAA/s score 0. One subject was transferred to the emergency room. The other subject had LOC at five different visits with onset 15 to 30 minutes after receiving esketamine; these episodes lasted between 15 and 35 minutes.

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Severe sedation showed markedly fluctuating patterns in several subjects. Most notably, one subject experienced minimal sedation at 45 minutes, was alert at 1 hour, then became severely sedated at 2 hours.

Time of onset, peak, resolution, and severity varied among visits in some subjects. For example, the event just described was the first time the subject experienced sedation with severity score 1, and it occurred on study day 277. Thus, it appears that the experience of previous visits cannot accurately predict future onset, peak, resolution time, or severity, and this has with implications for monitoring and labeling.

Little data on sedation were collected after 1.5 hours in phase 3 studies; however, sedation was monitored for an extended period in the phase 1 Study 1005. In this study, sedation was assessed using the Karolinska sleepiness scale at regular intervals through 6 hours post-dose. Although most subjects reported that they were "alert" by 6 hours, there were subjects who felt "sleepy" around 4 to 6 hours post-dose in both placebo and esketamine groups.

Because of the fluctuating pattern of sedation and the potential severity of sedation events, patients will need to be monitored following administration of esketamine until sedation resolves or until they have passed the period of greatest risk for sedation. In the clinical development program, sedation resolved within 2 hours of dosing (with rare exceptions). Thus, it seems reasonable to monitor patients for 2 hours following administration of esketamine to mitigate the risk of adverse events associated with excessive sedation (e.g., falls, motor vehicle accidents).

7.5.2. Dissociation

Dissociation was evaluated by Clinician-Administered Dissociative States Scale (CADSS) questionnaire pre-dose, and 40 and 90 minutes post-dose. The total CADSS score ranges from 0 to 92, with a higher score representing more severe dissociation. Scores between 0 and 4 are considered to be in the normal range.

Table 19: CADSS Median Score and Incidence of Increases in Score >4 at Any Time Post-dose in Studies 3001, 3002 and 3005

Study	3001			3002		3005	
Treatment	Placebo	ESK 56 mg	ESK 84 mg	Placebo	ESK 56 to 84 mg	Placebo	ESK 28 to 84 mg
N	113	113	116	109	114	65	72
Median (25%, 75%)	0 (0, 1)	6 (2, 14)	8 (3, 16)	0 (0, 1)	9.5 (3, 17)	0 (0, 2)	8.5 (4.5, 15)
Dissociation change >4 n (%)	10 (9%)	68 (60%)	83 (72%)	16 (15%)	80 (70%)	15 (23%)	57 (79%)

Source: Qi Chen, MD, MPH, Safety Reviewer

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Based on analyses of CADSS data from both the short-term and long-term studies, it appears that treatment with esketamine leads to dissociation. Although the highest dissociation scores were observed, on average, following initial treatment, the dissociative effects were only partially attenuated with repeat administration. For example, across trials, the mean increase in CADSS score at 40 minutes after first-time esketamine administration was approximately 6 points. In contrast, the mean increase in CADSS at 40 minutes after placebo administration was about 1 point. After 4 weeks of treatment, the mean increase in CADSS after esketamine administration was still approximately 2.4 points; no further decrease was observed with continued treatment in patients who continued esketamine treatment in longer-term trials.

There was also evidence of dose effect: In Study 3001, the average increase in CADSS at 40 minutes relative to baseline was 1.3 points greater with 84 mg than with 56 mg. No difference between dosages on dissociation was observed at 1.5 hours.

7.5.3. Impaired Cognition

In the phase 3 studies, cognition was evaluated by the CogState computerized test battery, which includes assessments of multiple cognitive domains, and Hopkins Verbal Learning Test-Revised (HVLT-R), which is a measure of verbal learning and memory. There were no significant differences between esketamine groups and placebo groups in Studies 3001, 3002, 3003, and 3005. In the long-term open-label Study 3004, there was some evidence of slowing reaction time (RT) in elderly subjects; however, there was high intra-individual variability, making it difficult to distinguish drug effects from other factors. No AEs related to cognitive impairment were reported in the phase 3 trials.

7.5.4. Suicidal Ideation and Behavior

Treatment-emergent suicidal ideation was assessed using both adverse event reports and the Columbia-Suicide Severity Rating Scale (C-SSRS). For adverse events, AEs coded with preferred terms “Suicide attempt," "Intentional self-injury," "Suicidal ideation," and "Suicidal behavior" were included in our analyses of suicidal ideation and behavior events; the results are summarized in Table 20.

Table 20: Subjects with AEs Related to Suicidal Ideation or Behavior (SI/B) During Double-Blind Phase

Study	3001			3002		3005	
Treatment	Placebo	ESK 56 mg	ESK 84 mg	Placebo	ESK 56 to 84 mg	Placebo	ESK 28 to 84 mg
n	113	115	113	109	112	65	71
Subjects with SI/B (%)	1 (1%)	2 (2%)	2 (2%)	1 (1%)	0 (0%)	0 (0%)	1 (1%)

Source: Qi Chen, MD, MPH, Safety Reviewer

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The odds ratio for suicide-related AEs was calculated using exact logistic regression stratified by study. Although the odds ratio (1.52) was suggestive of a higher risk with esketamine treatment, this was not statistically significant (p=0.71, 95% confidence interval 0.24 to 16.3).

Results for the C-SSRS are summarized in Table 21.

Table 21: Subjects with Suicidal Ideation or Behavior as Measured by C-SSRS

Study	3001			3002		3005	
Treatment	ESK 56 mg	ESK 84 mg	Placebo	ESK 56 to 84 mg	Placebo	ESK 28 to 84 mg	Placebo
N	115	113	113	112	109	71	65
Suicidal Ideation (Score >0)							
N (%)	29 (25%)	37 (33%)	40 (35%)	23 (21%)	24 (22%)	20 (28%)	20 (31%)
Clinical significant suicidal ideation or Suicidal Behavior (Score≥4)							
N (%)	2 (2%)	1 (1%)	0 (0%)	0 (0%)	0 (0%)	1 (1%)	0 (0%)

Source: Qi Chen, MD, MPH, Safety Reviewer

The odds ratio for suicidal ideation (0.82) was suggestive of a lower risk with esketamine treatment but not statistically significant (p=0.26, 95% confidence interval 0.57 to 1.16). Suicidal behavior was reported in four esketamine-treated subjects and no placebo subjects (median unbiased estimate odds ratio 3.17) but, again, was not statistically significant (p=0.30, 95% confidence interval 0.39 to infinity).

7.6. Other Pertinent Safety Studies

7.6.1. Human Factors Validation Study

The results of the Human Factors (HF) validation study did not demonstrate that the user interface supports the safe and effective use of this product. Of particular concern were errors and confusion observed regarding strength and dosing for this product. The Applicant proposes the product be supplied in a carton containing one 28-mg nasal spray device (28-mg total dose), a carton containing two 28-mg nasal spray devices (56-mg total dose), and a carton containing three 28-mg nasal spray devices (84-mg total dose). Based on the HF data submitted, confusion occurred between the proposed packages regarding strength and dosing, and the proposed packaging may contribute to product selection medication errors and wrong dose errors. In the HF validation study, healthcare providers cited confusion regarding how much drug is available per spray, how much drug is available per device, and how many devices should be administered to achieve the correct dose. It was not clear to all study participants that the number of devices per carton is dose-specific. Thus, it may be appropriate, in light of the findings from the HF validation study, that Janssen consider marketing a single packaging configuration of one device in one carton with labeling improvements to increase clarity and decrease the risk for medication errors.

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7.6.2. Driving Studies

The effect of intranasal esketamine on driving performance was assessed by an on-road driving test using the standard deviation of lateral position as the primary end point. The results from two individual studies (i.e., Studies 1006 and 1019) demonstrated that the driving performance after 84 mg intranasal esketamine was not different from placebo 6 hours post-dose or later (i.e., 8 and 18 hours) if they met other requirements for discharge. Two subjects from Study 1006 discontinued the driving test due to persistent and worsening of treatment-emergent adverse events. No information on the driving performance between 0 to 6 hours post-dose is available.

Neither driving study included elderly subjects (≥ 60 years); the median age was approximately 25 to 35 years. Elderly subjects have a relatively higher exposure of esketamine as compared to younger adults administered the same dose, and there may be altered ability in operating a motor vehicle with aging; therefore, it is unclear whether the same results can be applied to elderly subjects.

Patients with moderate hepatic impairment have a longer elimination half-life of esketamine as compared to those with normal hepatic function. Changes in cognitive function, upon esketamine treatment, would need to be monitored for a longer period of time in such patients.

Overall, we recommend that the patients should not drive on the day of intranasal esketamine dosing, but may drive the next day following a restful sleep.

7.7. Ketamine Postmarketing Safety Concerns and Potential Relevance to Esketamine

7.7.1. Adverse Events Related to Repeated Off-label Use of Ketamine

In recent post-market safety assessments relating to ketamine, the Division of Pharmacovigilance (DPV) has identified concerns relating to the potential risk of genitourinary, hepatobiliary and cognitive effects associated with repeated exposure to ketamine for the treatment of depression or pain. DPV prioritized these signals based upon routine surveillance of the literature; however, DPV's review of these potential risks does not address all potential safety concerns regarding ketamine. The post-market safety data do not provide a sufficient basis to conclude whether such risks are specific to particular routes of administration or doses (examined routes of administration in off-label use were oral or parenteral). Nevertheless, findings from our review of ketamine may be considered relevant to discussions regarding the safety of esketamine.

Our assessment of data within the FDA Adverse Event Reporting System (FAERS) and the published literature suggests a likely causal relationship between repeated ketamine exposure and the onset of genitourinary (e.g., cystitis) and hepatobiliary events (e.g., cholestasis, periductal fibrosis, elevated transaminases). We also reviewed a number of small studies (i.e., randomized controlled trials and observational studies), which suggested that sub-anesthetic doses of ketamine may have negative short-term effects on memory and cognitive function, though it remains unclear whether or under what circumstances such effects persist over the long-term. Although we did not assess patients noted to be abusing ketamine in this review,

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similar pathologies have been reported among patients abusing ketamine. The full DPV review is provided for reference in section 13.1 of Attachment 1.

7.7.2. Ketamine Abuse and Associated Harms

Attachment 2 contains a review of postmarketing data on ketamine abuse and associated harms, including a review of recently published literature as well as information from two national surveys (National Survey on Drug Use and Health and Monitoring the Future), U.S. poison center calls (National Poison Data System), a representative sample of emergency department visits (National Electronic Injury Surveillance System-Cooperative Adverse Drug Event Surveillance), and spontaneous adverse event reports (FAERS). A summary of the recent ketamine drug utilization analysis (conducted as part of the integrated safety review included as Attachment 1) is included to provide context for the abuse-related data. The review findings are summarized briefly here.

Based on national sales distribution patterns of ketamine vials (excluding veterinary sales), ketamine utilization appears to be largely in the hospital setting. Ketamine sales increased approximately 72% from 2013 to 2017 overall and sales to clinic settings, specifically, more than doubled during this five-year period. Numerous off-label uses of ketamine have been proposed and implemented, including treatment-resistant depression, and recent literature suggests growth in some of these off-label uses of ketamine.

National survey data and the published literature indicate that ketamine abuse is relatively uncommon in the general population, with a reported lifetime prevalence of 1.3% among persons age 12 years and older, which is lower than that for other hallucinogens such as ecstasy and LSD (Acid). Among 12th graders, the annual prevalence of ketamine use has declined from 2.5% in 2000 to 1.2% in 2017. Exposure calls to U.S. poison centers involving ketamine abuse or misuse also declined slightly from 2013 to 2017 (176 calls in 2013 to 116 calls in 2017), despite the growth in non-veterinary ketamine sales. Single-substance exposure calls involving ketamine abuse or misuse were most commonly associated with minor or moderate health effects, and there were no deaths identified among these calls. In a representative sample of approximately 60 U.S. emergency departments, there were 44 ketamine-related ED cases in 2016-2017, corresponding to an estimated 669 visits nationally. Of the 44 ketamine-related ED cases, 35 (81.5%) were classified as abuse. Only six (17.1%) of these cases resulted in hospitalization. From 2015 to 2017, FAERS received 17 reports of death involving ketamine abuse. Of note, only one of these reports listed ketamine as the only suspected drug, and the drug-event causal association has not been assessed for any of these FAERS cases.

Overall, this analysis suggests that ketamine abuse continues to occur but has remained relatively limited with modest associated harms. The available data are insufficient to determine the extent to which U.S. pharmaceutical ketamine for humans contributes to abuse, relative to ketamine that is smuggled into the country or diverted from veterinary settings. Nonetheless, the risks of abuse and associated harms are important considerations in determining appropriate risk mitigation strategies and post marketing surveillance for esketamine, if approved.

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8. Risk Mitigation

The FDA has used a variety of strategies to minimize risks associated with drugs and therapeutic biologics. The primary risk management tool is communicating through FDA-approved product labeling, which includes a summary of the essential information needed by health care providers for the safe and effective use of the drug. Labeling is sufficient for most drugs to ensure that the benefits outweigh the risks. But in some cases, FDA may determine that a Risk Evaluation and Mitigation Strategy (REMS) will also be needed to help ensure that the benefits of the drug outweigh its risks. A REMS is a drug safety program that the FDA can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks. REMS are designed to reinforce medication use behaviors and actions that support the safe use of that medication.

REMS can communicate specific risk information, as well as information regarding safe use of the product. In addition, a REMS program can provide guidance and encourage, remind, or support adherence to certain prescribing, dispensing, or monitoring requirements, and/or limit use of a product to only the most appropriate patients or healthcare setting where the benefits outweigh the risks. The safety concerns for esketamine for which a REMS is being considered are misuse, abuse, dissociation, and sedation.

8.1. Safety Concerns Associated with Esketamine

Sedation and dissociation are adverse events that were observed in the clinical program. We are particularly concerned that patient harm could result if patients leave the healthcare setting before these symptoms have resolved. Concerns also include the potential for misuse and abuse, known effects associated with the currently approved related product, ketamine.

If approved for TRD, patients who take esketamine are at risk for sedation and could be impaired and unable to perform certain tasks. In the clinical development program, sedation was observed at high rates in the treatment population with about 50% esketamine-treated patients experiencing sedation versus 15% in placebo-treated patients. Of the patients treated with esketamine in the phase 3 studies (n=1051), 24 participants experienced severe sedation after esketamine use. Severe sedation was defined by scores of 0-2 out of 5 total on the Modified Observer's Alertness/Sedation scale (MOAA/S) scale. On this scale, 0 is a patient response only to painful stimulus, 1 is patient response only after painful stimulus, and 2 is a patient response only after mild prodding or shaking. The majority of patients had onset of sedation within 15-30 minutes after esketamine administration; this peaked around 30-45 minutes and in most cases resolved (MOAA/S score of 5 corresponding to fully awake) by 75 minutes after administration.

Esketamine administration was associated with dissociation. This was described in the clinical program with various terms including feeling "spacey" or a sensation of "floating." As part of the dissociation, patients experienced visual disturbances, had trouble speaking, and experienced confusion, numbness, and feelings of dizziness/faintness. The sponsor has also stated that dissociation/perceptual changes include distortion of time and space, illusions, derealization, and depersonalization. Resolution of these symptoms generally occurred about 90 minutes after

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administration. Similar to the risks with sedation discussed above, patients would be at risk for potential accidents if they experienced these dissociative effects and were allowed to leave the health care setting prior to resolution of these symptoms. In the clinical trials, patients were observed by a healthcare professional after esketamine dosing and did not leave the clinical site until they were clinically stable and symptoms had resolved.

The dissociative sensations experienced in the esketamine program are known effects of ketamine. Ketamine is classified as a Schedule III substance under the Controlled Substances Act. Ketamine is misused and abused for its dissociative and hallucinogenic effects. In the clinical program, esketamine was self-administered under medical supervision in healthcare settings; misuse and abuse were, therefore, not observed. However, the potential for misuse and abuse remains a concern, especially if the distribution of esketamine was not restricted and esketamine was available in retail pharmacies for use outside of a healthcare setting.

Therefore, because of the adverse reactions of sedation and dissociation during the immediate two hours after administration, patients should be monitored to ensure that sedation and dissociation have resolved and should be instructed not to drive or engage in other activities for the remainder of the day.

The Agency is concerned about the increased rate of excessive blood pressure increases (systolic BP≥180 and increase ≥20; diastolic BP≥105 and increase ≥15) observed in the clinical program (see Table 17). The peak in BP occurred approximately 40 minutes post-dose.

8.2. Risk Evaluation and Mitigation Strategy (REMS) Background

Section 505-1 of the Food, Drug, and Cosmetic Act (FDCA), added to the law by the Food Drug Administration Amendments Act of 2007 (FDAAA) authorizes the FDA to require pharmaceutical manufacturers to develop and comply with a REMS for a drug if FDA determines that a REMS is necessary to ensure that the benefits of the drug outweigh the risks. A REMS is a required risk management plan that uses risk minimization strategies beyond the professional labeling. The elements of a REMS can include: a Medication Guide or patient package insert (PPI), a communication plan to healthcare providers, elements to assure safe use, and an implementation system. FDAAA also requires that all REMS approved for drugs or biologics under New Drug Applications (NDA) and Biologics License Applications (BLA) have a timetable for submission of assessments of the REMS. These assessments are prepared by the sponsor and reviewed by FDA.

A communication plan consists of FDA approved materials used to aid a sponsor's implementation of the REMS and/or inform healthcare providers about serious risk(s) of an approved product. This can include, for example, "Dear Healthcare Professional" letters, collaboration with professional societies, and education pieces (such as letters, drug fact sheets) to inform prescribers of the risks and the safe use practices for the drug.

Elements to assure safe use (ETASU) can include one or more of the following requirements:

- Healthcare providers who prescribe the drug have training or experience or special certifications

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- Pharmacies, practitioners, or healthcare settings that dispense the drug are specially certified
- The drug may be dispensed only in certain healthcare settings
- The drug may be dispensed to patients with evidence of safe-use conditions
- Each patient must be subject to monitoring
- Patients must be enrolled in a registry

Because ETASU can impose significant burdens on the healthcare system and reduce patient access to treatment, ETASU are required only if FDA determines that the product could be approved only if, or would be withdrawn unless, ETASU are required to mitigate a specific serious risk listed in the labeling. Accordingly, the statute [FDCA 505-1(f)(2)] specifies that ETASU:

- Must be commensurate with specific serious risk(s) listed in the labeling.
- Cannot be unduly burdensome on patient access to the drug.
- To minimize the burden on the healthcare delivery system, must, to the extent practicable, conform with REMS elements for other drugs with similar serious risks and be designed for compatibility with established distribution, procurement, and dispensing systems for drugs.

8.3. Applicant's REMS Proposal

The Applicant has proposed a REMS with the following goal:

To mitigate the risk of misuse and abuse of esketamine while ensuring patient access for the approved indication, as well as to mitigate the risk of administration without appropriate monitoring as per the product label by:

- Ensuring esketamine is distributed/dispensed only to hospitals, certified outpatient pharmacies, and certified outpatient sites of care,

- Ensuring esketamine is not dispensed to a patient to take home for self-administration,

- Ensuring healthcare facilities are educated about the requirement for patient monitoring for transient dissociation and blood pressure changes after esketamine administration.

To support their proposed REMS, the Applicant plans to certify healthcare settings and outpatient pharmacies that dispense esketamine. They propose to require that the healthcare settings would have procedures in place for a healthcare professional to monitor patients when they self-administer esketamine and that patients would be monitored for transient dissociative and blood pressure changes until the patient is stable and ready to leave the healthcare setting, based on clinical judgment.

The Applicant is also proposing to identify suspicious orders and a timetable for submission of assessments of the REMS.

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8.4. Agency Proposed REMS

Should esketamine be approved, the REMS will be necessary to mitigate the risk of misuse and abuse and to prevent harm that could result from the adverse events of dissociation and sedation. At this time, labeling is being developed to address the concerns with elevated blood pressure.

Consistent with study protocols in the clinical program, the current Agency thinking is that to prevent harm such as falls or other accidents resulting from sedation and dissociation, the REMS would require that esketamine be self-administered under direct medical supervision and that patients then be monitored for a minimum of 2 hours post-dose. We are also recommending that after receiving esketamine, patients should not drive or operate heavy machinery for the rest of the day.

FDA is proposing the following REMS components to mitigate the risk of misuse, abuse and serious adverse outcomes from dissociation and sedation as a result of esketamine administration:

1. Elements to assure safe use including:

    - Prescriber training on the risks of esketamine and importance of monitoring patients after their dose is administered and the need to register patients

    - Administration of esketamine only in certain health care settings that ensure patient monitoring by a healthcare provider for two hours after administration

    - Pharmacies, practitioners, or healthcare settings that dispense the drug are specially certified to ensure that esketamine is not dispensed directly to patients and that patients are monitored

    - Enrollment of patients who are treated with esketamine in a registry to better characterize the risks associated with esketamine administration and inform risk mitigation strategies

2. An implementation system

3. A timetable for submission of assessments

Administration only in certain healthcare settings
Restricting the distribution of esketamine to certain healthcare settings would ensure that the patient is monitored by a healthcare provider until the sedation and dissociation subside. In the clinical development program, sedation resolved within 2 hours of dosing (with rare exceptions). Thus, it seems reasonable to monitor patients for 2 hours following administration of esketamine (see Section 7.5.1). This would prevent patients from engaging in activities that may be dangerous given these effects. Healthcare settings would also be required to counsel patients to

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refrain from driving for the remainder of the day of esketamine administration. To become certified, the healthcare setting must attest that HCPs are available to monitor patients.

Prescriber Training
Prescribers would be educated about the risks of esketamine and the importance of monitoring patients after the dose is self-administered. In addition, prescribers would register their patients in the REMS program (see below) and monitor their patients for adverse events.

Enrollment of Patients in a Registry
Enrollment of esketamine-treated patients in a registry would allow for the collection of additional data to characterize further the risks of esketamine post-administration. For example, the registry could collect adverse events that occur immediately after administration or between patient visits and provide insight into serious adverse outcomes associated with treatment. This would allow us to capture systematically information on events and potentially provide data that further characterizes adverse outcomes. Information collected from the registry may also be used to evaluate the risk mitigation strategies and determine the need for modification to the REMS or approved labeling.

As part of the enrollment process, patients would be informed of the risks and the need for patients to report adverse events to their provider between patient visits.

In conclusion, the FDA has the authority to require a REMS if additional measures beyond the labeling are necessary to ensure the benefits of a drug outweigh the risks. The committee will be asked if the FDA's proposed REMS will help ensure the safe use of esketamine and what components of this REMS are necessary to ensure that the benefits outweigh the risks.

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9. Attachments

9.1. Attachment 1

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Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology
Office of Pharmacovigilance and Epidemiology

Pharmacovigilance and Drug Utilization Review

Date:	December 21, 2018
Primary Reviewers:	Mallika Mundkur, MD, MPH, Medical Officer *Division of Pharmacovigilance II (DPV II)* Samantha Cotter, PharmD, BCPS, FISMP, Safety Evaluator *DPV II* LCDR Jennie Wong, PharmD, Drug Utilization Analyst, *Division of Epidemiology II (DEPI II)*
Secondary Reviewers:	Rajdeep Gill, PharmD, Drug Utilization Analyst Team Lead *DEPI II* Neha Gada, PharmD, BCPS, Team Lead *DPV II*
Tertiary Reviewers:	LCDR Grace Chai, PharmD, Deputy Director for Drug Utilization *DEPI II* S. Christopher Jones, PharmD, MPH, MS, Director of DPV DPV II
Product Name:	Ketalar (ketamine hydrochloride)
Subject:	Adverse Events with Repeated Off-Label Use of Ketamine
Application Type/Number:	NDA 016812, ANDA 074524, ANDA 074549, ANDA 076092, NDA 211243
Applicants/Sponsors:	Par Sterile, West-Ward Pharmaceuticals, Hospira, Mylan
OSE RCM #:	2018-302
TSI #:	1940 (cognitive impairment) and 1941 (hepatobiliary adverse events)

****This document contains proprietary drug use data obtained by FDA under contract. The drug use data/information cannot be released to the public/non-FDA personnel without contractor approval obtained through the FDA/CDER Office of Surveillance and Epidemiology.****

We acknowledge Mark Avigan, MD, Associate Director for Critical Path Initiatives, for his invaluable clinical expertise on the hepatobiliary adverse events.

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EXECUTIVE SUMMARY

Through routine surveillance of the medical literature, the Division of Pharmacovigilance identified concerns regarding genitourinary, hepatobiliary and cognitive effects associated with off-label, repeated use of ketamine. In this review, we describe our assessment of the FDA Adverse Event Reporting System (FAERS) and the published literature for evidence of such risks. To place these potential risks into context, the Division of Epidemiology evaluated drug utilization data for trends in use of ketamine. This review presents methods and results pertaining to hepatobiliary and cognitive effects and new data on drug utilization. A previously completed memorandum regarding genitourinary effects is referenced within. Key findings from the hepatobiliary and cognitive effects review are summarized below:

- We identified several cases in FAERS and the published literature to support a probable/likely causal relationship between repeated ketamine exposure and the development of a range of hepatobiliary effects in the context of medically-supervised, off-label, repeated use (e.g., cholestasis, periductal fibrosis, elevated transaminases).
- We only identified two cases in FAERS that suggested a possible causal relationship between ketamine exposure and persistent cognitive impairment, although interpretation of these cases is complicated by the presence of confounders.
- We also identified a number of small studies (randomized controlled trials and observational studies) which evaluated short-term effects of ketamine upon memory and other cognitive function, although in these studies, ketamine was not always administered in a repeated fashion, and long-term persistence of these effects was not evaluated in the majority of studies.
- Data from proprietary drug sales distribution and utilization databases suggest increasing administration of ketamine in outpatient clinic settings. The total number of ketamine vials sold from manufacturers to all channels of distribution increased in the 5 years examined to approximately 2.1 million vials in 2017 from 1.2 million in 2013. The increase was most notable in the clinic setting, where the number of vials sold more than doubled in the past 5 years from an estimated 332,000 vials sold in 2013 to 765,500 vials sold in 2017. These findings suggest increased use of ketamine in recent years although the reasons and potential factors that may have contributed to increased use were not formally studied in this review.

Given these findings, we recommend updating ketamine product labels (Warnings) to include the potential for hepatobiliary adverse effects. In addition, we recommend consideration for updating ketamine product labels (Adverse Reactions) to include that ketamine may be associated with short-term cognitive impairment at subanesthetic doses, although the long-term cognitive effects of repeated exposure to ketamine are not well understood.

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1 INTRODUCTION

The purpose of this review was to evaluate risks associated with the off-label, repeated use of ketamine. Ketamine is a schedule III agent, originally approved by the Food and Drug Administration (FDA) in 1970 for use as a dissociative anesthetic.[1] Since the time of its approval, numerous off-label uses of ketamine have been proposed and implemented, including, but not limited to, treatment of complex-regional pain syndrome (CRPS), chronic pain, and treatment resistant depression.[2-6] Emerging guidelines describing protocols for off-label use of ketamine provide some standardization,[3,7] though such guidelines are neither based upon strong evidence nor strictly implemented.

Although few data are available regarding trends or patterns in off-label use of ketamine, one recently published survey of physicians advertising ketamine therapy for treatment of psychiatric disorders provides some insight, albeit with limited generalizability given the small size and sampling strategy.[8] In this study, 85 clinicians were identified through the internet or by prior relationships with the author team, 76 were emailed a survey, and 57 clinicians responded (75% response rate). Among respondents, the number of clinicians offering such therapy increased over time, with the greatest change apparently occuring during the years 2015-2016 (Figure 1). Of the clinicians surveyed, the majority of clinicians worked in a private practice setting (73%), with a smaller proportion working in academia (14%) or a health maintenance organization (9%). Clinician specialties included Psychiatry (67%) Anesthesiology (23%), Emergency Medicine (4%) and Familiy Medicine (4%). The majority of clinicians surveyed administered ketamine in an office-based setting (72%) with the remainder offering treatment in a hospital-based setting or surgical/procedural suite. Clinicians reported administering ketamine primarily via the intravenous route (88%), followed by oral (23%) and intranasal routes (19%). Commonly treated psychiatric conditions included major depressive disorder (72%), bipolar disorder (15%) and post-traumatic stress disorder (6%). Respondents reported repeated administration of ketamine, ranging from every 2 weeks (12%) to monthly (30%), and over two-thirds (64%) reported receiving out-of-pocket reimbursement for treatment sessions.

Figure 1. Number of providers offering ketamine treatment for psychiatric disorders (2005-2016)

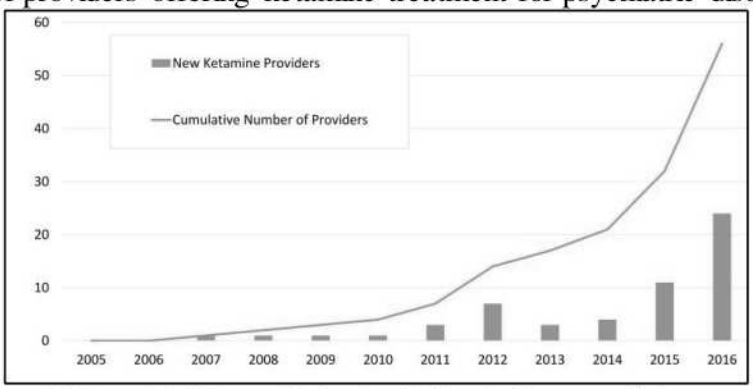

Figure Source: Wilkinson ST, Toprak M, Turner M, Levine S, Katz R, Sanacora G. A survey of the clinical, off-label use of ketamine as a treatment for psychiatric disorders. Am J Psychiatry. 2017 Jul 1; 174(7): 695–696. doi: [10.1176/appi.ajp.2017.17020239]

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Seminal studies have suggested that for carefully selected patients, ketamine use may offer some benefits with repeated use, though such benefits are short-term. For instance, in one small (n=18) randomized, placebo-controlled clinical trial led by Zarate et al., the majority of patients with treatment resistant major depression who received intravenous ketamine demonstrated significant improvement in depression scores one day after treatment.[4] However, only 6 out of 17 patients who received ketamine maintained a response at 1 week, and only 2 patients maintained a response at 2 weeks. In another blinded study led by Sigtermans et al., 60 patients with CRPS type I were randomized to receipt of ketamine or placebo, study findings demonstrated pain scores were significantly lower in the treatment group than in the placebo group, though this difference was no longer significant at 12 weeks.[6] Findings from such studies as well as anecdotes from clinical practice suggest that repeat dosing of ketamine, possibly at increasing doses as drug tolerance develops, may be required to sustain a treatment response for chronic comborbidities such as pain or depression.

Recently, experts in clinical practice have voiced concern that unapproved uses of ketamine pose under-recognized risks to patients, particularly those receiving repeated exposure, with proposed risks including genitourinary, hepatobiliary and cognitive adverse effects.[7-10] Analagous effects have been observed among patients abusing ketamine[11], with several case reports or case series describing a range of genitourinary[12-14] and hepatobiliary effects[15-18] associated with ketamine exposure in ketamine abusers, and some data suggesting cognitive impairment, [19] though with fewer data on chronic than acute cognitive impairment. Risks to patients receiving ketamine repeatedly, or over prolonged periods, in the context of medical supervision at doses less than those presumably used by abuse populations, have not been as well characterized.

The Division of Pharmacovigilance (DPV), the Division of Anesthesia, Analgesia, and Addiction Products (DAAAP), and the Division of Psychiatric Products (DPP) met on December 19, 2017 and May 16, 2018 to discuss potential safety signals identified by DPV through routine surveillance of the literature. Based upon preliminary data presented by DPV, including discussion of select FAERS cases and literature reports, DPV, DAAAP and DPP made a joint decision to assess the risk of genitourinary (GU), hepatobiliary and cognitive adverse events with repeated exposure to ketamine in medically supervised settings (i.e., non-abuse). In addition, DPV consulted the Division of Epidemiology II (DEPI II, Drug Utilization) to assess recent patterns in use of ketamine, with an emphasis on use in outpatient settings where much of the off-label ketamine administration is presumed to occur.

As requested by DAAAP, DPV prioritized the review of GU adverse effects and completed the review in an expedited memorandum[20]; our recommendation to incorporate GU adverse effects into the ketamine labeling has been endorsed by DAAAP. We also note that DPV previously completed a review relating to delayed onset/prolonged duration neuropsychiatric events occurring in the context of both on and off-label medically supervised ketamine administration and recommended labeling changes.[21] However, for the purpose of this review, we focus on presentation of methods and results relating to potential hepatobiliary or cognitive adverse events and data relating to ketamine drug utilizaton.

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1.1 REGULATORY HISTORY

Ketamine was approved for use in the United States in 1970 and is currently indicated for use as 1) the sole anesthetic agent for diagnostic and surgical procedures that do not require skeletal muscle relaxation, 2) the induction of anesthesia prior to the administration of other general anesthetic agents, and 3) as a supplement to low-potency anesthetic agents, such as nitrous oxide.[22]

As noted above, DPV has previously completed two safety assessments relating to ketamine which are briefly summarized below:

- September 2014: Ketamine and Delayed or Prolonged Psychiatric Reactions[20]
    - DAAAP consulted DPV to assess prolonged duration or delayed-onset psychiatric adverse events occurring with ketamine, after two published case reports described delayed onset suicidal ideation with ketamine administration for treatment of obsessive-compulsive disorder.
    - DPV's safety review focused on all medically-supervised administration of ketamine, with specific examination of events occurring within 3 hours of ketamine administration, lasting for at least 3 hours OR events developing at least 3 hours after completion of ketamine administration.
    - DPV identified cases for which the duration of psychiatric reactions following ketamine exposure ranged from 3 hours to several weeks, and time to onset ranging from immediate to several weeks.
    - DPV recommended revision of labeling language in existing "Special Note" (though ideally in Warnings/Precautions of PLR format) to state that adverse psychiatric events have emerged or persisted days to weeks following ketamine exposure (including beyond the 24 hours that is currently described in product labeling).
- July, 2018: Repeated/Prolonged Use of Ketamine and Risk of GU Events[21]
    - DPV conducted a self-generated safety assessment based upon routine surveillance of the literature.
    - DPV's memorandum focused on patients receiving medically supervised, off-label use of ketamine, repeatedly, for the treatment of such conditions as chronic pain.
    - DPV recommended inclusion of risk for genitourinary events (e.g., cystitis) (ideally in Warnings/Precautions of PLR format)
    - The most recent label (8/7/2018) now includes the following language in "Adverse Reactions" though labeling remains in non-Physician Labeling Rule (PLR) format.[1]

      Genitourinary: In individuals with history of chronic ketamine use or abuse, lower urinary tract and bladder symptoms including dysuria, increased urinary frequency, urgency, urge incontinence, and hematuria have been reported (see DOSAGE AND ADMINISTRATION Section). In addition, diagnostic studies performed to assess the cause of these symptoms have reported cystitis (including

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cystitis noninfective, cystitis interstitial, cystitis ulcerative, cystitis erosive and cystitis hemorrhagic) as well as hydronephrosis and reduced bladder capacity.

1.2 PRODUCT LABELING: AUGUST 7, 2018

The current label[1,22] for KETALAR does not contain language regarding hepatobiliary or cognitive adverse effects. The label for Ketalar is currently under the non-PLR format.

Warnings

Cardiac function should be continually monitored during the procedure in patients found to have hypertension or cardiac decompensation.

Postoperative confusional states may occur during the recovery period.

Respiratory depression may occur with overdosage or too rapid a rate of administration of KETALAR, in which case supportive ventilation should be employed. Mechanical support of respiration is preferred to administration of analeptics

Adverse Reactions

Cardiovascular: Blood pressure and pulse rate are frequently elevated following administration of KETALAR alone. However, hypotension and bradycardia have been observed. Arrhythmia has also occurred.

Respiration: Although respiration is frequently stimulated, severe depression of respiration or apnea may occur following rapid intravenous administration of high doses of KETALAR. Laryngospasms and other forms of airway obstruction have occurred during KETALAR anesthesia.

Eye: Diplopia and nystagmus have been noted following KETALAR administration. It also may cause a slight elevation in intraocular pressure measurement.

Genitourinary: In individuals with history of chronic ketamine use or abuse, lower urinary tract and bladder symptoms including dysuria, increased urinary frequency, urgency, urge incontinence, and hematuria have been reported (see DOSAGE AND ADMINISTRATION Section). In addition, diagnostic studies performed to assess the cause of these symptoms have reported cystitis (including cystitis noninfective, cystitis interstitial, cystitis ulcerative, cystitis erosive and cystitis hemorrhagic) as well as hydronephrosis and reduced bladder capacity.

Psychological: (See Special Note).

Neurological: In some patients, enhanced skeletal muscle tone may be manifested by tonic and clonic movements sometimes resembling seizures (see DOSAGE AND ADMINISTRATION Section).

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Gastrointestinal: Anorexia, nausea and vomiting have been observed; however, this is not usually severe and allows the great majority of patients to take liquids by mouth shortly after regaining consciousness (see DOSAGE AND ADMINISTRATION Section).

General: Anaphylaxis. Local pain and exanthema at the injection site have infrequently been reported. Transient erythema and/or morbilliform rash have also been reported.

Drug abuse and dependence

Ketamine has been reported being used as a drug of abuse.

Reports suggest that ketamine produces a variety of symptoms including, but not limited to anxiety, dysphoria, disorientation, insomnia, flashbacks, hallucinations, and psychotic episodes.

Ketamine dependence and tolerance are possible following prolonged administration. A withdrawal syndrome with psychotic features has been described following discontinuation of long-term ketamine use. Therefore, ketamine should be prescribed and administered with caution.

SPECIAL NOTE

EMERGENCE REACTIONS HAVE OCCURRED IN APPROXIMATELY 12 PERCENT OF PATIENTS.

THE PSYCHOLOGICAL MANIFESTATIONS VARY IN SEVERITY BETWEEN PLEASANT DREAM-LIKE STATES, VIVID IMAGERY, HALLUCINATIONS, AND EMERGENCE DELIRIUM. IN SOME CASES THESE STATES HAVE BEEN ACCOMPANIED BY CONFUSION, EXCITEMENT, AND IRRATIONAL BEHAVIOR WHICH A FEW PATIENTS RECALL AS AN UNPLEASANT EXPERIENCE. THE DURATION ORDINARILY IS NO MORE THAN A FEW HOURS; IN A FEW CASES, HOWEVER, RECURRENCES HAVE TAKEN PLACE UP TO 24 HOURS POSTOPERATIVELY. NO RESIDUAL PSYCHOLOGICAL EFFECTS ARE KNOWN TO HAVE RESULTED FROM USE OF KETALAR.

THE INCIDENCE OF THESE EMERGENCE PHENOMENA IS LEAST IN THE ELDERLY (OVER 65 YEARS OF AGE) PATIENT. ALSO, THEY ARE LESS FREQUENT WHEN THE DRUG IS GIVEN INTRAMUSCULARLY AND THE INCIDENCE IS REDUCED AS EXPERIENCE WITH THE DRUG IS GAINED.

THE INCIDENCE OF PSYCHOLOGICAL MANIFESTATIONS DURING EMERGENCE, PARTICULARLY DREAM-LIKE OBSERVATIONS AND EMERGENCE DELIRIUM, MAY BE REDUCED BY USING LOWER RECOMMENDED DOSAGES OF KETALAR IN CONJUNCTION WITH INTRAVENOUS DIAZEPAM DURING INDUCTION AND MAINTENANCE OF ANESTHESIA. (See **DOSAGE AND ADMINISTRATION** Section). ALSO, THESE REACTIONS MAY BE REDUCED IF VERBAL, TACTILE, AND VISUAL STIMULATION OF THE PATIENT IS MINIMIZED DURING THE RECOVERY PERIOD. THIS DOES NOT PRECLUDE THE MONITORING OF VITAL SIGNS.

IN ORDER TO TERMINATE A SEVERE EMERGENCE REACTION, THE USE OF A SMALL HYPNOTIC DOSE OF A SHORT-ACTING OR ULTRA SHORT-ACTING BARBITURATE MAY BE REQUIRED.

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WHEN KETALAR IS USED ON AN OUTPATIENT BASIS, THE PATIENT SHOULD NOT BE RELEASED UNTIL RECOVERY FROM ANESTHESIA IS COMPLETE AND THEN SHOULD BE ACCOMPANIED BY A RESPONSIBLE ADULT.

2 METHODS AND MATERIALS

For this review, we used a number of data sources: IQVIA, National Sales Perspectives™ (NSP), reports submitted through the FDA Adverse Event Reporting System (FAERS) and published case reports in the literature. The databases used are described briefly below, with more detail included in Appendices A-B.

2.1 DRUG UTILIZATION

IQVIA, National Sales Perspectives™ (NSP)

The NSP database was used to provide the nationally estimated number of vials sold for injectable ketamine from the manufacturer to all U.S. channels of distribution[1] from 2013 through 2017. The sales distribution data represent the amount of product sold from manufacturers to various settings of care and does not reflect what is being sold to or administered to patients directly. The amount of product purchased by various settings of care may be a possible surrogate for use, if we assume the facilities purchase drugs in quantities reflective of actual patient use.

Syneos Health Research & Insights LLC., TreatmentAnswers™ with Pain Panel

This U.S. office-based physician survey database, was used to obtain groups of diagnoses associated with the use of ketamine in 2017 as reported by a sample of approximately 3,200 office-based physicians. Diagnoses data by number of drug use mentions[2] were captured based on International Classification of Diseases (ICD-10-CM) codes and 95% confidence were applied to the estimates. Indications for the use of ketamine in the hospitals, clinics, and other settings were not available for this review.

2.2 FAERS/LITERATURE: CASE DEFINITION AND SIGNAL-SPECIFIC SEARCH STRATEGIES

We selected reports submitted through FAERS or published in the literature for inclusion in the review if they met all elements of the case definition constructed by the review team. The case definition below was applied to resulting reports to select relevant cases.

Case Definition

[1] Various channels of distribution include retail (i.e., independent and chain pharmacies), non-retail (i.e. non-federal hospitals, federal facilities, clinics, long-term care), and mail-order (i.e., standard and specialty mail).

[2] A "drug use mention" refers to mentions of a drug in association with a diagnosis during a patient visit to an office-based physician. This term may be duplicated by the number of diagnoses for which the drug is mentioned. It is important to note that a "drug use" does not necessarily result in a prescription being generated. Rather, the term indicates that a given drug was mentioned during an office visit.

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Inclusion criteria:
Cases were included for review if hepatobiliary, or cognitive adverse events were reported in association with prolonged/repeated, off-label, prescribed, therapeutic ketamine exposure.

- Hepatobiliary events considered included events ranging from asymptomatic elevation in liver enzymes to irreversible structural damage to the liver or biliary system and/or clinical signs of liver failure.
- Our definition of cognitive events included events related to any aspect of cognitive functioning, including memory, language, attention and other mental processing capabilities— events that were described as primarily psychiatric in nature such as psychosis, hallucination or mania were not included in the definition for the purposes of this review and were addressed in a previous review by DPV.[10]

Exclusion criteria:

- Reports of abuse, misuse, and overdose with ketamine and in persons who had a past medical history of abuse and misuse of other pharmaceutical medications or illicit substances
- Ketamine administration for labeled indications including anesthesia for diagnostic and surgical procedures that do not require skeletal muscle relaxation and for the induction of anesthesia prior to the administration of other general anesthetic agents.
- The presence of the same symptoms as reported preceding the initiation of ketamine.

We then assessed cases meeting the inclusion and exclusion criteria for causality using the modified World Health Organization—Uppsala Monitoring Center (WHO-UMC) causality assessment (see Appendix D). Cases that were assessed as "unassessable" or "unlikely" to be related to ketamine were excluded from further review.

DPV signal-specific FAERS and literature search strategies to identify reports for potential events of interest are described below.

Observational studies and randomized controlled trials were also included if they evaluated or reported the signals of interest in the context of off-label, medically-supervised ketamine administration at subanesthetic doses.

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2.2.1 Hepatobiliary Events

Table 1. FAERS Search Strategy*	
Date of Search	May 2, 2018
Time Period of Search	All reports through April 30, 2018
Search Type	FBIS Quick Query
Product Terms	Product Active Ingredients: Norketamine, Ketamine Hydrocholoride, N-ethylnorketamine, Esketamine, Ketamine, Esketamine Hydrochloride, Deschlorketamine
MedDRA Search Terms (Version 20.1)	SMQ: • Biliary Disorders (Broad) • Biliary Malignant Tumours • Biliary Neoplasms • Biliary Neoplasms Benign (Incl Cysts and Polyps) • Biliary Neoplasms Malignant and Unspecified • Biliary System Related Investigations, Signs and Symptoms (Broad) • Biliary Tract Disorders • Biliary Tumours Of Unspecified Malignancy • Cholestasis and Jaundice of Hepatic Origin (Broad) • Congenital Biliary Disorders • Congenital, Familial, Neonatal and Genetic Disorders Of The Liver (Broad) • Drug Related Hepatic Disorders - Comprehensive Search (Broad) • Drug Related Hepatic Disorders - Severe Events Only (Broad) • Functional, Inflammatory and Gallstone Related Biliary Disorders (Broad) • Gallbladder Related Disorders • Gallstone Related Disorders • Hepatic Disorders Specifically Reported as Alcohol-Related • Hepatic Failure, Fibrosis and Cirrhosis and Other Liver Damage-Related Conditions (Broad) • Infectious Biliary Disorders • Liver Infections (Broad) • Liver Malignant Tumours (Broad) • Liver Neoplasms, Benign (Incl Cysts and Polyps) • Liver Neoplasms, Malignant and Unspecified (Broad) • Liver Related Investigations, Signs and Symptoms (Broad) • Liver Tumours Of Unspecified Malignancy • Liver-Related Coagulation and Bleeding Disturbances • Pregnancy, Labour And Delivery Complications and Risk Factors (Excl Abortions and Stillbirth) (Broad) • Pregnancy-Related Hepatic Disorders SOC: Hepatobiliary Disorders HLGT: Hepatic and Biliary Neoplasms Benign Verbatim: *DILIN*, *ALFSG*
* See Appendix C for a description of the FAERS database.	

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Table 2. Literature Search Strategy	
Date of Search 1	July 13, 2018
Database	PubMed@FDA
Search Terms	ketamine[tiab] and (biliary OR cholestasis OR hepatic OR hepatobiliary OR cholangitis OR hepatitis OR cholangiopathy)
Date of Search 2	July 16, 2018
Database	Embase
Search Terms	'ketamine'/exp AND ('hepatobiliary system'/exp OR 'biliary tract disease'/exp OR 'hyperbilirubinemia'/exp OR 'cholestasis'/exp OR 'obstructive jaundice'/exp OR 'intrahepatic cholestasis'/exp OR 'liver disease'/exp OR 'sclerosing cholangitis'/exp OR 'hepatitis'/exp OR 'toxic hepatitis'/exp OR 'bile duct disease'/exp)
Years Included in Search 1 and 2	All
*In addition to the search strategy above, we mined references from identified reports	

2.2.2 Cognitive Events

Table 3. FAERS Search Strategy*	
Date of Search	8/1/2018
Time Period of Search	All dates through 8/1/2018
Search Type	Mercado Quick Search
Product Terms (Product Active Ingredient)	Esketamine, Deschloroketamine, Esketamine Hydrochloride, Ketamine, Ketamine Hydrochloride, Norketamine,N-Ethylnorketamine
MedDRA Search Terms (Version 21.0)	High Level Group Term (HLGT): Cognitive and attention disorders and disturbances, Communication disorders and disturbances, Dementia and amnestic conditions, Disturbances in thinking and perception
* See Appendix C for a description of the FAERS database.	

Table 4. Literature Search Strategy	
Date of Search 1	July 30, 2018
Database	PubMed
Search Terms	ketamine[tiab] AND "cognitive function"[tiab]
Years Included in Search	All
Date of Search 2	July 30, 2018*
Database	Google Scholar†
Search Terms	cognitive effects of ketamine
Years Included in Search	All
*Reviewed titles and/or abstract from 500 most relevant articles, as ranked by search tool †Embase was initially searched but failed to capture key articles that the safety reviewer was aware of	

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Table 4. Literature Search Strategy
through preliminary literature review. Accordingly, the search strategy in this case was expanded to utilize Google Scholar in order to increase the number of articles retrieved.

3 RESULTS

3.1 DRUG UTILIZATION

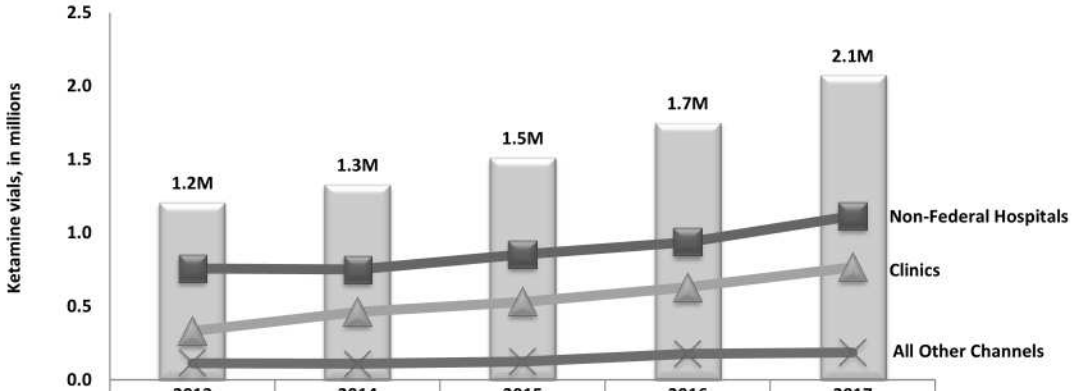
3.1.1 Sales and Distribution Data

Figure 2 below displays the nationally estimated number of ketamine vials sold from manufacturers to various channels of distribution, from 2013 through 2017, annually. The estimated total number of ketamine vials sold increased approximately 72%, from 1.2 million vials in 2013 to 2.1 million vials in 2017.

In 2017, the largest proportion of ketamine vials were sold primarily to non-federal hospitals at approximately 54%, followed by 37% and 9% of vials sold to clinics and all other channels, respectively. Although manufacturer sales of ketamine to all channels of distribution increased; the increase was most notable in the clinic settings, where the number of vials sold more than doubled in the past 5 years from an estimated 332,000 vials sold in 2013 to 765,500 vials sold in 2017. The reasons and potential factors that may have contributed to increased use over the examined time were not formally studied in this review.

Figure 2

Nationally estimated number of ketamine vials sold from manufacturers, stratified by channels of distribution



	2013	2014	2015	2016	2017
Grand Total	1,202,806	1,325,303	1,506,861	1,744,693	2,068,220
Non-Federal Hospitals	757,914	752,503	853,182	936,944	1,116,286
Clinics†	331,824	463,504	530,108	631,134	765,540
All Other Channels††	113,068	109,296	123,571	176,615	186,394

Source: IQVIA, National Sales Perspectives TM (NSP). Years 2013-2017. Extracted July 2018.
† Clinics include but are not limited to dialysis, family planning, x-ray, oncology, emergicenters, and surgicenters. Veterinary clinics not included.
†† All other channels include but are not limited to federal facilities, long-term care, mail-order, and chain/independent pharmacies

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3.1.2 Diagnosis data: U.S. office-based physician survey data

National estimates of use based on the number of drug use mentions in office-based physician surveys was assessed to provide insight into diagnoses (ICD-10 codes) associated with the utilization of ketamine. A very low number of reports for ketamine were captured in this datasource for 2017. The only reported diagnoses mentioned in association with ketamine were for "unspecified soft tissue disorders", "malignant neoplasm of bronchus and lung", "open wound of elbow and forearm", "headaches", and "gangrene". However, the results of office-based physican survey data were too low to derive reliable estimates of ketamine use likely due to minimal utilization in this setting of care. Although these data are not representative or generalizable across other settings of care where ketamine may be used (e.g., hospitals and clinics), the findings are reflective of the sales distribution patterns that suggest that the majority of use is largely in hospital and clinic settings.

3.2 FAERS AND MEDICAL LITERATURE

3.2.1 Hepatobiliary Events

3.2.1.1 FAERS Case Selection

The FAERS search retrieved 395 reports. After applying the case definition in Section 2.2, we excluded duplicate reports (n=143), reports not meeting the case definition (n=213), and those that were unassessable per WHO causality assessment (n = 28), leaving a total of 11 FAERS cases in the case series of hepatobiliary events with ketamine use. Reports that did not meet the case definition were excluded for the following reasons: abuse (n=136), anesthesia/single dose/single day of therapy (n=56), not a hepatobiliary event (n=10), time to onset preceded ketamine use (n=8), and overdose (n=3).

3.2.1.2 Literature Case Selection

A total of 252 published articles or reports were identified with the first search strategy described above (Section 2.2.2, Table 4). Of these, three articles met the case definition criteria. A total of 1,256 reports were identified with the second search strategy, of which two additional articles meeting the case definition were identified. Mining references from the selected articles identified one additional article. A total of 6 published literature articles or abstracts were thus identified.[23-29] From these articles, some of which included multiple reports meeting case definition criteria, a total of 12 reports met the case definition, of which 3 were also retrieved in the FAERS database search. Thus, a total of 9 reports, in addition to the FAERS cases, were relevant to this review.

Tables 6-9 summarize the 20 FAERS and literature cases of hepatobiliary events reported with ketamine for this case series.

Appendix B contains a line listing of all the FAERS case numbers, FAERS version numbers, and Manufacturer Control numbers for the 11 FAERS cases and a line listing of the 9 literature cases in this case series.

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Table 6. Descriptive Characteristics of Cases Reporting Hepatobiliary Events with Ketamine in FAERS and the Published Medical Literature, Received by FDA or Published, All Dates through April 30, 2018 (FAERS) or July 30, 2018 (Literature) (N= 20)	
Case Source*	
FAERS	11†
Literature	9
Year Received by FDA (Initial) or Published	
1995	2
2002 – 2004	6
2010 – 2012	6
2014 – 2017	6
Sex:	
Female	11
Male	9
Age: (yrs)	
Mean	54
Median	48
Range	33-72
Report Type	
Expedited	10
Direct	1‡
Literature only	9
Country	
Foreign	17
Domestic	3
Serious Regulatory Outcomes §, ‖	
Death	1¶
Hospitalization	6
Other Serious	4
Not Reported (literature reports)	9
Not Serious	1

* Case Source- 'FAERS' includes any case identified in either FAERS alone or in both FAERS and the literature and 'Literature' includes cases only identified in the literature.

† 3 of the FAERS cases were also found in the literature (FAERS Case numbers 10398893,[23] 11968665,[24,25] and 14227949[26]).

‡ The one direct report was submitted by the Drug Induced Liver Injury Network (DILIN).

§ For the purposes of this review, the following outcomes qualify as serious: death, life-threatening, hospitalization (initial or prolonged), disability, congenital anomaly, required intervention and other serious important medical events.

‖ A case may have more than one serious outcome.

¶This case met our case definition for hepatobiliary event, but the patient likely died due his underlying esophageal cancer.

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Table 7. Descriptive Characteristics of Ketamine Route of Administration, Reasons for Use, Risk Factors, and Time to Onset of Hepatobiliary Events with Ketamine in FAERS and the Published Medical Literature, Received by FDA or Published, All Dates through April 30, 2018 (FAERS) or July 30, 2018 (Literature) (N= 20)	
Ketamine Route	
Parenteral[*]	16
Oral	3
Not Reported	1
Reason for Ketamine Use	
Complex regional pain syndrome	11
Pain [†]	4
Post-herpetic neuralgia	2
Chronic migraines	1
Palliative care	1
Fibromyositis	1
# of Reported Risk Factors[‡] for hepatobiliary event	
0 risk factors[||]	3
1 risk factor	7
2 risk factors	3
Not Reported	7

[*] Parenteral route includes: infusion not otherwise specified (NOS), injection NOS, IV infusion, SC, or SC infusion.
[†] Pain included chronic facial pain, pain not otherwise specified, phantom limb pain, or sciatic pain.
[‡] Risk factors for hepatobiliary events evaluated included: viral hepatitis A, B, C, or E, cytomegalovirus, Epstein Barr Virus, preexisting or autoimmune hepatitis, history of alcoholism, use of one or more concomitant drugs with a NIH Liver Tox Likelihood score of A, B, or C (See Appendix F), past medical history of biliary disease including, but not limited to gallstones, cholecystitis, gallbladder disease unspecified, and cholangitis.
[||] We classified cases documenting negative pertinent history for risk factors as reporting no risk factors.

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Table 8 details the reported time to onset and correlating cycle for each hepatobiliary event. There were a total of 28 hepatobiliary events that occurred among the 20 cases (two cases reporting two events each and three cases experiencing three events each). A cumulative list for time to onset for each event is documented in the far right column. Time to onset following the administration of ketamine was reported for 18 of the 28 events (64%). The majority of the events (61%) with a reported time to onset occurred within 4 days following ketamine.

A cumulative list for the cycle for each event is documented in the bottom row of table 8. Sixteen events (within 12 unique cases) reported the details of the cycle number (57%). The majority of the events (75%) with a reported cycle occurred following cycle 1 or cycle 2, however, this likely indicates that once the event occurred, the ketamine was not resumed. The term "cycle" may be a bit nebulous, as each cycle is defined by the individual patient ketamine regimen, and is not standardized, though we provide this descriptive data for awareness.

Table 8. Time to Onset of Hepatobiliary Event by Ketamine Treatment Cycle Number* (n= 28)

	Cycle 1	Cycle 2	Cycle 3	Cycle 4	Cycle 5	Cycle Not Reported†	**Total Events per Time to Onset**
6 hours	0	1	0	0	0	0	1
1 day	1	0	0	0	0	0	1
2 – 4 days	2	4	2	1	0	0	9
1 – 2 weeks	1	1	0	0	0	1	3
Less than 30 days	1	0	0	0	0	0	1
1 – 2 months	0	0	0	0	0	1	1
+ 4years	0	0	0	0	0	1	1
10 years	0	0	0	0	0	1	1
Total Time to Onset Not Reported	0	1	0	0	1	8	10
Total Events per Cycle	5	7	2	1	1	12	28±

*Patients may have experienced the event following more than one cycle in positive rechallenges.
† Cycle may not have been reported for patients on repeated oral doses, as well in other cases where cycle number was not specified.
± There was a total of 28 events among the 20 cases in our case series, with 2 cases reporting 2 events each and three patients experiencing three events each.

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Table 9. Descriptive Characteristics of Hepatobiliary Events, Dechallenge and Rechallenge Information, Causality and Outcome with Ketamine in FAERS and the Published Medical Literature, Received by FDA or Published, All Dates through April 30, 2018 (FAERS) or July 30, 2018 (Literature) **(N= 20)**	
Characteristics of Hepatobiliary Event*	
Increased ALT/SGPT	10
Increased GGT	9
Unspecified liver enzymes increased	8
Increased AST/SGOT	9
Increased ALP	8
Elevated bilirubin levels	3
Cholangitis	2
Biliary dilation	2
Jaundice	2
Unspecified liver disorder	1
Chronic hepatitis	1
Hepatic fibrosis	1
Liver cirrhosis	1
Hepatic cytolysis	1
Intrahepatic cholestasis	1
Cholangiopathy	1
Pericholeductal fibrosis	1
Dechallenge/Rechallenge Information Reports (number of patients)	
Rechallenge Positive†	9 (5)
Dechallenge Positive	11(11)
Dechallenge Negative	1 (1)
Fatal	1 (1)
Ketamine continued	1 (1)
Not Reported	1 (1)
WHO-UMC Causality Category	
Probable/Likely	10
Possible	10
Outcome	
Recovered/Resolved	10
Recovering/Resolving	4
Not Recovered/Not Resolved	2
Unknown	3
Fatal	1‡

* Cases may include more than one characteristic describing the hepatobiliary event.

† There was a total of 9 positive rechallenges among 5 patients.

‡ This case met our case definition for hepatobiliary event, but the patient likely died due his underlying esophageal cancer.

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We highlight the following cases of hepatobiliary events that occurred in patients exposed to repeated, unapproved indications of ketamine that were not otherwise published in the medical literature.

- **FAERS Case # 8341142 (DILIN Case 109-0030)**: A 51 year-old female with a history of Reflex Sympathetic Dystrophy (RSD) experienced elevated liver enzymes following ketamine infusions on at least three occasions. In the most recent infusion, the ALT was >5 x the upper limit of normal (ULN). The next set of labs drawn approximately one month after the date of onset had decreased below the Drug-Induced Liver Injury Network (DILIN) Prospecitve Study laboratory entry criteria. The entry criteria was defined as elevations in ALT or AST > 5 x baseline values times two consecutive occasions. An exemption was requested and granted and the patient was enrolled in the study. The patient had a past medical history of abnormal liver enzymes tests detected during treatment for hyperlipidemia. Following ketamine infusions, the patient experienced a pattern of "spiking" liver enzymes increasing from normal levels to several fold elevations documented on three separate occurrences in which liver enzymes reached peak elevations within 1-2 weeks. In September 2010 following the administration of ketamine, the ALT jumped from 9 to 283, and the AST from 15 to 94. Liver enzymes were normal in August 2010 prior to the ketamine infusion. The patient had a past medical history of negative serologies documented in 2005 and 2006 for antimitochondrial antibodies (AMA), antinuclear antibodies (ANA), smooth muscle antibodies (SMA), hepatitis B surface antigen (HBsAg), hepatitis A virus (HAV) total and immune globulin antibody (IgM), hepatitis C virus (HCV) antibody, Eptstein-Barr virus (EBV), and normal ceruloplasmin. AST (36) and ALT (45) were mildly elevated at the time of the 6 month follow-up visit in 2011.

  Reviewer comments:
  This directly submitted domestic FAERS case (submitted by the Drug Induced Liver Injury Network) supports a probable relationship between hepatobiliary events in a patient receiving ketamine for CRPS for elevations in ALT and AST. We note that the patient had no history of chronic liver disease, no liver transplant, occasional alcohol use and negative serologies for AMA, ANA, SMA, HBsAg, total and IgM, HCV antibody, EBV, and normal ceruloplasmin. There were no concomitant medications listed for this patient. The patient experienced two positive rechallenges one to two weeks following the administration of ketamine infusions in which there was a pattern of "spiking" enzymes (of ALT and AST) from normal levels to several fold elevations. We acknowledge and do not know the reason why the patient had several years pass between the second and third reported dose of ketamine.
  WHO causality assessment- probable

- **FAERS Case # 10740815:** This spontaneous report from a non-clinical-study program, Pfizer Rx Pathways, is for a 49-year-old female patient with a history of reflex sympathetic dystrophy receiving ketamine infusions every month since 2008, and prior to 2008, every other month starting in 2007. She took a break from the infusions for about one year, due to an increase in liver enzymes in 2012. Ketamine infusions were restarted in 2014 for which she was hospitalized to receive a five day infusion. Ketamine was

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infused into her port "every other month 2 days 5 hrs" [*sic*], but ketamine was stopped 'waiting for enzymes to drop which happen before they stopped ketamine for a while then they resume it.' Patient reported "I took ketamine for approx. 4 years. Ketamine is tough on liver so they stopped it. Now it is up again but not a whole lot but they want me to take a break for 3 months and test me to see if they resume it." The patient was started on pregabalin to cover her pain while the healthcare providers were "waiting for enzymes to drop." The patient was having trouble covering her costs of pregabalin therapy. Additional past medical history included hypothyroidism, ongoing acid reflux, thoracic outlet syndrome, ongoing asthma, and multiple shoulder surgeries. Concomitant medications included pregabalin, duloxetine hydrochloride, citalopram, omeprazole, levothyroxine, trazodone, and montelukast sodium. The patient was started on pregabalin to cover her pain while the healthcare providers were 'waiting for enzymes to drop.'

Reviewer comments:
This expedited domestic FAERS case supports a possible relationship between hepatobiliary events in a patient receiving ketamine for complex regional pain syndrome for elevations in unspecified liver enzymes. We note that although general past medical history and concomitant medications were addressed, risks factors for and a history of hepatobiliary health was not addressed including viral etiologies, alcohol status, and other liver diseases. Of the reported concomitant medications,the National Instidutes of Health has categoried omeprazole as liver tox B, duloxetine as liver tox B, and citalopram as liver tox C. (See Appendix F for NIH Likelihood LiverTox Categories). Despite the use of concomitant drugs that may be associated with liver toxicity, there is a strong temporal relationship to the use of ketamine and the onset of elevation in liver enzymes. The patient experienced at least one positive rechallenge following the repeat administration of ketamine for which it had been put on hold due to an increase in liver enzymes.
WHO causality assessment- possible

Literature

Case characteristics from the 12 identified literature case reports, of which 3 were also retrieved in the FAERS database search, are summarized together with other cases identified through FAERS in Tables 6,7,8 above. Narrative detail on select literature cases is also provided below.

- Tofani C, Gandhi K, Haleguoa-DeMarzio. Acute Liver Injury Related to Intermittent Intravenous Ketamine for the Treatment of Migraines. Am J Gastro. 2015 Oct; 110 (1): S334-S335.[25]

  This US based published abstract reports a case of a 58-year-old female who received a multi-day ketamine infusion (dose/rate not specified) with largely normal liver enzymes at baseline (total bilirubin 0.2 mg/dL, AST 20 IU/L, ALT 17 IU/L, alkaline phosphatase 111 IU/L), rise in liver enzymes one day following initiation of the ketamine infusion, and peak in ketamine on the third day following initiation of ketamine (total bilirubin 1.0 mg/dL, direct bilirubin 0.4 mg/dL, AST 721 IU/L, ALT 1034 IU/L, alkaline phosphatase 289 IU/L). Abdominal ultrasound revealed gallstones without gallbladder thickening and

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a mildly dilated common bile duct without choledocholithiasis as well as mild hepatic steatosis. Liver function studies began declining one day following discontinuation of ketamine infusion. Similar elevation in liver function studies occurred during next two admissions with rise in liver function studies following ketamine initiation, with decline following discontinuation of ketamine. (See Appendix E for graph of Dechallenge Rechallenge Information with Ketamine Infusions and ALP, AST, ALT, and T.bili levels).

Reviewer comments:
The pattern of injury here appears to be slightly more hepatocellular than cholestatic. Bilirubin levels are normal suggesting no extrahepatic obstruction (i.e., choledocholithiasis). Though occult gallstones may be suggested by ultrasound findings, lack of bilirubin elevation is not supportive, and cannot explain why liver enzymes decline consistently following discontinuation of ketamine in three separate hospital admissions. The infusion dose was not specified in this case. The history appears consistent with a diagnosis of drug-induced hepatitis.
WHO causality assessment- probable

- Noppers IM, Niesters M, Aarts LP, et al. Drug-induced liver injury following a repeated course of ketamine treatment for chronic pain in CRPS type 1 patients: A report of 3 cases. Pain. 2011 Sep;152(9):2173-8.[27]

  This was a pilot study evaluating the effect of two 5-day intravenous ketamine infusions on pain relief in CRPS type 1 patients, with a 16-day ketamine-free interval separating treatment sessions. Of the six patients randomized to the treatment arm with a short-interval between treatment episodes (i.e., 16-day interval), three patients were excluded due to elevated liver enzymes, which developed during the second treatment week. The dosing regimen for ketamine was weight dosed and dynamically titrated based on pain scales.[3] Details of one of these three cases is summarized below with figures from the paper depicting the pattern of change in liver enzymes:

  A 65 year-old woman with a 6 year history of CRPS in her left foot, on chronic tramadol and paracetamol/codeine, and a baseline pain score of 7/10, experienced some pain relief with ketamine infusion during the first week of treatment, though was unable to tolerate maximum titration due to side effects (i.e., psychotropic effects, nausea, dizziness) on the second treatment day. During the second week, pain was back to baseline, and similar side effects occurred upon initiation of the infusion as well as an generalized rash and fever at approximately 72 hours; liver enzymes at this time were also elevated, with ALT peaking at approximately 400, AST at 380, GGT at 340 and alkaline phosphatase at 200—though without any noted abdominal pain, jaundice or hepatic enlargement. At this point, ketamine was discontinued, with a total of 1.3 grams of ketamine that had been administered. Hematologic labs were notable for mild eosinophilia (8%). The rash

[3] "On day 1, infusion started at 8 am at 1.2 ug/kg/hr. Three times a day (at 8 am, noon, and 4 pm), the infusion rate could be increased in steps of 0.6 ug/kg/h until a maximum infusion rate of 7.2 ug/kg/hr was reached. When the patient reached a pain rating of zero, the infusion rate was not further changed. In case of severe side effects, the infusion rate was lowered in steps of 0.6 ug/kg/h and later increased again if possible."

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improved and the liver enzymes decreased following ketamine discontinuation other than GGT and alkaline phosphatase which increased for one additional day; enzymes further normalized over the course of 1 month. The patient's pain returned to baseline 5 weeks after the second treatment.

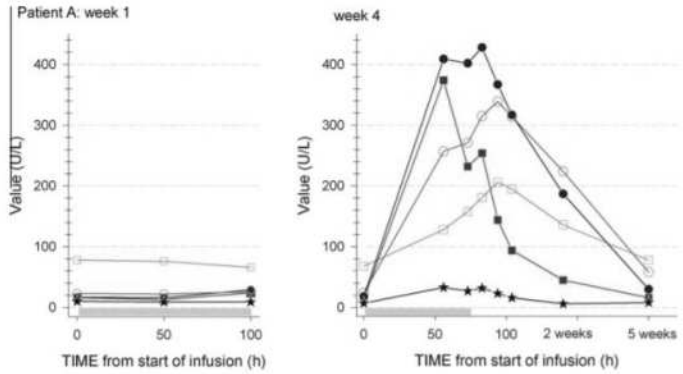

Fig. 2. Serum liver enzymes in the first (left) and second (right) S(+)-ketamine treatment week (= study week 4) of patient A. Alkaline phosphatase, alanine transaminase, aspartate transaminase, total bilirubin, and γ-glutamyl transferase exceeded the upper reference values. Reference values: alkaline phosphatase (orange open square) 40–120 U/L, alanine transaminase (blue closed circle) 5–34 U/L, aspartate transaminase (red closed square) 5–30 U/L, total bilirubin (black star) 0–17 U/L, and γ-glutamyl transferase (green open circle) 5–40 U/L. The gray bar indicates the ketamine infusion.

Reviewer comments:
The pattern of injury appears mixed hepatocellular/cholestatic. The temporal association between onset of elevation in enzymes following ketamine initiation as well as positive dechallenge information is convincing that there was a causative relationship between ketamine exposure and elevation in liver enzymes.
WHO causality assessment- probable

- Correll GE, Maleki J, Gracely EJ, Muir JJ, Harbut RE. Subanesthetic Ketamine Infusion Therapy: A Retrospective Analysis of a Novel Therapeutic Approach to Complex Regional Pain Syndrome. Pain Med. 2004 Sep;5(3):263-75.[29]

This US study involved retrospective chart review of 33 patients in Australia who received subanesthetic intravenous infusion for CRPS with variable doses. Among these patients, 4 experienced elevation in liver enzymes which resolved upon discontinuation of ketamine. In the case of one patient, liver enzymes prevented completion of the protocol, and in two subsequent admissions for ketamine infusion, elevation of liver enzymes was observed.

Reviewer comments:
Although little information is provided regarding the levels of rise in liver enzymes, or pattern of injury, the temporal association between ketamine exposure and onset of elevation in liver enzymes, dechallenge and rechallenge information appear supportive.
WHO causality assessment- probable

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3.2.2 Cognitive Events

FAERS
We identified a total of 172 FAERS reports using the search strategy above. We excluded reports not meeting the case definition (n=128), duplicates (n=18), those that were confounded by the presence of multiple medications or comorbidity (n=9), and those with insufficient information (n=15), leaving a total of 2 cases meeting the case definition.

Details from these cases are summarized below:

- FAERS # 8555950 (literature article, sponsor-submitted, expedited)
  A 36-year-old male with a history of CRPS and depression underwent a ketamine-midazolam induced coma for treatment of refractory pain. Ketamine was infused reportedly at a rate of 700 mg/hour intravenously and continued for 5 days. Upon awakening, the patient reported reduced levels of pain, though also reported anxiety, hallucinations and fear. Persistence of these symptoms for two days prompted a psychiatric evaluation which also identified a short-term memory deficit—the patient was able to recall only 2 out of 4 words after a 5- minute delay. The patient was initiated on quetiapine, after which time he no longer experienced hallucinations and short-term memory testing improved, with a delayed recall of 4 out of 4 words.

  Reviewer comments:
  In this case, a strong temporal relationship between exposure to ketamine and the onset of a persistent memory deficit is reported. However, the apparent cognitive impairment (i.e., short-term recall) appeared to occur in the context of concomitant hallucinations, anxiety and fear. In addition, treatment with quetiapine, an antipsychotic, appeared to relieve the entire constellation of symptoms, suggesting that cognitive impairment in this case could have occurred in the context of drug-induced psychosis, in which case it would have not met the case definition specified for this review. However, we are given insufficient detail in the case to definitively diagnose the patient with psychosis. For additional detail regarding prolonged neurospychiatric events following ketamine exposure see prior DPV review or the summary provided on page 4 of this document.[21]
  WHO causality assessment- possible

- FAERS # 11693064 (direct report, submitted by affected individual)
  A 58-year-old male with a history of depression and mild cognitive impairment underwent treatment with ketamine for treatment of depression symptoms. Ketamine was infused at a rate of 2 mg/kg, for a total of 5 infusions over a period of 2 weeks. It is not clear that he received more than a single series of infusions. Subsequently the patient experienced changes in behavior, which he reported to be unusual such as writing "dozens of emails of confusing and scary content" leading to a charge of email harrassment. The patient reports additional symptoms—decline in functionality, difficulty with oral communication without arguments, severe limitations in working memory, and poor control of emotions—all of which reportedly began following the infusions, and persisted for two years following the treatment, up until the time of

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reporting. The report, in the patient's own words, is copied below. We have removed select content to protect the identity of the reporter who is also the patient.

"I was administered ketamine IV for the symptoms of depression under the direction of [*my physician*] , with a questionable diagnosis of bipolar and a recent prior diagnosis of MCI with indications of early inset[*sic*] dementia. [*My physician*] prescribed a series of 5 infusions over two weeks, each at the dosage of 2.0 mg/kg, a level I have recently found is quadruple the accepted dose for depression. I have reason to believe [*my physician*] used a similar protocol on three other patients suffering from neurological deficits and two of them suffered adverse events similar to mine. I have also recently found out that the prescribed dosage is in the range of abuse for ketamine, and that any unnecessary anesthesia is contraindicated in the case of neurological problems of unknown cause. After the series of infusions, I exhibited such unusual behavior (dozens of emails of confusing and scary content) that I was charged with email harassment and put under court ordered treatment for presupposed bipolar. At this point I should say that I am a retired prodpfessional [*sic*] with a jacket of five speeding tickets -,this was all very bizarre behavior for me. I have now been diagnosed with the progressive neurological disorder called by-FTD, formally Pick's disease. Pick's patients are especially sensitive to anesthesiaj[*sic*], with marked and often permanent decline. [*My physician*] also has solicited and received millions of dollars in investments from me during the period I was being given IV ketsmine [*sic*] - I believe July 2013. My functionality has declined significantly - oral communications are almost impossible without arguments starting, especially with strangers or in environments with lots of stimulation. I am largely confined to email. Despite a graduate degree from Harvard I cannot follow a sitcom. My working memory extends back only one day. My executive control of emotions is so poor that I have to isolate for peace. All of these symptoms are new since the infusions in Jsnuary [*sic*]."

Reviewer comments: The reporting patient in this case suggests a causal relationship between ketamine exposure and the onset of his symptoms, which include severe deficits in memory (i.e., working memory extending back only one day, loss of attention span). However, the reporter suggests the presence of baseline mild cognitive impairment, in which case it is not clear whether the condition he had would have deteriorated regardless of the ketamine exposure, whether ketamine accelerated the process, or whether the cognitive symptoms that the reporter perceived as new were solely due to the ketamine. Alternatively, some of the behavior that is described (i.e., speeding while driving, argumentativeness) may be explained by a prolonged manic episode that may have occurred in the context of ketamine exposure or the reporter's baseline possible diagnosis of bipolar disorder, although there is not sufficient information to diagnose the patient with mania. For additional detail regarding prolonged neurospychiatric events following ketamine exposure see prior DPV review or summary provided on page 4 of this document.[21]

<u>WHO causality assessment- possible</u>

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Literature

The PubMed search retrieved 69 articles, while the Google Scholar search resulted in greater than 500 articles. Screening of titles and abstracts resulted in 8 full-length articles that were reviewed further for relevance.[30-37]

Of the 8 relevant articles, 5 evaluated the effects of ketamine upon memory or other cognitive functions in healthy adults, 2 articles assessed such effects in patients with CRPS, and 1 article assessed these effects in patients with treatment resistant depression. No published case reports met our case definition. Studies were generally small, with patient sample sizes ranging from 9 (Koffler, 2007)[36] to 32 (Kim, 2016)[35]. Study design included double -blind placebo-controlled randomized trials (n=4), prospective cohort studies (n=2), and retrospective cohort studies (n=2). Though they all included parenteral (intravenous or intramuscular) formulations, dosing protocols for ketamine were highly variable across studies—for instance, one study (Ghoneim, 1985)[30] compared the effect of two doses of ketamine, 0.25 mg/kg, 0.5 mg/kg with placebo, where ketamine was provided as a one-time only intramuscular injection; another study (Newcomer, 1999)[32] compared three doses of ketamine, provided as an intravenous bolus, followed by maintenance infusions. Measurements of cognition and memory were also highly variable across the studies, and included tests of attention (e.g., color-word interference test), information recall (e.g., delayed free recall), verbal fluency and recognition, among other measures of cognitive function. A subset of studies also assessed outcomes related to psychiatric adverse effects (i.e., Brief Psychiatric Rating Scale), or treatment efficacy (e.g., Beck Depression Inventory, McGill Pain Questionairre).

Several studies identified significant negative effects of ketamine upon specific aspects of cognitive function. These studies are highlighted below:

- Ghoneim, 1985[30]: immediate recall and delayed recall, learning performance
- Malhotra, 1996[31]: recognition memory, free recall, attention
- Newcomer, 1999[32]: dose-dependent decrease in learning, verbal/non-verbal declarative memory
- Krystal, 2000[33]: Wisconsin Card Sorting Test (i.e., attention, mental shifting, information storage)
- Diamond, 2014[34]: episodic memory, immediate and delayed recall, autobiographical memory
- Kim, 2016[35]: digit span/symbol test (i.e., memory, attention, concentration, working memory)

One study did not detect negative effects of ketamine upon asssessed measures of cognitive function, and identified potential improvement in some areas of function:

- Koffler, 2007[36]: no change in learning/memory; attention and processing speed reported to have improved in patients with CRPS type I after treatment with ketamine

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One study reported negative effects of ketamine on very specific aspects of cognitive function, while not appearing to affect the majority of cognitive functions assessed:

- Honey, 2003[37]: negative effects- verbal working memory, manipulation only; no effects on other aspects of verbal working memory (i.e., forward/backward digit span),spatial working memory, or planning

In general, many of the studies were limited by small sample sizes, in most cases without statistical significance adjustment for multiple testing (e.g., Bonferroni adjustment). While the majority of the studies evaluated suggest that ketamine may have stronger negative effects on specific cognitive domains, such as immediate/delayed recall, which may be dose-dependent, one study (Koffler) identified potential positive effects of ketamine upon cognition. Finally, none of the studies prospectively examined long-term persistence of cognitive effects resulting from repeated exposure to ketamine. Overall, these studies suggested possible short-term effects of ketamine upon cognitive function that may be independent of neuropsychiatric changes, though there is a need for additional prospective data to better understand persistence of these effects over time.

4 DISCUSSION

Our review of FAERS and the published literature confirm that ketamine is being used off-label to treat a number of conditions, such as pain and depression. We identified a number of strong cases that appear to support a causal relationship between repeated ketamine exposure and the onset of hepatobiliary adverse events, and some data to support a possible relationship between ketamine exposure and the onset of negative cognitive effects. Although it is difficult to estimate the size of the at-risk population of patients who are receiving ketamine off-label in this manner, as such use is typically reimbursed through cash payment only, trends in outpatient sales of ketamine in recent years provides some indirect evidence to suggest growing popularity of the drug.

We also note that esketamine (the S-enantiomer of racemic ketamine) nasal spray, NDA 211243, is currently in-house. The sponsor of this product is seeking approval for induction and maintenance treatment of adults with treatment-resistant depression. If approved, esketamine would likely be dosed once or twice a week, or every other week, under the supervision of a health care professional. Consideration of the safety findings from this ketamine review, which relates to risks of repeated administration, as is proposed for NDA 211243, may be informative when considering the drug safety profile of esketamine, although some adverse events may be route-specific, a factor we have not examined in this review.

Ketamine Utilization Trends

Sales distribution data were assessed to provide a national estimate of the number of ketamine vials sold from manufacturers into all channels of distribution. Although sales data do not provide a direct measure of patient use, the amount of product purchased by various settings of care may be a possible surrogate for use, if we assume the facilities purchase drugs in quantities reflective of actual patient use. Based on national sales distribution patterns of ketamine vials, the utilization appears to be largely in the hospital setting. Notably, we also found sales to clinic

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settings appears to have more than doubled in the five years examined suggesting changes in utilization patterns. However, national data on diagnoses or indications directly linked with the administration of ketamine in the clinic or hospital settings were not available for review. In order to obtain some insight into reported indications for the use of ketamine, U.S. office-based physician survey data were assessed for prescriber reported use of ketamine. However, the results of office-based physican survey data were too low to derive reliable national estimates of ketamine use. Due to the low utilization of ketamine outside of hospital and clinic settings, the results from the office-based physician survey data are not generalizable nor representative of ketamine use across all settings of care.

Data on repeated use of ketamine as well as national esimates of use in the clinic or hospital settings by indication were not conducted for this review. Additional analyses are necessary to characterize off-label, repeated use of ketamine. However, our findings suggest increasing use of ketamine in recent years, although the reasons and potential factors that may have contributed to increased use were not formally studied in this review.

Ketamine and Hepatobiliary Events

The FAERS and literature cases support an association between hepatobiliary events and the off-label, repeated use of ketamine. Our findings are consistent with previous inferences made by the medical community regarding potential hepatotoxicity associated with chronic ketamine use.[38] Additionally, in 2017, the French National Agency for the Safety of Medicines and Health Products (ANSM) published a Dear Healthcare Professional Communication (DHPC) letter regarding the risk of severe liver damage during repeated and/or prolonged use of high-dose ketamine.[39] The letter reported ten cases of serious liver damage (cholestatic cholangitis), including four cases requiring liver transplantation, since 2014. ANSM stated that cases may be linked to repeated or prolonged use of ketamine and at high doses in the management of severe pain or severe burns. The letter reminded healthcare professionals to follow the recommended dosage for palliative care practice, that treatment should be initiated by a specialized team, and patients should undergo close observation and monitoring, including liver function monitoring. In response, to the ANSM letter, Malaysia's National Pharmaceutical Regulatory Agency (NPRA) also issued an advisory to clinicians to "monitor patient's liver function closely if repeated and/or prolonged high dose of ketamine is used."[40]

Although there are a limited number of cases in our case series, it is important to note that we only reviewed cases of off-label, prolonged/repeated use of ketamine. Due to the complex nature of patients and confounding that can complicate reports, we did not review cases of labeled use of ketamine (e.g. sedation) or abuse cases of ketamine. We noted the repeated off-label use cases to be less confounded than abuse cases, allowing us to evaluate a drug-event relationship.

Of the events that occurred, the majority of the cases documented liver transaminase elevations, including increases in ALT, GGT, AST, and ALP with a close temporal relationship to the ketamine administration. In addition, we identified cases with elevated transaminases further complicated by cholangitis, biliary dilation, jaundice, chronic hepatitis, hepatic fibrosis, liver cirrhosis, intrahepatic cholestasis, cholangiopathy, and pericholeductal fibrosis. Although health authorities from other countries, as noted above, have received reports of liver damage from repeated or prolonged ketamine use resulting in transplant, at the time of this review there were

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no cases of fulminant hepatic necrosis or transplant identified from FAERS or the literature for the case definition applied.

Our case series had a strong positive dechallenge and rechallenge correlation of events with the administration of ketamine. Of the seventeen reports in which the ketamine was discontinued, sixteen documented a positive dechallenge (94%), and five more patients went on to develop positive rechallenges, including four cases with two positive rechallenges each. We feel the strength of the evidence lies in the number of positive dechallenges and rechallenges in our case series. Additionally, two of the probable cases (FAERS Case # 14227949 and Kato Case #1) experienced an ALT level greater than 3 times the ULN and a total bilirubin level greater than 2 times the ULN after receiveing ketamine. In FAERS Case # 14227949, on day three after 2nd dose, the patient experienced epigastric pain and elevated bilirubin (90 mmol/L) and ALT (868 u/l). In Kato Case #1, it was documented that the total bilirubin (4.0 mg/dl) and ALT (204 IU/l) were elevated 53 days after starting ketamine. In summary, we reviewed several cases where liver enzymes returned to normal upon discontinuing ketamine, although in some cases, enzymes did not normalize even over a period of several months and repeat assessment of the pathology (e.g., fibrosis) was not available to characterize the extent of residual injury.[28]

There was one death case in our case series (FAERS case # 12801413). However, we note that at the time of the events, the patient was hospitalized for palliative care for esophageal cancer. The patient had experienced mental confusion, intrahepatic cholestasis, with cytolisis and increased levels of hepatic enzymes which were considered by the DPV reviewers (MM/SC) to be possibly related to ketamine. However, the patient was also receiving ceftriaxone, and haloperidol at the time of the events— in the literature, ceftriaxone has been associated with development of biliary sludge and biliary colic, and haloperidol is commonly associated with minor serum aminotransferase elevations and rare instances of acute liver injury, thus the case was confounded by the concomitant use of these medications.[41,42] The reporter attributed the death to progression of cancer.

Ketamine has been shown to cause transient abnormalities in LFTs when used as an anaesthetic agent.[43] The exact mechanism for injury is unknown[23], but has been hypothesized to be due to a reduction in hepatic oxygen delivery, and increased lipid peroxidation with free radical formation.[44] Although the patients receiving ketamine for anesthesia were excluded from our review, a literature article from Hong Kong identified abnormal LFTs in 16% of ketamine abusers who sought care at the hospital emergency departments.[45] Animal studies performed in mice treated with ketamine showed fatty degeneration of liver cells, fibrosis and a rise in liver enzymes.[46] Effects were noted to be more severe if the animals were also treated with alcohol.

We note that there is a clear pattern of elevation in transaminases, temporal relationship, multiple positive rechallenges, and biologic plausibility leading us to believe that there is a probable drug-event relationship. Furthermore, early detection of drug-induced hepatic injury along with immediate discontinuation of the suspected drug may enhance the likelihood of recovery.

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Ketamine and Cognitive Events

Ketamine's activity on NMDA receptors form a potential mechanistic basis for adverse effects relating to cognitive function.[47] NMDA antagonists, such as ketamine and phencyclidine (i.e., PCP) are known to bind with high affinity to structures in the central nervous system, such as the cortex and limbic system. Although the exact mechanism by which ketamine and PCP cause "dissociation" between sensation and higher cognitive functions is not known, ketamine's activity on NMDA receptors are hypothesized to play a central role in its effects on cognition and memory, and both ketamine and PCP have been demonstrated to reliably induce schizophrenia-like states.

Despite the few FAERS cases reporting potential cognitive adverse effects of repeated doses of ketamine and lack of published case reports, we identified 8 studies that have attempted to assess the effects of ketamine upon memory and other aspects of cognitive function. Although findings from some of these studies are somewhat mixed, and many do not specifically assess the effects of repeated dosing, several studies of healthy adults suggest that specific aspects of cognitive function (e.g., immediate/delayed recall, working memory) appear to be negatively affected by ketamine use in the short-term, even with subanesthetic doses. It is also worth noting that these effects may be even more pronounced, or altogether distinct, among patient populations that were excluded from several of the studies who may receive ketamine in the real-world setting, such as the cases we noted from FAERS (e.g., patients with baseline cognitive impairment, dementia, substance use disorder or history of psychosis).

Underscoring the complexity of the risk-benefit assessment in deciding whether ketamine may be appropriate for use despite potential adverse effects, one study of patients with CRPS I suggested potential for improvement with ketamine treatment in certain aspects of cognitive function such as attention and processing speed, which is conceivable in the context of the impact that debilitating pain may have on baseline cognitive processes.[36] Additional prospectively collected data are required to better understand risks of persistent cognitive changes (positive or negative) resulting from ketamine exposure in specific patient populations.

5 CONCLUSION

In conclusion, we find an association between ketamine and a range of hepatobiliary events in the context of off-label, repeated use.

In addition, available studies support a possible association between ketamine and short-term cognitive impairment with subanesthetic doses of ketamine, having potential implications for post-treatment monitoring or restrictions on activity. However, it remains to be determined whether or not the cognitive effects observed with ketamine are sustained and in which populations, and in which populations such risks are outweighed by potential benefits.

The current ketamine labeling does not convey potential for either hepatobiliary or cognitive complications in the context of subanesthetic doses, and increased awareness among clinicians may mitigate adverse outcomes, especially in the context of growing ketamine utilization.

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6 RECOMMENDATIONS

Based on this review, DPV recommends the following:

- Add a statement to the Warnings section of ketamine product labels to reflect the potential risk of hepatobiliary events with ketamine, and routine monitoring of liver function studies in the context of repeated use

  Consider use or modification of the following proposed language: "In individuals with a history of prolonged/repeated off-label ketamine use, post-marketing case reports of hepatobiliary events have been reported, including positive rechallenges, that sugest a causal relationship with ketamine. These events have ranged from reversible elevation in transaminases to irreversible liver damage (e.g., fibrosis, biliary ductal changes). Routine monitoring of liver function studies may help mitigate irreversible or long-term consquences of these hepatobiliary events."

- Consider a statement to the Adverse Reactions section of ketamine product labels to reflect that ketamine may be associated with short-term cognitive impairment at subanesthetic doses, although the long-term cognitive effects of repeated exposure to ketamine are not well understood.

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8 APPENDICES

8.1 APPENDIX A. FDA ADVERSE EVENT REPORTING SYSTEM (FAERS)

FDA Adverse Event Reporting System (FAERS)

The FDA Adverse Event Reporting System (FAERS) is a database that contains information on adverse event and medication error reports submitted to FDA. The database is designed to support the FDA's post-marketing safety surveillance program for drug and therapeutic biologic products. The informatic structure of the database adheres to the international safety reporting guidance issued by the International Conference on Harmonisation. Adverse events and medication errors are coded to terms in the Medical Dictionary for Regulatory Activities (MedDRA) terminology. The suspect products are coded to valid tradenames or active ingredients in the FAERS Product Dictionary (FPD).

FAERS data have limitations. First, there is no certainty that the reported event was actually due to the product. FDA does not require that a causal relationship between a product and event be proven, and reports do not always contain enough detail to properly evaluate an event. Further, FDA does not receive reports for every adverse event or medication error that occurs with a product. Many factors can influence whether or not an event will be reported, such as the time a product has been marketed and publicity about an event. Therefore, FAERS data cannot be used to calculate the incidence of an adverse event or medication error in the U.S. population.

8.2 APPENDIX B. DRUG USE DATABASE DESCRIPTIONS

IQVIA, National Sales Perspectives™: Retail and Non-Retail

The IQVIA National Sales Perspectives™ measures the volume of drug products, both prescription and over-the-counter, and selected diagnostic products moving from manufacturers into various outlets within the retail and non-retail markets. Volume is expressed in terms of sales dollars, eaches, extended units, and share of market. These data are based on national projections. Outlets within the retail market include the following pharmacy settings: chain drug stores, independent drug stores, mass merchandisers, food stores, and mail service. Outlets within the non-retail market include clinics, non-federal hospitals, federal facilities, HMOs, long-term care facilities, home health care, and other miscellaneous settings.

Syneos Health Research & Insights LLC., TreatmentAnswers™

Syneos Health Research & Insights, LLC., TreatmentAnswers™ and TreatmentAnswers™ with Pain Panel is a monthly survey designed to provide descriptive information on the patterns and treatment of diseases encountered in office-based physician practices in the U.S. The survey consists of data collected from over 3,200 office-based physicians representing 30 specialties across the United States that report on all patient activity during one typical workday per month.

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These data may include profiles and trends of diagnoses, patients, drug products mentioned during the office visit and treatment patterns. The Pain Panel supplement surveys over 115 pain specialists physicians each month. With the inclusion of visits to pain specialists, this will allow additional insight into the pain market. The data are then projected nationally by physician specialty and region to reflect national prescribing patterns.

Results should not be overstated when nationally projected estimates of annual uses or mentions fall below 100,000 as the sample size is very small with correspondingly large confidence intervals.. Data below 100,000 (mentions) do not represent sufficient portion of the population and is not representative of actual physician prescribing habits at a national level. In general, this physician survey database is most appropriate to identify the typical uses for a product in office-based physician's clinical practice. Therefore, the patient exposure estimates reported in this review may not apply to other settings of care or other specialty offices in which these products may be prescribed or dispensed.

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8.3 APPENDIX C. FAERS AND LITERATURE LINE LISTING OF HEPATOBILIARY EVENTS WITH KETAMINE CASE SERIES (N=20)

	Initial FDA Received Date (YYYY)	FAERS Case #	Version #	Manufacturer Control #	Case Type	Age (years)	Sex	Country Derived	Serious Outcome(s)*	Hepatobiliary Event	WHO Causality Assesment
1	2002	3875443	1	061-0945-M0200098	Expedited (15-Day)	66	F	AUS	HO	increased ALP, GGT, ALT, AST	possible
2	2003	4010195	3	BE-JNJFOC-20030902027	Expedited (15-Day)	72	M	BEL	HO	chronic active hepatitits, hepatic fibrosis, increased GGT, cholangitis	possible
3	2010	7239418	3	FR-BAYER-201010444GPV	Expedited (15-Day)	53	F	FRA	HO	increased ALP, GGT, ALT, AST	possible
4	2011	8311223	1	JP-JNJFOC-20111210634	Expedited (15-Day)	50	F	JPN	OT	unsp liver disorder	possible
5	2012	8341142	1	N/A	Direct	50	F	USA	NR	increased ALT, AST	probable
6	2014	10398893	1	GB-PAR PHARMACEUTICAL, INC-2014SCPR009340	Expedited (15-Day)	55	F	GBR	OT	liver cirrhosis, biliary dilation, increased ALP, ALT, AST, GGT	possible
7	2015	10740815	4	US-PFIZER INC-2015029624	Expedited (15-Day)	49	F	USA	OT	unsp liver enzymes increased	possible
8	2016	11968665	1	US-PAR PHARMACEUTICAL COMPANIES-2016SCPR015101	Expedited (15-Day)	58	F	USA	OT	Liver injury, increased AST, ALT, ALP	probable
9	2016	12644054	1	FR-PFIZER INC-2016378768	Expedited (15-Day)	48	F	FRA	HO	hepatic cytolysis, elevated	possible

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	Initial FDA Received Date (YYYY)	FAERS Case #	Version #	Manufacturer Control #	Case Type	Age (years)	Sex	Country Derived	Serious Outcome(s)*	Hepatobiliary Event	WHO Causality Assesment
										LFTs (unsp)	
10	2016	12801413	1	FR-ROCHE-232584	Expedited (15-Day)	60	M	FRA	DE,HO	intrahepatic cholestasis, elevated t bili, d bili, GGT, ALP, AST, ALT	possible
11	2017	14227949	2	AU-PFIZER INC-2017501613	Expedited (15-Day)	42	M	AUS	HO	severe cholangiopathy, jaundice and cholangistis, biliary dilation elevated bilirubin, ALP, GGT, ALT, AST	probable
12	1995	Kato-Case1	N/A	N/A	Literature	70	M	JPN	NR	jaundice, increased ALP, GGT, tbil, dbil, AST, ALT, imaging showing deformity of the liver, and biopsy with "extensive pericholeductal fibrosis compatible with drug-induced hepatitis"	possible
13	1995	Kato-Case2	N/A	N/A	Literature	83	F	JPN	NR	increased ALP, GGT, AST, ALT	probable

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	Initial FDA Received Date (YYYY)	FAERS Case #	Version #	Manufacturer Control #	Case Type	Age (years)	Sex	Country Derived	Serious Outcome(s)*	Hepatobiliary Event	WHO Causality Assesment
14	2004	Correll - Case 1 (patient 9)	N/A	N/A	Literature	33	M	AUS	NR	elevated LFTs (unsp)	probable
15	2004	Correll - Case 2 (patient 21)	N/A	N/A	Literature	46	M	AUS	NR	elevated LFTs (unsp)	probable
16	2004	Correll - Case 3 (patient 25)	N/A	N/A	Literature	45	M	AUS	NR	elevated LFTs (unsp)	possible
17	2004	Correll - Case 4 (patient 30)	N/A	N/A	Literature	47	M	AUS	NR	elevated LFTs (unsp)	probable
18	2011	Noppers-Case1 (patient A)	N/A	N/A	Literature	65	F	NLD	NR	elevated LFTs (unsp)	probable
19	2011	Noppers-Case2 (patient E)	N/A	N/A	Literature	48	F	NLD	NR	elevated LFTs (unsp)	probable
20	2011	Noppers-Case3 (patient F)	N/A	N/A	Literature	46	M	NLD	NR	elevated ALT, GGT	probable

*As per 21 CFR 314.80, the regulatory definition of serious is any adverse drug experience occurring at any dose that results in any of the following outcomes: Death, a life-threatening adverse drug experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect, and other serious important medical events. This outcome should not be confused with the clinical outcome of the reported adverse drug experience. Those which are blank were not marked as serious (per the previous definition) by the reporter, and are coded as non-serious. A report may have more than one serious outcome.
Abbreviations: DE=Death, HO=Hospitalization, OT=Other medically significant, N/A = not applicable, NR = not reported, AUS = Australia, JPN = Japan, NLD = Netherlands, USA = United states of America, BEL = Beligium, FRA = France, LFTs = Liver Function Tests, ALT = alanine aminotransferase, AST = aspartate aminotransferase, ALP = alkaline phosphatase, GGT = Gamma-glutamyl transferase, tbili = total bilirubin, dbili = direct bilirubin

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8.4 APPENDIX D. WORLD HEALTH ORGANIZATION-UPPSALA MONITORING CENTRE (WHO-UMC) CAUSALITY ASSESSMENT CATEGORIES

World Health Organization-Uppsala Monitoring Centre (WHO-UMC) Causality Assessment Categories[48]	
Causality term	**Assessment criteria**
Certain	*Due to the spontaneous nature and quality of FAERS reports, no case would be considered certain.*
Probable/Likely	• Event or laboratory test abnormality, with reasonable time relationship to drug intake • Unlikely to be attributed to disease or other drugs • Response to withdrawal clinically reasonable • Rechallenge not required
Possible	• Event or laboratory test abnormality, with reasonable time relationship to drug intake • Could also be explained by disease or other drugs • Information on drug withdrawal may be lacking or unclear
Unlikely	• Event or laboratory test abnormality, with a time to drug intake that makes a relationship improbable (but not impossible) • Disease or other drugs provide plausible explanations
Conditional/ Unclassified	• Event or laboratory test abnormality • More data for proper assessment needed, or • Additional data under examination
Unassessable/ Unclassifiable	• Report suggesting an adverse reaction • Cannot be judged because information is insufficient or contradictory • Data cannot be supplemented or verified

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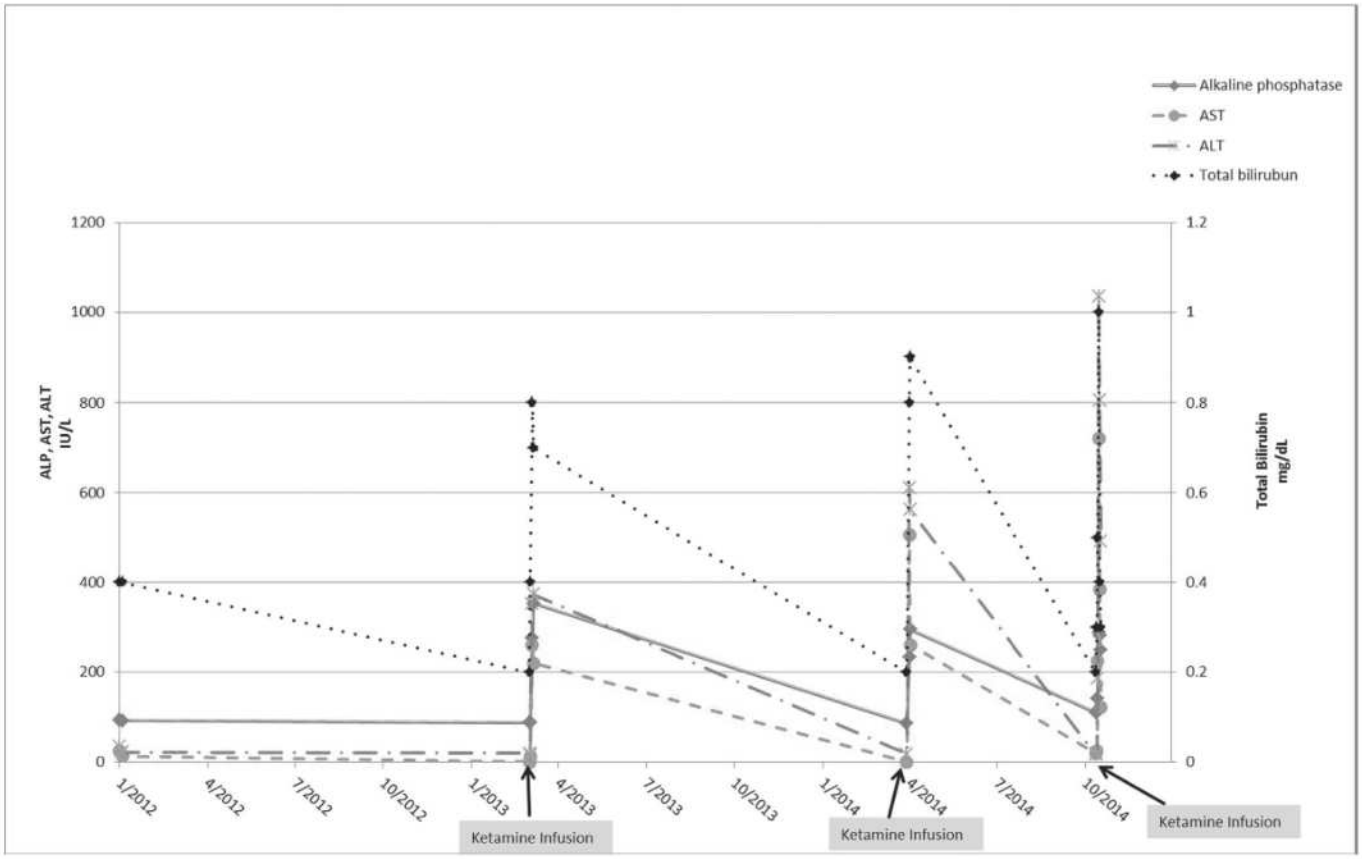
8.5 APPENDIX E. DECHALLENGE RECHALLENGE INFORMATION FOR LITERATURE CASE REPORT BY TOFANI C, ET AL.



8.6 APPENDIX F. NATIONAL INSTITUTES OF HEALTH LIVERTOX CATEGORIZATION OF THE LIKELIHOOD OF DRUG INDUCED LIVER INJURY SCALE [49]

Category A.	The drug is well known, well described and well reported to cause either direct or idiosyncratic liver injury, and has a characteristic signature; more than 50 cases including case series have been described.
Category B.	The drug is reported and known or highly likely to cause idiosyncratic liver injury and has a characteristic signature; between 12 and 50 cases including small case series have been described.
Category C.	The drug is probably linked to idiosyncratic liver injury, but has been reported uncommonly and no characteristic signature has been identified; the number of identified cases is less than 12 without significant case series.
Category D.	Single case reports have appeared implicating the drug, but fewer than 3 cases have been reported in the literature, no characteristic signature has been identified, and the case reports may not have been very convincing. Thus, the agent can only be said to be a possible hepatotoxin and only a rare cause of liver injury.

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Category E.	Despite extensive use, no evidence that the drug has caused liver injury. Single case reports may have been published, but they were largely unconvincing. The agent is not believed or is unlikely to cause liver injury.
Category E.	The drug is suspected to be capable of causing liver injury or idiosyncratic acute liver injury but there have been no convincing cases in the medical literature. In some situations cases of acute liver injury have been reported to regulatory agencies or mentioned in large clinical studies of the drug, but the specifics and details supportive of causality assessment are not available. The agent is unproven, but suspected to cause liver injury.
Category X.	For medications recently introduced into or rarely used in clinical medicine, there may be inadequate information on the risks of developing liver injury to place it in any of the five categories, and the category is characterized as "unknown."
Categorization Of The Likelihood Of Drug Induced Liver Injury. Accessed on 9/6/2018 at https://livertox.nih.gov/DrugCategory.html	

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9.2. Attachment 2

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Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology
Division of Epidemiology II

Drug Abuse Epidemiology Review

Date: January 7, 2019

Primary Reviewers: Amy Seitz, PhD, MPH, Epidemiologist
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Division of Epidemiology II

Subject: **NDA 211243 – esketamine**
Abuse and misuse of ketamine and associated harms

****This document contains proprietary drug use data and American Association of Poison Control Centers data obtained by FDA under contract. These data/information cannot be released to the public/non-FDA personnel without contractor approval obtained through the FDA/CDER Office of Surveillance and Epidemiology. All product codes must be redacted for public release.****

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VA-19-1109-B-001949

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EXECUTIVE SUMMARY

Ketamine is a rapidly acting dissociative anesthetic, marketed in the U.S. since the 1970s for use in humans and animals. For many decades, ketamine has been reported as a drug of abuse, and in 1999, ketamine and its salts were designated as Schedule III substances under the Controlled Substances Act. Ketamine is abused for its dissociative and hallucinogenic effects and has been termed a "club drug" or "party drug" because of its popularity for use at nightclubs and raves. According to the DEA, most of the ketamine illegally distributed in the U.S. is diverted or stolen from legitimate sources such veterinary clinics or smuggled from Mexico and then sold or shared at parties or nightclubs.

For this review, drug utilization data are referenced from **Attachment 1** of this briefing document to provide context for recent data on ketamine abuse. Previously published literature and national estimates from National Survey on Drug Use and Health and the Monitoring the Future survey are provided to understand the prevalence of ketamine abuse. We also provide information on ketamine abuse and associated adverse outcomes, analyzing data from calls to U.S. poison centers (National Poison Data System), emergency department visits (National Electronic Injury Surveillance System-Cooperative Adverse Drug Event), and spontaneous adverse event reports (FDA Adverse Drug Event Reporting System).

Based on national sales distribution patterns of ketamine vials (excluding veterinary sales), ketamine utilization appears to be largely in the hospital setting. Ketamine sales increased approximately 72% from 2013 to 2017 overall and sales to clinic settings, specifically, more than doubled during this five-year period. Numerous off-label uses of ketamine have been proposed and implemented, including treatment resistant depression, and recent literature suggests growth in some of these off-label uses of ketamine.

National survey data and the published literature indicate that ketamine abuse is relatively uncommon in the general population, with a reported lifetime prevalence of 1.3% among persons age 12 years and older, which is lower than that for other hallucinogens such as ecstasy and LSD (Acid). Among 12th graders, the annual prevalence of ketamine use has declined from 2.5% in 2000 to 1.2% in 2017. Exposure calls to U.S. poison centers involving ketamine abuse or misuse also declined slightly from 2013 to 2017 (176 calls in 2013 to 116 calls in 2017), despite the growth in non-veterinary ketamine sales. Single-substance exposure calls to poison control centers involving ketamine abuse or misuse were most commonly associated with minor or moderate health effects, and there were no deaths identified among these calls. In a representative sample of approximately 60 U.S. emergency departments, there were 44 ketamine-related ED cases in 2016-2017, corresponding to an estimated 669 visits nationally. Of the 44 ketamine-related ED cases, 35 (81.5%) were classified as abuse. Only six (17.1%) of these cases resulted in hospitalization. From 2015-2017, the FDA Adverse Event Reporting System (FAERS) received 17 reports of death involving ketamine abuse. Of note, only one of these reports listed ketamine as the only suspected drug, and the drug-event causal association has not been assessed for any of these FAERS cases.

Overall, this analysis suggests that ketamine abuse continues to occur but has remained relatively limited with modest associated harms. The available data are insufficient to determine the extent to which U.S. pharmaceutical ketamine for humans contributes to abuse, relative to ketamine that is smuggled into the country or diverted from veterinary settings. Nonetheless, the risks of abuse

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and associated harms are important considerations in determining appropriate risk mitigation strategies and post marketing surveillance for esketamine, if approved.

1. INTRODUCTION

The Division of Epidemiology II (DEPI) was asked by the FDA Controlled Substances Staff to provide current information on ketamine abuse and misuse and associated adverse events, for consideration at the joint meeting of the Psychopharmacologic Drugs and the Drug Safety and Risk Management Advisory Committees on February 12, 2019. The committees will discuss the New Drug Application 211243 for esketamine, an enantiomer of ketamine, for treatment resistant depression in adults.

Ketamine is a noncompetitive antagonist of N-methyl-D-asparate (NMDA) receptor and is a rapidly acting dissociative anesthetic marketed in the U.S. since the 1970s for use in humans and animals. In humans, it is indicated for 1) diagnostic and surgical procedures that do not require skeletal muscle relaxation, as the sole anesthetic, 2) administration prior to other general anesthetic agents, and 3) supplementing low-potency agents, such as nitrous oxide.(1) In the U.S., injectable ketamine is the only approved formulation for humans. Since the time of its approval, numerous off-label uses of ketamine have been proposed and implemented, including, but not limited to, treatment of complex-regional pain syndrome (CRPS), chronic pain, and treatment resistant depression.(2-6) Emerging literature describes some of these off-label uses of ketamine,(3, 7) providing some standardization, but in practice, treatment regimens can vary.

Ketamine has been reported in the literature as a drug of abuse for many decades, and in 1999, ketamine and its salts were designated as Schedule III substances under the Controlled Substances Act. Also known as "Special K" and by multiple other slang terms, ketamine is abused for its dissociative and hallucinogenic effects and has been termed a "club drug" or "party drug" because of its popularity for use at nightclubs and raves.(8, 9) Due to its sedative and amnesic effects, ketamine has also been used for facilitating sexual assault and nonconsensual sexual intercourse.(8, 9) Powdered ketamine can be snorted or smoked, and liquid ketamine can be injected, mixed into drinks, placed on materials to be smoked, or evaporated by heating and ground into a powder.(8, 9) According to the DEA, most of the ketamine illegally distributed in the U.S. is diverted or stolen from legitimate sources such veterinary clinics or smuggled from Mexico and then sold or shared at parties or nightclubs.(8)

The purpose of this review is to provide current information on the scope and patterns of ketamine abuse and associated harms in the U.S.

2 MATERIAL AND METHODS

This review includes information from the epidemiologic literature, the National Electronic Injury Surveillance System-Cooperative Adverse Drug Event (NEISS-CADES) database, the American Association of Poison Control Centers (AAPCC) National Poison Data System (NPDS), the National Survey on Drug Use and Health (NSDUH), and the Monitoring the Future (MTF) survey. Also, we considered estimates of annual U.S. sales of ketamine vials analyzed by the DEPI-Drug Use team for a previous review (October 2018, DARRTS ref ID 4367425) and

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FDA Adverse Event Reporting System (FAERS) results analyzed by the Division of Pharmacovigilance for a previous memo (October 2017; DARRTS ref ID 4161583).

The purpose for including multiple data sources is to provide a robust description of ketamine abuse and misuse through complementary data sources because each of these data sources has strengths and limitations. Details on each data source are provided below. Definitions of misuse and abuse vary by data source and will be described as appropriate. The following standard regulatory definitions of misuse/abuse were applied throughout this review, unless otherwise indicated:(10, 11)

Misuse: the intentional therapeutic use of a drug product in an inappropriate way and specifically excludes the definition of abuse

Abuse: the intentional, non-therapeutic use of a drug product or substance, even once, to achieve a desirable psychological or physiological effect

2.1 Drug Utilization

Drug utilization data provide context for data on misuse and abuse of pharmaceutical products. For drug utilization information, we referenced the recent integrated review by the Division of Pharmacovigilance (DPV) II and DEPI-Drug Use (DARRTS ref ID 4367425), which is included in this briefing document as **Attachment 1**. This review focused on the hepatobiliary and cognitive impairment adverse events associated with repeated off-label use of ketamine and also provided results of a sales and distribution analysis from the IQVIA, National Sales Perspectives (NSP) database.

2.2 Pharmacoepidemiology Literature Search

Using the search terms and parameters described in **Table 2.2**, DEPI II conducted a literature search using PubMed.gov to identify recent published observational epidemiologic studies on ketamine misuse and abuse, and their consequences (e.g., addiction/ substance use disorder, overdose).

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Table 2.2 Literature Search Strategy	
Date of Search	November 29, 2018
Database	PubMed
Search Terms	Ketamine, ketalar, abuse, addiction, diversion, substance use disorder, misuse
Search parameters	(((((((ketamine[tw] OR ketalar) AND (abuse[tw] OR abuses[tw] OR addiction[tw] OR addictions[tw] OR diversion[tw] OR "drug dependence"[tw] OR "substance use disorder"[tw] OR "substance use disorders"[tw] OR substance-related disorders[tw] OR substance-related disorder[tw] OR "drug misuse"[tw] OR "drug misuses"[tw])))) AND English[Language]) NOT (("Animals"[Mesh] NOT ("Animals"[Mesh] AND "Humans"[Mesh])))))) AND ("2016"[Date - Publication] : "2018"[Date - Publication])))) AND ("2016/01/01"[Date - Publication] : "2018/11/28"[Date - Publication])
Years included in search	2016-2018
Other criteria	English language articles, observational epidemiologic studies
Note: In addition to the search strategy above, we mined primary sources from secondary references	

2.3 National Survey on Drug Use and Health (NSDUH)

The National Survey on Drug Use and Health (NSDUH) is an annual survey conducted nationwide by the Substance Abuse and Mental Health Services Administration (SAMHSA). NSDUH collects information on drug use, mental health, and other health related issues with the goal of providing accurate, nationally representative data about the use of alcohol, tobacco, other drugs and substance use and misuse. NSDUH also aims to "assess the consequences of substance use and misuse." Information is collected from civilian, noninstitutionalized participants aged 12 years and older. Population subgroups not covered by the survey include individuals residing within institutional facilities (e.g., jails, nursing homes), as well as those without a permanent address (e.g., homeless individuals). The survey is conducted in a face-to-face manner, and during the year 2017, the interview response rate of 50.4% included 68,032 completed interviews.(12) In NSDUH, misuse is defined as "*use in a way not directed by a doctor, including use without a prescription of one's own; use in greater amounts, more often, or longer than told to take a drug; or use in any other way not directed by a doctor."* However, because NSDUH categorizes ketamine as a hallucinogen and includes it in the same section with illicit drugs such as cocaine and heroin, misuse of ketamine is termed "*ketamine use*."(12, 13)

A partial redesign of the NSDUH questionnaire occurred in 2015 so trends are limited for many estimates.(12) We extracted and summarized information on hallucinogens and ketamine use from the most recent publicly available reports of NSDUH results.(12, 13)

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2.4 MONITORING THE FUTURE (MTF)

The Monitoring the Future survey (MTF) is an annual survey monitoring the "behaviors, attitudes, and values of American secondary school students, college students, and young adults." The survey is supported with grants from the National Institute on Drug Abuse, National Institutes of Health.(14)

MTF uses the term "misuse" for prescription medications to mean "use outside of a doctor's orders." They describe ketamine abuse and misuse as the annual prevalence of use, meaning "the percent of the study sample that report using a drug once or more during a given period- i.e. past 12 months."(15) We extracted and summarized the findings relating to ketamine from the published report of 2017 MTF survey results.

2.5 NATIONAL POISON DATA SYSTEM (NPDS) ANALYSIS

The NPDS database includes calls from individuals, healthcare professionals, and other interested persons regarding exposures to prescription drugs, over-the-counter medications, unapproved products, and other substances, to all poison control centers in the U.S.(16) NPDS is managed by the American Association of Poison Control Centers (AAPCC). The AAPCC Annual Report contains additional information.(17)

The NPDS calls for exposures may result in provision of information or advice regarding medical management, and AAPCC staff managing these calls undergo training to standardize documentation across centers. Documentation of calls includes detail on the drug(s), patient characteristics, route of exposure, reported reasons for exposure, level of care received, medical, and other variables. Reasons for exposure are categorized into groups by AAPCC, and include such categories as "intentional", "unintentional," the former encompassing the subgroups of intentional misuse, abuse, suspected suicide or unknown intent. Additional detail regarding the definition of these variables is provided in **Appendix A** of this review. Medical outcomes are based on all information known at the conclusion of the case and coded as "No effect," "Minor effect," "Moderate effect," or "Major effect." *Medical outcome* was characterized for the subset of calls with a "Related" clinical effect. NPDS defines "Related" clinical effects as exposures where the following criteria are satisfied: the timing and severity of clinical effects are reasonable for the reported exposure, the clinical effect is consistent with the anticipated substance, and the clinical assessment is made by a physician. Exposures with "Related" clinical effects were identified if any listed clinical effect for a given exposure call involving the drug of interest was designated as "(R)." If not appropriate or possible to follow a case, the case is labeled as "case not followed to known outcome." Additional detail regarding the definition of these variables is provided in **Appendix B** of this review. Follow-up calls to NPDS from the same exposure event are recorded as a single exposure; a person can have more than one call for an exposure to the same substance if they happen at different times.

We searched NPDS using the criteria described in **Table 2.3.** For the purposes of this descriptive analysis, we included all "*closed cases*" of human exposure to ketamine, January 1, 2013 to December 31, 2017, including cases with multiple drug exposures. *Closed cases* have been through quality assurance procedures by AAPCC. We identified generic and product codes for pharmaceutical preparations for ketamine, including human and veterinary products from the

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U.S. and other countries (n=105 generic and product codes), using Micromedex® Solutions (**Appendix C of this review**).

Analysis of NPDS consisted of tabulating counts of ketamine exposure calls by year. We separated intentional exposures from unintentional exposures/adverse reactions and cross-tabulated various characteristics of the exposure--i.e., reason for exposure, related medical outcome, number of substances involved, and route of exposure--by year. These analyses were replicated by a second analyst for quality assurance.

Table 2.3. AAPCC-NPDS Search Strategy-Ketamine	
Database	National Poison Data System
Report name	Case Log (Generic and Product Code)
Month/year of query	12/2018
Date range for query	01/01/2013- 12/31/2017
Call type	Exposure
Case status	Closed
Species	Human
Exposure reason	All
Age	0-120 years
Product codes	See Appendix C of this review

2.6 National Electronic Injury Surveillance System- Cooperative Adverse Drug Event Surveillance (NEISS-CADES) Analysis

DEPI consulted with Centers for Disease Control and Prevention to identify ketamine-related adverse drug event (ADE) cases in the NEISS-CADES database. NEISS-CADES data comprise a national stratified probability sample of approximately 60 hospitals with a minimum of 6 beds and a 24-hour ED in the U.S. and its territories. The NEISS-CADES project, which has been described in detail elsewhere, is a joint effort of the Centers for Disease Control and Prevention, the U.S. Consumer Product Safety Commission, and the U.S. Food and Drug Administration.(18-21) In brief, trained coders located at each participating hospital review clinical records of every ED visit to identify clinician-diagnosed drug related adverse events, to report up to 4 medications implicated in each adverse event, and to record narrative descriptions of the incident.

NEISS-CADES has historically focused exclusively on ED visits due to use of medications for a therapeutic indication, or unintended medication exposures by young children. However, in 2016 NEISS-CADES surveillance activities were expanded to represent a wider spectrum of pharmaceutical-related harm, encompassing ED visits resulting from abuse, self-harm, overdoses without indication of intent, therapeutic misuse and assault, in addition to therapeutic adverse drug events.

The 2016-2017 NEISS-CADES database was searched for ADEs related to ketamine, including cases of nonmedical use (i.e., abuse, therapeutic misuse, or overdose with unknown intent), therapeutic adverse event, assault, and self-harm/suicide (search date: November 28, 2018). Definitions for these case types are provided in **Appendix D** of this review**.** National projections of ED visits for ADEs associated with ketamine were estimated using hospital-based sample weights. National projections of the number of cases can only be made when there are sufficient

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number of cases (≥20 cases in the sample and ≥1,200 cases in the national estimate) and level of variability (coefficient of variation ≤0.3).

2.7 FDA Adverse Event Reporting System (FAERS) Case Definition and Search Strategy

FAERS is a database that contains spontaneously reported information on adverse event and medication error reports submitted to FDA. The database is designed to support the FDA's post-marketing safety surveillance program for drug and therapeutic biologic products. FAERS was previously searched by DPV II for ketamine and its abuse, and the results were included in an October 2017 review memo (October 2017; DARRTS ref ID 4161583). The description of the FAERS search below is from this memo.

"For the purposes of this descriptive analysis, we included all serious U.S. reports coded to the Standardized MedDRA Query (SMQ), *Drug abuse, dependence, and withdrawal (SMQ) Broad* and listing ketamine-containing product as a suspect product.

Table 2.7. Ketamine FAERS Search Strategy*

Date of Search	September 11, 2017
Time Period of Search	FDA initial received date: January 1, 2015† - Completed date:‡ September 11, 2017
Search Type	FBIS Quick Query
Product Terms[a]	Product active ingredient: Norketamine; Baclofen\clonidine\ diclofenac\gabapentin\ketamine\prilocaine; Bupivacaine\ cyclobenzaprine\fluticasone\gabapentin\ketamine\ketoprofen; Ketamine hydrochloride; Bupivacaine\clonidine\ cyclobenzaprine\flurbiprofen\ketamine; Amitriptyline\baclofen\ bupivacaine\diclofenac\gabapentin\ketamine; N-Ethylnorketamine; Baclofen\gabapentin\ketamine\ketoprofen; esketamine; Ketamine; Amitriptyline\gabapentin\ketamine; Esketamine hydrochloride; Diazepam\diclofenac sodium \gabapentin\ketamine; Deschloroketamine
MedDRA Search (Version 20.0)	*Drug abuse, dependence, and withdrawal (SMQ) Broad* search
Other Filters	Case outcome: Serious Country (Derived): USA

MedDRA= Medical Dictionary for Regulatory Activities, SMQ = Standardized MedDRA Query
* See **Appendix E** of this review for a description of the FAERS database is included in the integrated review by DPV II and DEPI Drug Use, included as an appendix to this briefing document.
† The search dates used represent recent use and were requested by the consultant – the Controlled Substance Staff.
‡ FDA data entry completion date.

[a] Product terms were used to encompass all potential formulations for off-label use

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3 RESULTS

3.1 DRUG UTILIZATION

As described in the recent DPV II and DEPI Drug Use review (included as **Attachment 1** of this background package), (DARRTS ref ID 4367425), the estimated total number of ketamine vials sold from manufacturers to all settings of care increased approximately 72% from 2013 to 2017, from 1.2 million vials to 2.1 million vials, respectively. In 2017, the largest proportion of ketamine vials were sold to non-federal hospitals, at approximately 54%, followed by 37% and 9% of vials sold to clinics and all other channels, respectively. Although manufacturer sales of ketamine to all channels of distribution increased; the increase was most notable in the clinic settings, where the number of vials sold more than doubled, from an estimated 332,000 vials sold in 2013 to 765,500 vials sold in 2017. Veterinary sales were not included in this analysis.

Data on indication for use were not available for ketamine, however recent publications propose numerous off-label uses(2-6) and guidelines for off-label use,(3, 7) suggesting an increasing interest in ketamine for off-label uses.

3.2 PHARMACOEPIDEMIOLOGY LITERATURE SEARCH

A total of 200 articles were identified using the search strategy described in **Table 2.2**. Of these 200 articles, 36 were determined to be relevant to this review, and additional articles were identified by mining primary sources through these articles. Articles included reviews, observational epidemiology studies, and ecologic studies. Individual case reports and case series were identified in the search but not included as part of the epidemiologic review.

Published reviews and other studies indicate that ketamine abuse began soon after its approval as an anesthetic agent in 1970, but its popularity at dance clubs and raves rose in the 1980s and 1990s.(22-24) Ketamine is described as a drug abused as a recreational drug worldwide, often in the setting of electronic music parties and dance clubs, and has also been used for drug-facilitated sexual assault.(22-24) Illicit ketamine is available as aqueous solution, capsules, powder, crystals and tablets.(22) Adulterants are often added to the illicit formulations, especially in tablets. Ketamine is also used as an adulterant of ecstasy.(22, 25) Ketamine can be abused by insufflating powder, but ingesting, smoking or injecting are also routes of administration for abuse, depending on the form.(9, 22, 24)

Multiple articles describe harms from ketamine abuse. One review of published case studies and case series focused on people in Hong Kong who abuse ketamine, describing urological complications, neuropsychiatric complications, hepatobiliary complications, and gastrointestinal complications.(26) One study from Taiwan described sexual and bladder dysfunction associated with ketamine abuse among participants presenting at clinics and men who encountered law enforcement.(27)

Original observational epidemiology studies described patterns of illegal drug use, including ketamine abuse, in specific populations such as people who had used ecstasy in the past year, men who have sex with men and persons attending dance clubs.(28-30) The prevalence of ketamine abuse varied by the population studied. For example, in a study conducting secondary analysis of NSDUH data, 6.5% of people ages 12-34 years who had used ecstasy in the past-year

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(N=332,560) reported past-year ketamine use in 2013-2014.(30) In a cohort of Australian gay and bisexual men (N=1,710), the twelve-month incidence rate of ketamine use (i.e., abuse or misuse) was 2.1 per 100 person-years, and varied by age group from 4.1 per 100 person-years for ages 16-24 years to 0.98 per 100 person-years for persons 40 years and older.(29) Multiple other studies report epidemiology of ketamine abuse and other illicit drugs in specific populations, many using convenience samples in non-U.S. populations.(31-33)

3.3 National Survey on Drug Use and Health (NSDUH)

In 2017, 1.3% of NSDUH survey respondents aged 12 or older reported using ketamine during their lifetime, corresponding to an estimated 3.4 million U.S. residents (Table 3.3a). Those aged 18-25 years had the highest prevalence, with 1.8% in 2017 reporting lifetime ketamine use. This was much lower compared to lifetime use of other hallucinogens. For example, 7.0% of respondents aged 12 years and older and 12.0% of respondents aged 18-25 years reported lifetime use of ecstasy. For LSD, 9.6% of respondents aged 12 years and older and 9.1% of respondents aged 18-25 years reported lifetime use. For hallucinogens overall (including ketamine), 15.5% of respondents aged 12 years and older and 17.1% of respondents aged 18-25 years reported lifetime use. For additional context, among respondents 12 years and older 45.2% of respondents reported lifetime use of marijuana, 14.9% reported lifetime use of cocaine, and 1.9% reported lifetime use of heroin in 2017 (data not shown).

Table 3.3a. Reported Lifetime Use of Ketamine and Related Drugs, by Age Group, National Survey on Drug Use and Health, 2017

		Aged 12 years or older	Aged 12-17 years	Aged 18 years or older	Aged 18-25 years	Aged 26 years or older
Ketamine	Percent reporting lifetime use	1.3	0.2	1.4	1.8	1.3
	Estimated number (in thousands)	3,463	46	3,417	632	2,785
Ecstasy	Percent reporting lifetime use	7.0	1.0	7.7	12.0	7.0
	Estimated number (in thousands)	19,173	257	18,915	4,105	14,811
LSD (Acid)	Percent reporting lifetime use	9.6	1.5	10.4	9.1	10.6
	Estimated number (in thousands)	26,069	364	25,705	3,125	22,581
Hallucinogens (including ketamine)	Percent reporting lifetime use	15.5	2.8	16.7	17.1	16.7
	Estimated number (in thousands)	42,072	700	41,372	5,859	35,513

Source: "Table 1.96A Specific Hallucinogen, Inhalant, Needle, Heroin, and other Drug Use in Lifetime among Persons Aged 12 or Older, by Age Group: Numbers in Thousands, 2016 and 2017 and Table 1.96B Specific Hallucinogen, Inhalant, Heroin and other Drug Use in Lifetime among Persons Aged 12 or Older, by Age Group:

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Percentages, 2016 and 2017; SAMHSA, Center for Behavioral Health Statistics and Quality, National Survey on Drug Use and Health, 2016 and 2017"(13)

The 2017 NSDUH Key Substance Use and Mental Health Indicators in the United States: Results from the 2017 National Survey on Drug Use and Health does not report past month or past year ketamine use separately but describes past month hallucinogen use, a category which includes ketamine, LSD, ecstasy and others.(12) Table 3.3b shows the estimated prevalence of past month use of hallucinogens, by age group, in 2017. Not surprisingly, past month estimates are considerably lower than lifetime prevalence estimates in all age groups (Table 3.3a).

Table 3.3b. Reported Past Month Hallucinogen Use, by Age Group, National Survey on Drug Use and Health, 2017

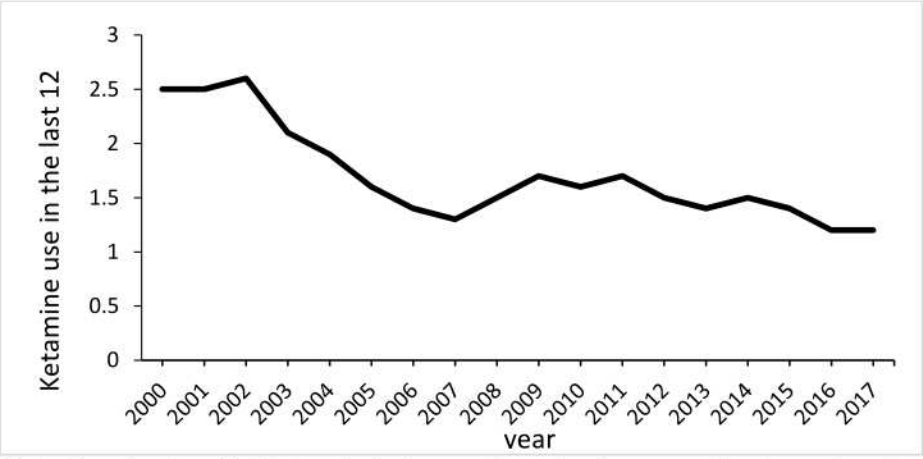
	Aged 12 years or older	Aged 12 to 17 years	Aged 18 to 25 years	Aged 26 years or older
Percent using in past month	0.5	0.6	1.7	0.3
Number (in thousands)	1,400	143	594	701

Source: "Figure 11. Numbers of Past Month Illicit Drug Users among People Aged 12 or Older: 2017. and Figure 17. Past Month Hallucinogen Use Among People Aged 12 or Older, by Age Group: Percentages, 2017. SAMHSA, Center for Behavioral Health Statistics and Quality, National Survey on Drug Use and Health, 2017.(12)

3.4 MONITORING THE FUTURE (MTF)

Among 12th graders, the estimated annual prevalence of ketamine use declined from 2.5% in 2000 to 1.2% in 2017 (1.4% for males and 0.7% for females), as shown in **Figure 3.4**.(15)

Figure 3.4 Annual prevalence of ketamine use among 12th graders, Monitoring the Future, 2000-2017



Note: In order to maintain trends during questionnaire changes, estimates are based on varying proportions of the sampled populations in some years. See MTF documentation for details(15)
Source: The Monitoring the Future study, the University of Michigan, Table 5-2. Long-Term Trends in Annual Prevalence of Use of Various Drugs for Grade 12(15)

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Estimated annual prevalence of use for ketamine and select additional drugs from 2008 to 2017 are presented in **Table 3.4** for context. The data suggest that, among 12th graders, the percentage who used ketamine in the last 12 months was generally lower than for other drugs, with the exception of heroin. In 2017, the he estimated annual prevalence of use for ketamine was most similar to that of Ritalin and inhalants. From 2007 to 2017, the percentage of 12th graders reporting past-year use of ketamine, Ritalin, OxyContin, Vicodin, heroin, inhalants, over the counter cough/cold medicines and cocaine all declined slightly.

Table 3.4 Trends in annual prevalence of use of ketamine and other drugs in Grade 12, 2008-2017, percentage who used in the last 12 months

	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
Ketamine	1.5	1.7	1.6	1.7	1.5	1.4	1.5	1.4	1.2	1.2
Ecstasy[a]	--	--	--	--	--	--	5.0	3.6	2.7	2.6
Ritalin[b]	3.4	2.1	2.7	2.6	2.6	2.3	1.8	2.0	1.2	1.3
OxyContin[b]	4.7	4.9	5.1	4.9	4.3	3.6	3.3	3.7	3.4	2.7
Vicodin[b]	9.7	9.7	8.0	8.1	7.5	5.3	4.8	4.4	2.9	2.0
Heroin	0.7	0.7	0.9	0.8	0.6	0.6	0.6	0.5	0.3	0.4
LSD	2.7	1.9	2.6	2.7	2.4	2.2	2.5	2.9	3.0	3.3
Inhalants	3.8	3.4	3.6	3.2	2.9	2.5	1.9	1.9	1.7	1.5
OTC Cough/ Cold Medicines[c]	5.5	5.9	6.6	5.3	5.6	5.0	4.1	4.6	4.0	3.2
Cocaine	4.4	3.4	2.9	2.9	2.7	2.6	2.6	2.5	2.3	2.7
Marijuana/ Hashish	32.4	32.8	34.8	36.4	36.4	36.4	35.1	34.9	35.6	37.1

Note: In order to maintain trends during survey changes, data for multiple years and multiple drugs are based on varying proportions of the sampled populations. See MTF documentation for details.(15)
[a] This question was revised in 2014 and earlier years are not presented due to this change.
[b] Only use not under a doctor's orders is included here.
[c] Only use "to get high" is included here.

Source: The Monitoring the Future study, the University of Michigan, Table 5-2. Long-Term Trends in Annual Prevalence of Use of Various Drugs for Grade 12

3.5 National Poison Data System (NPDS) Analysis

From January 1, 2013 to December 31, 2017 there were 1,454 ketamine exposure calls to U.S. poison control centers. The majority of these calls (67.8%) were due to intentional exposures, and intentional abuse and misuse contributed to more than half of all exposure calls (53.5%). Characteristics of all ketamine exposure calls and abuse and misuse exposure calls are described in **Table 3.5a and 3.5b,** respectively.

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Table 3.5a. Ketamine Exposure calls in the U.S. National Poison Data System, January 1, 2013 to December 31, 2017						
Year	**2013 N**	**2014 N**	**2015 N**	**2016 N**	**2017 N**	**Total**
Total Exposures	309	327	308	260	250	1454
Intentional	208	227	223	164	164	986
Suspected suicide	24	32	32	35	38	161
Abuse	169	174	165	114	109	731
Misuse	7	12	14	7	7	47
Unknown	8	9	12	8	10	47
Unintentional	62	63	43	57	55	280
Adverse Reactions	22	21	17	23	21	104
Other	11	7	17	7	6	48
Unknown	6	9	8	9	4	36

Source: American Association of Poison Control Centers- National Poison Data System, January 1, 2013-December 31, 2017.

Among the 778 intentional abuse and misuse ketamine exposure calls, a little more than half (53.4%) involved only one substance. Among cases with only one substance, moderate effect was the most frequent related clinical effect, and ingestion was the most commonly reported route of exposure. Inhalation was the second most frequent route of exposure. Multiple routes of exposure could be selected for a single case. These descriptive characteristics for intentional abuse and misuse exposures are shown below in **Table 3.5b**.

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Table 3.5b. Descriptive Case Characteristics of Ketamine Intentional Abuse and Misuse Exposure Calls in the U.S. National Poison Data System, January 1, 2013 to December 31, 2017						
Year	**2013**	**2014**	**2015**	**2016**	**2017**	**Total**
Total Intentional Abuse and Misuse	176	186	179	121	116	778
Number of substances						
Single	103	96	99	61	57	416
Multiple	73	90	80	60	59	362
Related Medical Outcome (single-substance exposures only)[a,b]						
No clinical effect	0	0	0	0	0	0
Minor effect	25	17	21	14	11	88
Moderate effect	51	37	43	23	24	178
Major effect	1	10	6	8	5	30
Death[c]	0	0	0	0	0	0
Other[d]	11	9	9	5	7	41
Route of exposure (single-substance exposures only)[a,e]						
Ingestion	41	43	39	29	22	174
Inhalation	30	34	39	17	24	144
Dermal	1	2	1	0	0	4
Parenteral	23	9	9	8	8	57
Other[f]	12	11	13	9	6	51

[a] Related medical outcome and route of exposure were characterized only for the subset of patients with single-substance exposure
[b] Medical outcomes among individuals with a related clinical effect.
[c] Includes "death" and "death, indirect report"
[d] Other includes: Not followed, judged as nontoxic exposure (clinical effects not expected), Not followed, minimal clinical effects possible (no more than minor effect possible)
[e] Multiple routes are possible for a single exposure.
[f] Other (Route) includes: aspiration (with ingestion), ocular, other, other (not ingestion, bite/sting or dermal), otic, rectal, unknown, and vaginal

Source: American Association of Poison Control Centers- National Poison Data System, January 1, 2013-December 31, 2017.

3.6 National Electronic Injury Surveillance System- Cooperative Adverse Drug Event Surveillance (NEISS-CADES) Analysis

In 2016-2017, based on 44 surveillance cases, there were an estimated 669 (95% CI 949-3,628) ED visits nationally for adverse events related to ketamine. Of the 44 cases identified in the surveillance sample, 35 (81.5% [95% CI 61.0-100.0%]) were classified as abuse. National estimates of the number of ED visits due to ketamine abuse were not stable due to a high coefficient of variation (>0.30). Of the 35 cases involving abuse, six were hospitalized. Routes of ketamine abuse included swallowing, inhaling/snorting and IV injection; however, in most cases the route of administration was unknown. No cases were found for overdose without indication of intent or therapeutic misuse. **Table 3.6** describes the NEISS-CADES cases for ketamine related ED cases.

Most (60%) of the 35 abuse cases also involved illicit drugs (cocaine, heroin, marijuana, methamphetamine, fentanyl, or other), alcohol, or both. Of all the ketamine abuse cases, 10

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involved another approved medication, dietary supplement, homeopathic product, or vaccine (data not shown).

Table 3.6 Ketamine Related Emergency Department Cases, National Electronic Injury Surveillance System- Cooperative Adverse Drug Event Surveillance Sample, 2016-2017

	Abuse	Therapeutic Use	Assault	Total
Total	35	8	1	44
Route				
Oral	1	0	1	2
Nasal	6	1	0	7
Injection	3	4	0	7
Infusion	0	1	0	1
Unknown	25	2	0	27
Medical disposition				
Hospitalized	6	1	0	7
Not hospitalized[a]	29	7	1	37

[a]Includes "left without being seen LWBS/ left against medical advice LAMA" (n=3 for abuse)

Source: National Electronic Injury Surveillance System – Cooperative Adverse Drug Event Surveillance (NEISS-CADES), 2016-2017.

3.7 FDA Adverse Event Reporting System (FAERS)

Below is a summary of results of the FAERS search conducted by DPV II for a memo on ketamine abuse in October 2017. (DARRTS ref ID 4161583)

The FAERS search from January 1, 2015 to September 11, 2017 for serious U.S. cases of ketamine associated with drug abuse retrieved 39 reports. Abuse reports for ketamine include all reports coded under the MedDRA *Drug abuse, Dependence, and Withdrawal (SMQ) Broad,* including reports coded to the preferred term (PT) Intentional product misuse. These reports have not been manually reviewed and, as such, the data may contain duplicates. Further, a causal association of the reported adverse event(s) or reported outcome(s) with ketamine exposure was not determined for this assessment. The 39 cases were received by FDA from 2015 to 2017 although some of these cases had occurred in previous years. Only 13 reports included information on event year, and these years ranged from 2013 to 2017. Approximately 43.6% (17/39) of the reports reported an outcome of death, and 53.8% (21/ 39) of the reports involved hospitalization. Deaths and hospitalizations were not mutually exclusive case outcomes. **Table 3.7** provides descriptive characteristics of the ketamine FAERS reports.

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Table 3.7. Descriptive Case Characteristics of U.S. FAERS Reports of Ketamine Associated with Abuse,* Received by FDA from January 1, 2015 to September 11, 2017 (N=39)†		
Sex	Male Female Unknown	16 15 8
Age (years)	1 – 12 13 – 18 19 – 40 41 – 60 61 and older Unknown	2 3 19 4 1 10
Reporter type	Health care professional‡ Consumer Unknown	32 5 2
Report type	Expedited (15-Day) Direct Non-expedited	36 2 1
Reported route (n=15)	Nasal/inhalation Intramuscular Intravenous Parenteral Oral/Buccal Transdermal	4 4 2 1 3 1
MedDRA preferred terms§ (n=37)	Drug use disorder Toxicity to various agents Overdose Unresponsive to stimuli Sedation Biliary dilatation Drug withdrawal syndrome Off label use Accidental overdose Hydronephrosis Intentional product misuse Pain	18 11 8 6 5 4 4 4 3 3 3 3
* All serious reports coded under the MedDRA *Drug abuse, dependence, and withdrawal (SMQ) Broad* were included. † These reports have not been manually reviewed and, as such, may include duplicates. ‡ Healthcare professional reports include those indicating the reporter's qualifications as a healthcare professional, physician, or a pharmacist. § Most frequently reported MedDRA preferred terms with n≥3. A report may include more than one preferred term.		

Reports were most frequently reported in the 19 – 40 year-old age group. The majority of the reporters identified themselves as a physician, pharmacist, or a healthcare professional. The routes of suspected abuse were described in 15 reports as parenteral/intravenous/intramuscular (n=7), nasal/inhalation (n=4), oral/buccal (n=3), or transdermal (n=1).

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The majority of the ketamine reports (28/39) reported one or more co-suspect drugs. These drugs included the Schedule 1 controlled substances, marijuana[b] (n=3), and heroin (n=2). The co-suspect drugs also included a substance that is not scheduled at the federal level, methoxetamine (n=1) – a dissociative hallucinogen, structurally similar to ketamine and phencyclidine (PCP), and other products from various drug classes. Of the remaining eleven reports listing ketamine as the only suspect drug, only one reported an outcome of death.

4 DISCUSSION

Ketamine abuse has been reported for decades, and recent data indicate that it continues to occur, resulting in more than a hundred calls to poison control centers annually. Ketamine use also led to an estimated 669 ED visits in the U.S. in 2016-2017, with a large majority of cases being classified as abuse. National survey data indicate that ketamine abuse is relatively uncommon in the general population, with a lifetime prevalence of 1.3%, lower than other commonly abused hallucinogens, such as ecstasy and LSD (Acid). While still relatively low, lifetime ketamine abuse prevalence is highest in the 18-25 year old age group (1.8% in 2017), consistent with literature describing its use predominantly by older adolescents and young adults attending dance clubs and "raves." Among 12th graders specifically, ketamine abuse is also relatively infrequent and has declined since 2000.

There were 35 ED cases involving abuse in the NEISS-CADES surveillance sample in 2016-2017 and 778 poison center exposure calls involving ketamine abuse or misuse (731 cases of abuse) in NPDS from 2013-2017. To help contextualize these numbers, we refer to recent FDA reviews describing abuse of propofol (another anesthetic agent with abuse potential), buprenorphine, and oxycodone (DARRTS Reference IDs: 4298560, 4361854, 4295073). The NEISS-CADES sample of EDs had no cases of propofol abuse and 751 cases of oxycodone non-medical use in 2016, and 287 cases of buprenorphine abuse in 2016-2017. NPDS contained 27 propofol and 3,233 buprenorphine abuse exposure calls from 2013-2017, 51,836 oxycodone abuse exposure calls from 2012-2016. These selected comparisons suggest that, not surprisingly, the public health burden of ketamine abuse is very low compared to that associated with prescription opioids.

When documented, the NPDS, NEISS-CADES, and FAERS data indicate that ketamine is abused via multiple routes—most commonly intranasal, ingestion/ oral, and injection (parenteral)—although the relative proportion of cases involving each of these routes varies by data source, and route is often unknown.

Clinical outcomes also varied by reporting system but, in general, suggest that ketamine abuse is infrequently associated with severe adverse outcomes, at least in the acute setting. A minority of the NEISS-CADES ED abuse visits resulted in hospitalization, even accounting for the three cases involving patients who left without being seen or against medical advice. Moderate health effects were the most commonly reported medical outcome among single-substance ketamine abuse and misuse exposure calls in NPDS, followed by minor effect, and there were no deaths

[b] Reported as cannabis sativa subsp. indica top.

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identified among those cases. Reports of deaths and hospitalization were identified in FAERS in association with ketamine abuse, but only one report listed ketamine as the only suspected drug, and drug-event causal association has not been assessed for any of the FAERS cases.

Sales data from the previous FDA review are provided in Background Package **Attachment 1** to provide insight into the magnitude of potential total use in the clinical setting and to provide context for the potential for diversion. Although sales data do not provide a direct measure of patient use, the amount of product purchased by various settings of care may be a possible surrogate for use if we assume the facilities purchase drugs in quantities reflective of actual patient use. Based on national sales distribution patterns of ketamine vials, the utilization appears to be largely in the hospital setting. Notably, sales to clinic settings more than doubled during 2013-2017, suggesting changes in utilization patterns. However, national data on diagnoses or indications directly linked with the administration of ketamine in the clinic or hospital settings were not available. We were not able to determine if the increasing sales are due to increases in off-label use, but literature suggests an increased interest in off-label use of ketamine. We were unable to assess off-label use as a source of diversion or abuse specifically. Despite increasing ketamine sales in recent years, and published literature suggesting growing interest in off-label therapeutic use of ketamine, the available trend data from NPDS and MTF do not suggest recent increases in ketamine abuse in the U.S. Rather, they suggest that ketamine abuse may even be declining. The U.S. DEA reports that most of the ketamine illegally distributed in the U.S. is diverted or stolen from sources such as veterinary clinics or smuggled into the U.S. from Mexico and then sold or shared among friends and acquaintances at parties or nightclubs,(8, 9) so it may be that increased use of ketamine in supervised medical settings has not translated to a corresponding growth in abuse.

Limitations of the Data

To summarize the most recent reports from epidemiologic studies on ketamine abuse, we restricted our literature review to the most recent publications (2016-2017). As a result, we identified only a subset of the many published studies on ketamine abuse since its approval. Additionally, many of the observational studies that we identified were limited to specific population subgroups or populations outside of the U.S., where abuse patterns may differ from those in the U.S.

Although NSDUH and MTF are capable of producing national estimates of drug misuse and abuse, they are subject to the inherent limitations of self-reported data, such as non-response bias, misclassification, and recall bias. Additionally, individuals with advanced substance use disorders may be underrepresented, particularly if they become homeless, incarcerated, or enter a residential treatment facility.

NPDS captures exposure events that are called in by someone asking for help with the exposure (public or healthcare professional), and information is limited to what is provided by the caller. These calls likely represent a small proportion of exposure events and are not likely to be representative of all abuse exposures, but it is informative for characterizing the public health burden of acute harms from ketamine abuse. AAPCC cautions that “data referenced from AAPCC should not be construed to represent the complete incidence of national exposures to

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any substance(s)" (AAPCC Data Policies, October 2015). In particular, unwitnessed out-of-hospital deaths due to drug overdoses are unlikely to generate a call to poison control centers.

We did not include NEISS-CADES data prior to 2016 because abuse related ED visits were not previously captured in this database. NEISS-CADES data include reports from approximately 60 hospitals throughout the United States and are nationally representative. However, the data may be limited by low sensitivity; NEISS-CADES reports an overall sensitivity of 33% but this varies by type of adverse drug event (NEISS-CADES user's manual, 2017).

We included FAERS data from a previous review by DPV II (October 2017; DARRTS ref ID 4161583) to add to our understanding of ketamine abuse and the nature of adverse events associated with this abuse. The FAERS assessment is a high-level overview of the reports in the database received from January 2015 to September 11, 2017. As such, individual cases have not been reviewed; therefore, the data may contain duplicates, and drug-event causal association has not been assessed. As part of the sponsor's pharmacovigilance regulatory requirements, they are required to monitor and report medical literature case reports. The FAERS database contains case reports from the NPDS database through the published American Association of Poison Control Centers annual reports; thus, there may be overlap in the data presented in the FAERS and NPDS sections of this review.

The FAERS database is a passive reporting system and has a number of limitations, including under-reporting. In particular, cases of drug abuse are likely under reported to FAERS because people who abuse drugs are unlikely to report, as supported by the relatively low number of consumer reports received for ketamine. Missing data from these systems, and the potential for misclassification (e.g., of abuse as non-abuse) are two limitations common to both FAERS and NPDS. This hinders our ability to provide comprehensive characteristics of patients abusing these drugs, and may lead to underestimates of the true public health burden caused by the abuse of these drugs. Given the spontaneous nature of adverse event reports and limitations described, these data cannot be used to inform the rate of abuse.

5 CONCLUSIONS

The risks of abuse and associated harms are important considerations in determining appropriate risk mitigation strategies and postmarket surveillance for esketamine, if approved. Ketamine abuse has been recognized for decades, and it is classified as a Schedule III drug under the Controlled Substances Act. In recent years, there have been numerous cases of ketamine abuse resulting in adverse events or the need for medical attention or advice; however, most of these cases resulted in minor or moderate adverse effects and did not require hospitalization. National surveys indicate a low prevalence of ketamine use in the general population and in high school students, consistent with literature suggesting that ketamine abuse is concentrated in smaller population subgroups such as older adolescents and young adults participating in "rave" or nightclub scenes. We did not observe increasing trends in ketamine abuse calls to poison centers or in self-reported abuse despite contemporaneous increasing sales and expanding off-label use of ketamine. According to DEA reports, much of the illegally distributed ketamine in the U.S. is smuggled in from other countries or diverted from veterinary sources, and the evidence is insufficient to know whether the distribution and use of pharmaceutical ketamine in humans contribute substantially to ketamine abuse in the U.S.

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APPENDICES

APPENDIX A. NPDS DEFINITIONS OF EXPOSURE REASONS

NPDS Definitions for Intentional Exposure Reason Categories from the NPDS Data Dictionary		
Intentional Exposure Reasons	**NPDS Definition**	**Case Inclusions/ Exclusions examples**
Suspected Suicides	"An exposure resulting in the inappropriate use of a substance for self-harm or self-destruction or manipulative reasons."	"Case Inclusions: Suicides, suicide attempts, and suicide gestures, whether suspected or confirmed • Cases in which history indicates patient was upset or depressed • Patients who provide explanations for their actions such as "arguing with parents," "disturbed about poor grades," or "having marital problems" • Ingestions of large quantities of one or more drugs where the only likely explanation is the patient's intent to harm himself"
Abuse	"An exposure resulting from the intentional improper or incorrect use of a substance where the victim was likely attempting to gain a high, euphoric effect or some other psychotropic effect", including recreational use of a substance for any effect.	"Case Inclusions: A person who inhales helium to talk funny • A person who uses GHB at a dance club • An infant with toxic effects or withdrawal symptoms as a result of the mother's drug abuse while the child was in utero or while breast-feeding"
Misuse	"An exposure resulting from the intentional improper or incorrect use of a substance for reasons other than the pursuit of a psychotropic effect."	"Case Inclusions: A person deliberately mixes or applies a pesticide inappropriately so it will be more effective • A person deliberately increases the dosage of a medication to enhance its therapeutic effect • Overuse of caffeine to study for an exam Case Exclusions: Patients who want to get high (should be INTENTIONAL ABUSE) • Suspected child abuse (should be OTHER-MALICIOUS)"
Unknown	Exposures that are deemed to be intentional although the specific motive is undetermined.	N/A

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APPENDIX B. NPDS DEFINITION FOR MEDICAL OUTCOME

NPDS Definitions for Medical Outcome from the NPDS Data Dictionary	
Medical Outcome	**NPDS Definition**
No Effect	"The patient developed no symptoms (clinical effects) as a result of the exposure. Follow-up is required to make this determination unless the initial poison center call occurs sufficiently long enough after the exposure that the poison center is reasonably certain no effects will occur."
Minor Effect	"The patient exhibited some symptoms as a result of the exposure, but they were minimally bothersome to the patient. The symptoms usually resolve rapidly and often involve skin or mucous membrane manifestations. The patient has returned to a pre-exposure state of well-being and has no residual disability or disfigurement. Follow-up is required to make this determination unless the initial poison center call occurs sufficiently long enough after the exposure that there is reasonable certainty that the clinical effect(s) will not worsen. Symptomatic patients must be followed until symptoms have resolved or nearly resolved, unless the residual symptoms are anticipated to be long-term and of minimal clinical significance."
Moderate Effect	"The patient exhibited symptoms as a result of the exposure which are more pronounced, more prolonged or more of a systemic nature than minor symptoms. Usually some form of treatment is or would have been indicated. Symptoms were not life-threatening and the patient has returned to a pre-exposure state of well-being with no residual disability or disfigurement. Follow-up is required to make this determination unless the initial regional poison center call occurs sufficiently long enough after the exposure that there is reasonable certainty that the clinical effect(s) will not get worse. Symptomatic patients must be followed until symptoms have resolved or nearly resolved, unless the residual symptoms are anticipated to be long-term and of minimal clinical significance."
Major Effect	"The patient has exhibited symptoms as a result of the exposure which were life-threatening or resulted in significant residual disability or disfigurement. Follow-up is required to make this determination unless the initial poison center call occurs sufficiently long enough after the exposure that there is reasonable certainty the clinical effect(s) will not get worse. Symptomatic patients must be followed until symptoms have resolved or nearly resolved, unless the symptoms are anticipated to be long-term or permanent."

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APPENDIX C. NPDS GENERIC AND PRODUCT CODES

NPDS Generic and Product Codes Use for NPDS Data Extraction		
	Generic Code	Product Code
Ketamine	[redacted] (b) (4)	
Note: These product codes must be redacted for public release		

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APPENDIX D. NEISS-CADES DEFINITIONS OF ADVERSE DRUG EVENTS

NEISS-CADES Definitions for Definitions of Case Type from NEISS-CADES Data Dictionary		
Analytic Category		**NEISS-CADES Definition**
Nonmedical Use	ABUSE	Clinician diagnosis of abuse (for current ED visits) or documentation of recreational use (e.g., "to get high", "at a party", "crushing and snorting", "bought off street")
	UNKNOWN INTENT	Clinician diagnosis of undetermined intent or insufficient documentation to categorize the case as abuse, therapeutic, self-harm/suicide, or assault. Also used for cases with conflicting information about intent without a clarifying clinician diagnosis.
	THERAPEUTIC MISUSE	Documentation of therapeutic intent, but the pharmaceutical was intentionally not used as directed OR case details call the therapeutic intent into question (e.g., taking someone else's prescription medication for pain, intentionally taking a very large dose with a stated therapeutic purpose)
UNSUPERVISED PEDIATRIC EXPOSURE		Access of a medication by a child aged <11 years without caregiver permission or oversight. Most cases involve ingestions or suspected ingestions.
THERAPEUTIC USE		Adverse events following drugs used for therapeutic intent with no indication of misuse. Includes adverse effects, allergic reactions, supratherapeutic effects, medication errors, vaccine reactions, and secondary effects (e.g., choking on a pill)
SELF-HARM/SUICIDE		Clinician diagnosis of self-harm or suicide attempt or documented intent to kill or injure oneself using pharmaceuticals
ASSAULT		Deliberate intent to cause harm to another individual with a pharmaceutical product

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APPENDIX E. FDA ADVERSE EVENT REPORTING SYSTEM (FAERS)

FDA Adverse Event Reporting System (FAERS)

FAERS is a database that contains information on adverse event and medication error reports submitted to FDA. The database is designed to support the FDA's post-marketing safety surveillance program for drug and therapeutic biologic products. The informatic structure of the database adheres to the international safety reporting guidance issued by the International Conference on Harmonisation. Adverse events and medication errors are coded to terms in the Medical Dictionary for Regulatory Activities terminology. The suspect products are coded to valid tradenames or active ingredients in the FAERS Product Dictionary.

FAERS data have limitations. First, there is no certainty that the reported event was actually due to the product. FDA does not require that a causal relationship between a product and event be proven, and reports do not always contain enough detail to properly evaluate an event. Further, FDA does not receive reports for every adverse event or medication error that occurs with a product. Many factors can influence whether or not an event will be reported, such as the time a product has been marketed and publicity about an event. Therefore, FAERS data cannot be used to calculate the incidence of an adverse event or medication error in the U.S. population.

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From:	Valentino, Michael (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO, (b)(6) @va.gov>
To:	Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M (b)(6) @va.gov>
CC:	Hastings, Patricia R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a504fbfe766048a5a65461c45f28e9de-Hastings, P (b)(6) @va.gov>
Subject:	FW: Briefing on formulary process
Date:	2019/06/21 11:57:52
Priority:	Normal
Type:	Note

FYI.....

AJ blind cc'd me on this request from the HVAC.....

I'll start working up some slides about our policy and general processes and will put together a brief overview of esketamine.

Mike

-----Original Message-----
From: Brooks, Aja
Sent: Friday, June 21, 2019 8:49 AM
To: Melendrez, Dahlia (Veterans Affairs) (b)(6) @vetaff.senate.gov>; Johnson, Glenn <(b)(6) @va.gov>
Cc: Campbell, Leslie (Veterans Affairs) <(b)(6) @vetaff.senate.gov>; Workman, Jillian (Veterans Affairs) <(b)(6) @vetaff.senate.gov>; Friedl, Sophia (Veterans Affairs) <(b)(6) @vetaff.senate.gov>; (b)(6) @mail.house.gov; (b)(6) @mail.house.gov
Subject: RE: Briefing on formulary process

Hi Dahlia -

OCLA acknowledges receipt of your request and I will alert the PBM team for action. I will get back with you on Tuesday, morning with dates and times w/in the next 2 weeks.
v/r

AJ

-----Original Message-----
From: Melendrez, Dahlia (Veterans Affairs) <(b)(6) @vetaff.senate.gov>
Sent: Friday, June 21, 2019 8:41 AM
To: Brooks, Aja <(b)(6) @va.gov>
Cc: Campbell, Leslie (Veterans Affairs) (b)(6) @vetaff.senate.gov>; Workman, Jillian (Veterans Affairs) (b)(6) @vetaff.senate.gov>; Friedl, Sophia (Veterans Affairs) (b)(6) @vetaff.senate.gov>; (b)(6) @mail.house.gov; (b)(6) house.gov
Subject: [EXTERNAL] Briefing on formulary process

Hi AJ -

We'd appreciate a briefing on VA's process to consider, deliberate and add drugs to its formulary. In particular, we'd like an overview of the drug Spravato - we understand it's under consideration. Sometime in the next two weeks would be great.

Thanks,
Dahlia

Sent from my iPhone

Sender:	Valentino, Michael (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO,

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	(b)(6) @va.gov>
Recipient:	Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M (b)(6) @va.gov>; Hastings, Patricia R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a504fbfe766048a5a65461c45f28e9de-Hastings, P (b)(6) @va.gov>
Sent Date:	2019/06/21 11:57:49
Delivered Date:	2019/06/21 11:57:52

AMERICAN OVERSIGHT

From:	Tucker, Brooks /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=24AE47CFF629405AA8557CC2CC792903-TUCKER, BRO (b)(6) @va.gov>
To:	Balland, David /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d8944409fdaa4c69a762cb70b7825acb-Balland, Da (b)(6) @va.gov>; Haverstock, Cathy /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4c3c46a7ea634b5a8a6d0618028d0f89-Haverstock, (b)(6) @va.gov>; Anderson, Christopher /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a6975381a335487284adae636cc3d666-Anderson, C (b)(6) @va.gov>; Barron, Michael J. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1dfb216bb08440f6bd633739e04bc935-Barron, Mic (b)(6) @va.gov>; Connell, Lawrence B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a3e7233376344045980ad214122389f4-Connell, La (b)(6) @va.gov>; Jensen, Jon M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddeb735ace76400db5c3f10603188a14-Jensen, Jon (b)(6) @va.gov>
Subject:	FW: Anti-Depression Drug
Date:	2019/06/22 09:16:02
Priority:	Normal
Type:	Note

FYI - this is a positive development, full stop.

Sent with BlackBerry Work
(www.blackberry.com)

From: Cashour, Curtis <(b)(6) @va.gov>
Date: Saturday, Jun 22, 2019, 7:36 AM
To: Tucker, Brooks (b)(6) @va.gov>, Stone, Richard A., MD <(b)(6) @va.gov>, Lieberman, Steven (b)(6) @va.gov>
Cc: Hutton, James (b)(6) @va.gov>, Eason, William J. <(b)(6) @va.gov>
Subject: RE: Anti-Depression Drug

Below is the statement we put out.
After reviewing the available published evidence regarding the safety and effectiveness of esketamine (Spravato), a team of VA clinicians approved on June 20 the use of esketamine (Spravato) on a non-formulary basis. This process is similar to "prior authorization" formulary designations used in non-VA health care systems, and will enable VA psychiatrists to offer esketamine to patients when clinically indicated.

In addition, VA developed clinical and procedural guidance and other tools to promote thoughtful patient selection and safe administration practices, in keeping with the FDA-approved indications for esketamine use and safety requirements. These evidence-based processes will ensure the medication is prioritized for use in Veterans who have not previously responded to adequate trials of other available treatments for major depression.

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VA will closely monitor the use of esketamine in Veterans to more fully understand its relative safety and effectiveness as compared to other available treatments. Based on this information, VA may revise its clinical guidance and formulary status if warranted.

This decision reflects VA's commitment to seek new ways to provide the best health care available for our nation's Veterans.

Sent with BlackBerry Work
(www.blackberry.com)

From: Tucker, Brooks <(b)(6) @va.gov>
Date: Saturday, Jun 22, 2019, 7:11 AM
To: Stone, Richard A., MD <(b)(6) @va.gov>, Lieberman, Steven (b)(6) @va.gov>
Cc: Cashour, Curtis <(b)(6) @va.gov>, Hutton, James <(b)(6) @va.gov>, Eason, William J. (b)(6) @va.gov>
Subject: RE: Anti-Depression Drug

Adding OPIA for any input.(b) (6)
(b) (6)

Sent with BlackBerry Work
(www.blackberry.com)

From: Stone, Richard A., MD (b)(6) @va.gov>
Date: Saturday, Jun 22, 2019, 7:08 AM
To: Tucker, Brooks (b)(6) @va.gov>, Lieberman, Steven <(b)(6) @va.gov>
Subject: RE: Anti-Depression Drug

Got it. We know that it is not a drug distributed by pharmacies directly to patients. It is given in controlled and supervised (certified) clinics that are prepared to respond to side effects. Since we are using IV Ketamine in multiple sites, these are the first to use the new delivery method this drug provides.
Rich

Sent with BlackBerry Work
(www.blackberry.com)

From: Tucker, Brooks (b)(6) @va.gov>
Date: Saturday, Jun 22, 2019, 7:00 AM
To: Stone, Richard A., MD <(b)(6) @va.gov>, Lieberman, Steven (b)(6) @va.gov>
Subject: RE: Anti-Depression Drug

Dr Stone, I've seen reports today that it will now be approved for use in VA for specific beneficiaries who haven't responded to other treatments. (b) (6)

AMERICAN OVERSIGHT

(b) (6)

Brooks

Sent with BlackBerry Work
(www.blackberry.com)

From: Stone, Richard A., MD <(b)(6) @va.gov>
Date: Saturday, Jun 22, 2019, 6:56 AM
To: RLW (b)(6) @va.gov>, Lieberman, Steven <(b)(6) @va.gov>
Cc: Powers, Pamela <(b)(6) @va.gov>, Tucker, Brooks <(b)(6) @va.gov>
Subject: RE: Anti-Depression Drug

Will check if something has happened while I have been away.
Rich

Sent with BlackBerry Work
(www.blackberry.com)

From: RLW (b)(6) @va.gov>
Date: Saturday, Jun 22, 2019, 6:49 AM
To: Stone, Richard A., MD <(b)(6) @va.gov>, Lieberman, Steven (b)(6) @va.gov>
Cc: Powers, Pamela(b)(6) @va.gov>, Tucker, Brooks <(b)(6) @va.gov>
Subject: Anti-Depression Drug

(b) (6) media is reporting that an internal VA Committee has denied coverage for the use of the J&J Drug I spoke with the President about and said go ahead and get in the pipeline. What are the ramifications of this and what is this committee? I told the President we had a successful application of the drug in Boston.
Robert

Sent with BlackBerry Work
(www.blackberry.com)

Sender:	Tucker, Brooks /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=24AE47CFF629405AA8557CC2CC792903-TUCKER, BRO (b)(6) @va.gov>
Recipient:	Balland, David /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d8944409fdaa4c69a762cb70b7825acb-Balland, Da (b)(6) @va.gov>; Haverstock, Cathy /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4c3c46a7ea634b5a8a6d0618028d0f89-Haverstock, (b)(6) @va.gov>; Anderson, Christopher /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a6975381a335487284adae636cc3d666-Anderson, C (b)(6) @va.gov>; Barron, Michael J. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1dfb216bb08440f6bd633739e04bc935-Barron, Mic

AMERICAN OVERSIGHT

	(b)(6) @va.gov>; Connell, Lawrence B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a3e7233376344045980ad214122389f4-Connell, La (b)(6) @va.gov>; Jensen, Jon M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddeb735ace76400db5c3f10603188a14-Jensen, Jon (b)(6) @va.gov>
Sent Date:	2019/06/22 09:16:01
Delivered Date:	2019/06/22 09:16:02

AMERICAN OVERSIGHT

From:	Smith, Avery /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9471C2D02A8B472B8543E09CB140085F-SMITH, AVER (b)(6) @va.gov>
To:	VHA 10P Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5098b521b1f34f8a97f74be24709d62f-VHA 10P Act <VHA10PActions@va.gov>
CC:	VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>; Hastings, Patricia R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a504fbfe766048a5a65461c45f28e9de-Hastings, P (b)(6) @va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M (b)(6) @va.gov>
Subject:	FW: 4- Corners Briefing on VA Formulary Process
Date:	2019/06/24 12:41:46
Priority:	Normal
Type:	Note

10P

Request:
OCLA request Michael Valentino and Thomas Emmendorfer to brief the 4-Corners on VA's formulary process, including an overview of the drug Spravato. Please list availabilities of the above mentioned SME's for the week of:

June 25 -28
July 1 – 3
OR
July 9, - 1 -3pm

Response:
Please see availability below:

June 25 -28 Mike Valentino is available the 27th and 28th but Tom Emmendorfer is on leave this week and not available.

July 1 – 3 Both are available the 1st and 2nd
OR
July 9, - 1 -3pm Both are available

Thank you

Avery E. Smith
Office of the ADUSH for Patient
Care Services (10P4)

AMERICAN OVERSIGHT

(b)(6) @va.gov
(b)(6)

From: Sandifer, Estella (Maria)
Sent: Monday, June 24, 2019 10:50 AM
To: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Cc: VHA 10P Actions <VHA10PActions@va.gov>
Subject: FW: 4- Corners Briefing on VA Formulary Process

10P4,

Please see the request below and provide availabilities to 10P no later than 3 p.m., today.

Request:
OCLA request Michael Valentino and Thomas Emmendorfer to brief the 4-Corners on VA's formulary process, including an overview of the drug Spravato. Please list availabilities of the above mentioned SME's for the week of:

June 25 -28
July 1 – 3
OR
July 9, - 1 -3pm

V/r,

Maria Sandifer
Office of the Deputy Under Secretary for Health
for Policy and Services (10P)
Work ph: (b)(6)
Cell: (b)(6)
Email: (b)(6) @va.gov

-----Original Message-----
From: Brooks, Aja
Sent: Monday, June 24, 2019 10:42 AM
To: VHA 10P Actions <VHA10PActions@va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Subject: RE: 4- Corners Briefing on VA Formulary Process

Good morning, VHA 10P

AMERICAN OVERSIGHT

OCLA request Michael Valentino and Thomas Emmendorfer to brief the 4-Corners on VA's formulary process, including an overview of the drug Spravato. Please list availabilities of the above mentioned SME's for the week of:

June 25 -28
July 1 - 3
OR
July 9, - 1 -3pm

v/r
AJ

-----Original Message-----
From: Melendrez, Dahlia (Veterans Affairs) (b)(6) @vetaff.senate.gov>
Sent: Friday, June 21, 2019 8:41 AM
To: Brooks, Aja (b)(6) @va.gov>
Cc: Campbell, Leslie (Veterans Affairs) (b)(6) @vetaff.senate.gov>; Workman, Jillian (Veterans Affairs) (b)(6) @vetaff.senate.gov>; Friedl, Sophia (Veterans Affairs) (b)(6) @vetaff.senate.gov>; (b)(6) @mail.house.gov; Christine.Hill@mail.house.gov
Subject: [EXTERNAL] Briefing on formulary process

Hi AJ -

We'd appreciate a briefing on VA's process to consider, deliberate and add drugs to its formulary. In particular, we'd like an overview of the drug Spravato - we understand it's under consideration. Sometime in the next two weeks would be great.

Thanks,
Dahlia

Sent from my iPhone

Sender:	Smith, Avery /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9471C2D02A8B472B8543E09CB140085F-SMITH, AVER (b)(6) @va.gov>
Recipient:	VHA 10P Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5098b521b1f34f8a97f74be24709d62f-VHA 10P Act <VHA10PActions@va.gov>; VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>; Hastings, Patricia R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a504fbfe766048a5a65461c45f28e9de-Hastings, P (b)(6) @va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M (b)(6) @va.gov>
Sent Date:	2019/06/24 12:41:45
Delivered Date:	2019/06/24 12:41:46

AMERICAN OVERSIGHT

AMERICAN OVERSIGHT

From:	Smith, Avery /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9471C2D02A8B472B8543E09CB140085F-SMITH, AVER (b)(6) @va.gov>
To:	VHA 10P Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5098b521b1f34f8a97f74be24709d62f-VHA 10P Act <VHA10PActions@va.gov>
CC:	VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M (b)(6) @va.gov>; Hastings, Patricia R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a504fbfe766048a5a65461c45f28e9de-Hastings, P (b)(6) @va.gov>
Subject:	FW: 4- Corners Briefing on VA Formulary Process
Date:	2019/06/26 11:15:50
Importance:	High
Priority:	Urgent
Type:	Note

Cleared for 10P4, please submit to OCLA

Request:
We'd appreciate a briefing on VA's process to consider, deliberate and add drugs to its formulary. In particular, we'd like an overview of the drug Spravato - we understand it's under consideration. Sometime in the next two weeks would be great.)

Response:
Please see the attached PPT to support the 4 corners briefing

NOTE: Dr. Maria Llorente's (ADUSH for PCS) name has been added to the title slide and she and Mr. Mike Valentino, Pharmacy Benefits Management will both participate in the briefing.

Thank you

Avery E. Smith
Office of the ADUSH for Patient
Care Services (10P4)
(b)(6) @va.gov
(b)(6)

AMERICAN OVERSIGHT

10P

Request:
OCLA request Michael Valentino and Thomas Emmendorfer to brief the 4-Corners on VA's formulary process, including an overview of the drug Spravato. Please list availabilities of the above mentioned SME's for the week of:

June 25 -28
July 1 – 3
OR
July 9, - 1 -3pm

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June 25 -28 Mike Valentino is available the 27th and 28th but Tom Emmendorfer is on leave this week and not available.
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OR
July 9, - 1 -3pm Both are available

Thank you

From: Sandifer, Estella (Maria)
Sent: Monday, June 24, 2019 10:50 AM
To: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Cc: VHA 10P Actions <VHA10PActions@va.gov>
Subject: FW: 4- Corners Briefing on VA Formulary Process

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OR

AMERICAN OVERSIGHT

July 9, - 1 -3pm We are both available

V/r,

Maria Sandifer
Office of the Deputy Under Secretary for Health
for Policy and Services (10P)
Work ph: (b)(6)
Cell: (b)(6)
Email: (b)(6) @va.gov

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Sent: Monday, June 24, 2019 10:42 AM
To: VHA 10P Actions <VHA10PActions@va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Subject: RE: 4- Corners Briefing on VA Formulary Process

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July 1 - 3
OR
July 9, - 1 -3pm

v/r
AJ

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Sent: Friday, June 21, 2019 8:41 AM
To: Brooks, Aja (b)(6) @va.gov>
Cc: Campbell, Leslie (Veterans Affairs) (b)(6) @vetaff.senate.gov>; Workman, Jillian (Veterans Affairs) (b)(6) @vetaff.senate.gov>; Friedl, Sophia (Veterans Affairs) (b)(6) @vetaff.senate.gov>; (b)(6) @mail.house.gov; (b)(6) @mail.house.gov
Subject: [EXTERNAL] Briefing on formulary process

Hi AJ -

We'd appreciate a briefing on VA's process to consider, deliberate and add drugs to its formulary. In particular, we'd like an overview of the drug Spravato - we understand it's under consideration. Sometime in the next two weeks would be great.

AMERICAN OVERSIGHT

Thanks,
Dahlia

Sent from my iPhone

Sender:	Smith, Avery /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9471C2D02A8B472B8543E09CB140085F-SMITH, AVER (b)(6) @va.gov>
Recipient:	VHA 10P Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5098b521b1f34f8a97f74be24709d62f-VHA 10P Act <VHA10PActions@va.gov>; VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M (b)(6) @va.gov>; Hastings, Patricia R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a504fbfe766048a5a65461c45f28e9de-Hastings, P (b)(6) @va.gov>
Sent Date:	2019/06/26 11:15:46
Delivered Date:	2019/06/26 11:15:50

AMERICAN OVERSIGHT

From:	Smith, Avery /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9471C2D02A8B472B8543E09CB140085F-SMITH, AVER (b)(6) @va.gov>
To:	VHA 10P4P Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8dc3dab451414f59b9797e8ed199c1e8-VHA 10P4P A <vha10P4Paction@va.gov>
CC:	VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>
Subject:	FW: 4- Corners Briefing on VA Formulary Process
Date:	2019/06/24 11:26:33
Priority:	Normal
Type:	Note

10P4P,

Please review the request below and provide response to **VHA 10P4 Actions before 1:30pm today June 24th.**

Thanks

Avery

From: Sandifer, Estella (Maria)
Sent: Monday, June 24, 2019 10:50 AM
To: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Cc: VHA 10P Actions <VHA10PActions@va.gov>
Subject: FW: 4- Corners Briefing on VA Formulary Process

10P4,

Please see the request below and provide availabilities to 10P no later than 3 p.m., today.

Request:
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July 1 - 3
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July 9, - 1 -3pm

AMERICAN OVERSIGHT

V/r,

Maria Sandifer
Office of the Deputy Under Secretary for Health
for Policy and Services (10P)
Work ph: (b)(6)
Cell: (b)(6)
Email: (b)(6) @va.gov

-----Original Message-----
From: Brooks, Aja
Sent: Monday, June 24, 2019 10:42 AM
To: VHA 10P Actions <VHA10PActions@va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Subject: RE: 4- Corners Briefing on VA Formulary Process

Good morning, VHA 10P

OCLA request Michael Valentino and Thomas Emmendorfer to brief the 4-Corners on VA's formulary process, including an overview of the drug Spravato. Please list availabilities of the above mentioned SME's for the week of:

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OR
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v/r
AJ

-----Original Message-----
From: Melendrez, Dahlia (Veterans Affairs) (b)(6) @vetaff.senate.gov>
Sent: Friday, June 21, 2019 8:41 AM
To: Brooks, Aja (b)(6) @va.gov>
Cc: Campbell, Leslie (Veterans Affairs) (b)(6) @vetaff.senate.gov>; Workman, Jillian (Veterans Affairs) (b)(6) @vetaff.senate.gov>; Friedl, Sophia (Veterans Affairs) (b)(6) @vetaff.senate.gov>; (b)(6) @mail.house.gov; (b)(6) @mail.house.gov
Subject: [EXTERNAL] Briefing on formulary process

Hi AJ -

We'd appreciate a briefing on VA's process to consider, deliberate and add drugs to its formulary. In particular, we'd like an overview of the drug Spravato - we understand it's under consideration. Sometime in the next two weeks would be great.

AMERICAN OVERSIGHT

Thanks,
Dahlia

Sent from my iPhone

Sender:	Smith, Avery /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9471C2D02A8B472B8543E09CB140085F-SMITH, AVER *(b)(6)* @va.gov>
Recipient:	VHA 10P4P Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8dc3dab451414f59b9797e8ed199c1e8-VHA 10P4P A <vha10P4Paction@va.gov>; VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>
Sent Date:	2019/06/24 11:26:25
Delivered Date:	2019/06/24 11:26:33

AMERICAN OVERSIGHT

From:	Snyder, Jill /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0B6E91EF72EE4A05ACC63873C64570E1-SNYDER, JIL (b)(6) @va.gov>
To:	VHA CO ELT Clips /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=47d7fa1e81c441ae95fcb118d95107d8-VHA CO ELT <VHACOELTClips@va.gov>
Subject:	FW: 27 August Veterans Affairs Media Summary and News Clips
Date:	2019/08/27 07:54:37
Priority:	Normal
Type:	Note

Good morning,

Today's clips feature many articles on Suicide prevention, including the VA/DoD suicide prevention conference, the Secretaries remarks on mental health in Boise and the new drug Spravato. CBS News aired a story inside the suicide prevention call center. Military.com featured an article about a Veteran who was on the high risk list, but that was removed and he committed suicide. Coverage continues on VA's removal of the ban on bibles. The Las Vegas Sun covered an editorial from Sec. Wilke on VA police officers when shots were fired at the Jesse Brown VAMC. Coverage continues on the suspicious deaths at the Louis A. Johnson VMAC. Reporting continued on the OIG report on the backlog of digitizing medical records. Military Times and others covered allegation leaders at the James A Haley ignored medical equipment recalls. Rep. Takano calls for VA to hold stand-down to address Veteran suicide. Locally, positive coverage includes opening of new VA clinics.

* indicates VHA assisted with the story

Significant Stories

1.1 - KIVI (ABC-6, Video): #FINDINGHOPE: US Secretary of VA works to open mental health dialogue in the armed forces Link

* 1.2 - CBS News (Video): Inside a suicide prevention call center for veterans responding to 1,700 calls each day Link

* 1.3 - ABC News (Video): Could a new drug treat veterans with severe depression? President Trump thinks so Link

1.7 - Las Vegas Sun: At VA, we protect those who protected us Link

5.2 - Federal News Network (Audio): House VA Committee chair calls for agencywide stand-down to address veteran suicide Link

5.3 - The Augusta Chronicle: Family of veteran treated at Augusta VA who killed self files negligence suit Link

Neutral/Positive Stories

1.5 - The Daily Signal: VA Lifts Ban on Bibles in Move to Support Religious Freedom Link

3.1 - The Virginian-Pilot: Editorial: Veterans clinic a welcome addition to region Link

3.2 - KCRG (ABC-9, Video): Dubuque VA clinic open to patients starting Monday Link

Negative Stories

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1.4 - Military.com: The VA Removed a Vet's High-Risk Label. The Patient Died by Suicide. What Went Wrong? Link
1.8 - The Exponent Telegram: Sen. Manchin: VA officials assure 'person of interest' in homicide no longer in contact with veterans in VA hospital Link
1.10 - WDTV (CBS-5, Video): Update: Veteran speaks out about his time at the Louis A. Johnson VA Medical Center Link
1.9 - Healthcare IT News: OIG audit: Massive backlog in digitizing VHA medical records Link
2.3 - KDKA (CBS-2, Video): Family Of Westmoreland County Veteran Files Federal Tort Claims Act Following Stay At West Virginia VA Hospital Link
2.2 - Military Times: Did VA hospital leaders ignore recalls on faulty medical equipment? Link
2.10 - MetroNews: Clarksburg VA death ruled homicide; VA investigating more possible victims Link
2.11 - MetroNews: Autopsy: Vietnam veteran was not diabetic but died of insulin injection Link
4.1 - FedScoop: Backlog of VA medical records awaiting digitization is 5 miles tall Link

Thank you,
Jill

From: VA Media Analysis <VAMediaAnalysis@barbaricum.com>
Sent: Tuesday, August 27, 2019 5:26 AM
To: Barbaricum VA Media Analysis <VAMediaAnalysis@barbaricum.com>
Subject: [EXTERNAL] 27 August Veterans Affairs Media Summary and News Clips

Good morning,

Please find the attached Veterans Affairs Media Summary and News Clips.

BARBARICUM http://fileshare.barbaricum.com.s3.amazonaws.com/BBCM.jpeg

Sender:	Snyder, Jill /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0B6E91EF72EE4A05ACC63873C64570E1-SNYDER, JIL *(b)(6)* @va.gov>
Recipient:	VHA CO ELT Clips /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=47d7fa1e81c441ae95fcb118d95107d8-VHA CO ELT <VHACOELTClips@va.gov>
Sent Date:	2019/08/27 07:54:32
Delivered Date:	2019/08/27 07:54:37
Message Flags:	Unread

AMERICAN OVERSIGHT

From:	Lahl, Dennis /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=39FBA8EA7CD941B3A0A4F79CA3C6EE87-LAHL, DENNI (b)(6) @va.gov>
To:	Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M (b)(6) @va.gov>
CC:	Law, Cassandra M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f888d507d6c54eb5a92fc44199eb5838-Law, Cassan (b)(6) @va.gov>; Hastings, Patricia R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a504fbfe766048a5a65461c45f28e9de-Hastings, P (b)(6) @va.gov>; VHA 10P4 Chief Consultants /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a87c5f11e8414617ac89553ec0973f08-VHA 10P4 Ch <VHA10P4ChiefConsultants@va.gov>; VHA 10P4 Communication Group /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4ba2ff9b4604547be7834a71415253c-VHA 10P4 Co <vha10p4comm@va.gov>
Subject:	FW: 26 June Veterans Affairs Media Summary and News Clips
Date:	2019/06/26 07:13:31
Priority:	Normal
Type:	Note

Morning,

The following are submitted FYSA:

- • Bill to require Spanish versions for all educational material, Medical Marijuana bill pulled due to VA concerns, VA's decision on Spravato, Veteran speaks out against Women Veterans Appreciation Day, local VAMC host Pride Month celebration,

Thanks. Have a great day.

Dennis

2.4 - Connecting Vets: Bill introduced to ensure VA education materials are available for Spanish-speaking veterans (25 June, Kaylah Jackson, 1.8M uvm; Washington, DC)
Currently, 7% of the veteran population is Hispanic. Pew Research Center predicts that number to grow to 13 percent in the near future. Which is why it was shocking to the House Committee on Veteran's Affairs Chairman Mark Takano, D-Calif. when he visited the VA facility in Puerto Rico to find a lack of Spanish language reading materials available to veterans.

Hyperlink to Above

2.10 - Portland Mercury: VA Blindsides Representative Blumenauer by Blocking Cannabis Access for Patients (25 June, Josh Jardine, 164k uvm; Portland, OR)
Last week, Oregon Congressperson Earl Blumenauer was in the midst of, uh, congressing, which for him includes introducing, co-sponsoring, and supporting congressional legislation, often around cannabis issues. In this case, Blumenauer was pushing for an amendment that would have allowed doctors within the Department of Veterans Affairs (VA) to recommend cannabis to patients if they're based in a state with a medical marijuana program.

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Hyperlink to Above

2.11 - FiercePharma: J&J depression drug Spravato gets half-hearted backing from VA doctors despite Trump's zeal (24 June, Eric Sagonowsky, 121k uvm; Washington, DC)
Despite unconventional support from President Donald Trump, Johnson &Johnson's Spravato didn't win broad backing at the U.S. Department of Veterans Affairs. Agency clinicians instead approved the depression spray's use on a limited basis, requiring patients to try other options first.

Hyperlink to Above

6.2 - Washington Examiner: Women don't need a separate Women Veterans Appreciation Day (25 June, Beth Bailey, 3.6M uvm; Washington, DC)
On June 17, Reps. Mikie Sherrill, D-N.J., Elaine Luria, D-Va., and Chrissy Houlahan, D-Pa., three women veterans, put forward a resolution to designate June 12 as Women Veterans Appreciation Day. On its face, like so many modern efforts to diversify and increase inclusivity, the idea sounds wonderful.

Hyperlink to Above

6.13 - WSEE (CBS-35): Erie VA Medical Center Hosts LGBT+ Pride Month Celebration (25 June, 63k uvm; Erie, PA)
The Erie VA Medical Center hosted an LGBT+ Pride Month celebration Tuesday. All veterans, their families and the community were invited to attend the event in the second floor conference center. The Erie VA wanted to celebrate the achievements of LGBT veterans and look back at the perseverance it took to be able to serve their country openly.

Hyperlink to Above

Dennis Lahl FAC-P/PM
Office of the Assistant Deputy Under Secretary for Health for Patient Care Services (10P4)
VACO PCS IT/BCAG/ISO Liaison
TMS OPCS DM
ph: *(b)(6)*
fax: 202-273-5483
Dennis Lahl

From: VA Media Analysis <VAMediaAnalysis@barbaricum.com>
Sent: Wednesday, June 26, 2019 5:22 AM
To: Barbaricum VA Media Analysis <VAMediaAnalysis@barbaricum.com>
Subject: [EXTERNAL] 26 June Veterans Affairs Media Summary and News Clips

Good morning,

AMERICAN OVERSIGHT

Please find the attached Veterans Affairs Media Summary and News Clips.

BARBARICUM http://fileshare.barbaricum.com.s3.amazonaws.com/BBCM.jpeg

Sender:	Lahl, Dennis /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=39FBA8EA7CD941B3A0A4F79CA3C6EE87-LAHL, DENNI (b)(6) @va.gov>
Recipient:	Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M (b)(6) @va.gov>; Law, Cassandra M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f888d507d6c54eb5a92fc44199eb5838-Law, Cassan (b)(6) @va.gov>; Hastings, Patricia R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a504fbfe766048a5a65461c45f28e9de-Hastings, P (b)(6) @va.gov>; VHA 10P4 Chief Consultants /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a87c5f11e8414617ac89553ec0973f08-VHA 10P4 Ch <VHA10P4ChiefConsultants@va.gov>; VHA 10P4 Communication Group /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4ba2ff9b4604547be7834a71415253c-VHA 10P4 Co <vha10p4comm@va.gov>
Sent Date:	2019/06/26 07:13:27
Delivered Date:	2019/06/26 07:13:31
Message Flags:	Unread

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From:	Lahl, Dennis /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=39FBA8EA7CD941B3A0A4F79CA3C6EE87-LAHL, DENNI (b)(6) @va.gov>
To:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>
CC:	Law, Cassandra M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f888d507d6c54eb5a92fc44199eb5838-Law, Cassan (b)(6) @va.gov>; VHA 10P4 Chief Consultants /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a87c5f11e8414617ac89553ec0973f08-VHA 10P4 Ch <VHA10P4ChiefConsultants@va.gov>; VHA 10P4 Communication Group /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4ba2ff9b4604547be7834a71415253c-VHA 10P4 Co <vha10p4comm@va.gov>; Costa, Francis R. (Frank) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce3e48b6fbcf4b40b30be399fb389ed4-Costa, Fran (b)(6) @va.gov>; Utech, Anne E. (HOU) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=da5fd2ae604b4384b33d451c137c3bae-Utech, Anne (b)(6) @va.gov>; Morgan, Mark (NOLA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e93d04bca2648b78a574942c6412a4f-Morgan, Mar (b)(6) @va.gov>
Subject:	FW: 26 August Veterans Affairs Media Summary and News Clips
Date:	2019/08/26 07:23:33
Priority:	Normal
Type:	Note

Morning,

The below are submitted FYSA:

August 24th:

- • President orders VA to purchase new drug – esketamine (1.4, 1.7), VA opens research center for Burn Pit related illness, Veterans have to ravel to cochlear implants, Physician Assistants fight for right to follow patients care in hospice facilities,

August 25th:

- • Exoskeleton helps Veteran walk again, local VAMC agrotherapy program, foundation raise funds for therapy golf course for Veterans, local VAMC honors women Veterans, local VAMC garden helps address food instability

August 26th:

- • Article highlighting "My Life My Story"

Dennis

August 24th

1.4 - The Atlantic: Trump Orders 'a Lot' of Ketamine for Depressed Veterans (23 August, James Hamblin, 22.4M uvm; Washington, DC)

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President Donald Trump said on Wednesday that the government will purchase “a lot” of the drug esketamine, a derivative of ketamine. Though ketamine is known as a recreational hallucinogen, Trump asserted that a new nasal-spray derivative would be of great benefit to veterans with depression. As he left the White House for a veterans’ conference in Kentucky, he told reporters that he had instructed the Department of Veterans Affairs to make a large purchase—overriding a recent decision by the doctors who manage the hospitals’ formulary of which drugs are to be prescribed.

Hyperlink to Above

1.7 - Government Executive: Trump Told the VA to Order ‘a Lot’ of Ketamine for Vets (23 August, James Hamblin, 250k uvm; Washington, DC)
President Donald Trump said on Wednesday that the government will purchase “a lot” of the drug esketamine, a derivative of ketamine. Though ketamine is known as a recreational hallucinogen, Trump asserted that a new nasal-spray derivative would be of great benefit to veterans with depression.

Hyperlink to Above

1.5 - Military.com: After Mandate from Congress, VA Opens Research Center for Burn Pit-Related Illnesses (23 August, Patricia Kime, 4.3M uvm; San Francisco, CA)
The Department of Veterans Affairs is increasing its focus on health conditions linked to burn pits and other airborne pollution in combat zones, establishing a "center of excellence" to better understand the extent of related illnesses and treatments for affected veterans.

Hyperlink to Above

2.1 - Reuters: VA facilities offering cochlear implants to vets are few and far between (23 August, Lisa Rapaport, 24.6M uvm; New York, NY)
Even though American veterans are at high risk for the type of hearing loss that may be improved with cochlear implants, many of them live hours from a VA facility that provides cochlear implant services, a U.S. study suggests.

Hyperlink to Above

2.3 - Medscape: PAs Fight for Right to Follow Patients Into Hospice (23 August, Ingrid Hein, 8.9M uvm; New York, NY)
"Every day I see someone we should have seen sooner," said Judy Knudson, PA-C, MPAS, Hospice and Palliative Medicine, University of Colorado Hospital, Aurora. She recalls a Veterans Affairs (VA) patient she saw briefly after treatment. His cancer therapy was ending, and he was preparing to die.

Hyperlink to Above

August 25th

2.6 - Kearney Hub: Device helps Lawter, a paraplegic, take first steps in 25 years (24 August, Mary Jane Skala, 71k uvm; Kearney, NE)
Tammy Lawter struggled to hold back tears. Paralyzed from the chest down 25 years ago, she slowly took her first steps this summer with the assistance of a device called an Indego Exoskeleton. “I couldn’t

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feel my legs, so it was kind of weird, but it felt really good," she said. "It was tempting to stare at my feet to see if they were moving. I was trying hard not to cry, but if I cried, I knew I wouldn't be able to see."

Hyperlink to Above

6.1 - U.S. News &World Report (AP): Veterans Program Yields More Than Just Honey (24 August, Michelle James, 23.3M uvm; Washington, DC)
For 10 days, Ed Forney chatted with each visitor who passed by his table at the West Virginia Grown Country Store at the State Fair of West Virginia. Forney's display attracted a lot of attention, too. Turns out, fairgoers have quite the sweet tooth and there isn't much sweeter — even at the state fair, where food lurks around every corner — than a bottle of honey.

Hyperlink to Above

6.3 - WSAW (CBS-7, Video): Simcakoski Foundation raises money for therapy golf course for veterans (24 August, Stella Porter, 212k uvm; Wausau, WI)
About 150 golfers hit the links at the Glacier Wood Golf Club in Iola on Saturday, playing a round to raise money for the Simcakoski Foundation as a part of their second annual golf outing. The foundation works to help veterans receive proper mental healthcare.

Hyperlink to Above

6.5 - WYOU (CBS-22, Video): Female veterans honored for their service (24 August, Morgan Parrish, 117k uvm; Wilkes Barre, PA)
Pennsylvania is home to the fourth-largest veteran population in the country. Female veterans, who account for roughly eight percent of that population, were honored Saturday morning for their service. Dozens of community members gathered at the Wilkes-Barre VA Center Saturday morning for a women veterans town hall and expo.

Hyperlink to Above

6.11 - The Sheridan Press: Feeding communities: Program helps bridge gap for affordable food (24 August, Claire Schnatterbeck, 18k uvm; Sheridan, WY)
When looking for food on a slim budget, people don't usually turn to the fruit and vegetable section of a grocery store or seek organic produce. Sometimes, when food instability is affecting families, healthy food and cheap food seem mutually exclusive. However, the Cent$able Nutrition program through University of Wyoming Extension at Sheridan College is looking…

Hyperlink to Above

August 26

1.4 - Forbes: A Novel Program at VA Hospitals Uses An Old-World Tradition To Advance Patient Care (25 August, Carmine Gallo, 59.9M uvm; New York, NY)
Humans are hardwired for narrative. We think in story, talk in story and connect with others through the power of story. Storytelling is at the heart of a novel program that's expanding across VA medical facilities across the country.

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Hyperlink to Above

Dennis Lahl FAC-P/PM

Office of the Assistant Deputy Under Secretary for Health for Patient Care Services (10P4)
VACO PCS IT/BCAG/ISO Liaison
TMS OPCS DM
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Dennis Lahl

From: VA Media Analysis <VAMediaAnalysis@barbaricum.com>
Sent: Monday, August 26, 2019 5:17 AM
To: Barbaricum VA Media Analysis <VAMediaAnalysis@barbaricum.com>
Subject: [EXTERNAL] 26 August Veterans Affairs Media Summary and News Clips

Good morning,

Please find the attached Veterans Affairs Media Summary and News Clips.

BARBARICUM http://fileshare.barbaricum.com.s3.amazonaws.com/BBCM.jpeg

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Recipient:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, *(b)(6)* @va.gov>; Law, Cassandra M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f888d507d6c54eb5a92fc44199eb5838-Law, Cassan *(b)(6)* @va.gov>; VHA 10P4 Chief Consultants /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a87c5f11e8414617ac89553ec0973f08-VHA 10P4 Ch <VHA10P4ChiefConsultants@va.gov>; VHA 10P4 Communication Group /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4ba2ff9b4604547be7834a71415253c-VHA 10P4 Co <vha10p4comm@va.gov>; Costa, Francis R. (Frank) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce3e48b6fbcf4b40b30be399fb389ed4-Costa, Fran *(b)(6)* @va.gov>; Utech, Anne E. (HOU) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=da5fd2ae604b4384b33d451c137c3bae-Utech, Anne *(b)(6)* @va.gov>; Morgan, Mark (NOLA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e93d04bca2648b78a574942c6412a4f-Morgan, Mar *(b)(6)* @va.gov>

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Sent Date:	2019/08/26 07:23:27
Delivered Date:	2019/08/26 07:23:33

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1. Top Stories

1.1 - Times and Democrat: Protecting those who served (25 August, Sec. Robert Wilkie, 158k uvm; Orangeburg, SC)
Cpl. Orlando Camacho, Lt. Kenneth Frazier and officer Miguel Calderon didn't know they would save lives when they woke up Aug. 12 and reported to the Jesse Brown VA Medical Center in Chicago. The three members of the Veterans Affairs Police were on duty when shots were fired just outside VA's doors. As alarms blared and people flooded 911 with calls, Camacho, Frazier and Calderon waded past panicked people toward a man with a rifle in his hand who entered the building.

Hyperlink to Above

1.2 - KIVI (ABC-6, Video): #FINDINGHOPE: Sec. Robert Wilkie works to open mental health dialogue (26 August, 111k uvm; Nampa, ID)
Since last October, U.S. Secretary of Veterans Affairs Robert Wilkie says every veteran who's come into the V.A. has received a mental health screening. He says they've now screened close to one million veterans. Wilkie tells 6 On Your Side he hopes to open dialogue when it comes to mental health in veterans and emphasizes that stigmas need to be broken.

Hyperlink to Above

1.3 - CNN (Video): VA staffers blasted 'ridiculous' meetings and questions with Trump allies in internal emails (25 August, Zachary Cohen, 123.6M uvm; Atlanta, GA)
Career officials at the Department of Veterans Affairs expressed deep frustrations over having to entertain "ridiculous" policy recommendations from a trio of influential Mar-a-Lago club members during President Donald Trump's time in office, according to documents released by Citizens for Responsibility and Ethics.

Hyperlink to Above

1.4 - Forbes: A Novel Program at VA Hospitals Uses An Old-World Tradition To Advance Patient Care (25 August, Carmine Gallo, 59.9M uvm; New York, NY)
Humans are hardwired for narrative. We think in story, talk in story and connect with others through the power of story. Storytelling is at the heart of a novel program that's expanding across VA medical facilities across the country.

Hyperlink to Above

1.5 - The Guardian: After the wildfire: treating the mental health crisis triggered by climate change (26 August, Dean Kuipers, 3.4M uvm; New York, NY)
The nightmares kept coming and David Leal knew he was in trouble. A navy veteran with a can-do attitude and a solidly middle-class IT job at a hospital in Santa Rosa, California, he didn't think of himself as mentally vulnerable. But when the Tubbs fire snatched his house off the face of the earth in the early morning hours of 9 October 2017, it hit him hard.

Hyperlink to Above

AMERICAN OVERSIGHT

1.6 - WAVE (NBC-3, WDTV/CBS-5, Video): Death of veteran at W.Va. VA hospital ruled homicide (25 August, 360k uvm; Louisville, KY)
A lawsuit filed by the Tiano O'Dell law firm claims that retired Army Sgt. Felix McDermott received a fatal dose of insulin while a patient at the Louis A. Johnson VA Medical Center, WDTV reported. According to the suit, McDermott, 82, was admitted to the VA medical center on April 6, 2018. He died of hypoglycemia, or severe low blood sugar, on April 9, 2018.

Hyperlink to Above

2. Improving Customer Service

2.1 - The New York Times: PTSD Made Him Walk Away From Public Life. Now He's Heading Back (25 August, 47.9M uvm; New York, NY)
Jason Kander was a rising political star, in the homestretch of a race for mayor of Kansas City that he was widely expected to win. And he was moments away from upending it all. His campaign manager, Abe Rakov, stopped him and asked, "Are you sure this is the thing you want everyone in the world to remember about you forever?"

Hyperlink to Above

2.2 - The Hill: VA officials labeled recommendations from Mar-a-Lago members 'ridiculous': report (25 August, Zack Budryk, 18.4M uvm; Washington, DC)
Staffers at the Department of Veterans Affairs blasted policy recommendations from members of President Trump's Mar-a-Lago club as "ridiculous," according to documents released by a Washington, D.C. governmental ethics watchdog.

Hyperlink to Above

2.3 - The American Legion: Legion briefed on 'exciting time' for VA (25 August, Steven B. Brooks, 378k uvm; Indianapolis, IN)
Implementation earlier this summer of the VA MISSION Act has created "an exciting time" for the Department of Veterans Affairs – specifically the Veterans Health Administration. The reason for that excitement was shared with The American Legion's Veterans Affairs and Rehabilitation Commission on Aug. 24 by Dr. Steven Lieberman, VA's Principle Deputy Under Secretary for Health.

Hyperlink to Above

2.4 - The American Legion: A 'fused, integrated system' of veterans healthcare (25 August, Steven B. Brooks, 378k uvm; Indianapolis, IN)
On June 6, the VA MISSION Act went into effect, with the intent of giving the Department of Veterans Affairs the ability to allow veterans increased access to care through outlets such as telehealth and VA-approved community care providers.

Hyperlink to Above

2.5 - WSAW (CBS-7, WDTV/CBS-5, Video): Death of veteran at Clarksburg VA ruled a homicide; Claim alleges there could be up to 10 more cases (25 August, 212k uvm; Wausau, WI)

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A claim filed by Tiano O'Dell law firm says that retired Army Sergeant Felix McDermott received a fatal dose of insulin while a patient at the Louis A. Johnson VA Medical Center. According to the claim obtained by 5 News, first reported by the Clarksburg Exponent-Telegram, McDermott was admitted to the VAMC on April 6, 2018. He died of hypoglycemia, or severe low blood sugar, on April 9, 2018. He was 82.

Hyperlink to Above

2.6 - KPAX (CBS-8): **Montana VA announces new Chief of Staff** (25 August, 116k uvm; Missoula, MT)
The Montana VA Health Care System welcomed Dr. JP Maganito as the new Chief of Staff on July 21, 2019. Dr. Maganito originally joined the Montana VA Health Care System, Fort Harrison in 2012, serving as the Staff Gynecologist and Occupational Health Medical Officer where he became the Women's Health Medical Director until 2015.

Hyperlink to Above

2.7 - The Intelligencer (Wheeling News-Register): **Act Now to Protect Military Veterans** (25 August, 35k uvm; Wheeling, WV)
Men and women who have served us in the military should not have to worry that they may be murdered if they seek treatment at a Veterans Affairs hospital. Federal authorities are investigating as many as 10 deaths at the Louis A. Johnson VA Medical Center in Clarksburg, it has been reported. At least one of those deaths has been ruled to have been homicide, according to the same reports.

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2.8 - Aberdeen News: **VA offers great health care, but too many changes** (25 August, Gerald Krueger, 16k uvm; Aberdeen, SD)
I am a serious patron of the Aberdeen Veterans Affairs clinic. It is full of friendly, kind, professional health care folks who do such a wonderful job caring for the health needs of us veterans. Every staff member I meet is always willing to do her or his best at caring for our personal health.

Hyperlink to Above

3. **Business Transformation**

3.1 - The Dallas Morning News: **Editorial: Thousands of D-FW veterans need better care. There is a plan to get it for them** (25 August, 4.7M uvm; Dallas, TX)
The North Texas region prides itself on being one of the fastest growing in the country. But a sobering reality is that a big part of that growth includes veterans who need health care at a time when there's a critical shortage of places to get it.

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4. **DOD Cooperation / Electronic Health Records / MISSION Act Implementation**

5. **Suicide Prevention**

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6. Women Veterans / Homelessness / Benefits / Cemeteries

6.1 - Bangor Daily News: A new veterans cemetery in Washington County will be the 2nd in Maine run by feds (25 August, Bill Trotter, 545k uvm; Bangor, ME)
For the first time in more than 80 years, the federal government is building a cemetery for veterans in Maine. The new cemetery is being developed in Jonesboro, with support from a local family, and is expected to be completed by spring of 2020. It will be the second such federal cemetery in Maine, with the first being Togus National Cemetery in Chelsea, near Augusta.

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6.2 - KRQE (CBS-13, Video): Boy Scout gives back to veterans for Eagle Scout project (25 August, Stephanie Chavez, 415k uvm; Albuquerque, NM)
An Albuquerque teen is determined to earn his Eagle Scout Rank and his big project is one that's close to his heart: helping local veterans. Arlen Lovesee is a decorated Boy Scout, with 19 patches, in everything from fitness, to first aid and even basket making. He's been a Scout since he was seven and since day one he's always been determined to earn his Eagle Scout Rank.

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6.3 - Las Vegas Sun: Whether citizens or not, veterans have earned a place in this country (25 August, 180k uvm; Henderson, NV)
An estimated 100,000 veterans of America's armed services are noncitizens who stepped up to protect the nation. But an alarming new report has revealed that the Department of Veterans Affairs and President Donald Trump won't protect them.

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6.4 - WWTV (CBS-9&10, Video): Military Expo Assists Veterans at Wexford Civic Center (25 August, 63k uvm; Tustin, MI)
Serving past, present and future veterans. The Wexford Civic Center in Cadillac hosted the Northwest Michigan Veteran and Military Expo for the first time on Saturday. Sponsors from around Northern Michigan collaborated to provide information for veterans and their families.

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6.5 - Wellsville Daily Reporter: Salute to Bath VA veterans much appreciated. Patriot Guard Ride Captain thanks community (25 August, Skip Merrick, 13k uvm; Wellsville, NY)
I would like to share a little different view of the escort for the veterans from the Bath VA on Aug. 10. Motorcycles rode to Bath to escort the veterans to Allegany County. We saw the New York State Police at the Steuben and Allegany County line; he jumped in and led the escort all the way to York's Corners to help protect the riders.

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7. Other

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7.1 - U.S. News & World Report (AP): Montana Men Get Writing Assignment for False Military Claims (25 August, 23.3M uvm; Washington, DC)
Two Montana men who were sentenced to prison for violating the terms of the probation in separate crimes won't be eligible for parole until they complete a writing assignment given because they falsely claimed to have served in the military to have their cases moved to a Veterans Court.

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1. Top Stories

1.1 - Times and Democrat: **Protecting those who served** (25 August, Sec. Robert Wilkie, 158k uvm; Orangeburg, SC)

Cpl. Orlando Camacho, Lt. Kenneth Frazier and officer Miguel Calderon didn't know they would save lives when they woke up Aug. 12 and reported to the Jesse Brown VA Medical Center in Chicago.

The three members of the Veterans Affairs Police were on duty when shots were fired just outside VA's doors. As alarms blared and people flooded 911 with calls, Camacho, Frazier and Calderon waded past panicked people toward a man with a rifle in his hand who entered the building.

All three drew their firearms and ordered him to drop the rifle. The suspect complied and was quickly handcuffed.

Less than a minute after the call went out, it was all over. VA Police had their man without firing a shot, and no one was hurt.

It's an incredible success story at a time when we continue to wake up to news of violence across the nation. Our hearts break when these tragedies occur, but when our first responders run toward danger and prevent tragedies as these three VA Police officers did that day, our hearts swell with pride.

On behalf of the entire VA family, I thank Camacho, Frazier and Calderon for their prompt, measured and heroic response.

The incident is just the latest point of pride for the VA Police, a family of 4,700 that works around the clock to ensure the safety and security of our medical centers and national cemeteries.

The origins of this police force date back to President Abraham Lincoln's time — they have been working alongside veterans for more than 150 years now, although their role has changed over the years.

The VA Police do more than just protect veterans, families and visitors from outsiders, they are also specially trained to ensure veterans are not a harm to themselves. Suicide prevention is our top clinical priority, and the decision to put our police through rigorous training on how to de-escalate potentially violent situations is a testament to our all-hands-on-deck approach to this issue.

Just months ago, a veteran on a VA campus in Atlanta threatened to take his life. VA Police officer Alonzo Pitmon found the veteran in a car in the parking lot, and repeated to the veteran, "I am here to help you and not hurt you."

This potential victim was taken into custody unharmed, thanks to Pitmen and others.

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These officers undergo specialized training at the VA Law Enforcement Training Center in Arkansas, where they are taught “veteran-centered policing,” which focuses on resolving incidents in a respectful manner that’s designed to ensure the maximum level of safety for anyone in one of our medical centers. They learn to de-escalate situations through apprehension techniques that minimize the amount of force officers use to gain control over these situations.

Our officers also have another edge — many are veterans themselves, and have deeper insight into the sorts of challenges that our veteran patients and their families are facing.

This nation has a duty to understand and treat mental health disorders affecting veterans and non-veterans that lead to violence against others and the tragedy of suicide. As a start, we need discussions at all levels about the value of life, and we must have a plan beyond hoping we can save people by making the equivalent of a last-second diving catch.

We are making important strides in that direction, particularly when it comes to addressing the issue of veteran suicide. Meantime, those VA officers in Chicago, Atlanta and elsewhere have our eternal thanks for engaging in situations in which there is only time to act, not plan, and for fearlessly serving as our last line of defense against the unthinkable.

Robert Wilkie is the secretary of Veterans Affairs. He wrote this for InsideSources.com.

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1.2 - KIVI (ABC-6, Video): #FINDINGHOPE: Sec. Robert Wilkie works to open mental health dialogue (26 August, 111k uvm; Nampa, ID)

BOISE, Idaho — Since last October, U.S. Secretary of Veterans Affairs Robert Wilkie says every veteran who's come into the V.A. has received a mental health screening.

He says they've now screened close to one million veterans.

Wilkie tells 6 On Your Side he hopes to open dialogue when it comes to mental health in veterans and emphasizes that stigmas need to be broken.

"It's a cultural phenomenon that needs to be addressed when that young American first entered the military. It's alright to go see the Chaplain, it's alright to tell us, and that attitude then becomes part of the mindset once that individual comes into the V.A." says WIlkie.

Wilkie also says he's working to create changes that he hopes will have impacts on generations to come by spreading awareness about how to identify warning signs.

6 On Your Side's Madeline White will have more from Secretary Wilkie in Monday night's Finding Hope at 10:00 p.m.

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1.3 - CNN (Video): VA staffers blasted 'ridiculous' meetings and questions with Trump allies in internal emails (25 August, Zachary Cohen, 123.6M uvm; Atlanta, GA)

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Washington (CNN) - Career officials at the Department of Veterans Affairs expressed deep frustrations over having to entertain "ridiculous" policy recommendations from a trio of influential Mar-a-Lago club members during President Donald Trump's time in office, according to documents released by Citizens for Responsibility and Ethics.

A series of internal emails spanning from November 2017 to June 2018, show that VA officials wrote to senior staffers with concerns about how this group of three, known within the department as "the Mar-a-Lago crowd," was given the authority to influence policy despite having no government experience or expertise in veterans issues.

CNN has previously reported how this trio, which included Marvel Entertainment chairman Ike Perlmutter, Bruce Moskowitz, a Palm Beach doctor, and lawyer Marc Sherman, was very open about the fact that they had been "anointed by the President and had his full support to influence policy at the VA" despite never being appointed or installed as formal advisers, sources told CNN.

A former VA official previously told CNN that it was almost as if the Mar-a-Lago group were given influence over the agency as "spoils" after Trump's election victory, adding that the dynamic was "unprecedented."

Their influence at the agency caused "frustration and confusion ... for career government employees having to work outside the bounds of what we know is right," one former department official told CNN last year. "We tried on the government side to keep things appropriate, but senior VA officials were applying pressure to meet these outside demands."

The emails released by CREW last week illustrate that frustration, showing how VA officials repeatedly chafed at having to meet with, and respond to, these informal advisers.

The documents also show that a VA official complained to one senior staffer that questions coming from one of the individuals were "just ridiculous" and "don't make sense."

In one email, VA staff wrote that an outside adviser was "out of his depth" in understanding the department's electronic health records system.

In another exchange, a senior VA official told staff members that Marc Sherman does not "understand the context of government nor does he understand the [app development] contract," noting that his involvement was causing those engaged in the process to "talk past each other."

Yet, VA officials were still obligated to engage with the Mar-a-Lago crowd, even if it was considered to be a waste of time, because of their ties to Trump, the emails suggest.

"They are coming from POTUS friend/doctor," reads one response to a frustrated official who was seeking guidance on how to address a series of "ridiculous" questions they received from one of the individuals.

"Handle sensitively and with facts," the response said.

In another email, a VA official characterized a meeting with two members of the Mar-a-Lago crowd as "just a grin and bear it session."

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"To me the session tomorrow is just a grin and bear it session. I will have my listening hat on for two hours," the official wrote.

The VA did not respond to CNN's request for comment about the comments made in the emails nor the meetings themselves. The White House also did not offer comment.

Veterans Affairs spokesman Curt Cashour, responding to CNN's request for comment last August, did not specifically address details about the three men but said in a statement that the department appreciates "hearing from experts both inside and outside VA as we look for better ways to serve our nation's heroes."

A representative for Perlmutter, Moskowitz, and Sherman did not immediately respond to CNN's request for comment.

Last year, an investigation by ProPublica found that Perlmutter, Moskowitz and Sherman pushed for expanded use of private-sector health options at the VA, proposing to invite "private health care executives to tell the VA which services they should outsource to private providers like themselves."

A former VA official corroborated that account to CNN, saying there was tension over the issue at the VA, with former Secretary David Shulkin accusing the Trump allies of wanting to privatize the VA's health services. The three men told ProPublica they never sought or received financial gain for their work with the VA.

"While we were always willing to share our thoughts, we did not make or implement any type of policy, possess any authority over agency decisions, or direct government officials to take any actions," the statement said.

Still, Congressional lawmakers have made it clear that they want to know more about their influence at the second largest federal agency and the current secretary of Veterans Affairs, Robert Wilkie, has been under pressure to address concerns of improper influence.

On Wednesday, an advocacy group called Democracy Forward announced it is suing Wilkie, alleging he failed "to recover and preserve emails his predecessor, David Shulkin, sent from a personal account used to conduct government business with outside advisers."

The suit alleges that Shulkin specifically created this private email account "to shield his discussions of VA business with the 'Mar-a-Lago Crowd,'" according to a statement from Democracy Forward.

A spokesperson for the VA told CNN that the department does not comment on pending litigation.

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1.4 - Forbes: **A Novel Program at VA Hospitals Uses An Old-World Tradition To Advance Patient Care** (25 August, Carmine Gallo, 59.9M uvm; New York, NY)

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Humans are hardwired for narrative. We think in story, talk in story and connect with others through the power of story. Storytelling is at the heart of a novel program that's expanding across VA medical facilities across the country.

The "My Life, My Story" program uses patient narratives to build a stronger connection and improve care between healthcare providers and their veteran patients. Veterans who choose to participate are interviewed ahead of their appointment by an interviewer who writes a 1,000 word story about the patient and submits it into the person's medical record.

I recently spoke to Thor Ringler, the Department of Veterans Affairs national program manager for My Life, My Story. Ringler's background is uniquely suited for this project. Ringler earned a masters degree in fine arts and poetry before he became a marriage and family therapist. Ringler piloted the narrative-based program at the VA hospital where he works in Madison, Wisconsin.

"If primary care providers know their patients better—what matters to the patient and what their values are—they are better able to approach conversations about care and health decisions," Ringler says.

More than 4,000 narratives have been written by VA hospital staff and volunteers since the program began in 2013. Ringler shared some samples with me. One story was about Joe, a veteran who joined the marines and fought in Vietnam in 1967.

We fought in Con Thien, Phu Bai, and even in the DMZ. We lost a lot of people. At one point our company was down from 500 guys to 100. I did get a hearing concussion from an explosion and was bleeding out of both ears. It was rough at times but I just kept going.

Joe's thirteen month tour in Vietnam haunts him to this day.

I still get flashbacks at night, maybe once a month…It's definitely better now than in the past. I'm able to wake up and calm myself down…I don't care to be unhappy, I just keep going. I'd rather be laughing than frowning.

Joe visited a VA hospital because his sodium levels were low, which may have contributed to his recent stroke. I asked Ringler to explain how writing and sharing these stories improves patient care. According to Ringler, Joe's story invites primary care providers to ask better questions or change a treatment plan. For example, reading Joe's story might prompt a provider to say:

"It seems like you've come up with some ways of calming down when you have flashbacks. I was wondering if you'd be interested in learning some other ways you might be able to handle flashbacks or perhaps even reduce them. We have a lot of treatments available through out mental health service that weren't around when you came home from Vietnam."

According to Ringler, "Stories let us walk in the shoes of our patients and that changes how we think and feel about them."

The story-based program is catching attention, and catching on. In a 2014 survey of healthcare providers at the VA in Madison, 32% strongly agreed that reading patient stories was a "good use of my clinical time." Three years later, the number of healthcare providers who "strongly

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agree" with the program's benefits had jumped to 67%. In addition, a majority of the healthcare providers surveyed say that reading the stories helps them provide better treatment and care.

The results of the program are so promising, the VA has approved an expansion of the program from several dozen medical centers who use it today to 1,500 VA medical facilities who choose to participate.

Effective healthcare leaders act as chief storytellers
Improving communication at all levels of healthcare is a significant area of focus at the VA as well as private hospitals around the country. For example, hospitals in America are rated on patient satisfaction (HCAHPS score). The scores are publicly reported. Government reimbursements to hospitals are also tied to the results. While conducting the research for one of my books, I learned that 70% of negative scores are directly related to a breakdown in communication.

This is a serious problem. Poor communication leads to decreased revenue for healthcare systems and more health problems for patients. Good communication and strong storytelling is directly correlated to better health outcomes and happier, healthy patients.

Dr. David Feinberg, former CEO of UCLA medical center and the current vice president of Google Health, once told me that storytelling is his most important tool as a healthcare leader. "I think of myself as the chief storytelling officer," he said.

When Feinberg was running hospitals, he changed the culture beginning with town halls, staff meetings , and monthly executive meetings. Instead of starting his meeting with PowerPoint slides, tables, charts and revenue graphs, Feinberg invited patients to share stories that reflected on the positive or negative experiences of their care.

At the VA, Ringler says the My Life, My Story program has also prompted leaders to begin their staff meetings by sharing stories of patients and their experiences.

"For veterans, the experience of being interviewed and the knowledge that their story will be shared with providers is an important recognition that they matter and have a voice in their health care," says Ringler.

"In a world of high-technology health care, where time is the only thing in short supply, My Life, My Story leverages the old-world technology of storytelling to bring providers and patients closer together."

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1.5 - The Guardian: **After the wildfire: treating the mental health crisis triggered by climate change** (26 August, Dean Kuipers, 3.4M uvm; New York, NY)

The nightmares kept coming and David Leal knew he was in trouble. A navy veteran with a can-do attitude and a solidly middle-class IT job at a hospital in Santa Rosa, California, he didn't think of himself as mentally vulnerable. But when the Tubbs fire snatched his house off the face of the earth in the early morning hours of 9 October 2017, it hit him hard.

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“Long story short, I went through a lot of PTSD,” Leal says, as we tour his nearly rebuilt home in Santa Rosa’s Coffey Park neighborhood. Wildfires are not uncommon in the mountains outside of this northern California town, but residents can’t remember one like this: the fire jumped six lanes of Highway 101, into the city, and licked up about 1,300 of the suburb’s 2,000 homes as if they’d just evaporated. Leal thought, I live in the city; it’s not supposed to burn.

“Retiring from the navy, I had a lot of junk in my head,” he adds. After the fire, it all came up. “I was having nightmares of occurrences that I went through in the military – but it was going even further back. My brain was just unloading. Every traumatic issue I ever had in my life was coming back to me. There were things that I went through as a little boy that I was waking up going, ‘Whoa. Where did that come from?’”

The climate crisis is manifesting as ever-bigger wildfires, hurricanes, floods and heat waves; and cities are just starting to grapple with the mental impact of the emergency. A climate task force of the American Psychological Association, citing scores of studies over the last decades, reports that survivors of these human-enhanced disasters are experiencing dramatic increases in depression, post-traumatic stress disorder (PTSD), anxiety disorders, suicide and suicidal thoughts, violent behavior and increased use of drugs and alcohol. A Rand study found that one-third of the adult survivors of California wildfires in 2003 suffered depression and one-quarter suffered PTSD.

Those with a history of mental or behavioral issues are particularly at risk. But many others are taken by surprise when they suddenly realize they can’t sleep or work, or can’t shake their sadness.

“It’s a normal human response to a terrible thing,” said Adrienne Heinz, a researcher at the US Department of Veterans Affairs (VA) Center for PTSD who lives in Sonoma.

The mental health effects of climate change have been known for quite some time now: a 1991 meta-study found that as many as 40% of those directly impacted by climate-enhanced superstorms and fires suffer acute negative mental health effects, some of which become chronic. Puerto Rico, for example, has seen an epidemic of suicide, PTSD and depression after hurricanes Irma and Maria. After Hurricane Katrina, some people referred to the sense of generalized anxiety and depression common to survivors as “Katrina brain”.

But it’s not just storms that impact mental health. An extensive 2018 Australian study established that extremes of both hot and cold are linked to suicide and mental illness, and the ensuing drought has contributed to a surge in deaths of Australian farmers. Even those not directly impacted by flood or fire can experience a sense of ecological loss termed “eco-anxiety” or “climate grief”.

Lila Iyer, a doctor of internal medicine who works for the VA, was in her home with her husband, Bala, in Santa Rosa’s high-end Fountaingrove neighborhood when 60mph winds pushing ahead of the Tubbs fire began battering their house. She jumped into one car and he into the other. The cars would be among the few possessions the couple managed to save.

The Iyers’ house was reduced to a blackened foundation, the window glass evaporated and metal melted into puddles. Still, within a few days Iyer went back to work. Helping people was her way to cope. Until she herself suddenly needed help.

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“After Thanksgiving, the stress hit me, bodily hit me,” she said. “I could feel the anxiety and all that coming.” Iyer saw a psychologist, who recommended she try out what she called a “soul yoga” session for fire victims. The sessions weren’t your typical workout yoga. The sequences of this “trauma-informed yoga” were designed to address the way pain and fear embed in the body, and for Iyer, they made a tremendous difference.

“This is like a PTSD,” Iyer said, “and for myself, the yoga was the best form of treatment.”

The yoga classes Iyer attended were the first initiative of an innovative program called the Wildfire Mental Health Collaborative.

The first-of-its-kind collaborative was established by a not-for-profit in Sonoma county, where Santa Rosa lies, following the fires. It offered residents a set of six tools, including a phone app that allows users to track their affect and behavior, private therapy and trauma-informed yoga – all at no cost.

The Healthcare Foundation of northern Sonoma county jumped in to organize the collaborative because residents who’d escaped the fire soon found themselves confronted by another hurdle: government disaster funding may help rebuild their town, but it doesn’t help them cope with the trauma.

In Sonoma, the needs were acute. Outreach workers funded by grants from the Federal Emergency Management Agency (Fema) had made contact with about 70,000 of Sonoma county’s half-million residents following the fires, and referred thousands for mental health services.

But disaster money doesn’t pay for long-term therapy, it’s meant for crisis contact. California’s Department of Health Care Services nor the local government had a pot of money bubbling for that purpose either.

“We knew as people left shelters that they were shellshocked. People were hurting, just really hurting,” said Debbie Mason, the CEO of the Healthcare Foundation of northern Sonoma county.

The collaborative came to life within weeks after the fire, as people who represented mental health professional associations, not-for-profits and clinics in the community asked themselves, “if we were building a fire response for mental health, what would that look like in our community?”, Mason recalled.

The group resolved to use private funding to provide some longer-term help to those identified by the Fema outreach.

The tools they came up with were meant to address residents’ varying needs. Some people just needed to know that their feelings were real and to have someplace to go with them or someone to talk to; others needed long-term psychotherapy.

The tools also included Skills for Psychological Recovery training for mental health professionals and first responders. The technique was developed by Heinz’s colleague Joe Ruzek, who formerly worked at the VA, together with the National Child Traumatic Stress Network. Unlike the widely used practice of Psychological First Aid, SPR is not about diagnosing people and getting them into therapy. Rather, it identifies disaster stressors, like not

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being able to reach the insurance company or missing meds or finding a new school for a child. In times of crisis, these critical tasks can snowball into a personal breakdown.

“SPR is not mental health treatment,” said Christine Naber, a neuropsychologist who co-founded the collaborative. Instead, Naber explained, providers ask clients what they need urgently, what they’re focused on relating to the fire and what they need assistance with – especially when it comes to issues over which clients’ have little control.

SPR was deployed in the aftermath of 9/11; in Newtown, Connecticut, after the school massacre at Sandy Hook; after hurricanes Katrina and Gustav; and after disasters in Canada and Australia. However, most crisis counselors, first responders, and psychological professionals are not currently trained in SPR. Leveraging private funding, the collaborative has now trained over 400 people in SPR, including first responders working on the 2018 Camp fire.

Researchers at Stanford are currently evaluating the impact of the tools offered by the collaborative. Besides the work of the app, they are also studying the usage of SPR by responders and how it affected survivors, as well as the effectiveness of the trauma-informed yoga.

“The biggest goal is being able to share with other communities some information about what works and what doesn’t, and some lessons learned,” said Dr Shannon Wiltsey Stirman, head of the Stanford study. “After a disaster, every community has to scramble and kind of reinvent the wheel.”

Meanwhile, Mason and others in the collaborative have been contacted by communities nationwide looking to share its approach. They’ve also presented the initiative at California’s Office of Emergency Services as a potential disaster response tool statewide. And she’s awaiting another round of presentations to state agencies this fall.

“I’m going to feel victorious if we can get the state to pick this up,” Mason said. “So when the next disaster happens, you go in and say: ‘Here’s the app, here’s the website, here’s the yoga, all that. And here’s the evidence that shows it all works.”

It’s not always easy.

Despite the massive and ongoing destruction caused by wildfires, hurricanes and floods in the US, even a cost-effective program like this is still a hard sell.

Many local governments bank on the belief that there won’t be another hurricane, that no place will burn twice in a lifetime. But that’s not how the world works now. One couple who were in David Leal’s yoga class had lost their home in the Valley fire in Lake county in 2015, then lost their house in Coffey Park in 2017, then moved to the town of Paradise – which was totally destroyed the following year. Last Leal heard, they were living in their pickup camper.

“Right now, when disasters happen in the United States, typically communities are not very well prepared for it,” said Ruzek. “We should be devoting more resources to strengthening and spreading and evolving disaster response and if we did that, that would presumably help communities through all kinds of things.”

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VA-19-1109-B-002017

To residents like Iyer and Leal, the initiative has been invaluable. “These people are angels,” said Leal of the collaborative. He took some of the free yoga classes and ended up teaching classes himself, crediting this with his own recovery. “They have helped so many people.”

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1.6 - WAVE (NBC-3, WDTV/CBS-5, Video): Death of veteran at W.Va. VA hospital ruled homicide (25 August, 360k uvm; Louisville, KY)

CLARKSBURG, W.Va. (WDTV/Gray News) - A lawsuit filed by the Tiano O’Dell law firm claims that retired Army Sgt. Felix McDermott received a fatal dose of insulin while a patient at the Louis A. Johnson VA Medical Center, WDTV reported.

According to the suit, McDermott, 82, was admitted to the VA medical center on April 6, 2018. He died of hypoglycemia, or severe low blood sugar, on April 9, 2018.

The claim stated that employees never told McDermott’s family how he died. He was buried four days later.

On Oct. 23, 2018, McDermott's remains were exhumed and sent to the Dover Air Force Base for an autopsy and investigation.

The autopsy completed in February confirmed that McDermott was not a diabetic and that he was showing improvement in his medical condition when was injected with insulin.

McDermott’s death was ruled a homicide.

The lawsuit also claims that nine or 10 other patients died of severe low blood sugar before McDermott’s death.

“It’s all very disturbing that people who served our country were being killed either extremely negligently, grossly negligently or intentionally, and nobody has done anything about it,” said Tony O’Dell, the family’s lawyer.

The VA medical center breached its duty and was negligent in several ways, the lawsuit said, and thus, their client, the estate of McDermott, is seeking damages of up to $5 million for wrongful death, $1 million for personal injuries and expenses for the funeral and other costs.

"Each time one of these deaths happened, they have an obligation to run at the ground to find out what happened, why it happened, how it could be prevented," O'Dell said.

McDermott was a Vietnam veteran who served for 20 years before retiring.

U.S. Senators Joe Manchin and Shelley Moore-Capito released statements about the claim.

“This news is sickening and troubling," Capito said. "My office has reached out to the VA to learn more details, and I will do everything I can to make sure this is fully investigated.”

Manchin release a statement on the lawsuit, saying: “This report is shocking and if accurate, I am appalled that these crimes were not only committed but that our Veterans, who have

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sacrificed so much for our country, were the victims. As a member of the Senate Veterans Affairs Committee I will do everything in my power to investigate these accusations and get to the bottom of what happened. These families and loved ones deserve answers as soon as possible and I will make sure they get them."

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2. Improving Customer Service

2.1 - The New York Times: PTSD Made Him Walk Away From Public Life. Now He's Heading Back (25 August, 47.9M uvm; New York, NY)

KANSAS CITY, Mo. — Jason Kander was a rising political star, in the homestretch of a race for mayor of Kansas City that he was widely expected to win. And he was moments away from upending it all.

His campaign manager, Abe Rakov, stopped him and asked, "Are you sure this is the thing you want everyone in the world to remember about you forever?"

Mr. Kander said yes. So his manager pressed Send.

In a strikingly candid public letter, Mr. Kander announced that day last October that he was dropping out of the race because of untreated post-traumatic stress disorder from his military service, saying it had become too much for him to bear.

"After 11 years of trying to outrun depression and PTSD symptoms, I have finally concluded that it's faster than me," he explained in the letter. "I have to stop running, turn around and confront it."

Mr. Kander is surely not the first politician to grapple with the psychological wounds of war, but he appears to have been the first to do it so publicly, in the middle of a campaign.

It was not what some close supporters hoped he would do.

"People were telling him to deal with it in secret and stay in the race, but to him that would be dishonest," Mr. Rakov recalled in a recent interview. "Hiding it would be a disservice to other people. He wanted to be part of changing a stigma."

Generations of politicians have assumed that openly acknowledging a psychiatric disorder would kill any chances of a public life. Mr. Kander now has a chance to test that assumption. After months of treatment, he has begun to take his first steps back into politics.

Mr. Kander, a Democrat, is not running for office, though he has not ruled out doing so in the future. He is leading a national expansion of a Kansas City nonprofit group called the Veterans Community Project that provides transitional housing and support services for homeless veterans. The group plans to build housing in eight other communities in the next three years.

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That job has put him in a position to host national candidates passing through Kansas City. And so far, three Democratic presidential candidates — Pete Buttigieg, Seth Moulton and Beto O'Rourke — have made campaign stops at the group this summer.

"I haven't experienced stigma," Mr. Kander said. "If anything, it's the opposite — party donors and boosters, candidates, they are asking me to get more involved."

Until the moment Mr. Kander dropped out last fall, he had led such a charmed political life that even his losses were treated as victories. A progressive in a conservative state, he had served two terms in the State Legislature and one as Missouri secretary of state, all before his 37th birthday. In 2016 he nearly unseated an incumbent Republican senator, Roy Blunt, while Hillary Clinton was losing Missouri by 19 points.

Though he lost that race, he gained national attention for a viral ad in which he assembles a military-style rifle blindfolded while explaining why, as a war veteran, he supported background checks on gun purchases. Soon after, when President Barack Obama was asked who best represented the future of the Democratic Party, Mr. Kander's name was first on the list.

But all that time, Mr. Kander said, he was racked by nightmares, depression and suicidal thoughts stemming from his time as an Army intelligence officer in Afghanistan. Those symptoms had grown so persistent last year that whenever his wife returned home with the couple's 5-year-old son, she made sure to enter the house first, in case she found her husband dead inside.

Mr. Kander joined the Army National Guard in 2005 after getting a law degree at Georgetown University. He deployed in 2006 to Afghanistan, where his mission was to assess the corruption levels of former Afghan warlords and government leaders.

That meant traveling dangerous roads in an unarmored S.U.V. to meet armed men with questionable allegiances. Usually he had no backup other than his Afghan interpreter.

Back in the United States, Mr. Kander would often shrug off his deployment as uneventful. He was never shot or blown up, no one close to him was wounded, and he had never killed anyone.

But deep down, he could not seem to shake the stress of walking into so many meetings where there was a reasonable possibility of his being kidnapped and held hostage, or worse.

He developed a twitch in his left eye, he said. Stopping for red lights made his heart race. Sitting in crowded restaurants became excruciating. He would find himself simmering with anger for no reason. Nightmares of being abducted and killed seemed to play on repeat.

For more than a decade, Mr. Kander said, he refused to acknowledge to himself or anyone else that these might be signs of post-traumatic stress. "I didn't feel like I did enough to earn it," he said, looking back. "I was just some jerk who went to meetings. To even consider I might have PTSD felt like stolen valor."

He dove headlong into politics, allowing himself few spare moments when his thoughts could wander. He would stay up late studying bills or answering constituents' emails to put off the nightmares that would rush in when he went to sleep.

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Mr. Rakov said Mr. Kander's military service was a crucial icebreaker on the campaign trail. "A politician doesn't start with the benefit of the doubt, but someone who served in the military does," he said. "People know you have sacrificed something. They may not agree with you, but they are willing to listen to you."

At the same time, Mr. Kander's military experiences, and their psychological aftermath, were undercutting his ability to function. Close friends and supporters started to notice, but said nothing. "I saw him every day, and saw his symptoms, and didn't do anything about it," Mr. Rakov said with regret.

Military service has long been a steppingstone to a political career. But whether they fought at Kip's Bay or Khe Sanh, political leaders have rarely been open about the aftereffects of combat.

Was George Washington jarred awake on winter nights by the memory of horses shot out from under him or musket balls passing so close that they ripped his coat? Was President Rutherford B. Hayes haunted by the memory of lying wounded in no man's land while the men of his Union Army brigade fell around him? Was Senator George McGovern troubled by the 30 bombing missions he flew during World War II, including the time his B-24 caught on fire and nearly crashed? If they were, they did not say so on the stump.

Few politicians have had to navigate this minefield quite like Senator John McCain, who was held prisoner and tortured for years in North Vietnam. The senator, who died last year, suffered permanent physical injuries, but said he had emerged essentially unscathed psychologically, except for an aversion to the sound of jangling keys, which reminded him of his jailers.

"I pressed him on it," his longtime aide and biographer Mark Salter said in an interview. "'Nothing? You got nothing? Nothing keeps you up at night?' He said no. He said he had left it all behind him."

Even so, Senator McCain was hounded during two presidential runs by whisper campaigns claiming that his years as a prisoner had made him erratic and unfit for office, even after he released thousands of pages of medical records to the media to support his denials.

Over more than 30 years in the Senate, Senator McCain never spoke in depth publicly about the mental toll of his war experience. Neither did his peers.

"We never talked about it, because we couldn't — you couldn't say you were having problems and still be elected," said Max Cleland, who lost both lower legs and part of an arm to a grenade in Vietnam, and went on to represent Georgia in the Senate from 1996 to 2002.

Mr. Cleland said several fellow senators who had fought in Vietnam had nightmares and other post-traumatic stress symptoms while in office, but they would only discuss them privately.

"There wasn't the acceptance there is today," he said. "And we didn't have a name for the issues from combat. We just called it alcoholism."

Mr. Kander decided to break with that tradition last fall. Feeling increasingly depressed and suicidal last fall as the mayoral campaign wore on, he decided to drop out of the race and seek help.

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“It was an incredibly difficult decision, because he didn’t know there was a solution,” said his wife, Diana Kander. “He didn’t know he was trading being mayor for getting healthy, he just knew he was trading away the one thing that was going well.”

In May, Mr. Moulton, the Massachusetts congressman and Marine Corps veteran running for president, revealed that he was haunted by regrets and intrusive memories from four deployments to Iraq, and was seeing a therapist regularly. When he suspended his presidential bid last week, political analysts generally blamed his failure to stand out from a crowded field of candidates, not his candor about his mental health. He remains in the House and said he would seek re-election.

When Mr. Kander dropped out of the mayoral race, he also tried to drop out of sight. He deleted his Twitter account, gave his phone to Mr. Rakov and changed his appearance, growing a beard and wearing a hat to be harder to recognize. He wanted to focus on healing, he said, and not the public reaction to his announcement.

Over the next several months, he went to regular therapy sessions at a Department of Veterans Affairs hospital in Kansas City. Just learning how to recognize and address the symptoms made a huge difference, he said.

His therapist had him record himself telling the stories of his most harrowing experiences in Afghanistan, and then play them back repeatedly until the emotional reins of the episodes loosened. As he did, the nightmares steadily waned.

Mr. Kander said he started exercising and meditating, and feels more at peace now than he had for a decade.

“I’m not cured, but I’m so much better,” he said. “PTSD is like an old knee injury. It’s always going to be there. If you treat it and manage it, it doesn’t have to restrict what you do.”

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2.2 - The Hill: **VA officials labeled recommendations from Mar-a-Lago members 'ridiculous': report** (25 August, Zack Budryk, 18.4M uvm; Washington, DC)

Staffers at the Department of Veterans Affairs blasted policy recommendations from members of President Trump’s Mar-a-Lago club as “ridiculous,” according to documents released by a Washington, D.C. governmental ethics watchdog.

In more than 300 pages of emails obtained by Citizens for Responsibility and Ethics in Washington (CREW) through a Freedom of Information Act request, career VA officials expressed frustration about having to entertain suggestions from Marvel Entertainment chairman Ike Perlmutter, attorney Marc Sherman and Palm Beach-area doctor Bruce Moskowitz.

In one email, a senior department official tells staffers Sherman does not “understand the context of government nor does he understand the [app development] contract,” and that due to his presence, those involved in the process are “talking past each other.”

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Another email, responding to an official questioning how they should address “ridiculous” questions, advised the official, “They are coming from POTUS friend/doctor … Handle sensitively and with facts.”

"To me the session tomorrow is just a grin and bear it session. I will have my listening hat on for two hours," another email says in reference to an upcoming meeting with two of the men.

The three’s influence on the VA was already publicly known, with a 2018 Pro Publica investigation finding they lobbied for increased use of private-sector services within the VA.

The three have denied they influenced policy beyond giving advice, telling Pro Publica, "While we were always willing to share our thoughts, we did not make or implement any type of policy, possess any authority over agency decisions, or direct government officials to take any actions.”

However, emails obtained by CREW show widespread confusion at the VA about the three men’s level of authority.

“He is a White House advisor. I don’t know much about him other than he is important,” one official says of Moskowitz in the emails.

The Hill has reached out to the VA and the White House for comment.

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2.3 - The American Legion: **Legion briefed on 'exciting time' for VA** (25 August, Steven B. Brooks, 378k uvm; Indianapolis, IN)

Implementation earlier this summer of the VA MISSION Act has created “an exciting time” for the Department of Veterans Affairs – specifically the Veterans Health Administration.

The reason for that excitement was shared with The American Legion’s Veterans Affairs and Rehabilitation Commission on Aug. 24 by Dr. Steven Lieberman, VA’s Principle Deputy Under Secretary for Health. Lieberman talked the MISSION Act, as well as VA’s women veterans healthcare and suicide prevention efforts, during his presentation at The American Legion National Convention in Indianapolis.

“It’s a time of big change for us,” Lieberman said. “We are working hard in VA to become what is called a ‘high-reliability organization.’ We want VA to become the safest healthcare system in the country. We want to prevent errors, and when an error does occur that it does not lead to harm.”

The MISSION Act will provide VA to deliver “anywhere to anywhere” care legally across state lines, Lieberman said. “We can fairly quickly start taking care of patients remotely,” he said. “Veterans wanted more choice. So if the wait time in primary care and mental health is over 20 days, or in specialty care over 28 days, we are going to give a veteran the option to go out for their care.”

Increased access to community care isn’t going to transform VA from being a federal agency. “We are not privatizing. That is not our goal,” Lieberman said. “Our goal is to keep strengthening within.”

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On the women veteran front, Lieberman said that veteran population is the fastest growing; VA currently serves approximately 510,000 female patients. Creating an environment in which those women feel safe and secure is a priority for VA.

“We hear that some (women) veterans don’t want to come to the VA,” Lieberman said. “We are constantly talking to women veterans to get their input on this. We heard at one VA in Virginia that they all, as they describe it, ‘dress down.’ They put on a baseball cap, a sweatshirts, jeans, because they think that helps them to get a decreased amount of unwanted comments. This is primarily coming from veterans.

“This is something that we’ve been working on since 2017, but it’s clear to me that we still have not made enough inroads when we’re hearing that our female veterans are afraid to walk into the main hospital.”

Lieberman said efforts have been made to get VA staff comfortable if they hear something from a veteran saying inappropriate comment, “that it’s OK to go up to them and say ‘please sir, we all are welcome here. That is an unwelcome comment. Please don’t make that comment.’ It’s really important to get that word out.”

Suicide-prevention efforts in the veteran community need to be collaborative. “Everybody’s got a responsibility with this,” Lieberman said. “That’s why it’s important to talk about it.”

Lieberman said there is a misconception that suicide is triggered mainly by a mental health issue. “Certainly that’s an issue with many of these suicides,” he said. “But suicides, the reasons for many times are not because of a mental health disease. Suicides are complex. There are maybe one or more reasons why someone chooses to (use) suicide. And we don’t have all the answers. Nobody has all the answers.”

Stressors such as financial difficulty, divorce and difficulty with transitioning into the civilian world can trigger suicidal thoughts and actions. Another, Lieberman said, is social isolation – something that he said The American Legion can assist with.

“If somebody loses their spouse, or moves, they go into isolation,” Lieberman said. “They don’t have that (prior) support system … and they suddenly are very lonely. We believe if you can get them involved in a veteran service organization … get them involved in something … this is just such an important aspect.”

The commission also got an update on Project Atlas, a collaboration between The American Legion, Philips Healthcare and VA. Philips is placing video communication technologies and medical devices in selected American Legion and VFW posts to enable remote examinations through a secure, high-speed internet line. Veterans will be examined and advised in real time through face-to-face video sessions with VA medical professionals, who may be located hundreds or thousands of miles away.

VA”s Kay Burnett, a primary care provider, said she sees patients both in-person and via telehealth. “Being able to have access to a space within a whole community where my veterans, my patients, can go and see me, versus having to come all the way into the facility is a great advantage,” she said. “Yes, there’s still appointments that we want them to come into the facility to, but there’s also appointments that I can see folks in their homes and in their home communities.”

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VA's Lesly Roose said Project Atlas also benefits those veterans in areas where cell connection can be spotty. "What Project Atlas is for those areas where you don't have really good cellular connectivity," she said. "I personally live in a rural area. I struggle with bandwidth sometimes at my own house, so I know what this can be like … Project Atlas will bring that connectivity to a local area where you can go."

Dr. Paul Lawrence, VA's Under Secretary for Benefits, briefed the commission on implantation of the Veterans Appeals Improvement and Modernization Act, and on the status of benefits for Blue Water Navy veterans.

On the latter, Lawrence said that while the Procopio v. Wilkie decision extending disability benefits for Agent Orange exposure to Blue Water Navy veterans won't go into effect until Jan. 1, 2020, work already is underway regarding those claims.

"We are processing and doing development (of claims) now," Lawrence said. "The law requires the benefits go into effect on Jan. 1. We will grant on Jan. 1 for those folks."

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2.4 - The American Legion: A 'fused, integrated system' of veterans healthcare (25 August, Steven B. Brooks, 378k uvm; Indianapolis, IN)

On June 6, the VA MISSION Act went into effect, with the intent of giving the Department of Veterans Affairs the ability to allow veterans increased access to care through outlets such as telehealth and VA-approved community care providers.

On Aug. 24, Legionnaires attending The American Legion National Convention in Indianapolis were given an update on the MISSION Act from those at the forefront of the initiative: Dr. Jennifer MacDonald, VA MISSION Act lead, and Dr. Kameron Matthews, Deputy Under Secretary for Health/Community Care.

The pair spoke to the Legion's Veterans Affairs and Rehabilitation Division about VA's core tenets and approach to implementing the MISSION Act, which included creating a community care network and veterans care agreement.

"We've actually been providing community care since 1945," MacDonald said. "This is a step forward, and it's an expansion in access to care. It's a way to meet the needs of our population that was really, really necessary. But that doesn't stop us from being one fused, integrated system."

Matthews said the MISSION Act replaces a program, Choice, that wasn't good answer to expand access to care. "We did not do that program well," she said. "It was an imperfect piece of legislation … and then we chose a very difficult and unnecessary set of rules to implement. Many of the changes that we put in place (through the MISSION Act) … were really meant to improve upon a lot of the lessons learned that we had in the Choice Program."

Matthews said VA is making it clear access to community care isn't a program on its own. "The idea is we wanted it to be unbranded," she said. "We want community care to eventually become invisible. It is a supplemental form of care that really helps you receive care when you

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do have access in the VA. But it's supplemental to the VA system. We don't want it to be this separate, free-standing, separate-branded program."

That community care is now subjected to new standards and expectations for the providers. "As a former community care provider, I wholeheartedly believe in this: expectations of competency when they are treating our veterans," Matthews said. "They need to have a better understanding of veteran-specific conditions (such as PTSD, military sexual trauma and traumatic brain injury). If community providers are treating those conditions, we expect them to undergo training. We built that training. We expect them to have the appropriate qualification. We must have a higher standard from a quality standpoint, because we want the same exact expectations of the care that we provide in the VA as it would be found in our community network."

Those standards include guidelines for community care providers prescribing opioids to patients. "There is training that all prescribers in the community care network are expected to take," Matthews said.

There is a copay for veterans seeking urgent care from a community provider. "This was not an easily come-to decision," Matthews said. "We looked at it in the sense (that) there needs to be some sort of disincentive to using urgent care more regularly."

MacDonald said the goal is for veterans to get the best care they can via any arm of VA. "We are evolved into what we call a high reliability organization that veterans get the same experience, the same high-quality ease and pleasant emotional experience any time they access care – no matter what facility, and whether that's in person or by telehealth, and any extent of our system they choose to access," she said.

MacDonald also stressed that increased access to community care isn't a step toward privatizing. "We intend to not just not be privatized – that's not what's happening here – but rather be the centerpiece of this and grow," she said. "We're actually starting to see growth in both our direct care system, as well the interest (in community care) but coordinated by VA. We need to embrace the whole spectrum of partners that we have. Community providers are part of that. We want to stay in the middle of this, and stay coordinating that care. This is not only not privatization. We are growing for the future, and we intend to lead."

Also during the meeting, Lee Becker – VA's Veterans Experience Office chief of staff – shared how his office is helping VA transform the way it deals with its stakeholders.

"The biggest thing we have to figure out is how we shift from a customer service to a customer experience mindset," he said. "It has to be provide effective care or benefits, it has to be easy. It cannot be difficult, filling out 20 different forms you pass over a wall and are told 'oh, you missed one part of the block.' And it has to feel good."

Randy Reeves, VA's Under Secretary for Memorial Affairs, praised The American Legion and other veterans service organizations for keeping both VA and Congress "honest … and make sure we do the right thing. So thank you what you're doing every day to protect and serve our veterans."

Reeves said the National Cemetery Administration (NCA) continues to excel at providing service to the nation's veterans and their families. The agency recently was awarded a score of 97 by ACSI (American Customer Satisfaction Index), the only national, cross-industry measure of satisfaction with the quality of goods and services available in the United States.

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“No one has ever scored higher than the National Cemetery Administration in providing service to those it cares for,” Reeves said. “The reason for that is not because of me, and it’s not because of our folks in Washington. It’s because of our personnel who are on the ground across the country in our cemeteries, our scheduling offices, our Memorial Products Services Division and all the other services that we do.

“Eighty percent of our workforce are veterans. If they’re not veterans, they’re connected to veterans in some way. And each and every person in the National Cemetery Administration knows we only have one chance to get it right.”

During a panel discussion, American Legion Past National Commander Ron Conley urged commission members to both participate in and spread the word about the Legion’s online mental health survey. More than 13,000 respondents have participated in the survey.

“It helps us understand how many veterans are out there dealing with (mental health issues),” Conley said.

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2.5 - WSAW (CBS-7, WDTV/CBS-5, Video): Death of veteran at Clarksburg VA ruled a homicide; Claim alleges there could be up to 10 more cases (25 August, 212k uvm; Wausau, WI)

CLARKSBURG, W.Va. (WDTV) - A claim filed by Tiano O'Dell law firm says that retired Army Sergeant Felix McDermott received a fatal dose of insulin while a patient at the Louis A. Johnson VA Medical Center.

According to the claim obtained by 5 News, first reported by the Clarksburg Exponent-Telegram, McDermott was admitted to the VAMC on April 6, 2018. He died of hypoglycemia, or severe low blood sugar, on April 9, 2018. He was 82.

The claim states that employees never told McDermott's family how he died. He was buried 4 days later.

On Oct. 23, 2018, McDermott's remains were exhumed and sent to the Dover Air Force Base for an autopsy and investigation.

The autopsy completed February 2019 confirmed that McDermott was not a diabetic and that he was showing improvement in his medical condition when was injected with insulin.

The autopsy ruled McDermott's death a homicide.

The claim also states that nine or 10 other patients died of severe low blood sugar before McDermott's death.

Tony O'Dell is the family's lawyer.

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"It's all very disturbing that people who served our country were being killed either extremely negligently, grossly negligently, or intentionally, and nobody has done anything about it," O'Dell said.

The claim says the VAMC breached its duty and was negligent in several ways.

The claim says their client, the estate of McDermott, is seeking damages of up to $5 million for wrongful death, $1 million for personal injuries and expenses for the funeral and other costs.

"Each time one of these deaths happened, they have an obligation to run at the ground to find out what happened, why it happened, how it could be prevented," O'Dell said.

McDermott was a Vietnam Veteran who served for 20 years before retiring.

U.S. Senators Joe Manchin and Shelley Moore-Capito released statements about the claim.

“This news is sickening and troubling," Capito said. My office has reached out to the VA to learn more details, and I will do everything I can to make sure this is fully investigated.”

5 news reached out to Congressman David McKinely's office for a statement.

“Congressman McKinley is aware of an ongoing investigation at Clarksburg by the Veterans Administration Office of the Inspector General," said McKinely's Communications Director Amanda Hyman "We hope to get more answers about this situation as that investigation progresses.”

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2.6 - KPAX (CBS-8): **Montana VA announces new Chief of Staff** (25 August, 116k uvm; Missoula, MT)

The Montana VA Health Care System welcomed Dr. JP Maganito as the new Chief of Staff on July 21, 2019.

Dr. Maganito originally joined the Montana VA Health Care System, Fort Harrison in 2012, serving as the Staff Gynecologist and Occupational Health Medical Officer where he became the Women’s Health Medical Director until 2015.

During his time at the VA, he was involved in multiple process improvement and women’s health committees helping increase access to care for our Veterans.

After finishing his internship and residency at Botsford Hospital in Farmington Hills, Michigan in 2009, he became and has maintained his board certification with the American Osteopathic Board of Obstetrics and Gynecologists.

He earned his Doctor of Osteopathic Medicine degree from Des Moines University College of Osteopathic Medicine and Surgery. While earning his doctorate, he simultaneously finished his Masters in Public Health and Masters in Healthcare Administration at Des Moines University College of Health Sciences – Division of Health Management. He’s also certified as a health education specialist and computer information specialist.

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He had left the VA in 2015 in pursuit of subspecialty training as a Female Pelvic Medicine and Reconstructive Surgery fellow with plans to return to the VA to apply this training in serving the Women Veterans.

He has spent the past few years as a lead Medical Director and became the Chief Medical Officer of Blue Cross Blue Shield of Montana whereby he was responsible for providing executive medical leadership as a spokesperson on medical affairs, management, policy, and procedure.

He is a graduate of the Montana Medical Association Physician Leadership Effectiveness Program in 2016 and was recently accepted as a fellow for the American Hospital Insurance Plan Physician Executive Leadership Program for 2020.

With his involvement in our local community and the State of Montana, Dr. Maganito is honored and looks forward to returning to the VA to apply all the experience he has learned both clinically, surgically, and administratively to represent and serve, not only those who have worked tirelessly within the VA system, but more importantly those who so nobly serve this country, our Veterans.

The Montana VA Health Care System serves over 47,000 enrolled Veterans across Montana—an area roughly 147,000 square miles in size. Veterans are cared for by a staff of nearly 1,200 at 17 sites of care across the state.

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2.7 - The Intelligencer (Wheeling News-Register): Act Now to Protect Military Veterans (25 August, 35k uvm; Wheeling, WV)

Men and women who have served us in the military should not have to worry that they may be murdered if they seek treatment at a Veterans Affairs hospital.

Federal authorities are investigating as many as 10 deaths at the Louis A. Johnson VA Medical Center in Clarksburg, it has been reported. At least one of those deaths has been ruled to have been homicide, according to the same reports.

A claim has been filed with the U.S. Department of Veterans Affairs by Charleston attorney Tony O'Dell, regarding the death of the late Felix McDermott, an Army veteran.

O'Dell's claim, filed on behalf of McDermott's daughter, states that though he was not a diabetic, he received an injection of insulin that may have killed him.

The investigation also concluded that "there was evidence that nine or ten other patients … had been wrongfully injected with insulin … thereby causing their deaths," according to O'Dell's claim.

Worse, the claim adds, hospital employees "were aware of each of the unexpected and suspicious deaths."

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VA officials need to get to the bottom of this. More important, they must take action to protect other patients at the Clarksburg facility — where some veterans from our area seek treatment.

The standard answer bureaucrats provide to such reports is that, well, they are just allegations. But if O'Dell is correct, these are conclusions reached by government investigators. That merits decisive, immediate action. We owe our veterans better than to worry that they may be killed because they sought VA medical treatment.

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2.8 - Aberdeen News: **VA offers great health care, but too many changes** (25 August, Gerald Krueger, 16k uvm; Aberdeen, SD)

I am a serious patron of the Aberdeen Veterans Affairs clinic. It is full of friendly, kind, professional health care folks who do such a wonderful job caring for the health needs of us veterans.

Every staff member I meet is always willing to do her or his best at caring for our personal health.

After praising this amazing health care provider, I would like to have the administrators of the national Veterans Health Administration take note of some healthy criticism of its health care facilities nationwide.

There are way too many changes being made, and some of them are just plain dumb and no help to us patients or those loyal providers who seem so dedicated to doing their best to deal with all of the changes. It sort of seems that someone in the upper echelon comes up with a brilliant idea and it gets administered before it is analyzed and vetted properly. It also seems as though they come up with all these ideas/changes and suddenly realize it's going to cost way too much money, so they start scrambling to get out of this new idea without too much damage to the quality of health care.

Their bookkeeping is abominable. They are eager to bill our insurance companies for a quick payment, which makes one wonder if we wouldn't be better off just getting our private provider to get good health care and just forget the VA. Then we get the invoice from our Medicare and supplemental insurance and it has absolutely no explanation of what the care entailed. It's pretty hard for us old vets to try and remember what happened on a particular date six months earlier.

After some serious miscues on the part of the national leaders of the veterans health care clinics, numerous attempts have been made to change veteran health care. I am not complaining about the type of care or the timeliness of such care. My criticism is they are making way too many changes.

The ink doesn't even dry on one change before they make more changes, and the whole thing affects the patrons of the VA as well as myriad staff members who deal with these constant changes. They also make a big deal out of a change with brochures and advertising only to discover the actual costs and realize there is no way they can afford this new idea. So they withdraw all of the publicity they have bought and paid for.

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Please don't get me wrong here, I have nothing but high praises for our own town's VA clinic. It is top-notch in all aspects of health care, but the masters at Veterans Affairs must stop making so many changes. Just pause for a time and take some deep breaths. Things will begin to develop and run more smoothly. We just might see some excellent developments take place.

Nuff said.

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3. Business Transformation

3.1 - The Dallas Morning News: Editorial: Thousands of D-FW veterans need better care. There is a plan to get it for them (25 August, 4.7M uvm; Dallas, TX)

The North Texas region prides itself on being one of the fastest growing in the country. But a sobering reality is that a big part of that growth includes veterans who need health care at a time when there's a critical shortage of places to get it.

That's why we encourage the Veterans Administration to get on board with a proposal to convert the now-abandoned Baylor Scott and White Hospital in Garland into a VA hospital. U.S. Rep. Colin Allred, D-Dallas, told us that he and a bipartisan group of five other area lawmakers are pushing hard to make it happen because it would help serve 184,000 more veterans in North Texas and reduce wait times to get care.

We see it as a way for more of the thousands of vets in this area to be treated the way they deserve.

As it stands, a quick scroll of the VA website reveals that the wait time to get an appointment to see a primary-care physician at the Dallas VA Medical Center in east Oak Cliff is 17 days. That balloons to 28 days at the Fort Worth VA Clinic. Emergency care takes several hours.

What's more, there are no facilities on the east side of the area — meaning if vets need emergency care and the full services a VA Hospital provides, they have to travel miles and miles to get it.

That's unacceptable. A VA acquisition of Baylor's facility makes sense on so many levels.

For starters, Baylor Scott and White's 470,000-square-foot hospital sits vacant. Allred is right that retrofitting a current hospital for VA needs could be much more efficient and less costly than building a hospital from the ground up.

Baylor's hospital is valued at $400 million. Building a new facility would cost up to $1 billion. That's the kind of taxpayer savings our lawmakers ought to be looking for.

And Baylor officials tell us that they are in discussions to either sell or even donate the property to the VA. Nothing's been decided, but they see it as a unique opportunity to further their service to the community.

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It would, of course, also be a win for the city of Garland that would gain about 5,000 jobs, filled by people who could also live and frequent restaurants and businesses there.

We know the glacial pace with which our government can move. And this plan has a long way to go. Still, we were glad to see Allred, on the Veterans Affairs committee, send a letter to the VA urging it to acquire the property. It's a hopeful sign that he was joined by Texas lawmakers that included Republicans Reps. Ron Wright of Arlington, Van Taylor of Plano, Kay Granger of Fort Worth and Michael Burgess of Pilot Point, along with Democrat Eddie Bernice Johnson of Dallas.

"It's a really, really big deal," Allred points out. "If we get it, it'd be enormous." And it could be lifesaving for the men and women who have served and currently serve this country.

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4. DOD Cooperation / Electronic Health Records / MISSION Act Implementation

5. Suicide Prevention

6. Women Veterans / Homelessness / Benefits / Cemeteries

6.1 - Bangor Daily News: **A new veterans cemetery in Washington County will be the 2nd in Maine run by feds** (25 August, Bill Trotter, 545k uvm; Bangor, ME)

For the first time in more than 80 years, the federal government is building a cemetery for veterans in Maine.

The new cemetery is being developed in Jonesboro, with support from a local family, and is expected to be completed by spring of 2020. It will be the second such federal cemetery in Maine, with the first being Togus National Cemetery in Chelsea, near Augusta.

The 6.2-acre property is under development on Route 1 in Jonesboro, near the Columbia Falls town line and the Balsam Valley Amphitheater outdoor music venue, on land donated by Worcester Holdings. The company is part of a group of entities founded by local residents Morrill and Karen Worcester, who also founded and run Worcester Wreath Co. and the nonprofit group Wreaths Across America, which is known for providing wreaths to place on veteran headstones and memorials across the country every Christmas.

Les Melnyk, spokesman for the National Cemetery Administration, said that the project is a result of an initiative by the federal Department of Veterans Affairs to improve burial access for veterans in rural parts of the country. The National Cemetery Administration is a part of the Department of Veterans Affairs.

Because burials at Togus have been restricted since 1961 to veterans, spouses or eligible family members who already have an immediate family member buried on site, Maine currently has no federal veterans cemetery that is accepting new interments, Melnyk said. More than

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5,300 people are buried at the Togus cemetery, which was first established in 1865. Cemetery space at Togus was expanded in 1936, marking the last time the federal government new cemetery space in Maine.

There are four state-run cemeteries for veterans in Maine, with locations in Springvale, Caribou, and two in Augusta. By building a cemetery in eastern Maine, Melnyk said, the VA hopes to better serve veterans and their families who live in the area.

“Currently, more than 92 percent of all veterans living in the U.S. have a burial option at a VA, state, territorial or tribal veterans cemetery within 75 miles of their home,” Melnyk said. The VA “continues to build cemeteries like the one under construction in [Jonesboro] and to fund state, territorial and tribal cemeteries with federal grants, in order to achieve our strategic goal of raising the percentage of those within 75 miles of a cemetery to 95 percent.”

The cemetery has not yet been named, Melnyk said, and a start date for burials at the site has not been determined.

Valiant Construction of Louisville, Kentucky, was awarded a $3.8 million contract in August 2018 to design and construct the cemetery, he said.

Attempts to contact the Worcesters about their donation and the project were unsuccessful.

In addition to building the new veterans’ cemetery in Jonesboro, the federal agency has awarded a $2 million grant to the state-run Southern Maine Veterans Cemetery in Springvale so it can expand, federal officials announced last week.

The expansion in Springvale will create 554 pre-placed crypts and 234 green burial gravesites and will include landscaping and supporting infrastructure, federal officials said. The project will develop approximately 1.6 acres and will enable the cemetery to serve an expanded total of approximately 40,000 veterans, their spouses and eligible family members.

The cemetery’s current design capacity is capped at 20,000 casket burials, according to that cemetery’s website.

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6.2 - KRQE (CBS-13, Video): Boy Scout gives back to veterans for Eagle Scout project (25 August, Stephanie Chavez, 415k uvm; Albuquerque, NM)

An Albuquerque teen is determined to earn his Eagle Scout Rank and his big project is one that’s close to his heart: helping local veterans.

Arlen Lovesee is a decorated Boy Scout, with 19 patches, in everything from fitness, to first aid and even basket making. He’s been a Scout since he was seven and since day one he’s always been determined to earn his Eagle Scout Rank.

“All of my brothers have completed their Eagle, so they were kind of inspiration,” said Arlen.

Over the past three months, he’s been collecting comfort items to donate to the Raymond G. Murphy V.A. Medical Center.

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“My grandfather was a World War II Veteran, so it’s kind of important to me,” said Arlen.

He spent more than 100 hours setting up donations booths, organizing volunteers of all ages and making greeting cards for the veterans.

“The main goal was to help the VA prepare for this winter, and make sure they have enough supplies,” he said.

He collected everything from socks to shaving cream and books and even handmade lap robes. On Friday afternoon Arlen delivered all 35 boxes to the VA.

He says the project showed him what it’s like to be a leader.

“I learned that people are willing to help and be apart of something if you just ask them,” he said.

The Eagle Scout rank is earned by getting 21 Merit Badges and completing a service project that demonstrates leadership and benefits the community. He’ll find out in September if he reached his goal.

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6.3 - Las Vegas Sun: **Whether citizens or not, veterans have earned a place in this country** (25 August, 180k uvm; Henderson, NV)

An estimated 100,000 veterans of America’s armed services are noncitizens who stepped up to protect the nation. But an alarming new report has revealed that the Department of Veterans Affairs and President Donald Trump won’t protect them.

Last week, ProPublica reported that the VA did nothing to shield noncitizen veterans and their families from a new Trump administration rule making it far easier to deny green cards and temporary visas to immigrants. That new rule, known as the public charge regulation, gives federal officials license to reject immigrants who have accessed public benefits or are deemed likely to rely on some forms of public assistance in the future. Other criteria include applicants’ income, credit scores and educational attainment.

It’s a racist and xenophobic policy across the board, but it’s especially unfair toward the nation’s immigrant veterans.

Those commendable individuals displayed a commitment to our country by serving it in uniform. They earned the public benefits they accessed.

But now, with the policy set to take effect in October, they’re on the verge of being punished for accepting assistance they and their families deserved.

That’s unfair and un-American.

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The Department of Defense certainly recognized as much in relation to active-duty military members. Unlike the VA, Defense officials worked extensively to protect current service members and their families from the policy. As ProPublica reported, here's the result:

"Active-duty military members can accept public benefits without jeopardizing their future immigration status; veterans and their families, however, cannot."

That means veterans will get black marks when applying for green cards if they've used public benefits, if they hold low-wage jobs and have meager savings, if they have no postsecondary education, and other factors.

Why didn't veterans get the same protection as active-duty military members? Apparently, it's because they get VA benefits that aren't counted against them, like health care for service-related medical problems and stipends for education. And unlike active-duty personnel, veterans are free to take higher-payingjobs.

But as ProPublica pointed out, not all veterans receive VA benefits. Plus, those benefits aren't designed to replace food stamps, Medicaid and other forms of public assistance that form the broader social safety net.

So think of the injustice of this. While serving, many of these veterans were locked into low military salaries and needed assistance. But now they're being punished for it.

It's unclear how many veterans haven't obtained green cards, but that doesn't matter. What matters is that this is no way to treat anyone who served honorably in a U.S. military uniform.

Surely, even Trump's bootlickers in Congress and his supporters understand what a gross injustice this is.

There's time to fix this before October. To demand change, Americans can comment to the White House by visiting whitehouse.gov/contact.

Meanwhile, here's a show of support for Nevada Attorney General Aaron Ford for signing Nevada into a lawsuit against the public charge regulation, as well as the many state leaders who expressed outrage over the measure and vowed to fight it.

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6.4 - WWTV (CBS-9&10, Video): Military Expo Assists Veterans at Wexford Civic Center
(25 August, 63k uvm; Tustin, MI)

Serving past, present and future veterans.

The Wexford Civic Center in Cadillac hosted the Northwest Michigan Veteran and Military Expo for the first time on Saturday.

Sponsors from around Northern Michigan collaborated to provide information for veterans and their families.

This included military recruiters, Veteran's Affairs officials, Operation Injured Soldiers representatives and more.

The goal of this expo was to support and provide services for our local veterans.

"It gives us an opportunity to make a connection with veterans. We don't pay for advertising," said Michelle Robins of Operation Injured Soldiers.

"93% of everything we bring in goes directly back to our veteran programming."

All of the booths at Saturday's event were sold out.

This means many veterans had the opportunity to get help and information with services in their communities.

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6.5 - Wellsville Daily Reporter: **Salute to Bath VA veterans much appreciated. Patriot Guard Ride Captain thanks community** (25 August, Skip Merrick, 13k uvm; Wellsville, NY)

I would like to share a little different view of the escort for the veterans from the Bath VA on Aug. 10. Motorcycles rode to Bath to escort the veterans to Allegany County. We saw the New York State Police at the Steuben and Allegany County line; he jumped in and led the escort all the way to York's Corners to help protect the riders.

Riding down Route 86 we came to Angelica and on the bridge running over 86 was the Angelica firemen with a Fire Truck, a big American flag draped over the edge of the bridge, plus people waving small flags.

We then continued to the Crossroads in Belvidere for a second staging. Big thanks to Mike Hennessy for opening the Veterans Service Officer Building so veterans could use the facility.

On to Belmont, with Jerome Hart leading the veteran's bus with his vintage police car. The folks in Belmont came out in force and stood with the Honor Guard saluting the veterans from the American Legion Post 808. Firemen helped block the intersection for the escort of 28 motorcycles, two buses of veterans, two cars and one truck flying an American flag.

On to Scio, firemen and women blocked the intersection in Scio, thank you — again making the escort easier.

Wellsville folks came out in force and waved flags and stood with the American Legion Post 702 Honor Guard — thank you. Wellsville Police blocked intersections, thank you.

Wellsville firemen wanted to raise the big flag but it was too windy. Thank you for trying and honoring the veterans.

What a surprise riding down Route 19 below Stannards. Willing fiiremen standing out in front of their fire truck in full turnout gear saluting the veterans, thank you.

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A big thank you to all the people who Saluted the Veterans. Riding a motorcycle in the escort were many veterans. We all felt very proud of the people of Allegany County. Thank you all.

Patriot Guard Ride Captain,

Skip Merrick

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7. Other

7.1 - U.S. News & World Report (AP): Montana Men Get Writing Assignment for False Military Claims (25 August, 23.3M uvm; Washington, DC)

GREAT FALLS, MONT. (AP) — Two Montana men who were sentenced to prison for violating the terms of the probation in separate crimes won't be eligible for parole until they complete a writing assignment given because they falsely claimed to have served in the military to have their cases moved to a Veterans Court.

Cascade County District Judge Greg Pinski sentenced Ryan Patrick Morris, 28, and Troy Allan Nelson, 33, on Friday. Morris got 10 years in prison for violating the terms of his probation for felony burglary, while Nelson got five years on a drug possession conviction. Pinski suspended three years of each defendant's sentence.

Before they can be eligible for parole, Pinski ordered both men to hand write the names of all 6,756 Americans killed in Iraq and Afghanistan; write out the obituaries of the 40 Montanans killed in Iraq and Afghanistan and send hand-written letters of apology to several veterans groups identifying themselves as having lied about military service to receive help and possibly a lesser sentence through a Veterans Court.

Veterans Court programs create and supervise treatment plans to address crimes that may be due to service-related post-traumatic stress disorder, traumatic brain injury, anger issues or substance abuse.

"I want to make sure that my message is received loud and clear by these two defendants," Pinski said Friday.

Morris claimed in 2016 he did seven combat tours in Iraq and Afghanistan, had PTSD and had his hip replaced after being injured by an improvised explosive device. He was sentenced to perform 441 hours of community service with a veteran's organization — one for each Montanan killed in combat since the Korean War. Court records said he only completed 10 hours.

Nelson managed to get himself enrolled in the Veterans Treatment Court before it was determined he hadn't served in the military, the Great Falls Tribune reported .

Once released from prison, they must perform 441 hours of community service.

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Pinski also ordered that during the suspended portions of the sentences the defendants must stand at the Montana Veterans Memorial in Great Falls for eight hours on each Memorial Day and Veterans Day wearing a placard that says: "I am a liar. I am not a veteran. I stole valor. I have dishonored all veterans."

Attorneys for both men objected to the placard condition.

Attorney Mark Frisbie said his client has not been charged with stolen valor, which is a federal crime, but was being punished for it.

Pinski said he was punishing the men for lying to the court. He also cited Montana Supreme Court rulings that give him discretion to take the stolen valor into account and others that upheld the placard requirements.

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Veterans Affairs Media Summary and News Clips

26 August 2019

1. Top Stories

1.1 - Times and Democrat: **Protecting those who served** (25 August, Sec. Robert Wilkie, 158k uvm; Orangeburg, SC)
Cpl. Orlando Camacho, Lt. Kenneth Frazier and officer Miguel Calderon didn't know they would save lives when they woke up Aug. 12 and reported to the Jesse Brown VA Medical Center in Chicago. The three members of the Veterans Affairs Police were on duty when shots were fired just outside VA's doors. As alarms blared and people flooded 911 with calls, Camacho, Frazier and Calderon waded past panicked people toward a man with a rifle in his hand who entered the building.

Hyperlink to Above

1.2 - KIVI (ABC-6, Video): **#FINDINGHOPE: Sec. Robert Wilkie works to open mental health dialogue** (26 August, 111k uvm; Nampa, ID)
Since last October, U.S. Secretary of Veterans Affairs Robert Wilkie says every veteran who's come into the V.A. has received a mental health screening. He says they've now screened close to one million veterans. Wilkie tells 6 On Your Side he hopes to open dialogue when it comes to mental health in veterans and emphasizes that stigmas need to be broken.

Hyperlink to Above

1.3 - CNN (Video): **VA staffers blasted 'ridiculous' meetings and questions with Trump allies in internal emails** (25 August, Zachary Cohen, 123.6M uvm; Atlanta, GA)
Career officials at the Department of Veterans Affairs expressed deep frustrations over having to entertain "ridiculous" policy recommendations from a trio of influential Mar-a-Lago club members during President Donald Trump's time in office, according to documents released by Citizens for Responsibility and Ethics.

Hyperlink to Above

1.4 - Forbes: **A Novel Program at VA Hospitals Uses An Old-World Tradition To Advance Patient Care** (25 August, Carmine Gallo, 59.9M uvm; New York, NY)
Humans are hardwired for narrative. We think in story, talk in story and connect with others through the power of story. Storytelling is at the heart of a novel program that's expanding across VA medical facilities across the country.

Hyperlink to Above

1.5 - The Guardian: **After the wildfire: treating the mental health crisis triggered by climate change** (26 August, Dean Kuipers, 3.4M uvm; New York, NY)
The nightmares kept coming and David Leal knew he was in trouble. A navy veteran with a can-do attitude and a solidly middle-class IT job at a hospital in Santa Rosa, California, he didn't think of himself as mentally vulnerable. But when the Tubbs fire snatched his house off the face of the earth in the early morning hours of 9 October 2017, it hit him hard.

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1.6 - WAVE (NBC-3, WDTV/CBS-5, Video): Death of veteran at W.Va. VA hospital ruled homicide (25 August, 360k uvm; Louisville, KY)
A lawsuit filed by the Tiano O'Dell law firm claims that retired Army Sgt. Felix McDermott received a fatal dose of insulin while a patient at the Louis A. Johnson VA Medical Center, WDTV reported. According to the suit, McDermott, 82, was admitted to the VA medical center on April 6, 2018. He died of hypoglycemia, or severe low blood sugar, on April 9, 2018.

Hyperlink to Above

2. Improving Customer Service

2.1 - The New York Times: PTSD Made Him Walk Away From Public Life. Now He's Heading Back (25 August, 47.9M uvm; New York, NY)
Jason Kander was a rising political star, in the homestretch of a race for mayor of Kansas City that he was widely expected to win. And he was moments away from upending it all. His campaign manager, Abe Rakov, stopped him and asked, "Are you sure this is the thing you want everyone in the world to remember about you forever?"

Hyperlink to Above

2.2 - The Hill: VA officials labeled recommendations from Mar-a-Lago members 'ridiculous': report (25 August, Zack Budryk, 18.4M uvm; Washington, DC)
Staffers at the Department of Veterans Affairs blasted policy recommendations from members of President Trump's Mar-a-Lago club as "ridiculous," according to documents released by a Washington, D.C. governmental ethics watchdog.

Hyperlink to Above

2.3 - The American Legion: Legion briefed on 'exciting time' for VA (25 August, Steven B. Brooks, 378k uvm; Indianapolis, IN)
Implementation earlier this summer of the VA MISSION Act has created "an exciting time" for the Department of Veterans Affairs – specifically the Veterans Health Administration. The reason for that excitement was shared with The American Legion's Veterans Affairs and Rehabilitation Commission on Aug. 24 by Dr. Steven Lieberman, VA's Principle Deputy Under Secretary for Health.

Hyperlink to Above

2.4 - The American Legion: A 'fused, integrated system' of veterans healthcare (25 August, Steven B. Brooks, 378k uvm; Indianapolis, IN)
On June 6, the VA MISSION Act went into effect, with the intent of giving the Department of Veterans Affairs the ability to allow veterans increased access to care through outlets such as telehealth and VA-approved community care providers.

Hyperlink to Above

2.5 - WSAW (CBS-7, WDTV/CBS-5, Video): Death of veteran at Clarksburg VA ruled a homicide; Claim alleges there could be up to 10 more cases (25 August, 212k uvm; Wausau, WI)

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A claim filed by Tiano O'Dell law firm says that retired Army Sergeant Felix McDermott received a fatal dose of insulin while a patient at the Louis A. Johnson VA Medical Center. According to the claim obtained by 5 News, first reported by the Clarksburg Exponent-Telegram, McDermott was admitted to the VAMC on April 6, 2018. He died of hypoglycemia, or severe low blood sugar, on April 9, 2018. He was 82.

Hyperlink to Above

2.6 - KPAX (CBS-8): Montana VA announces new Chief of Staff (25 August, 116k uvm; Missoula, MT)
The Montana VA Health Care System welcomed Dr. JP Maganito as the new Chief of Staff on July 21, 2019. Dr. Maganito originally joined the Montana VA Health Care System, Fort Harrison in 2012, serving as the Staff Gynecologist and Occupational Health Medical Officer where he became the Women's Health Medical Director until 2015.

Hyperlink to Above

2.7 - The Intelligencer (Wheeling News-Register): Act Now to Protect Military Veterans (25 August, 35k uvm; Wheeling, WV)
Men and women who have served us in the military should not have to worry that they may be murdered if they seek treatment at a Veterans Affairs hospital. Federal authorities are investigating as many as 10 deaths at the Louis A. Johnson VA Medical Center in Clarksburg, it has been reported. At least one of those deaths has been ruled to have been homicide, according to the same reports.

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2.8 - Aberdeen News: VA offers great health care, but too many changes (25 August, Gerald Krueger, 16k uvm; Aberdeen, SD)
I am a serious patron of the Aberdeen Veterans Affairs clinic. It is full of friendly, kind, professional health care folks who do such a wonderful job caring for the health needs of us veterans. Every staff member I meet is always willing to do her or his best at caring for our personal health.

Hyperlink to Above

3. Business Transformation

3.1 - The Dallas Morning News: Editorial: Thousands of D-FW veterans need better care. There is a plan to get it for them (25 August, 4.7M uvm; Dallas, TX)
The North Texas region prides itself on being one of the fastest growing in the country. But a sobering reality is that a big part of that growth includes veterans who need health care at a time when there's a critical shortage of places to get it.

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4. DOD Cooperation / Electronic Health Records / MISSION Act Implementation

5. Suicide Prevention

6. Women Veterans / Homelessness / Benefits / Cemeteries

6.1 - Bangor Daily News: A new veterans cemetery in Washington County will be the 2nd in Maine run by feds (25 August, Bill Trotter, 545k uvm; Bangor, ME)
For the first time in more than 80 years, the federal government is building a cemetery for veterans in Maine. The new cemetery is being developed in Jonesboro, with support from a local family, and is expected to be completed by spring of 2020. It will be the second such federal cemetery in Maine, with the first being Togus National Cemetery in Chelsea, near Augusta.

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The three members of the Veterans Affairs Police were on duty when shots were fired just outside VA's doors. As alarms blared and people flooded 911 with calls, Camacho, Frazier and Calderon waded past panicked people toward a man with a rifle in his hand who entered the building.

All three drew their firearms and ordered him to drop the rifle. The suspect complied and was quickly handcuffed.

Less than a minute after the call went out, it was all over. VA Police had their man without firing a shot, and no one was hurt.

It's an incredible success story at a time when we continue to wake up to news of violence across the nation. Our hearts break when these tragedies occur, but when our first responders run toward danger and prevent tragedies as these three VA Police officers did that day, our hearts swell with pride.

On behalf of the entire VA family, I thank Camacho, Frazier and Calderon for their prompt, measured and heroic response.

The incident is just the latest point of pride for the VA Police, a family of 4,700 that works around the clock to ensure the safety and security of our medical centers and national cemeteries.

The origins of this police force date back to President Abraham Lincoln's time — they have been working alongside veterans for more than 150 years now, although their role has changed over the years.

The VA Police do more than just protect veterans, families and visitors from outsiders, they are also specially trained to ensure veterans are not a harm to themselves. Suicide prevention is our top clinical priority, and the decision to put our police through rigorous training on how to de-escalate potentially violent situations is a testament to our all-hands-on-deck approach to this issue.

Just months ago, a veteran on a VA campus in Atlanta threatened to take his life. VA Police officer Alonzo Pitmon found the veteran in a car in the parking lot, and repeated to the veteran, "I am here to help you and not hurt you."

This potential victim was taken into custody unharmed, thanks to Pitmen and others.

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These officers undergo specialized training at the VA Law Enforcement Training Center in Arkansas, where they are taught “veteran-centered policing,” which focuses on resolving incidents in a respectful manner that’s designed to ensure the maximum level of safety for anyone in one of our medical centers. They learn to de-escalate situations through apprehension techniques that minimize the amount of force officers use to gain control over these situations.

Our officers also have another edge — many are veterans themselves, and have deeper insight into the sorts of challenges that our veteran patients and their families are facing.

This nation has a duty to understand and treat mental health disorders affecting veterans and non-veterans that lead to violence against others and the tragedy of suicide. As a start, we need discussions at all levels about the value of life, and we must have a plan beyond hoping we can save people by making the equivalent of a last-second diving catch.

We are making important strides in that direction, particularly when it comes to addressing the issue of veteran suicide. Meantime, those VA officers in Chicago, Atlanta and elsewhere have our eternal thanks for engaging in situations in which there is only time to act, not plan, and for fearlessly serving as our last line of defense against the unthinkable.

Robert Wilkie is the secretary of Veterans Affairs. He wrote this for InsideSources.com.

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1.2 - KIVI (ABC-6, Video): #FINDINGHOPE: Sec. Robert Wilkie works to open mental health dialogue (26 August, 111k uvm; Nampa, ID)

BOISE, Idaho — Since last October, U.S. Secretary of Veterans Affairs Robert Wilkie says every veteran who's come into the V.A. has received a mental health screening.

He says they've now screened close to one million veterans.

Wilkie tells 6 On Your Side he hopes to open dialogue when it comes to mental health in veterans and emphasizes that stigmas need to be broken.

"It's a cultural phenomenon that needs to be addressed when that young American first entered the military. It's alright to go see the Chaplain, it's alright to tell us, and that attitude then becomes part of the mindset once that individual comes into the V.A." says WIlkie.

Wilkie also says he's working to create changes that he hopes will have impacts on generations to come by spreading awareness about how to identify warning signs.

6 On Your Side's Madeline White will have more from Secretary Wilkie in Monday night's Finding Hope at 10:00 p.m.

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1.3 - CNN (Video): VA staffers blasted 'ridiculous' meetings and questions with Trump allies in internal emails (25 August, Zachary Cohen, 123.6M uvm; Atlanta, GA)

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Washington (CNN) - Career officials at the Department of Veterans Affairs expressed deep frustrations over having to entertain "ridiculous" policy recommendations from a trio of influential Mar-a-Lago club members during President Donald Trump's time in office, according to documents released by Citizens for Responsibility and Ethics.

A series of internal emails spanning from November 2017 to June 2018, show that VA officials wrote to senior staffers with concerns about how this group of three, known within the department as "the Mar-a-Lago crowd," was given the authority to influence policy despite having no government experience or expertise in veterans issues.

CNN has previously reported how this trio, which included Marvel Entertainment chairman Ike Perlmutter, Bruce Moskowitz, a Palm Beach doctor, and lawyer Marc Sherman, was very open about the fact that they had been "anointed by the President and had his full support to influence policy at the VA" despite never being appointed or installed as formal advisers, sources told CNN.

A former VA official previously told CNN that it was almost as if the Mar-a-Lago group were given influence over the agency as "spoils" after Trump's election victory, adding that the dynamic was "unprecedented."

Their influence at the agency caused "frustration and confusion ... for career government employees having to work outside the bounds of what we know is right," one former department official told CNN last year. "We tried on the government side to keep things appropriate, but senior VA officials were applying pressure to meet these outside demands."

The emails released by CREW last week illustrate that frustration, showing how VA officials repeatedly chafed at having to meet with, and respond to, these informal advisers.

The documents also show that a VA official complained to one senior staffer that questions coming from one of the individuals were "just ridiculous" and "don't make sense."

In one email, VA staff wrote that an outside adviser was "out of his depth" in understanding the department's electronic health records system.

In another exchange, a senior VA official told staff members that Marc Sherman does not "understand the context of government nor does he understand the [app development] contract," noting that his involvement was causing those engaged in the process to "talk past each other."

Yet, VA officials were still obligated to engage with the Mar-a-Lago crowd, even if it was considered to be a waste of time, because of their ties to Trump, the emails suggest.

"They are coming from POTUS friend/doctor," reads one response to a frustrated official who was seeking guidance on how to address a series of "ridiculous" questions they received from one of the individuals.

"Handle sensitively and with facts," the response said.

In another email, a VA official characterized a meeting with two members of the Mar-a-Lago crowd as "just a grin and bear it session."

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"To me the session tomorrow is just a grin and bear it session. I will have my listening hat on for two hours," the official wrote.

The VA did not respond to CNN's request for comment about the comments made in the emails nor the meetings themselves. The White House also did not offer comment.

Veterans Affairs spokesman Curt Cashour, responding to CNN's request for comment last August, did not specifically address details about the three men but said in a statement that the department appreciates "hearing from experts both inside and outside VA as we look for better ways to serve our nation's heroes."

A representative for Perlmutter, Moskowitz, and Sherman did not immediately respond to CNN's request for comment.

Last year, an investigation by ProPublica found that Perlmutter, Moskowitz and Sherman pushed for expanded use of private-sector health options at the VA, proposing to invite "private health care executives to tell the VA which services they should outsource to private providers like themselves."

A former VA official corroborated that account to CNN, saying there was tension over the issue at the VA, with former Secretary David Shulkin accusing the Trump allies of wanting to privatize the VA's health services. The three men told ProPublica they never sought or received financial gain for their work with the VA.

"While we were always willing to share our thoughts, we did not make or implement any type of policy, possess any authority over agency decisions, or direct government officials to take any actions," the statement said.

Still, Congressional lawmakers have made it clear that they want to know more about their influence at the second largest federal agency and the current secretary of Veterans Affairs, Robert Wilkie, has been under pressure to address concerns of improper influence.

On Wednesday, an advocacy group called Democracy Forward announced it is suing Wilkie, alleging he failed "to recover and preserve emails his predecessor, David Shulkin, sent from a personal account used to conduct government business with outside advisers."

The suit alleges that Shulkin specifically created this private email account "to shield his discussions of VA business with the 'Mar-a-Lago Crowd,'" according to a statement from Democracy Forward.

A spokesperson for the VA told CNN that the department does not comment on pending litigation.

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1.4 - Forbes: **A Novel Program at VA Hospitals Uses An Old-World Tradition To Advance Patient Care** (25 August, Carmine Gallo, 59.9M uvm; New York, NY)

Humans are hardwired for narrative. We think in story, talk in story and connect with others through the power of story. Storytelling is at the heart of a novel program that's expanding across VA medical facilities across the country.

The "My Life, My Story" program uses patient narratives to build a stronger connection and improve care between healthcare providers and their veteran patients. Veterans who choose to participate are interviewed ahead of their appointment by an interviewer who writes a 1,000 word story about the patient and submits it into the person's medical record.

I recently spoke to Thor Ringler, the Department of Veterans Affairs national program manager for My Life, My Story. Ringler's background is uniquely suited for this project. Ringler earned a masters degree in fine arts and poetry before he became a marriage and family therapist. Ringler piloted the narrative-based program at the VA hospital where he works in Madison, Wisconsin.

"If primary care providers know their patients better—what matters to the patient and what their values are—they are better able to approach conversations about care and health decisions," Ringler says.

More than 4,000 narratives have been written by VA hospital staff and volunteers since the program began in 2013. Ringler shared some samples with me. One story was about Joe, a veteran who joined the marines and fought in Vietnam in 1967.

We fought in Con Thien, Phu Bai, and even in the DMZ. We lost a lot of people. At one point our company was down from 500 guys to 100. I did get a hearing concussion from an explosion and was bleeding out of both ears. It was rough at times but I just kept going.

Joe's thirteen month tour in Vietnam haunts him to this day.

I still get flashbacks at night, maybe once a month…It's definitely better now than in the past. I'm able to wake up and calm myself down…I don't care to be unhappy, I just keep going. I'd rather be laughing than frowning.

Joe visited a VA hospital because his sodium levels were low, which may have contributed to his recent stroke. I asked Ringler to explain how writing and sharing these stories improves patient care. According to Ringler, Joe's story invites primary care providers to ask better questions or change a treatment plan. For example, reading Joe's story might prompt a provider to say:

"It seems like you've come up with some ways of calming down when you have flashbacks. I was wondering if you'd be interested in learning some other ways you might be able to handle flashbacks or perhaps even reduce them. We have a lot of treatments available through out mental health service that weren't around when you came home from Vietnam."

According to Ringler, "Stories let us walk in the shoes of our patients and that changes how we think and feel about them."

The story-based program is catching attention, and catching on. In a 2014 survey of healthcare providers at the VA in Madison, 32% strongly agreed that reading patient stories was a "good use of my clinical time." Three years later, the number of healthcare providers who "strongly

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agree" with the program's benefits had jumped to 67%. In addition, a majority of the healthcare providers surveyed say that reading the stories helps them provide better treatment and care.

The results of the program are so promising, the VA has approved an expansion of the program from several dozen medical centers who use it today to 1,500 VA medical facilities who choose to participate.

Effective healthcare leaders act as chief storytellers
Improving communication at all levels of healthcare is a significant area of focus at the VA as well as private hospitals around the country. For example, hospitals in America are rated on patient satisfaction (HCAHPS score). The scores are publicly reported. Government reimbursements to hospitals are also tied to the results. While conducting the research for one of my books, I learned that 70% of negative scores are directly related to a breakdown in communication.

This is a serious problem. Poor communication leads to decreased revenue for healthcare systems and more health problems for patients. Good communication and strong storytelling is directly correlated to better health outcomes and happier, healthy patients.

Dr. David Feinberg, former CEO of UCLA medical center and the current vice president of Google Health, once told me that storytelling is his most important tool as a healthcare leader. "I think of myself as the chief storytelling officer," he said.

When Feinberg was running hospitals, he changed the culture beginning with town halls, staff meetings , and monthly executive meetings. Instead of starting his meeting with PowerPoint slides, tables, charts and revenue graphs, Feinberg invited patients to share stories that reflected on the positive or negative experiences of their care.

At the VA, Ringler says the My Life, My Story program has also prompted leaders to begin their staff meetings by sharing stories of patients and their experiences.

"For veterans, the experience of being interviewed and the knowledge that their story will be shared with providers is an important recognition that they matter and have a voice in their health care," says Ringler.

"In a world of high-technology health care, where time is the only thing in short supply, My Life, My Story leverages the old-world technology of storytelling to bring providers and patients closer together."

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1.5 - The Guardian: **After the wildfire: treating the mental health crisis triggered by climate change** (26 August, Dean Kuipers, 3.4M uvm; New York, NY)

The nightmares kept coming and David Leal knew he was in trouble. A navy veteran with a can-do attitude and a solidly middle-class IT job at a hospital in Santa Rosa, California, he didn't think of himself as mentally vulnerable. But when the Tubbs fire snatched his house off the face of the earth in the early morning hours of 9 October 2017, it hit him hard.

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“Long story short, I went through a lot of PTSD,” Leal says, as we tour his nearly rebuilt home in Santa Rosa’s Coffey Park neighborhood. Wildfires are not uncommon in the mountains outside of this northern California town, but residents can’t remember one like this: the fire jumped six lanes of Highway 101, into the city, and licked up about 1,300 of the suburb’s 2,000 homes as if they’d just evaporated. Leal thought, I live in the city; it’s not supposed to burn.

“Retiring from the navy, I had a lot of junk in my head,” he adds. After the fire, it all came up. “I was having nightmares of occurrences that I went through in the military – but it was going even further back. My brain was just unloading. Every traumatic issue I ever had in my life was coming back to me. There were things that I went through as a little boy that I was waking up going, ‘Whoa. Where did that come from?’”

The climate crisis is manifesting as ever-bigger wildfires, hurricanes, floods and heat waves; and cities are just starting to grapple with the mental impact of the emergency. A climate task force of the American Psychological Association, citing scores of studies over the last decades, reports that survivors of these human-enhanced disasters are experiencing dramatic increases in depression, post-traumatic stress disorder (PTSD), anxiety disorders, suicide and suicidal thoughts, violent behavior and increased use of drugs and alcohol. A Rand study found that one-third of the adult survivors of California wildfires in 2003 suffered depression and one-quarter suffered PTSD.

Those with a history of mental or behavioral issues are particularly at risk. But many others are taken by surprise when they suddenly realize they can’t sleep or work, or can’t shake their sadness.

“It’s a normal human response to a terrible thing,” said Adrienne Heinz, a researcher at the US Department of Veterans Affairs (VA) Center for PTSD who lives in Sonoma.

The mental health effects of climate change have been known for quite some time now: a 1991 meta-study found that as many as 40% of those directly impacted by climate-enhanced superstorms and fires suffer acute negative mental health effects, some of which become chronic. Puerto Rico, for example, has seen an epidemic of suicide, PTSD and depression after hurricanes Irma and Maria. After Hurricane Katrina, some people referred to the sense of generalized anxiety and depression common to survivors as “Katrina brain”.

But it’s not just storms that impact mental health. An extensive 2018 Australian study established that extremes of both hot and cold are linked to suicide and mental illness, and the ensuing drought has contributed to a surge in deaths of Australian farmers. Even those not directly impacted by flood or fire can experience a sense of ecological loss termed “eco-anxiety” or “climate grief”.

Lila Iyer, a doctor of internal medicine who works for the VA, was in her home with her husband, Bala, in Santa Rosa’s high-end Fountaingrove neighborhood when 60mph winds pushing ahead of the Tubbs fire began battering their house. She jumped into one car and he into the other. The cars would be among the few possessions the couple managed to save.

The Iyers’ house was reduced to a blackened foundation, the window glass evaporated and metal melted into puddles. Still, within a few days Iyer went back to work. Helping people was her way to cope. Until she herself suddenly needed help.

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“After Thanksgiving, the stress hit me, bodily hit me,” she said. “I could feel the anxiety and all that coming.” Iyer saw a psychologist, who recommended she try out what she called a “soul yoga” session for fire victims. The sessions weren’t your typical workout yoga. The sequences of this “trauma-informed yoga” were designed to address the way pain and fear embed in the body, and for Iyer, they made a tremendous difference.

“This is like a PTSD,” Iyer said, “and for myself, the yoga was the best form of treatment.”

The yoga classes Iyer attended were the first initiative of an innovative program called the Wildfire Mental Health Collaborative.

The first-of-its-kind collaborative was established by a not-for-profit in Sonoma county, where Santa Rosa lies, following the fires. It offered residents a set of six tools, including a phone app that allows users to track their affect and behavior, private therapy and trauma-informed yoga – all at no cost.

The Healthcare Foundation of northern Sonoma county jumped in to organize the collaborative because residents who’d escaped the fire soon found themselves confronted by another hurdle: government disaster funding may help rebuild their town, but it doesn’t help them cope with the trauma.

In Sonoma, the needs were acute. Outreach workers funded by grants from the Federal Emergency Management Agency (Fema) had made contact with about 70,000 of Sonoma county’s half-million residents following the fires, and referred thousands for mental health services.

But disaster money doesn’t pay for long-term therapy, it’s meant for crisis contact. California’s Department of Health Care Services nor the local government had a pot of money bubbling for that purpose either.

“We knew as people left shelters that they were shellshocked. People were hurting, just really hurting,” said Debbie Mason, the CEO of the Healthcare Foundation of northern Sonoma county.

The collaborative came to life within weeks after the fire, as people who represented mental health professional associations, not-for-profits and clinics in the community asked themselves, “if we were building a fire response for mental health, what would that look like in our community?”, Mason recalled.

The group resolved to use private funding to provide some longer-term help to those identified by the Fema outreach.

The tools they came up with were meant to address residents’ varying needs. Some people just needed to know that their feelings were real and to have someplace to go with them or someone to talk to; others needed long-term psychotherapy.

The tools also included Skills for Psychological Recovery training for mental health professionals and first responders. The technique was developed by Heinz’s colleague Joe Ruzek, who formerly worked at the VA, together with the National Child Traumatic Stress Network. Unlike the widely used practice of Psychological First Aid, SPR is not about diagnosing people and getting them into therapy. Rather, it identifies disaster stressors, like not

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being able to reach the insurance company or missing meds or finding a new school for a child. In times of crisis, these critical tasks can snowball into a personal breakdown.

“SPR is not mental health treatment,” said Christine Naber, a neuropsychologist who co-founded the collaborative. Instead, Naber explained, providers ask clients what they need urgently, what they’re focused on relating to the fire and what they need assistance with – especially when it comes to issues over which clients’ have little control.

SPR was deployed in the aftermath of 9/11; in Newtown, Connecticut, after the school massacre at Sandy Hook; after hurricanes Katrina and Gustav; and after disasters in Canada and Australia. However, most crisis counselors, first responders, and psychological professionals are not currently trained in SPR. Leveraging private funding, the collaborative has now trained over 400 people in SPR, including first responders working on the 2018 Camp fire.

Researchers at Stanford are currently evaluating the impact of the tools offered by the collaborative. Besides the work of the app, they are also studying the usage of SPR by responders and how it affected survivors, as well as the effectiveness of the trauma-informed yoga.

“The biggest goal is being able to share with other communities some information about what works and what doesn’t, and some lessons learned,” said Dr Shannon Wiltsey Stirman, head of the Stanford study. “After a disaster, every community has to scramble and kind of reinvent the wheel.”

Meanwhile, Mason and others in the collaborative have been contacted by communities nationwide looking to share its approach. They’ve also presented the initiative at California’s Office of Emergency Services as a potential disaster response tool statewide. And she’s awaiting another round of presentations to state agencies this fall.

“I’m going to feel victorious if we can get the state to pick this up,” Mason said. “So when the next disaster happens, you go in and say: ‘Here’s the app, here’s the website, here’s the yoga, all that. And here’s the evidence that shows it all works.”

It’s not always easy.

Despite the massive and ongoing destruction caused by wildfires, hurricanes and floods in the US, even a cost-effective program like this is still a hard sell.

Many local governments bank on the belief that there won’t be another hurricane, that no place will burn twice in a lifetime. But that’s not how the world works now. One couple who were in David Leal’s yoga class had lost their home in the Valley fire in Lake county in 2015, then lost their house in Coffey Park in 2017, then moved to the town of Paradise – which was totally destroyed the following year. Last Leal heard, they were living in their pickup camper.

“Right now, when disasters happen in the United States, typically communities are not very well prepared for it,” said Ruzek. “We should be devoting more resources to strengthening and spreading and evolving disaster response and if we did that, that would presumably help communities through all kinds of things.”

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To residents like Iyer and Leal, the initiative has been invaluable. “These people are angels,” said Leal of the collaborative. He took some of the free yoga classes and ended up teaching classes himself, crediting this with his own recovery. “They have helped so many people.”

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1.6 - WAVE (NBC-3, WDTV/CBS-5, Video): Death of veteran at W.Va. VA hospital ruled homicide (25 August, 360k uvm; Louisville, KY)

CLARKSBURG, W.Va. (WDTV/Gray News) - A lawsuit filed by the Tiano O’Dell law firm claims that retired Army Sgt. Felix McDermott received a fatal dose of insulin while a patient at the Louis A. Johnson VA Medical Center, WDTV reported.

According to the suit, McDermott, 82, was admitted to the VA medical center on April 6, 2018. He died of hypoglycemia, or severe low blood sugar, on April 9, 2018.

The claim stated that employees never told McDermott’s family how he died. He was buried four days later.

On Oct. 23, 2018, McDermott's remains were exhumed and sent to the Dover Air Force Base for an autopsy and investigation.

The autopsy completed in February confirmed that McDermott was not a diabetic and that he was showing improvement in his medical condition when was injected with insulin.

McDermott’s death was ruled a homicide.

The lawsuit also claims that nine or 10 other patients died of severe low blood sugar before McDermott’s death.

“It’s all very disturbing that people who served our country were being killed either extremely negligently, grossly negligently or intentionally, and nobody has done anything about it,” said Tony O’Dell, the family’s lawyer.

The VA medical center breached its duty and was negligent in several ways, the lawsuit said, and thus, their client, the estate of McDermott, is seeking damages of up to $5 million for wrongful death, $1 million for personal injuries and expenses for the funeral and other costs.

"Each time one of these deaths happened, they have an obligation to run at the ground to find out what happened, why it happened, how it could be prevented," O'Dell said.

McDermott was a Vietnam veteran who served for 20 years before retiring.

U.S. Senators Joe Manchin and Shelley Moore-Capito released statements about the claim.

“This news is sickening and troubling," Capito said. "My office has reached out to the VA to learn more details, and I will do everything I can to make sure this is fully investigated.”

Manchin release a statement on the lawsuit, saying: “This report is shocking and if accurate, I am appalled that these crimes were not only committed but that our Veterans, who have

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sacrificed so much for our country, were the victims. As a member of the Senate Veterans Affairs Committee I will do everything in my power to investigate these accusations and get to the bottom of what happened. These families and loved ones deserve answers as soon as possible and I will make sure they get them."

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2. Improving Customer Service

2.1 - The New York Times: PTSD Made Him Walk Away From Public Life. Now He's Heading Back (25 August, 47.9M uvm; New York, NY)

KANSAS CITY, Mo. — Jason Kander was a rising political star, in the homestretch of a race for mayor of Kansas City that he was widely expected to win. And he was moments away from upending it all.

His campaign manager, Abe Rakov, stopped him and asked, "Are you sure this is the thing you want everyone in the world to remember about you forever?"

Mr. Kander said yes. So his manager pressed Send.

In a strikingly candid public letter, Mr. Kander announced that day last October that he was dropping out of the race because of untreated post-traumatic stress disorder from his military service, saying it had become too much for him to bear.

"After 11 years of trying to outrun depression and PTSD symptoms, I have finally concluded that it's faster than me," he explained in the letter. "I have to stop running, turn around and confront it."

Mr. Kander is surely not the first politician to grapple with the psychological wounds of war, but he appears to have been the first to do it so publicly, in the middle of a campaign.

It was not what some close supporters hoped he would do.

"People were telling him to deal with it in secret and stay in the race, but to him that would be dishonest," Mr. Rakov recalled in a recent interview. "Hiding it would be a disservice to other people. He wanted to be part of changing a stigma."

Generations of politicians have assumed that openly acknowledging a psychiatric disorder would kill any chances of a public life. Mr. Kander now has a chance to test that assumption. After months of treatment, he has begun to take his first steps back into politics.

Mr. Kander, a Democrat, is not running for office, though he has not ruled out doing so in the future. He is leading a national expansion of a Kansas City nonprofit group called the Veterans Community Project that provides transitional housing and support services for homeless veterans. The group plans to build housing in eight other communities in the next three years.

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That job has put him in a position to host national candidates passing through Kansas City. And so far, three Democratic presidential candidates — Pete Buttigieg, Seth Moulton and Beto O'Rourke — have made campaign stops at the group this summer.

"I haven't experienced stigma," Mr. Kander said. "If anything, it's the opposite — party donors and boosters, candidates, they are asking me to get more involved."

Until the moment Mr. Kander dropped out last fall, he had led such a charmed political life that even his losses were treated as victories. A progressive in a conservative state, he had served two terms in the State Legislature and one as Missouri secretary of state, all before his 37th birthday. In 2016 he nearly unseated an incumbent Republican senator, Roy Blunt, while Hillary Clinton was losing Missouri by 19 points.

Though he lost that race, he gained national attention for a viral ad in which he assembles a military-style rifle blindfolded while explaining why, as a war veteran, he supported background checks on gun purchases. Soon after, when President Barack Obama was asked who best represented the future of the Democratic Party, Mr. Kander's name was first on the list.

But all that time, Mr. Kander said, he was racked by nightmares, depression and suicidal thoughts stemming from his time as an Army intelligence officer in Afghanistan. Those symptoms had grown so persistent last year that whenever his wife returned home with the couple's 5-year-old son, she made sure to enter the house first, in case she found her husband dead inside.

Mr. Kander joined the Army National Guard in 2005 after getting a law degree at Georgetown University. He deployed in 2006 to Afghanistan, where his mission was to assess the corruption levels of former Afghan warlords and government leaders.

That meant traveling dangerous roads in an unarmored S.U.V. to meet armed men with questionable allegiances. Usually he had no backup other than his Afghan interpreter.

Back in the United States, Mr. Kander would often shrug off his deployment as uneventful. He was never shot or blown up, no one close to him was wounded, and he had never killed anyone.

But deep down, he could not seem to shake the stress of walking into so many meetings where there was a reasonable possibility of his being kidnapped and held hostage, or worse.

He developed a twitch in his left eye, he said. Stopping for red lights made his heart race. Sitting in crowded restaurants became excruciating. He would find himself simmering with anger for no reason. Nightmares of being abducted and killed seemed to play on repeat.

For more than a decade, Mr. Kander said, he refused to acknowledge to himself or anyone else that these might be signs of post-traumatic stress. "I didn't feel like I did enough to earn it," he said, looking back. "I was just some jerk who went to meetings. To even consider I might have PTSD felt like stolen valor."

He dove headlong into politics, allowing himself few spare moments when his thoughts could wander. He would stay up late studying bills or answering constituents' emails to put off the nightmares that would rush in when he went to sleep.

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Mr. Rakov said Mr. Kander's military service was a crucial icebreaker on the campaign trail. "A politician doesn't start with the benefit of the doubt, but someone who served in the military does," he said. "People know you have sacrificed something. They may not agree with you, but they are willing to listen to you."

At the same time, Mr. Kander's military experiences, and their psychological aftermath, were undercutting his ability to function. Close friends and supporters started to notice, but said nothing. "I saw him every day, and saw his symptoms, and didn't do anything about it," Mr. Rakov said with regret.

Military service has long been a steppingstone to a political career. But whether they fought at Kip's Bay or Khe Sanh, political leaders have rarely been open about the aftereffects of combat.

Was George Washington jarred awake on winter nights by the memory of horses shot out from under him or musket balls passing so close that they ripped his coat? Was President Rutherford B. Hayes haunted by the memory of lying wounded in no man's land while the men of his Union Army brigade fell around him? Was Senator George McGovern troubled by the 30 bombing missions he flew during World War II, including the time his B-24 caught on fire and nearly crashed? If they were, they did not say so on the stump.

Few politicians have had to navigate this minefield quite like Senator John McCain, who was held prisoner and tortured for years in North Vietnam. The senator, who died last year, suffered permanent physical injuries, but said he had emerged essentially unscathed psychologically, except for an aversion to the sound of jangling keys, which reminded him of his jailers.

"I pressed him on it," his longtime aide and biographer Mark Salter said in an interview. "'Nothing? You got nothing? Nothing keeps you up at night?' He said no. He said he had left it all behind him."

Even so, Senator McCain was hounded during two presidential runs by whisper campaigns claiming that his years as a prisoner had made him erratic and unfit for office, even after he released thousands of pages of medical records to the media to support his denials.

Over more than 30 years in the Senate, Senator McCain never spoke in depth publicly about the mental toll of his war experience. Neither did his peers.

"We never talked about it, because we couldn't — you couldn't say you were having problems and still be elected," said Max Cleland, who lost both lower legs and part of an arm to a grenade in Vietnam, and went on to represent Georgia in the Senate from 1996 to 2002.

Mr. Cleland said several fellow senators who had fought in Vietnam had nightmares and other post-traumatic stress symptoms while in office, but they would only discuss them privately.

"There wasn't the acceptance there is today," he said. "And we didn't have a name for the issues from combat. We just called it alcoholism."

Mr. Kander decided to break with that tradition last fall. Feeling increasingly depressed and suicidal last fall as the mayoral campaign wore on, he decided to drop out of the race and seek help.

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“It was an incredibly difficult decision, because he didn’t know there was a solution,” said his wife, Diana Kander. “He didn’t know he was trading being mayor for getting healthy, he just knew he was trading away the one thing that was going well.”

In May, Mr. Moulton, the Massachusetts congressman and Marine Corps veteran running for president, revealed that he was haunted by regrets and intrusive memories from four deployments to Iraq, and was seeing a therapist regularly. When he suspended his presidential bid last week, political analysts generally blamed his failure to stand out from a crowded field of candidates, not his candor about his mental health. He remains in the House and said he would seek re-election.

When Mr. Kander dropped out of the mayoral race, he also tried to drop out of sight. He deleted his Twitter account, gave his phone to Mr. Rakov and changed his appearance, growing a beard and wearing a hat to be harder to recognize. He wanted to focus on healing, he said, and not the public reaction to his announcement.

Over the next several months, he went to regular therapy sessions at a Department of Veterans Affairs hospital in Kansas City. Just learning how to recognize and address the symptoms made a huge difference, he said.

His therapist had him record himself telling the stories of his most harrowing experiences in Afghanistan, and then play them back repeatedly until the emotional reins of the episodes loosened. As he did, the nightmares steadily waned.

Mr. Kander said he started exercising and meditating, and feels more at peace now than he had for a decade.

“I’m not cured, but I’m so much better,” he said. “PTSD is like an old knee injury. It’s always going to be there. If you treat it and manage it, it doesn’t have to restrict what you do.”

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2.2 - The Hill: **VA officials labeled recommendations from Mar-a-Lago members 'ridiculous': report** (25 August, Zack Budryk, 18.4M uvm; Washington, DC)

Staffers at the Department of Veterans Affairs blasted policy recommendations from members of President Trump’s Mar-a-Lago club as “ridiculous,” according to documents released by a Washington, D.C. governmental ethics watchdog.

In more than 300 pages of emails obtained by Citizens for Responsibility and Ethics in Washington (CREW) through a Freedom of Information Act request, career VA officials expressed frustration about having to entertain suggestions from Marvel Entertainment chairman Ike Perlmutter, attorney Marc Sherman and Palm Beach-area doctor Bruce Moskowitz.

In one email, a senior department official tells staffers Sherman does not “understand the context of government nor does he understand the [app development] contract,” and that due to his presence, those involved in the process are “talking past each other.”

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Another email, responding to an official questioning how they should address “ridiculous” questions, advised the official, “They are coming from POTUS friend/doctor … Handle sensitively and with facts.”

"To me the session tomorrow is just a grin and bear it session. I will have my listening hat on for two hours," another email says in reference to an upcoming meeting with two of the men.

The three’s influence on the VA was already publicly known, with a 2018 Pro Publica investigation finding they lobbied for increased use of private-sector services within the VA.

The three have denied they influenced policy beyond giving advice, telling Pro Publica, "While we were always willing to share our thoughts, we did not make or implement any type of policy, possess any authority over agency decisions, or direct government officials to take any actions.”

However, emails obtained by CREW show widespread confusion at the VA about the three men’s level of authority.

“He is a White House advisor. I don’t know much about him other than he is important,” one official says of Moskowitz in the emails.

The Hill has reached out to the VA and the White House for comment.

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2.3 - The American Legion: **Legion briefed on 'exciting time' for VA** (25 August, Steven B. Brooks, 378k uvm; Indianapolis, IN)

Implementation earlier this summer of the VA MISSION Act has created “an exciting time” for the Department of Veterans Affairs – specifically the Veterans Health Administration.

The reason for that excitement was shared with The American Legion’s Veterans Affairs and Rehabilitation Commission on Aug. 24 by Dr. Steven Lieberman, VA’s Principle Deputy Under Secretary for Health. Lieberman talked the MISSION Act, as well as VA’s women veterans healthcare and suicide prevention efforts, during his presentation at The American Legion National Convention in Indianapolis.

“It’s a time of big change for us,” Lieberman said. “We are working hard in VA to become what is called a ‘high-reliability organization.’ We want VA to become the safest healthcare system in the country. We want to prevent errors, and when an error does occur that it does not lead to harm.”

The MISSION Act will provide VA to deliver “anywhere to anywhere” care legally across state lines, Lieberman said. “We can fairly quickly start taking care of patients remotely,” he said. “Veterans wanted more choice. So if the wait time in primary care and mental health is over 20 days, or in specialty care over 28 days, we are going to give a veteran the option to go out for their care.”

Increased access to community care isn’t going to transform VA from being a federal agency. “We are not privatizing. That is not our goal,” Lieberman said. “Our goal is to keep strengthening within.”

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On the women veteran front, Lieberman said that veteran population is the fastest growing; VA currently serves approximately 510,000 female patients. Creating an environment in which those women feel safe and secure is a priority for VA.

“We hear that some (women) veterans don’t want to come to the VA,” Lieberman said. “We are constantly talking to women veterans to get their input on this. We heard at one VA in Virginia that they all, as they describe it, ‘dress down.’ They put on a baseball cap, a sweatshirts, jeans, because they think that helps them to get a decreased amount of unwanted comments. This is primarily coming from veterans.

“This is something that we’ve been working on since 2017, but it’s clear to me that we still have not made enough inroads when we’re hearing that our female veterans are afraid to walk into the main hospital.”

Lieberman said efforts have been made to get VA staff comfortable if they hear something from a veteran saying inappropriate comment, “that it’s OK to go up to them and say ‘please sir, we all are welcome here. That is an unwelcome comment. Please don’t make that comment.’ It’s really important to get that word out.”

Suicide-prevention efforts in the veteran community need to be collaborative. “Everybody’s got a responsibility with this,” Lieberman said. “That’s why it’s important to talk about it.”

Lieberman said there is a misconception that suicide is triggered mainly by a mental health issue. “Certainly that’s an issue with many of these suicides,” he said. “But suicides, the reasons for many times are not because of a mental health disease. Suicides are complex. There are maybe one or more reasons why someone chooses to (use) suicide. And we don’t have all the answers. Nobody has all the answers.”

Stressors such as financial difficulty, divorce and difficulty with transitioning into the civilian world can trigger suicidal thoughts and actions. Another, Lieberman said, is social isolation – something that he said The American Legion can assist with.

“If somebody loses their spouse, or moves, they go into isolation,” Lieberman said. “They don’t have that (prior) support system … and they suddenly are very lonely. We believe if you can get them involved in a veteran service organization … get them involved in something … this is just such an important aspect.”

The commission also got an update on Project Atlas, a collaboration between The American Legion, Philips Healthcare and VA. Philips is placing video communication technologies and medical devices in selected American Legion and VFW posts to enable remote examinations through a secure, high-speed internet line. Veterans will be examined and advised in real time through face-to-face video sessions with VA medical professionals, who may be located hundreds or thousands of miles away.

VA”s Kay Burnett, a primary care provider, said she sees patients both in-person and via telehealth. “Being able to have access to a space within a whole community where my veterans, my patients, can go and see me, versus having to come all the way into the facility is a great advantage,” she said. “Yes, there’s still appointments that we want them to come into the facility to, but there’s also appointments that I can see folks in their homes and in their home communities.”

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VA's Lesly Roose said Project Atlas also benefits those veterans in areas where cell connection can be spotty. "What Project Atlas is for those areas where you don't have really good cellular connectivity," she said. "I personally live in a rural area. I struggle with bandwidth sometimes at my own house, so I know what this can be like … Project Atlas will bring that connectivity to a local area where you can go."

Dr. Paul Lawrence, VA's Under Secretary for Benefits, briefed the commission on implantation of the Veterans Appeals Improvement and Modernization Act, and on the status of benefits for Blue Water Navy veterans.

On the latter, Lawrence said that while the Procopio v. Wilkie decision extending disability benefits for Agent Orange exposure to Blue Water Navy veterans won't go into effect until Jan. 1, 2020, work already is underway regarding those claims.

"We are processing and doing development (of claims) now," Lawrence said. "The law requires the benefits go into effect on Jan. 1. We will grant on Jan. 1 for those folks."

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2.4 - The American Legion: A 'fused, integrated system' of veterans healthcare (25 August, Steven B. Brooks, 378k uvm; Indianapolis, IN)

On June 6, the VA MISSION Act went into effect, with the intent of giving the Department of Veterans Affairs the ability to allow veterans increased access to care through outlets such as telehealth and VA-approved community care providers.

On Aug. 24, Legionnaires attending The American Legion National Convention in Indianapolis were given an update on the MISSION Act from those at the forefront of the initiative: Dr. Jennifer MacDonald, VA MISSION Act lead, and Dr. Kameron Matthews, Deputy Under Secretary for Health/Community Care.

The pair spoke to the Legion's Veterans Affairs and Rehabilitation Division about VA's core tenets and approach to implementing the MISSION Act, which included creating a community care network and veterans care agreement.

"We've actually been providing community care since 1945," MacDonald said. "This is a step forward, and it's an expansion in access to care. It's a way to meet the needs of our population that was really, really necessary. But that doesn't stop us from being one fused, integrated system."

Matthews said the MISSION Act replaces a program, Choice, that wasn't good answer to expand access to care. "We did not do that program well," she said. "It was an imperfect piece of legislation … and then we chose a very difficult and unnecessary set of rules to implement. Many of the changes that we put in place (through the MISSION Act) … were really meant to improve upon a lot of the lessons learned that we had in the Choice Program."

Matthews said VA is making it clear access to community care isn't a program on its own. "The idea is we wanted it to be unbranded," she said. "We want community care to eventually become invisible. It is a supplemental form of care that really helps you receive care when you

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do have access in the VA. But it's supplemental to the VA system. We don't want it to be this separate, free-standing, separate-branded program."

That community care is now subjected to new standards and expectations for the providers. "As a former community care provider, I wholeheartedly believe in this: expectations of competency when they are treating our veterans," Matthews said. "They need to have a better understanding of veteran-specific conditions (such as PTSD, military sexual trauma and traumatic brain injury). If community providers are treating those conditions, we expect them to undergo training. We built that training. We expect them to have the appropriate qualification. We must have a higher standard from a quality standpoint, because we want the same exact expectations of the care that we provide in the VA as it would be found in our community network."

Those standards include guidelines for community care providers prescribing opioids to patients. "There is training that all prescribers in the community care network are expected to take," Matthews said.

There is a copay for veterans seeking urgent care from a community provider. "This was not an easily come-to decision," Matthews said. "We looked at it in the sense (that) there needs to be some sort of disincentive to using urgent care more regularly."

MacDonald said the goal is for veterans to get the best care they can via any arm of VA. "We are evolved into what we call a high reliability organization that veterans get the same experience, the same high-quality ease and pleasant emotional experience any time they access care – no matter what facility, and whether that's in person or by telehealth, and any extent of our system they choose to access," she said.

MacDonald also stressed that increased access to community care isn't a step toward privatizing. "We intend to not just not be privatized – that's not what's happening here – but rather be the centerpiece of this and grow," she said. "We're actually starting to see growth in both our direct care system, as well the interest (in community care) but coordinated by VA. We need to embrace the whole spectrum of partners that we have. Community providers are part of that. We want to stay in the middle of this, and stay coordinating that care. This is not only not privatization. We are growing for the future, and we intend to lead."

Also during the meeting, Lee Becker – VA's Veterans Experience Office chief of staff – shared how his office is helping VA transform the way it deals with its stakeholders.

"The biggest thing we have to figure out is how we shift from a customer service to a customer experience mindset," he said. "It has to be provide effective care or benefits, it has to be easy. It cannot be difficult, filling out 20 different forms you pass over a wall and are told 'oh, you missed one part of the block.' And it has to feel good."

Randy Reeves, VA's Under Secretary for Memorial Affairs, praised The American Legion and other veterans service organizations for keeping both VA and Congress "honest … and make sure we do the right thing. So thank you what you're doing every day to protect and serve our veterans."

Reeves said the National Cemetery Administration (NCA) continues to excel at providing service to the nation's veterans and their families. The agency recently was awarded a score of 97 by ACSI (American Customer Satisfaction Index), the only national, cross-industry measure of satisfaction with the quality of goods and services available in the United States.

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“No one has ever scored higher than the National Cemetery Administration in providing service to those it cares for,” Reeves said. “The reason for that is not because of me, and it’s not because of our folks in Washington. It’s because of our personnel who are on the ground across the country in our cemeteries, our scheduling offices, our Memorial Products Services Division and all the other services that we do.

“Eighty percent of our workforce are veterans. If they’re not veterans, they’re connected to veterans in some way. And each and every person in the National Cemetery Administration knows we only have one chance to get it right.”

During a panel discussion, American Legion Past National Commander Ron Conley urged commission members to both participate in and spread the word about the Legion’s online mental health survey. More than 13,000 respondents have participated in the survey.

“It helps us understand how many veterans are out there dealing with (mental health issues),” Conley said.

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2.5 - WSAW (CBS-7, WDTV/CBS-5, Video): Death of veteran at Clarksburg VA ruled a homicide; Claim alleges there could be up to 10 more cases (25 August, 212k uvm; Wausau, WI)

CLARKSBURG, W.Va. (WDTV) - A claim filed by Tiano O'Dell law firm says that retired Army Sergeant Felix McDermott received a fatal dose of insulin while a patient at the Louis A. Johnson VA Medical Center.

According to the claim obtained by 5 News, first reported by the Clarksburg Exponent-Telegram, McDermott was admitted to the VAMC on April 6, 2018. He died of hypoglycemia, or severe low blood sugar, on April 9, 2018. He was 82.

The claim states that employees never told McDermott's family how he died. He was buried 4 days later.

On Oct. 23, 2018, McDermott's remains were exhumed and sent to the Dover Air Force Base for an autopsy and investigation.

The autopsy completed February 2019 confirmed that McDermott was not a diabetic and that he was showing improvement in his medical condition when was injected with insulin.

The autopsy ruled McDermott's death a homicide.

The claim also states that nine or 10 other patients died of severe low blood sugar before McDermott's death.

Tony O'Dell is the family's lawyer.

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"It's all very disturbing that people who served our country were being killed either extremely negligently, grossly negligently, or intentionally, and nobody has done anything about it," O'Dell said.

The claim says the VAMC breached its duty and was negligent in several ways.

The claim says their client, the estate of McDermott, is seeking damages of up to $5 million for wrongful death, $1 million for personal injuries and expenses for the funeral and other costs.

"Each time one of these deaths happened, they have an obligation to run at the ground to find out what happened, why it happened, how it could be prevented," O'Dell said.

McDermott was a Vietnam Veteran who served for 20 years before retiring.

U.S. Senators Joe Manchin and Shelley Moore-Capito released statements about the claim.

“This news is sickening and troubling," Capito said. My office has reached out to the VA to learn more details, and I will do everything I can to make sure this is fully investigated.”

5 news reached out to Congressman David McKinely's office for a statement.

“Congressman McKinley is aware of an ongoing investigation at Clarksburg by the Veterans Administration Office of the Inspector General," said McKinely's Communications Director Amanda Hyman "We hope to get more answers about this situation as that investigation progresses.”

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2.6 - KPAX (CBS-8): Montana VA announces new Chief of Staff (25 August, 116k uvm; Missoula, MT)

The Montana VA Health Care System welcomed Dr. JP Maganito as the new Chief of Staff on July 21, 2019.

Dr. Maganito originally joined the Montana VA Health Care System, Fort Harrison in 2012, serving as the Staff Gynecologist and Occupational Health Medical Officer where he became the Women’s Health Medical Director until 2015.

During his time at the VA, he was involved in multiple process improvement and women’s health committees helping increase access to care for our Veterans.

After finishing his internship and residency at Botsford Hospital in Farmington Hills, Michigan in 2009, he became and has maintained his board certification with the American Osteopathic Board of Obstetrics and Gynecologists.

He earned his Doctor of Osteopathic Medicine degree from Des Moines University College of Osteopathic Medicine and Surgery. While earning his doctorate, he simultaneously finished his Masters in Public Health and Masters in Healthcare Administration at Des Moines University College of Health Sciences – Division of Health Management. He’s also certified as a health education specialist and computer information specialist.

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He had left the VA in 2015 in pursuit of subspecialty training as a Female Pelvic Medicine and Reconstructive Surgery fellow with plans to return to the VA to apply this training in serving the Women Veterans.

He has spent the past few years as a lead Medical Director and became the Chief Medical Officer of Blue Cross Blue Shield of Montana whereby he was responsible for providing executive medical leadership as a spokesperson on medical affairs, management, policy, and procedure.

He is a graduate of the Montana Medical Association Physician Leadership Effectiveness Program in 2016 and was recently accepted as a fellow for the American Hospital Insurance Plan Physician Executive Leadership Program for 2020.

With his involvement in our local community and the State of Montana, Dr. Maganito is honored and looks forward to returning to the VA to apply all the experience he has learned both clinically, surgically, and administratively to represent and serve, not only those who have worked tirelessly within the VA system, but more importantly those who so nobly serve this country, our Veterans.

The Montana VA Health Care System serves over 47,000 enrolled Veterans across Montana—an area roughly 147,000 square miles in size. Veterans are cared for by a staff of nearly 1,200 at 17 sites of care across the state.

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2.7 - The Intelligencer (Wheeling News-Register): Act Now to Protect Military Veterans (25 August, 35k uvm; Wheeling, WV)

Men and women who have served us in the military should not have to worry that they may be murdered if they seek treatment at a Veterans Affairs hospital.

Federal authorities are investigating as many as 10 deaths at the Louis A. Johnson VA Medical Center in Clarksburg, it has been reported. At least one of those deaths has been ruled to have been homicide, according to the same reports.

A claim has been filed with the U.S. Department of Veterans Affairs by Charleston attorney Tony O'Dell, regarding the death of the late Felix McDermott, an Army veteran.

O'Dell's claim, filed on behalf of McDermott's daughter, states that though he was not a diabetic, he received an injection of insulin that may have killed him.

The investigation also concluded that "there was evidence that nine or ten other patients … had been wrongfully injected with insulin … thereby causing their deaths," according to O'Dell's claim.

Worse, the claim adds, hospital employees "were aware of each of the unexpected and suspicious deaths."

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VA officials need to get to the bottom of this. More important, they must take action to protect other patients at the Clarksburg facility — where some veterans from our area seek treatment.

The standard answer bureaucrats provide to such reports is that, well, they are just allegations. But if O'Dell is correct, these are conclusions reached by government investigators. That merits decisive, immediate action. We owe our veterans better than to worry that they may be killed because they sought VA medical treatment.

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2.8 - Aberdeen News: VA offers great health care, but too many changes (25 August, Gerald Krueger, 16k uvm; Aberdeen, SD)

I am a serious patron of the Aberdeen Veterans Affairs clinic. It is full of friendly, kind, professional health care folks who do such a wonderful job caring for the health needs of us veterans.

Every staff member I meet is always willing to do her or his best at caring for our personal health.

After praising this amazing health care provider, I would like to have the administrators of the national Veterans Health Administration take note of some healthy criticism of its health care facilities nationwide.

There are way too many changes being made, and some of them are just plain dumb and no help to us patients or those loyal providers who seem so dedicated to doing their best to deal with all of the changes. It sort of seems that someone in the upper echelon comes up with a brilliant idea and it gets administered before it is analyzed and vetted properly. It also seems as though they come up with all these ideas/changes and suddenly realize it's going to cost way too much money, so they start scrambling to get out of this new idea without too much damage to the quality of health care.

Their bookkeeping is abominable. They are eager to bill our insurance companies for a quick payment, which makes one wonder if we wouldn't be better off just getting our private provider to get good health care and just forget the VA. Then we get the invoice from our Medicare and supplemental insurance and it has absolutely no explanation of what the care entailed. It's pretty hard for us old vets to try and remember what happened on a particular date six months earlier.

After some serious miscues on the part of the national leaders of the veterans health care clinics, numerous attempts have been made to change veteran health care. I am not complaining about the type of care or the timeliness of such care. My criticism is they are making way too many changes.

The ink doesn't even dry on one change before they make more changes, and the whole thing affects the patrons of the VA as well as myriad staff members who deal with these constant changes. They also make a big deal out of a change with brochures and advertising only to discover the actual costs and realize there is no way they can afford this new idea. So they withdraw all of the publicity they have bought and paid for.

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Please don't get me wrong here, I have nothing but high praises for our own town's VA clinic. It is top-notch in all aspects of health care, but the masters at Veterans Affairs must stop making so many changes. Just pause for a time and take some deep breaths. Things will begin to develop and run more smoothly. We just might see some excellent developments take place.

Nuff said.

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3. Business Transformation

3.1 - The Dallas Morning News: Editorial: Thousands of D-FW veterans need better care. There is a plan to get it for them (25 August, 4.7M uvm; Dallas, TX)

The North Texas region prides itself on being one of the fastest growing in the country. But a sobering reality is that a big part of that growth includes veterans who need health care at a time when there's a critical shortage of places to get it.

That's why we encourage the Veterans Administration to get on board with a proposal to convert the now-abandoned Baylor Scott and White Hospital in Garland into a VA hospital. U.S. Rep. Colin Allred, D-Dallas, told us that he and a bipartisan group of five other area lawmakers are pushing hard to make it happen because it would help serve 184,000 more veterans in North Texas and reduce wait times to get care.

We see it as a way for more of the thousands of vets in this area to be treated the way they deserve.

As it stands, a quick scroll of the VA website reveals that the wait time to get an appointment to see a primary-care physician at the Dallas VA Medical Center in east Oak Cliff is 17 days. That balloons to 28 days at the Fort Worth VA Clinic. Emergency care takes several hours.

What's more, there are no facilities on the east side of the area — meaning if vets need emergency care and the full services a VA Hospital provides, they have to travel miles and miles to get it.

That's unacceptable. A VA acquisition of Baylor's facility makes sense on so many levels.

For starters, Baylor Scott and White's 470,000-square-foot hospital sits vacant. Allred is right that retrofitting a current hospital for VA needs could be much more efficient and less costly than building a hospital from the ground up.

Baylor's hospital is valued at $400 million. Building a new facility would cost up to $1 billion. That's the kind of taxpayer savings our lawmakers ought to be looking for.

And Baylor officials tell us that they are in discussions to either sell or even donate the property to the VA. Nothing's been decided, but they see it as a unique opportunity to further their service to the community.

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It would, of course, also be a win for the city of Garland that would gain about 5,000 jobs, filled by people who could also live and frequent restaurants and businesses there.

We know the glacial pace with which our government can move. And this plan has a long way to go. Still, we were glad to see Allred, on the Veterans Affairs committee, send a letter to the VA urging it to acquire the property. It's a hopeful sign that he was joined by Texas lawmakers that included Republicans Reps. Ron Wright of Arlington, Van Taylor of Plano, Kay Granger of Fort Worth and Michael Burgess of Pilot Point, along with Democrat Eddie Bernice Johnson of Dallas.

"It's a really, really big deal," Allred points out. "If we get it, it'd be enormous." And it could be lifesaving for the men and women who have served and currently serve this country.

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4. DOD Cooperation / Electronic Health Records / MISSION Act Implementation

5. Suicide Prevention

6. Women Veterans / Homelessness / Benefits / Cemeteries

6.1 - Bangor Daily News: **A new veterans cemetery in Washington County will be the 2nd in Maine run by feds** (25 August, Bill Trotter, 545k uvm; Bangor, ME)

For the first time in more than 80 years, the federal government is building a cemetery for veterans in Maine.

The new cemetery is being developed in Jonesboro, with support from a local family, and is expected to be completed by spring of 2020. It will be the second such federal cemetery in Maine, with the first being Togus National Cemetery in Chelsea, near Augusta.

The 6.2-acre property is under development on Route 1 in Jonesboro, near the Columbia Falls town line and the Balsam Valley Amphitheater outdoor music venue, on land donated by Worcester Holdings. The company is part of a group of entities founded by local residents Morrill and Karen Worcester, who also founded and run Worcester Wreath Co. and the nonprofit group Wreaths Across America, which is known for providing wreaths to place on veteran headstones and memorials across the country every Christmas.

Les Melnyk, spokesman for the National Cemetery Administration, said that the project is a result of an initiative by the federal Department of Veterans Affairs to improve burial access for veterans in rural parts of the country. The National Cemetery Administration is a part of the Department of Veterans Affairs.

Because burials at Togus have been restricted since 1961 to veterans, spouses or eligible family members who already have an immediate family member buried on site, Maine currently has no federal veterans cemetery that is accepting new interments, Melnyk said. More than

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5,300 people are buried at the Togus cemetery, which was first established in 1865. Cemetery space at Togus was expanded in 1936, marking the last time the federal government new cemetery space in Maine.

There are four state-run cemeteries for veterans in Maine, with locations in Springvale, Caribou, and two in Augusta. By building a cemetery in eastern Maine, Melnyk said, the VA hopes to better serve veterans and their families who live in the area.

“Currently, more than 92 percent of all veterans living in the U.S. have a burial option at a VA, state, territorial or tribal veterans cemetery within 75 miles of their home,” Melnyk said. The VA “continues to build cemeteries like the one under construction in [Jonesboro] and to fund state, territorial and tribal cemeteries with federal grants, in order to achieve our strategic goal of raising the percentage of those within 75 miles of a cemetery to 95 percent.”

The cemetery has not yet been named, Melnyk said, and a start date for burials at the site has not been determined.

Valiant Construction of Louisville, Kentucky, was awarded a $3.8 million contract in August 2018 to design and construct the cemetery, he said.

Attempts to contact the Worcesters about their donation and the project were unsuccessful.

In addition to building the new veterans’ cemetery in Jonesboro, the federal agency has awarded a $2 million grant to the state-run Southern Maine Veterans Cemetery in Springvale so it can expand, federal officials announced last week.

The expansion in Springvale will create 554 pre-placed crypts and 234 green burial gravesites and will include landscaping and supporting infrastructure, federal officials said. The project will develop approximately 1.6 acres and will enable the cemetery to serve an expanded total of approximately 40,000 veterans, their spouses and eligible family members.

The cemetery’s current design capacity is capped at 20,000 casket burials, according to that cemetery’s website.

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6.2 - KRQE (CBS-13, Video): Boy Scout gives back to veterans for Eagle Scout project (25 August, Stephanie Chavez, 415k uvm; Albuquerque, NM)

An Albuquerque teen is determined to earn his Eagle Scout Rank and his big project is one that’s close to his heart: helping local veterans.

Arlen Lovesee is a decorated Boy Scout, with 19 patches, in everything from fitness, to first aid and even basket making. He’s been a Scout since he was seven and since day one he’s always been determined to earn his Eagle Scout Rank.

“All of my brothers have completed their Eagle, so they were kind of inspiration,” said Arlen.

Over the past three months, he’s been collecting comfort items to donate to the Raymond G. Murphy V.A. Medical Center.

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“My grandfather was a World War II Veteran, so it’s kind of important to me,” said Arlen.

He spent more than 100 hours setting up donations booths, organizing volunteers of all ages and making greeting cards for the veterans.

“The main goal was to help the VA prepare for this winter, and make sure they have enough supplies,” he said.

He collected everything from socks to shaving cream and books and even handmade lap robes. On Friday afternoon Arlen delivered all 35 boxes to the VA.

He says the project showed him what it’s like to be a leader.

“I learned that people are willing to help and be apart of something if you just ask them,” he said.

The Eagle Scout rank is earned by getting 21 Merit Badges and completing a service project that demonstrates leadership and benefits the community. He’ll find out in September if he reached his goal.

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6.3 - Las Vegas Sun: **Whether citizens or not, veterans have earned a place in this country** (25 August, 180k uvm; Henderson, NV)

An estimated 100,000 veterans of America’s armed services are noncitizens who stepped up to protect the nation. But an alarming new report has revealed that the Department of Veterans Affairs and President Donald Trump won’t protect them.

Last week, ProPublica reported that the VA did nothing to shield noncitizen veterans and their families from a new Trump administration rule making it far easier to deny green cards and temporary visas to immigrants. That new rule, known as the public charge regulation, gives federal officials license to reject immigrants who have accessed public benefits or are deemed likely to rely on some forms of public assistance in the future. Other criteria include applicants’ income, credit scores and educational attainment.

It’s a racist and xenophobic policy across the board, but it’s especially unfair toward the nation’s immigrant veterans.

Those commendable individuals displayed a commitment to our country by serving it in uniform. They earned the public benefits they accessed.

But now, with the policy set to take effect in October, they’re on the verge of being punished for accepting assistance they and their families deserved.

That’s unfair and un-American.

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The Department of Defense certainly recognized as much in relation to active-duty military members. Unlike the VA, Defense officials worked extensively to protect current service members and their families from the policy. As ProPublica reported, here's the result:

"Active-duty military members can accept public benefits without jeopardizing their future immigration status; veterans and their families, however, cannot."

That means veterans will get black marks when applying for green cards if they've used public benefits, if they hold low-wage jobs and have meager savings, if they have no postsecondary education, and other factors.

Why didn't veterans get the same protection as active-duty military members? Apparently, it's because they get VA benefits that aren't counted against them, like health care for service-related medical problems and stipends for education. And unlike active-duty personnel, veterans are free to take higher-payingjobs.

But as ProPublica pointed out, not all veterans receive VA benefits. Plus, those benefits aren't designed to replace food stamps, Medicaid and other forms of public assistance that form the broader social safety net.

So think of the injustice of this. While serving, many of these veterans were locked into low military salaries and needed assistance. But now they're being punished for it.

It's unclear how many veterans haven't obtained green cards, but that doesn't matter. What matters is that this is no way to treat anyone who served honorably in a U.S. military uniform.

Surely, even Trump's bootlickers in Congress and his supporters understand what a gross injustice this is.

There's time to fix this before October. To demand change, Americans can comment to the White House by visiting whitehouse.gov/contact.

Meanwhile, here's a show of support for Nevada Attorney General Aaron Ford for signing Nevada into a lawsuit against the public charge regulation, as well as the many state leaders who expressed outrage over the measure and vowed to fight it.

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6.4 - WWTV (CBS-9&10, Video): Military Expo Assists Veterans at Wexford Civic Center
(25 August, 63k uvm; Tustin, MI)

Serving past, present and future veterans.

The Wexford Civic Center in Cadillac hosted the Northwest Michigan Veteran and Military Expo for the first time on Saturday.

Sponsors from around Northern Michigan collaborated to provide information for veterans and their families.

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This included military recruiters, Veteran's Affairs officials, Operation Injured Soldiers representatives and more.

The goal of this expo was to support and provide services for our local veterans.

"It gives us an opportunity to make a connection with veterans. We don't pay for advertising," said Michelle Robins of Operation Injured Soldiers.

"93% of everything we bring in goes directly back to our veteran programming."

All of the booths at Saturday's event were sold out.

This means many veterans had the opportunity to get help and information with services in their communities.

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6.5 - Wellsville Daily Reporter: **Salute to Bath VA veterans much appreciated. Patriot Guard Ride Captain thanks community** (25 August, Skip Merrick, 13k uvm; Wellsville, NY)

I would like to share a little different view of the escort for the veterans from the Bath VA on Aug. 10. Motorcycles rode to Bath to escort the veterans to Allegany County. We saw the New York State Police at the Steuben and Allegany County line; he jumped in and led the escort all the way to York's Corners to help protect the riders.

Riding down Route 86 we came to Angelica and on the bridge running over 86 was the Angelica firemen with a Fire Truck, a big American flag draped over the edge of the bridge, plus people waving small flags.

We then continued to the Crossroads in Belvidere for a second staging. Big thanks to Mike Hennessy for opening the Veterans Service Officer Building so veterans could use the facility.

On to Belmont, with Jerome Hart leading the veteran's bus with his vintage police car. The folks in Belmont came out in force and stood with the Honor Guard saluting the veterans from the American Legion Post 808. Firemen helped block the intersection for the escort of 28 motorcycles, two buses of veterans, two cars and one truck flying an American flag.

On to Scio, firemen and women blocked the intersection in Scio, thank you — again making the escort easier.

Wellsville folks came out in force and waved flags and stood with the American Legion Post 702 Honor Guard — thank you. Wellsville Police blocked intersections, thank you.

Wellsville firemen wanted to raise the big flag but it was too windy. Thank you for trying and honoring the veterans.

What a surprise riding down Route 19 below Stannards. Willing fiiremen standing out in front of their fire truck in full turnout gear saluting the veterans, thank you.

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A big thank you to all the people who Saluted the Veterans. Riding a motorcycle in the escort were many veterans. We all felt very proud of the people of Allegany County. Thank you all.

Patriot Guard Ride Captain,

Skip Merrick

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7. Other

7.1 - U.S. News & World Report (AP): Montana Men Get Writing Assignment for False Military Claims (25 August, 23.3M uvm; Washington, DC)

GREAT FALLS, MONT. (AP) — Two Montana men who were sentenced to prison for violating the terms of the probation in separate crimes won't be eligible for parole until they complete a writing assignment given because they falsely claimed to have served in the military to have their cases moved to a Veterans Court.

Cascade County District Judge Greg Pinski sentenced Ryan Patrick Morris, 28, and Troy Allan Nelson, 33, on Friday. Morris got 10 years in prison for violating the terms of his probation for felony burglary, while Nelson got five years on a drug possession conviction. Pinski suspended three years of each defendant's sentence.

Before they can be eligible for parole, Pinski ordered both men to hand write the names of all 6,756 Americans killed in Iraq and Afghanistan; write out the obituaries of the 40 Montanans killed in Iraq and Afghanistan and send hand-written letters of apology to several veterans groups identifying themselves as having lied about military service to receive help and possibly a lesser sentence through a Veterans Court.

Veterans Court programs create and supervise treatment plans to address crimes that may be due to service-related post-traumatic stress disorder, traumatic brain injury, anger issues or substance abuse.

"I want to make sure that my message is received loud and clear by these two defendants," Pinski said Friday.

Morris claimed in 2016 he did seven combat tours in Iraq and Afghanistan, had PTSD and had his hip replaced after being injured by an improvised explosive device. He was sentenced to perform 441 hours of community service with a veteran's organization — one for each Montanan killed in combat since the Korean War. Court records said he only completed 10 hours.

Nelson managed to get himself enrolled in the Veterans Treatment Court before it was determined he hadn't served in the military, the Great Falls Tribune reported .

Once released from prison, they must perform 441 hours of community service.

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Pinski also ordered that during the suspended portions of the sentences the defendants must stand at the Montana Veterans Memorial in Great Falls for eight hours on each Memorial Day and Veterans Day wearing a placard that says: "I am a liar. I am not a veteran. I stole valor. I have dishonored all veterans."

Attorneys for both men objected to the placard condition.

Attorney Mark Frisbie said his client has not been charged with stolen valor, which is a federal crime, but was being punished for it.

Pinski said he was punishing the men for lying to the court. He also cited Montana Supreme Court rulings that give him discretion to take the stolen valor into account and others that upheld the placard requirements.

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To:	VHA CO ELT Clips /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=47d7fa1e81c441ae95fcb118d95107d8-VHA CO ELT <VHACOELTClips@va.gov>
CC:	VHA CO 10B2B Media /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12e0caca48054b8da1e793651a89d81c-VHA CO 10B2 <VHACO10B2BMedia@va.gov>
Subject:	FW: 23 August Veterans Affairs Media Summary and News Clips
Date:	2019/08/23 08:24:11
Priority:	Normal
Type:	Note

Good morning,

Significant VHA-related stories from this morning's clips include stories from Politico and NextGov covering VA's health records system roll out; continued coverage of President Trump and Secretary Wilkie's comments regarding PTSD drug, Spravato, following an AMVETS convention earlier this week; continued coverage of the investigation into the Fayetteville pathologist; a negative story highlighting a Kansas whistleblower's allegations of retribution following his comments about deficiencies within the Topeka VAMC police force; and a positive story highlighting a rugby playing Veteran who participated in last month's 2019 National Veterans Wheelchair Games.

NOTE: Stories below with asterisks indicate **VHA assisted with this story.**

Significant Stories

***Politico:** $16B veterans' health project hits major snag link (story published after the clips)

***1.1 - FOX News (Video):** New VA drug aims to 'make a dent' in vet suicide crisis, Secretary Wilkie says link

2.3 - Daily Kos: Veterans Affairs made no effort to protect non-citizen vets, families from new immigration rule link

2.13 - KNWA (FOX-24, Video): "We're working very hard to make sure our veterans are taken care of," Senator Boozman responds to impaired pathologist investigation link

***5.4 - The Palm Beach Post:** Report faults West Palm VA center's procedures, training prior to veteran's suicide link

Neutral and Positive Stories

***1.2 - CBS News (Video):** Wounded veterans find solace in wheelchair rugby: "It becomes the brotherhood" link

***2.14 - KFDA (CBS-10):** Amarillo VA Health Care System hosts Town Hall link

***2.15 - SoundCloud (Audio):** Albany Stratton Veterans Affairs Medical Center link

***3.1 - KNVN (NBC-24, Video):** New Veterans Affairs Clinic Connects Patients, Doctors Via Computer link

***6.1 - U.S. News &World Report (AP):** Officials Break Ground on $47M Tennessee Vets Home link

***6.5 - The Fayetteville Observer:** "Stand Down" event at Festival Parks hooks homeless veterans up with services link

Negative Stories

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*1.5 - **The Kansas City Star:** Kansas VA cops break rules, lack training, official says. He spoke up and lost his job link
*1.6 - **Military Times:** How multiple leadership failures contributed to a patient's suicide at Florida VA hospital link
2.12 - **The Herald-Dispatch:** Feds say a veteran's medical records were leaked; Ojeda says they were his link

VHA News Releases (8/16-8/22)

- • VA modifies smoke-free policies at health care facilities to include workers aimed at increasing the quality of care for Veterans
- • Operation Song continues mission of telling stories through music

Thank you,
Maegan

Maegan Edmondson
Communications Specialist
VHA | Office of Communications (10B23)
Office - (b)(6)
Mobile - (b)(6)
(b)(6) @va.gov

From: VA Media Analysis <VAMediaAnalysis@barbaricum.com>
Sent: Friday, August 23, 2019 5:15 AM
To: Barbaricum VA Media Analysis <VAMediaAnalysis@barbaricum.com>
Subject: [EXTERNAL] 23 August Veterans Affairs Media Summary and News Clips

Good morning,

Please find the attached Veterans Affairs Media Summary and News Clips.

BARBARICUM http://fileshare.barbaricum.com.s3.amazonaws.com/BBCM.jpeg

Sender:	Edmondson, Maegan /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BCDFD72164AA4171A9CEF5D21810CF71-HESTER, MAE (b)(6) @va.gov>
Recipient:	VHA CO ELT Clips /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=47d7fa1e81c441ae95fcb118d95107d8-VHA CO ELT <VHACOELTClips@va.gov>; VHA CO 10B2B Media /o=ExchangeLabs/ou=Exchange Administrative Group

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	(FYDIBOHF23SPDLT)/cn=Recipients/cn=12e0caca48054b8da1e793651a89d81c-VHA CO 10B2 <VHACO10B2BMedia@va.gov>
Sent Date:	2019/08/23 08:24:07
Delivered Date:	2019/08/23 08:24:11
Message Flags:	Unread

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From:	Lahl, Dennis /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=39FBA8EA7CD941B3A0A4F79CA3C6EE87-LAHL, DENNI (b)(6) @va.gov>
To:	Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M (b)(6) @va.gov>; Beck, Lucille B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=845480228a8b43e7a5fef5716ded04c2-Beck, Lucil (b)(6) @va.gov>
CC:	Law, Cassandra M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f888d507d6c54eb5a92fc44199eb5838-Law, Cassan (b)(6) @va.gov>; Hastings, Patricia R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a504fbfe766048a5a65461c45f28e9de-Hastings, P (b)(6) @va.gov>; Meyer, Laurence /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=56f0ba2c110d4e60863b66f9728f669d-Meyer, Laur (b)(6) @va.gov>; Utech, Anne E. (HOU) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=da5fd2ae604b4384b33d451c137c3bae-Utech, Anne (b)(6) @va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>; Mole, Larry A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7f4eed603a543398e4e0b0bbe52cf41-Mole, Larry (b)(6) @va.gov>; Backus, Lisa (Palo Alto) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=66b04fd82eaf4792a9827e59397fc20e-Backus, Lis (b)(6) @va.gov>; Pape, Lisa M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=068e20409e4340d1b889a63c4279d638-Pape, Lisa (b)(6) @va.gov>; Taylor, Laura D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5ada267ef73448bfbb44c5d7fa955592-Taylor, Lau (b)(6) @va.gov>; Costa, Francis R. (Frank) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce3e48b6fbcf4b40b30be399fb389ed4-Costa, Fran (b)(6) @va.gov>; VHA 10P4 Communication Group /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4ba2ff9b4604547be7834a71415253c-VHA 10P4 Co <vha10p4comm@va.gov>
Subject:	FW: 21 March Veterans Affairs Media Summary and News Clips
Date:	2019/03/21 07:11:00
Priority:	Normal
Type:	Note

Morning,

The below are submitted FYSA:

- • VA's plan for the Opioid Crisis, VMET team pilot program in Long Beach (interesting read – social worker is a team member), Ketamine spray for depression, Shingles Shot, legalizing marijuana, dangers of legalization marijuana,

AMERICAN OVERSIGHT

Thanks and have a great day.

Dennis

1.1 - The Lars Larson Show (Audio): What Is The VA's Plan Of Attack To Combat The Opioid Crisis? (20 March, 27k uvm; Portland, OR)
VA is recognized by many as a leader in the pain management field for the responsible use of opioids, and the department is sharing its knowledge and experience with federal and local governments and across the nation's health-care networks. Lars speaks with Secretary of the Department of Veterans Affairs Robert Wilkie, to speak on the opioid crisis. Listen below.

Hyperlink to Above

1.3 - The Washington Post: Veterans talking veterans back from the brink: A new approach to policing and lives in crisis (20 March, Rob Kuznia, 32.2M uvm; Washington, DC)
The former Army soldier was slumped in the back seat of a sheriff's department squad car when Shannon Teague and Tyrone "T-bone" Anderson arrived on the scene. A couple of hours earlier, high on meth, he'd been yelling "you will die" from the front porch of a transition house for homeless veterans. Teague made the introductions. Neither she nor Anderson wore a uniform, except for the patch on their jackets and the ID tags clipped to their shirts.

Hyperlink to Above

2.1 - Military.com: VA to Offer New Ketamine-Based Nasal Spray for Depression (20 March, Richard Sisk, 1.6M uvm; San Francisco, CA)
The newest FDA-approved medication to treat severe depression, a nasal spray based on the anesthetic (and misused hallucinogenic party drug) ketamine, will soon be available to veterans treated within the Department of Veterans Affairs.

Hyperlink to Above

2.2 - The Spokesman-Review: Shooting for that shingles shot (20 March, Treva Lind, 438k uvm; Spokane, WA)
Despite ongoing shortages, Spokane doctors say it's worth a shot to seek the newer Shingrix vaccine to prevent shingles if you're 50 or older. Shingles occurs when the chickenpox virus resurfaces in adulthood and causes skin rashes, blisters and possible long-term pain. About 1 in 3 U.S. residents will get shingles in their lifetime, and about 15 percent develop severe pain from a complication called postherpetic neuralgia.

Hyperlink to Above

2.3 - News Times: Steve Kennedy: Why taking care of our veterans means legalizing cannabis (20 March, Steve Kennedy, 117k uvm; Danbury, CT)
This year, Connecticut lawmakers face a choice: to fully legalize cannabis, or to continue enforcing harmful drug laws that unfairly burden the sick, the poor, people of color, and veterans like me. There has been robust debate in the state over the merits of legalization of adult-use cannabis. Missing from many of these conversations, however, are veterans, who have much to gain from full legalization.

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Hyperlink to Above

2.9 - Connecticut Magazine: A Yale Doctor Warns of Dangers of Pot Legalization (20 March, Albie Yuravich, 24k uvm; New Haven, CT)
One of the state's most vocal opponents of legalizing recreational marijuana in recent years has been Dr. Deepak D'Souza, a research scientist and professor of psychiatry at the Yale School of Medicine. In testimony before the legislature and in his role as a member of the state medical marijuana program's board of physicians, an advisory group for lawmakers, D'Souza has laid out what he says are the dangers of legalization.

Hyperlink to Above

Dennis Lahl FAC-P/PM
Office of the Assistant Deputy Under Secretary for Health for Patient Care Services (10P4)
VACO PCS IT/BCAG/ISO Liaison
TMS OPCS DM
ph: *(b)(6)*
fax: 202-273-5483
Dennis Lahl

From: VA Media Analysis <VAMediaAnalysis@barbaricum.com>
Sent: Thursday, March 21, 2019 5:25 AM
To: Barbaricum VA Media Analysis <VAMediaAnalysis@barbaricum.com>
Subject: [EXTERNAL] 21 March Veterans Affairs Media Summary and News Clips

Good morning,

Please find the attached Veterans Affairs Media Summary and News Clips.

BARBARICUM http://fileshare.barbaricum.com.s3.amazonaws.com/BBCM.jpeg

Sender:	Lahl, Dennis /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=39FBA8EA7CD941B3A0A4F79CA3C6EE87-LAHL, DENNI *(b)(6)* @va.gov>
Recipient:	Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M *(b)(6)* @va.gov>; Beck, Lucille B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=845480228a8b43e7a5fef5716ded04c2-Beck, Lucil

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	(b)(6) @va.gov>; Law, Cassandra M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f888d507d6c54eb5a92fc44199eb5838-Law, Cassan (b)(6) @va.gov>; Hastings, Patricia R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a504fbfe766048a5a65461c45f28e9de-Hastings, P (b)(6) @va.gov>; Meyer, Laurence /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=56f0ba2c110d4e60863b66f9728f669d-Meyer, Laur (b)(6) @va.gov>; Utech, Anne E. (HOU) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=da5fd2ae604b4384b33d451c137c3bae-Utech, Anne (b)(6) @va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>; Mole, Larry A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7f4eed603a543398e4e0b0bbe52cf41-Mole, Larry (b)(6) @va.gov>; Backus, Lisa (Palo Alto) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=66b04fd82eaf4792a9827e59397fc20e-Backus, Lis (b)(6) @va.gov>; Pape, Lisa M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=068e20409e4340d1b889a63c4279d638-Pape, Lisa (b)(6) @va.gov>; Taylor, Laura D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5ada267ef73448bfbb44c5d7fa955592-Taylor, Lau (b)(6) @va.gov>; Costa, Francis R. (Frank) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce3e48b6fbcf4b40b30be399fb389ed4-Costa, Fran (b)(6) @va.gov>; VHA 10P4 Communication Group /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4ba2ff9b4604547be7834a71415253c-VHA 10P4 Co <vha10p4comm@va.gov>
Sent Date:	2019/03/21 07:10:56
Delivered Date:	2019/03/21 07:11:00

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From:	Hammonds, Michele /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C03C261B4ADD4A6A9923F5C5335ACB42-HAMMONDS, M (b)(6) @va.gov>
To:	VHA CO ELT Clips /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=47d7fa1e81c441ae95fcb118d95107d8-VHA CO ELT <VHACOELTClips@va.gov>
CC:	Hammonds, Michele /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c03c261b4add4a6a9923f5c5335acb42-Hammonds, M (b)(6) @va.gov>
Subject:	FW: 21 March Veterans Affairs Media Summary and News Clips
Date:	2019/03/21 08:50:57
Priority:	Normal
Type:	Note

Good morning,

Significant VHA-related stories captured from the morning clips include VA is recognized by many as a leader in the pain management field for the responsible use of opioids, and the department is sharing its knowledge and experience with federal and local governments and across the nation's health-care networks; continuing negative coverage with stories covering an allegedly flawed software tool developed by the department to determine whether veterans are eligible for private health care; VA to offer new ketamine based nasal spray for depression will be available soon to Veterans treated within the Department of Veterans Affairs.

Note: Stories below with asterisk indicates **VHA assisted with this story.**

Significant Stories
***1.1 - The Lars Larson Show (Audio):** What Is The VA's Plan Of Attack To Combat The Opioid Crisis? link
***1.2 - WMAL (CM-630, Audio):** Secretary Robert Wilkie, Jamie McIntyre, Dan Gainor &Ken Klukowski on The Larry O'Connor Show link

Neutral and Positive Stories
1.3 - The Washington Post: Veterans talking veterans back from the brink: A new approach to policing and lives in crisis link
***2.1 - Military.com**: VA to Offer New Ketamine-Based Nasal Spray for Depression link
*2.2 - **The Spokesman-Review:** Shooting for that shingles shot link
2.3 - News Times: Steve Kennedy: Why taking care of our veterans means legalizing cannabis link
2.6 - Chico Enterprise-Record: Veterans hear about new Chico clinic, coming changes link
***2.8 - The World:** New veteran-run mental health council set to visit Coos County link
3.1 - Dayton Daily News: Springfield steps closer to getting new VA clinic link
3.2 - The Courier of Montgomery County: New dental facility opens at VA Outpatient Clinic in Conroe link

Negative Stories
***1.7 - Nextgov:** Lawmaker Wants VA to Explain a Software Tool USDS Flagged as Flawed link
7.1 - NBC News (Video): Trump rips McCain on veterans: 'Didn't get the job done' link

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Kind Regards,

Michele R. Hammonds
Office of Media Relations (10B2B)
Veterans Health Administration
Office: (b)(6)
Cell Phone: (b)(6)

Sender:	Hammonds, Michele /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C03C261B4ADD4A6A9923F5C5335ACB42-HAMMONDS, M (b)(6) @va.gov>
Recipient:	VHA CO ELT Clips /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=47d7fa1e81c441ae95fcb118d95107d8-VHA CO ELT <VHACOELTClips@va.gov>; Hammonds, Michele /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c03c261b4add4a6a9923f5c5335acb42-Hammonds, M (b)(6) @va.gov>
Sent Date:	2019/03/21 08:50:52
Delivered Date:	2019/03/21 08:50:57
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AMERICAN OVERSIGHT

From:	Lahl, Dennis /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=39FBA8EA7CD941B3A0A4F79CA3C6EE87-LAHL, DENNI (b)(6) @va.gov>
To:	Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M (b)(6) @va.gov>; Beck, Lucille B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=845480228a8b43e7a5fef5716ded04c2-Beck, Lucil (b)(6) @va.gov>
CC:	Law, Cassandra M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f888d507d6c54eb5a92fc44199eb5838-Law, Cassan (b)(6) @va.gov>; VHA 10P4 Chief Consultants /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a87c5f11e8414617ac89553ec0973f08-VHA 10P4 Ch <VHA10P4ChiefConsultants@va.gov>; VHA 10P4 Communication Group /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4ba2ff9b4604547be7834a71415253c-VHA 10P4 Co <vha10p4comm@va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>
Subject:	FW: 14 August Veterans Affairs Media Summary and News Clips
Date:	2019/08/14 06:44:17
Priority:	Normal
Type:	Note

Morning,

The below are submitted FYSA:

- • Spravato for depressed patients, VetLinks holds KayFest to help Veterans and their Caregivers,

Dennis

2.6 - Hartford Courant (Conn. Health I-Team): Nasal spray Spravato, offering fresh hope for severely depressed patients, arrives in Connecticut (13 August, Peggy McCarthy, 1.4M uvm; Hartford, CT)
Spravato, which received Food and Drug Administration (FDA) approval in March, has raised hopes for preventing suicides and relieving depression after other treatments have failed. But there are concerns about possible side effects, including drug abuse, elevated blood pressure and heart rate, sedation, and hypersensitivity to surroundings.

Hyperlink to Above

6.4 - The Norman Transcript: Task force advocates for veterans at D.C. (13 August, Dale K. Graham, 95k uvm; Norman, OK)
Dale K. Graham Veterans Foundation's board of directors formed a task force to visit the offices of various Congressional members to discuss issues affecting veterans and the work our 60-plus volunteers are doing to address those issues. On Aug. 8, our task force began a two-day assignment in Washington, D.C.

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Hyperlink to Above

Dennis Lahl FAC-P/PM

Office of the Assistant Deputy Under Secretary for Health for Patient Care Services (10P4)
VACO PCS IT/BCAG/ISO Liaison
TMS OPCS DM
ph: *(b)(6)*
fax: 202-273-5483
Dennis Lahl

From: VA Media Analysis <VAMediaAnalysis@barbaricum.com>
Sent: Wednesday, August 14, 2019 5:17 AM
To: Barbaricum VA Media Analysis <VAMediaAnalysis@barbaricum.com>
Subject: [EXTERNAL] 14 August Veterans Affairs Media Summary and News Clips

Good morning,

Please find the attached Veterans Affairs Media Summary and News Clips.

BARBARICUM http://fileshare.barbaricum.com.s3.amazonaws.com/BBCM.jpeg

Sender:	Lahl, Dennis /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=39FBA8EA7CD941B3A0A4F79CA3C6EE87-LAHL, DENNI *(b)(6)* @va.gov>
Recipient:	Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M *(b)(6)* @va.gov>; Beck, Lucille B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=845480228a8b43e7a5fef5716ded04c2-Beck, Lucil *(b)(6)* @va.gov>; Law, Cassandra M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f888d507d6c54eb5a92fc44199eb5838-Law, Cassan *(b)(6)* @va.gov>; VHA 10P4 Chief Consultants /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a87c5f11e8414617ac89553ec0973f08-VHA 10P4 Ch <VHA10P4ChiefConsultants@va.gov>; VHA 10P4 Communication Group /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4ba2ff9b4604547be7834a71415253c-VHA 10P4 Co <vha10p4comm@va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer *(b)(6)* @va.gov>
Sent Date:	2019/08/14 06:44:14
Delivered Date:	2019/08/14 06:44:17
Message Flags:	Unread

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From:	Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd.PDLT)/CN=RECIPIENTS/CN=9872F41BF2844C8085D371E21482B635-STRMISKA, J (b)(6) @va.gov>
To:	Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da (b)(6) @va.gov>
CC:	Daniels, Lindsay /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ed253196fb6b4f32aa922c90dbd05f29-Daniels, Li (b)(6) @va.gov>
Subject:	FW: [EXTERNAL] Task & Purpose media query: President Trump says the VA is buying a product from Johnson and Johnson to combat veterans suicide
Date:	2019/08/21 15:46:12
Priority:	Normal
Type:	Note

Dave,

Please review and clear.

Jon G. Strmiska
Business Operations Manager (10NC5)
Phone: (b)(6) **FAX: 202.495.5933**

From: Wiechers, Ilse
Sent: Wednesday, August 21, 2019 2:40 PM
To: Valentino, Michael (VACO) (b)(6) @va.gov>; Emmendorfer, Thomas (PBM) (b)(6) @va.gov>
Cc: Law, Cassandra M. (b)(6) @va.gov>; Lahl, Dennis (b)(6) @va.gov>; Strmiska, Jon G. (b)(6) @va.gov>; Daniels, Lindsay (b)(6) @va.gov>
Subject: RE: [EXTERNAL] Task &Purpose media query: President Trump says the VA is buying a product from Johnson and Johnson to combat veterans suicide

Adding back Jon &Lindsey in 10NC5 to help get this cleared there as well.

From: Valentino, Michael (VACO)
Sent: Wednesday, August 21, 2019 11:39 AM
To: Wiechers, Ilse (b)(6) @va.gov>; Emmendorfer, Thomas (PBM) (b)(6) @va.gov>
Cc: Law, Cassandra M. (b)(6) @va.gov>; Lahl, Dennis (b)(6) @va.gov>
Subject: RE: [EXTERNAL] Task &Purpose media query: President Trump says the VA is buying a product from Johnson and Johnson to combat veterans suicide

Fantastic Ilse!

Tom, would you package this up and send it for clearance?

I clear for PBM and PCS

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Sent with BlackBerry Work
(www.blackberry.com)

From: Wiechers, Ilse (b)(6) @va.gov>
Date: Wednesday, Aug 21, 2019, 2:33 PM
To: Valentino, Michael (VACO) (b)(6) @va.gov>, Emmendorfer, Thomas (PBM) (b)(6) @va.gov>
Subject: RE: [EXTERNAL] Task &Purpose media query: President Trump says the VA is buying a product from Johnson and Johnson to combat veterans suicide

Some edits to #2 &#5.

From: Valentino, Michael (VACO)
Sent: Wednesday, August 21, 2019 11:28 AM
To: Wiechers, Ilse (b)(6) @va.gov>; Emmendorfer, Thomas (PBM) (b)(6) @va.gov>
Subject: RE: [EXTERNAL] Task &Purpose media query: President Trump says the VA is buying a product from Johnson and Johnson to combat veterans suicide

My thoughts below:

Sent with BlackBerry Work
(www.blackberry.com)

From: Wiechers, Ilse (b)(6) @va.gov>
Date: Wednesday, Aug 21, 2019, 2:15 PM
To: Strmiska, Jon G. (b)(6) @va.gov>, Valentino, Michael (VACO) (b)(6) @va.gov>, Emmendorfer, Thomas (PBM) (b)(6) @va.gov>
Cc: Daniels, Lindsay (b)(6) @va.gov>
Subject: RE: [EXTERNAL] Task &Purpose media query: President Trump says the VA is buying a product from Johnson and Johnson to combat veterans suicide

Jon – I should work directly with Mike Valentino and the PBM team on response to all of these.

I'm cc'ing Mike and Tom (looks like Jen is OOO) and will work with them on this now.

Ilse

From: Strmiska, Jon G.
Sent: Wednesday, August 21, 2019 10:58 AM
To: Wiechers, Ilse <(b)(6) @va.gov>
Cc: Daniels, Lindsay (b)(6) @va.gov>
Subject: FW: [EXTERNAL] Task &Purpose media query: President Trump says the VA is buying a product from Johnson and Johnson to combat veterans suicide
Importance: High

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Ilse,

Looks like 2 and 5 are assigned to 10NC5.

Please review and provide response as soon as reasonably possible.

Thanks!

Jon G. Strmiska
Business Operations Manager (10NC5)
Phone: (b)(6) **FAX: 202.495.5933**

From: Hammonds, Michele
Sent: Wednesday, August 21, 2019 1:33 PM
To: VHA 10P Actions <VHA10PActions@va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>; VHA 10NC Action <vha10ncaction@va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>
Cc: VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: FW: [EXTERNAL] Task &Purpose media query: President Trump says the VA is buying a product from Johnson and Johnson to combat veterans suicide
Importance: High

Dennis /10P – Hot -This is another Spravato/esketamine query from the president's recent comment earlier today.
Seeking written responses to the following questions

Deadline is today

Q1: What is the product?
(b5)

Q2: How exactly does it work to reduce veterans suicides? Mental Health 10NC5
(b5)

Q3: Has it been approved by the FDA?
(b5)

Q4: How can veterans get this product?
(b5)

Q5: What results has this product shown in reducing veterans suicides?

AMERICAN OVERSIGHT

(b5)

Michele Hammonds
Office of Communications (10b2B)
(b)(6)

From: Carter, Susan
Sent: Wednesday, August 21, 2019 1:17 PM
To: Hammonds, Michele (b)(6) @va.gov>; Greilsamer, Alan (b)(6) @va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Cc: Noller, Randal (b)(6) @va.gov>; Mandreucci, Christina M. <(b)(6) @va.gov>
Subject: FW: [EXTERNAL] Task &Purpose media query: President Trump says the VA is buying a product from Johnson and Johnson to combat veterans suicide

This is another Spravato/esketamine query from the president's recent comment earlier today. Deadline is today. Thanks – Susan

Q1: What is the product?
A1:

Q2: How exactly does it work to reduce veterans suicides?
A1:

Q3: Has it been approved by the FDA?
A3: Yes (please insert date)

Q4: How can veterans get this product?
A4:

Q5: What results has this product shown in reducing veterans suicides?
A5:

Susan Carter
Director, Office of Media Relations
U.S. Department of Veterans Affairs
(b)(6) @va.gov
Desk: (b)(6)
Cell: (b)(6)



cid:image002.jpg@01D3D61E.49531160

AMERICAN OVERSIGHT

From: Jeff Schogol <(b)(6) @taskandpurpose.com>
Sent: Wednesday, August 21, 2019 12:49 PM
To: Carter, Susan <(b)(6) @va.gov>
Subject: [EXTERNAL] Task &Purpose media query: President Trump says the VA is buying a product from Johnson and Johnson to combat veterans suicide

Good afternoon Ms. Carter,

Thank you for taking my call!

President Trump told reporters today that the VA is buying a new product from Johnson and Johnson that has proven to be effective in combating veterans suicide:

"There's a product that's made right now that just came out by Johnson and Johnson, which has a tremendously positive – pretty short-term – but nevertheless a positive effect.

"I've instructed the head of the VA to go out and buy a lot of it, and we are buying a lot of it. Hopefully, we're getting it at a very good cost. And this is a – I guess it's a form of a stimulant, where if somebody is really in trouble, from the standpoint of suicide, it can do something.

"It's pretty well know, just came out. It's made, I believe, by Johnson and Johnson, and we have calls in now to Johnson and Johnson. Those calls – we've been dealing with them for two months and buying a lot of it."

Can the VA say:

1. What is the product?
2. How exactly does it work to reduce veterans suicides?
3. Has it been approved by the FDA?
4. How can veterans get this product?
5. What results has this product shown in reducing veterans suicides?

My deadline is today. Please feel free to email or call me at 703-697-6623.

Thank you.

Jeff Schogol

Sender:	Strmiska, Jon G. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9872F41BF2844C8085D371E21482B635-STRMISKA, J (b)(6) @va.gov>
Recipient:	Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da (b)(6) @va.gov>; Daniels, Lindsay /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ed253196fb6b4f32aa922c90dbd05f29-Daniels, Li (b)(6) @va.gov>
Sent Date:	2019/08/21 15:46:10

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Delivered Date:	2019/08/21 15:46:12

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From:	Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd.OHF23SPDLT)/CN=RECIPIENTS/CN=4FF0FE692B31483E909235222067A767-GRAHAM, CHR *(b)(6)* @va.gov>
To:	Hammonds, Michele /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c03c261b4add4a6a9923f5c5335acb42-Hammonds, M *(b)(6)* @va.gov>; VHA CO 10B2B Media /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12e0caca48054b8da1e793651a89d81c-VHA CO 10B2 <VHACO10B2BMedia@va.gov>
CC:	VHA 10P Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5098b521b1f34f8a97f74be24709d62f-VHA 10P Act <VHA10PActions@va.gov>; VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>; VHA 10P4 Communication Group /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4ba2ff9b4604547be7834a71415253c-VHA 10P4 Co <vha10p4comm@va.gov>; VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>; VHA CO 10NC Front Office HSSs /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcf91f73967a49c287d8747b7aee675e-VHA CO 10NC <VHACO10NCFOHSSs@va.gov>; VHA 10NC Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aeebc70340b3476a87b15fbe600f1888-VHA 10NC Ac <vha10ncaction@va.gov>
Subject:	FW: [EXTERNAL] Task & Purpose media query: President Trump says the VA is buying a product from Johnson and Johnson to combat veterans suicide
Date:	2019/08/21 16:33:07
Priority:	Normal
Type:	Note

Michele,

10P clears the responses to the questions below, reviewed and cleared by 10NC as well.

Q1: What is the product?

(b5)

Q2: How exactly does it work to reduce veterans suicides? Mental Health 10NC5

(b5)

Q3: Has it been approved by the FDA?

(b5)

Q4: How can veterans get this product?

(b5)

AMERICAN OVERSIGHT

Q5: What results has this product shown in reducing veterans suicides?

(b5)

Thanks,
Chris Graham, MHA
Health Systems Specialist
Department of Veterans Affairs
Office of the Deputy Under Secretary for Health for Policy and Services (10P)
Office: *(b)(6)*

From: Hammonds, Michele
Sent: Wednesday, August 21, 2019 1:33 PM
To: VHA 10P Actions <VHA10PActions@va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>; VHA 10NC Action <vha10ncaction@va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>
Cc: VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: FW: [EXTERNAL] Task &Purpose media query: President Trump says the VA is buying a product from Johnson and Johnson to combat veterans suicide
Importance: High

Dennis /10P – Hot -This is another Spravato/esketamine query from the president's recent comment earlier today.
Seeking written responses to the following questions

Deadline is today

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(b5)

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(b5)

Q3: Has it been approved by the FDA?

(b5)

Q4: How can veterans get this product?

AMERICAN OVERSIGHT

(b5) d

Q5: What results has this product shown in reducing veterans suicides?

(b5)

Michele Hammonds
Office of Communications (10b2B)
(b)(6)

From: Carter, Susan
Sent: Wednesday, August 21, 2019 1:17 PM
To: Hammonds, Michele *(b)(6)* @va.gov>; Greilsamer, Alan <*(b)(6)* @va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Cc: Noller, Randal *(b)(6)* @va.gov>; Mandreucci, Christina M. <*(b)(6)* @va.gov>
Subject: FW: [EXTERNAL] Task &Purpose media query: President Trump says the VA is buying a product from Johnson and Johnson to combat veterans suicide

This is another Spravato/esketamine query from the president's recent comment earlier today. Deadline is today. Thanks – Susan

Q1: What is the product?
A1:

Q2: How exactly does it work to reduce veterans suicides?
A1:

Q3: Has it been approved by the FDA?
A3: Yes (please insert date)

Q4: How can veterans get this product?
A4:

Q5: What results has this product shown in reducing veterans suicides?
A5:

Susan Carter
Director, Office of Media Relations
U.S. Department of Veterans Affairs
(b)(6) @va.gov

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Desk: (b)(6)
Cell: (b)(6)



cid:image002.jpg@01D3D61E.49531160

From: Jeff Schogol <(b)(6) @taskandpurpose.com>
Sent: Wednesday, August 21, 2019 12:49 PM
To: Carter, Susan (b)(6) @va.gov>
Subject: [EXTERNAL] Task &Purpose media query: President Trump says the VA is buying a product from Johnson and Johnson to combat veterans suicide

Good afternoon Ms. Carter,

Thank you for taking my call!

President Trump told reporters today that the VA is buying a new product from Johnson and Johnson that has proven to be effective in combating veterans suicide:

"There's a product that's made right now that just came out by Johnson and Johnson, which has a tremendously positive – pretty short-term – but nevertheless a positive effect.

"I've instructed the head of the VA to go out and buy a lot of it, and we are buying a lot of it. Hopefully, we're getting it at a very good cost. And this is a – I guess it's a form of a stimulant, where if somebody is really in trouble, from the standpoint of suicide, it can do something.

"It's pretty well know, just came out. It's made, I believe, by Johnson and Johnson, and we have calls in now to Johnson and Johnson. Those calls – we've been dealing with them for two months and buying a lot of it."

Can the VA say:

1. What is the product?
2. How exactly does it work to reduce veterans suicides?
3. Has it been approved by the FDA?
4. How can veterans get this product?
5. What results has this product shown in reducing veterans suicides?

My deadline is today. Please feel free to email or call me at 703-697-6623.

Thank you.

Jeff Schogol

Sender:	Graham, Christopher L. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4FF0FE692B31483E909235222067A767-GRAHAM, CHR (b)(6) @va.gov>
Recipient:	Hammonds, Michele /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c03c261b4add4a6a9923f5c5335acb42-Hammonds, M

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	(b)(6) @va.gov>; VHA CO 10B2B Media /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12e0caca48054b8da1e793651a89d81c-VHA CO 10B2 <VHACO10B2BMedia@va.gov>; VHA 10P Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5098b521b1f34f8a97f74be24709d62f-VHA 10P Act <VHA10PActions@va.gov>; VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>; VHA 10P4 Communication Group /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4ba2ff9b4604547be7834a71415253c-VHA 10P4 Co <vha10p4comm@va.gov>; VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>; VHA CO 10NC Front Office HSSs /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcf91f73967a49c287d8747b7aee675e-VHA CO 10NC <VHACO10NCFOHSSs@va.gov>; VHA 10NC Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aeebc70340b3476a87b15fbe600f1888-VHA 10NC Ac <vha10ncaction@va.gov>
Sent Date:	2019/08/21 16:33:05
Delivered Date:	2019/08/21 16:33:07

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From:	Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd.HF23SPDLT)/CN=RECIPIENTS/CN=182805D689894DA4B2D00810DA5E305C-STEWART, KA (b)(6) @va.gov>
To:	VHA 10P Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5098b521b1f34f8a97f74be24709d62f-VHA 10P Act <VHA10PActions@va.gov>
CC:	VHA CO 10NC Front Office HSSs /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcf91f73967a49c287d8747b7aee675e-VHA CO 10NC <VHACO10NCFOHSSs@va.gov>; VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>
Subject:	FW: [EXTERNAL] Task & Purpose media query: President Trump says the VA is buying a product from Johnson and Johnson to combat veterans suicide
Date:	2019/08/21 16:28:03
Priority:	Normal
Type:	Note

Good Afternoon 10P,

On behalf of 10N/10NC, Dr. Sherrie Schuldheis clears the below responses.

10P, per the below email – 10NC5 requested that we clear to you – and that 10P will clear to VHA Communications.

Thank you,

Katie Stewart, MSW, LCSW
Health Systems Specialist
Office of the ADUSH for Clinical Operations (10NC)
(b)(6) (office)
(b)(6) cell)

From: Schuldheis, Sherrie L, Ph.D
Sent: Wednesday, August 21, 2019 4:24 PM
To: Stewart, Katharine E. (b)(6) @va.gov>; VHA 10NC Clearance <VHA10NCClearance2@va.gov>
Subject: RE: [EXTERNAL] Task &Purpose media query: President Trump says the VA is buying a product from Johnson and Johnson to combat veterans suicide

10NC clears

Sherrie Schuldheis, PhD, RN, CENP
Special Assistant, ADUSH Clinical Operations
VHA 10NC
810 Vermont NW

AMERICAN OVERSIGHT

Washington, DC 20420
(b)(6) (cell)
(b)(6) @va.gov

From: Strmiska, Jon G.
Sent: Wednesday, August 21, 2019 3:55 PM
To: VHA CO 10NC Front Office HSSs <VHACO10NCFOHSSs@va.gov>
Cc: VHA 10P Actions <VHA10PActions@va.gov>; Sandifer, Estella (Maria) (b)(6) @va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>
Subject: RE: [EXTERNAL] Task &Purpose media query: President Trump says the VA is buying a product from Johnson and Johnson to combat veterans suicide

10NC,

Dr. Carroll clears. Please not that this Please note collaboration with PBM. Please review and clear back to 10P who will move on to VHA Comms. Thanks!

Response:

10P4 clears the below responses, however we still need 10NC5 to clear also as this was a joint response. Let me know if you have any questions or concerns.

Q1: What is the product?
(b5)

Q2: How exactly does it work to reduce veterans suicides? Mental Health 10NC5
(b5)

Q3: Has it been approved by the FDA?
(b5)

Q4: How can veterans get this product?
(b5)

Q5: What results has this product shown in reducing veterans suicides?
(b5)

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Jon G. Strmiska
Business Operations Manager (10NC5)
Phone: (b)(6) **FAX: 202.495.5933**

From: Sandifer, Estella (Maria)
Sent: Wednesday, August 21, 2019 3:47 PM
To: VHA 10NC5 Action <VHA10NC5Action@va.gov>
Cc: Hammonds, Michele (b)(6) @va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: FW: [EXTERNAL] Task &Purpose media query: President Trump says the VA is buying a product from Johnson and Johnson to combat veterans suicide

Good afternoon 10NC5,

10P clears the following responses. 10NC5 concurrence is needed prior to submitting to VHA Communications.

Response:

10P4 clears the below responses, however we still need 10NC5 to clear also as this was a joint response. Let me know if you have any questions or concerns.

Q1: What is the product?
(b5)

Q2: How exactly does it work to reduce veterans suicides? Mental Health 10NC5
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Q3: Has it been approved by the FDA?
(b5)

Q4: How can veterans get this product?
(b5)

Q5: What results has this product shown in reducing veterans suicides?
(b5)

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V/r,

Maria Sandifer
Office of the Deputy Under Secretary for Health
for Policy and Services (10P)
Work ph: (b)(6)
Cell: (b)(6)
Email: (b)(6) @va.gov

From: Hammonds, Michele
Sent: Wednesday, August 21, 2019 1:33 PM
To: VHA 10P Actions <VHA10PActions@va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>; VHA 10NC Action <vha10ncaction@va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>
Cc: VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: FW: [EXTERNAL] Task &Purpose media query: President Trump says the VA is buying a product from Johnson and Johnson to combat veterans suicide
Importance: High

Dennis /10P – Hot -This is another Spravato/esketamine query from the president's recent comment earlier today.
Seeking written responses to the following questions

Deadline is today

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(b5)

Q4: How can veterans get this product?
(b5)

Q5: What results has this product shown in reducing veterans suicides?

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(b5)

Michele Hammonds
Office of Communications (10b2B)
(b)(6)

From: Carter, Susan
Sent: Wednesday, August 21, 2019 1:17 PM
To: Hammonds, Michele <(b)(6) @va.gov>; Greilsamer, Alan <(b)(6) @va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Cc: Noller, Randal (b)(6) @va.gov>; Mandreucci, Christina M. (b)(6) @va.gov>
Subject: FW: [EXTERNAL] Task &Purpose media query: President Trump says the VA is buying a product from Johnson and Johnson to combat veterans suicide

This is another Spravato/esketamine query from the president's recent comment earlier today. Deadline is today. Thanks – Susan

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Q3: Has it been approved by the FDA?
A3: Yes (please insert date)

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A4:

Q5: What results has this product shown in reducing veterans suicides?
A5:

Susan Carter
Director, Office of Media Relations
U.S. Department of Veterans Affairs
(b)(6) @va.gov
Desk: (b)(6)
Cell: (b)(6)



cid:image002.jpg@01D3D61E.49531160

AMERICAN OVERSIGHT

From: Jeff Schogol (b)(6) @taskandpurpose.com>
Sent: Wednesday, August 21, 2019 12:49 PM
To: Carter, Susan (b)(6) @va.gov>
Subject: [EXTERNAL] Task &Purpose media query: President Trump says the VA is buying a product from Johnson and Johnson to combat veterans suicide

Good afternoon Ms. Carter,

Thank you for taking my call!

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"There's a product that's made right now that just came out by Johnson and Johnson, which has a tremendously positive – pretty short-term – but nevertheless a positive effect.

"I've instructed the head of the VA to go out and buy a lot of it, and we are buying a lot of it. Hopefully, we're getting it at a very good cost. And this is a – I guess it's a form of a stimulant, where if somebody is really in trouble, from the standpoint of suicide, it can do something.

"It's pretty well know, just came out. It's made, I believe, by Johnson and Johnson, and we have calls in now to Johnson and Johnson. Those calls – we've been dealing with them for two months and buying a lot of it."

Can the VA say:

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3. Has it been approved by the FDA?
4. How can veterans get this product?
5. What results has this product shown in reducing veterans suicides?

My deadline is today. Please feel free to email or call me at 703-697-6623.

Thank you.

Jeff Schogol

Sender:	Stewart, Katharine E. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=182805D689894DA4B2D00810DA5E305C-STEWART, KA (b)(6) @va.gov>
Recipient:	VHA 10P Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5098b521b1f34f8a97f74be24709d62f-VHA 10P Act <VHA10PActions@va.gov>; VHA CO 10NC Front Office HSSs /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcf91f73967a49c287d8747b7aee675e-VHA CO 10NC <VHACO10NCFOHSSs@va.gov>; VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>

AMERICAN OVERSIGHT

Sent Date:	2019/08/21 16:28:02
Delivered Date:	2019/08/21 16:28:03

AMERICAN OVERSIGHT

From:	Lahl, Dennis /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=39FBA8EA7CD941B3A0A4F79CA3C6EE87-LAHL, DENNI (b)(6) @va.gov>
To:	VHA 10P4P Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8dc3dab451414f59b9797e8ed199c1e8-VHA 10P4P A <vha10P4Paction@va.gov>
CC:	VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>; VHA 10P4 Communication Group /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4ba2ff9b4604547be7834a71415253c-VHA 10P4 Co <vha10p4comm@va.gov>
Subject:	FW: [EXTERNAL] Task & Purpose media query: President Trump says the VA is buying a product from Johnson and Johnson to combat veterans suicide
Date:	2019/08/21 13:41:12
Importance:	High
Priority:	Urgent
Type:	Note

10P4P Actions,

Please see the below inquiry OPIA is looking for responses by 15:30 today. I asked them to defer 2 and 5 to 10NC5 let me know if I was incorrect or need another one deferred.

Q1: What is the product?
A1:

Q2: How exactly does it work to reduce veterans suicides? Mental Health 10NC5
A1:

Q3: Has it been approved by the FDA?
A3: Yes (please insert date)

Q4: How can veterans get this product?
A4:

Q5: What results has this product shown in reducing veterans suicides?
A5:

Dennis

Dennis Lahl FAC-P/PM
Office of the Assistant Deputy Under Secretary for Health for Patient Care Services (10P4)

AMERICAN OVERSIGHT

VACO PCS IT/BCAG/ISO Liaison
TMS OPCS DM
ph: *(b)(6)*
fax: 202-273-5483
Dennis Lahl

From: Hammonds, Michele
Sent: Wednesday, August 21, 2019 1:33 PM
To: VHA 10P Actions <VHA10PActions@va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>; VHA 10NC Action <vha10ncaction@va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>
Cc: VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: FW: [EXTERNAL] Task &Purpose media query: President Trump says the VA is buying a product from Johnson and Johnson to combat veterans suicide
Importance: High

Dennis /10P – Hot -This is another Spravato/esketamine query from the president's recent comment earlier today.
Seeking written responses to the following questions

Deadline is today

Q1: What is the product?
A1:

Q2: How exactly does it work to reduce veterans suicides? Mental Health 10NC5
A1:

Q3: Has it been approved by the FDA?
A3: Yes (please insert date)

Q4: How can veterans get this product?
A4:

Q5: What results has this product shown in reducing veterans suicides?
A5:

Michele Hammonds
Office of Communications (10b2B)
(b)(6)

From: Carter, Susan
Sent: Wednesday, August 21, 2019 1:17 PM

AMERICAN OVERSIGHT

To: Hammonds, Michele (b)(6) @va.gov>; Greilsamer, Alan (b)(6) @va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Cc: Noller, Randal (b)(6) @va.gov>; Mandreucci, Christina M. (b)(6) @va.gov>
Subject: FW: [EXTERNAL] Task &Purpose media query: President Trump says the VA is buying a product from Johnson and Johnson to combat veterans suicide

This is another Spravato/esketamine query from the president's recent comment earlier today. Deadline is today. Thanks – Susan

Q1: What is the product?
A1:

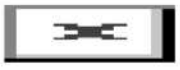
Q2: How exactly does it work to reduce veterans suicides?
A1:

Q3: Has it been approved by the FDA?
A3: Yes (please insert date)

Q4: How can veterans get this product?
A4:

Q5: What results has this product shown in reducing veterans suicides?
A5:

Susan Carter
Director, Office of Media Relations
U.S. Department of Veterans Affairs
(b)(6) @va.gov
Desk: (b)(6)
Cell: (b)(6)



cid:image002.jpg@01D3D61E.49531160

From: Jeff Schogol (b)(6) @taskandpurpose.com>
Sent: Wednesday, August 21, 2019 12:49 PM
To: Carter, Susan (b)(6) @va.gov>
Subject: [EXTERNAL] Task &Purpose media query: President Trump says the VA is buying a product from Johnson and Johnson to combat veterans suicide

Good afternoon Ms. Carter,

Thank you for taking my call!

President Trump told reporters today that the VA is buying a new product from Johnson and Johnson that has proven to be effective in combating veterans suicide:

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"There's a product that's made right now that just came out by Johnson and Johnson, which has a tremendously positive – pretty short-term – but nevertheless a positive effect.

"I've instructed the head of the VA to go out and buy a lot of it, and we are buying a lot of it. Hopefully, we're getting it at a very good cost. And this is a – I guess it's a form of a stimulant, where if somebody is really in trouble, from the standpoint of suicide, it can do something.

"It's pretty well know, just came out. It's made, I believe, by Johnson and Johnson, and we have calls in now to Johnson and Johnson. Those calls – we've been dealing with them for two months and buying a lot of it."

Can the VA say:

1. What is the product?
2. How exactly does it work to reduce veterans suicides?
3. Has it been approved by the FDA?
4. How can veterans get this product?
5. What results has this product shown in reducing veterans suicides?

My deadline is today. Please feel free to email or call me at 703-697-6623.

Thank you.

Jeff Schogol

Sender:	Lahl, Dennis /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=39FBA8EA7CD941B3A0A4F79CA3C6EE87-LAHL, DENNI *(b)(6)* @va.gov>
Recipient:	VHA 10P4P Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8dc3dab451414f59b9797e8ed199c1e8-VHA 10P4P A <vha10P4Paction@va.gov>; VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>; VHA 10P4 Communication Group /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4ba2ff9b4604547be7834a71415253c-VHA 10P4 Co <vha10p4comm@va.gov>
Sent Date:	2019/08/21 13:41:10
Delivered Date:	2019/08/21 13:41:12
Message Flags:	Unread

AMERICAN OVERSIGHT

From:	Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd.)/CN=RECIPIENTS/CN=39FBA8EA7CD941B3A0A4F79CA3C6EE87-LAHL, DENNI (b)(6) @va.gov>
To:	VHA 10P Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5098b521b1f34f8a97f74be24709d62f-VHA 10P Act <VHA10PActions@va.gov>
CC:	VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>; VHA 10P4 Communication Group /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4ba2ff9b4604547be7834a71415253c-VHA 10P4 Co <vha10p4comm@va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b)(6) @va.gov>; Strmiska, Jon G. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9872f41bf2844c8085d371e21482b635-Strmiska, J (b)(6) @va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b)(6) @va.gov>
Subject:	FW: [EXTERNAL] Task & Purpose media query: President Trump says the VA is buying a product from Johnson and Johnson to combat veterans suicide
Date:	2019/08/21 15:28:22
Due Date:	2019/08/20 20:00:00
Priority:	Normal
Type:	Note

10P,

10P4 clears the below responses, however we still need 10NC5 to clear also as this was a joint response. Let me know if you have any questions or concerns.

Q1: What is the product?

(b5)

Q2: How exactly does it work to reduce veterans suicides? Mental Health 10NC5

(b5)

Q3: Has it been approved by the FDA?

(b5)

Q4: How can veterans get this product?

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(b5)

treatment plan developed by their provider in collaboration with the Veteran.

Q5: What results has this product shown in reducing veterans suicides?

(b5)

Dennis

Dennis Lahl FAC-P/PM
Office of the Assistant Deputy Under Secretary for Health for Patient Care Services (10P4)
VACO PCS IT/BCAG/ISO Liaison
TMS OPCS DM
ph: (b)(6)
fax: 202-273-5483
Dennis Lahl

From: Emmendorfer, Thomas (PBM)
Sent: Wednesday, August 21, 2019 3:23 PM
To: Lahl, Dennis (b)(6) @va.gov>
Cc: Wiechers, Ilse (b)(6) @va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>; Valentino, Michael (VACO) (b)(6) @va.gov>; Emmendorfer. Thomas (PBM) (b)(6) @va.gov>; Strmiska, Jon G. <(b)(6) @va.gov>
Subject: FW: [EXTERNAL] Task &Purpose media query: President Trump says the VA is buying a product from Johnson and Johnson to combat veterans suicide

Hi Dennis,

Please see Mike's e-mail below clearing for 10P4P and 10P4. This is ready for clearance back to Communications. Including Ilse/Jon from 10NC5 as well.

Thank you Ilse!

Tom

Dennis /10P – Hot -This is another Spravato/esketamine query from the president's recent comment earlier today.
Seeking written responses to the following questions

Deadline is today

Q1: What is the product?

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(b5)

Q2: How exactly does it work to reduce veterans suicides? Mental Health 10NC5

(b5)

Q3: Has it been approved by the FDA?

(b5)

Q4: How can veterans get this product?

(b5)

Q5: What results has this product shown in reducing veterans suicides?

(b5)

From: Michael Valentino (b)(6) @va.gov>
Date: Wednesday, August 21, 2019 at 2:39 PM
To: "Wiechers, Ilse" (b)(6) @va.gov>, Thomas Emmendorfer (b)(6) @va.gov>
Cc: "Law, Cassandra M." (b)(6) @va.gov>, Dennis Lahl (b)(6) @va.gov>
Subject: RE: [EXTERNAL] Task &Purpose media query: President Trump says the VA is buying a product from Johnson and Johnson to combat veterans suicide

Fantastic Ilse!

Tom, would you package this up and send it for clearance?

I clear for PBM and PCS

Sent with BlackBerry Work
(www.blackberry.com)

From: Wiechers, Ilse (b)(6) @va.gov>
Date: Wednesday, Aug 21, 2019, 2:33 PM
To: Valentino, Michael (VACO) (b)(6) @va.gov>, Emmendorfer, Thomas (PBM) (b)(6) @va.gov>
Subject: RE: [EXTERNAL] Task &Purpose media query: President Trump says the VA is buying a product from Johnson and Johnson to combat veterans suicide

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Some edits to #2 &#5.

From: Valentino, Michael (VACO)
Sent: Wednesday, August 21, 2019 11:28 AM
To: Wiechers, Ilse (b)(6) @va.gov>; Emmendorfer, Thomas (PBM) (b)(6) @va.gov>
Subject: RE: [EXTERNAL] Task &Purpose media query: President Trump says the VA is buying a product from Johnson and Johnson to combat veterans suicide

My thoughts below:

Sent with BlackBerry Work
(www.blackberry.com)

From: Wiechers, Ilse (b)(6) @va.gov>
Date: Wednesday, Aug 21, 2019, 2:15 PM
To: Strmiska, Jon G. (b)(6) @va.gov>, Valentino, Michael (VACO) (b)(6) @va.gov>, Emmendorfer, Thomas (PBM) (b)(6) @va.gov>
Cc: Daniels, Lindsay (b)(6) @va.gov>
Subject: RE: [EXTERNAL] Task &Purpose media query: President Trump says the VA is buying a product from Johnson and Johnson to combat veterans suicide

Jon – I should work directly with Mike Valentino and the PBM team on response to all of these.

I'm cc'ing Mike and Tom (looks like Jen is OOO) and will work with them on this now.

Ilse

From: Strmiska, Jon G.
Sent: Wednesday, August 21, 2019 10:58 AM
To: Wiechers, Ilse (b)(6) @va.gov>
Cc: Daniels, Lindsay (b)(6) @va.gov>
Subject: FW: [EXTERNAL] Task &Purpose media query: President Trump says the VA is buying a product from Johnson and Johnson to combat veterans suicide
Importance: High

Ilse,

Looks like 2 and 5 are assigned to 10NC5.

Please review and provide response as soon as reasonably possible.

Thanks!

Jon G. Strmiska
Business Operations Manager (10NC5)

AMERICAN OVERSIGHT

Phone: (b)(6) FAX: 202.495.5933

From: Hammonds, Michele
Sent: Wednesday, August 21, 2019 1:33 PM
To: VHA 10P Actions <VHA10PActions@va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>; VHA 10NC Action <vha10ncaction@va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>
Cc: VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: FW: [EXTERNAL] Task &Purpose media query: President Trump says the VA is buying a product from Johnson and Johnson to combat veterans suicide
Importance: High

Dennis /10P – Hot -This is another Spravato/esketamine query from the president's recent comment earlier today.
Seeking written responses to the following questions

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Q1: What is the product?
(b5)

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(b5)

Q3: Has it been approved by the FDA?
(b5)

Q4: How can veterans get this product?
(b5)

Q5: What results has this product shown in reducing veterans suicides?
(b5)

Michele Hammonds
Office of Communications (10b2B)
(b)(6)

AMERICAN OVERSIGHT

From: Carter, Susan
Sent: Wednesday, August 21, 2019 1:17 PM
To: Hammonds, Michele (b)(6) @va.gov>; Greilsamer, Alan <(b)(6) @va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Cc: Noller, Randal (b)(6) @va.gov>; Mandreucci, Christina M. (b)(6) @va.gov>
Subject: FW: [EXTERNAL] Task &Purpose media query: President Trump says the VA is buying a product from Johnson and Johnson to combat veterans suicide

This is another Spravato/esketamine query from the president's recent comment earlier today. Deadline is today. Thanks – Susan

Q1: What is the product?
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A4:

Q5: What results has this product shown in reducing veterans suicides?
A5:

Susan Carter
Director, Office of Media Relations
U.S. Department of Veterans Affairs
(b)(6) @va.gov
Desk:(b)(6)
Cell: (b)(6)



cid:image002.jpg@01D3D61E.49531160

From: Jeff Schogo (b)(6) @taskandpurpose.com>
Sent: Wednesday, August 21, 2019 12:49 PM
To: Carter, Susan (b)(6) @va.gov>
Subject: [EXTERNAL] Task &Purpose media query: President Trump says the VA is buying a product from Johnson and Johnson to combat veterans suicide

Good afternoon Ms. Carter,

AMERICAN OVERSIGHT

Thank you for taking my call!

President Trump told reporters today that the VA is buying a new product from Johnson and Johnson that has proven to be effective in combating veterans suicide:

"There's a product that's made right now that just came out by Johnson and Johnson, which has a tremendously positive – pretty short-term – but nevertheless a positive effect.

"I've instructed the head of the VA to go out and buy a lot of it, and we are buying a lot of it. Hopefully, we're getting it at a very good cost. And this is a – I guess it's a form of a stimulant, where if somebody is really in trouble, from the standpoint of suicide, it can do something.

"It's pretty well know, just came out. It's made, I believe, by Johnson and Johnson, and we have calls in now to Johnson and Johnson. Those calls – we've been dealing with them for two months and buying a lot of it."

Can the VA say:

1. What is the product?
2. How exactly does it work to reduce veterans suicides?
3. Has it been approved by the FDA?
4. How can veterans get this product?
5. What results has this product shown in reducing veterans suicides?

My deadline is today. Please feel free to email or call me at 703-697-6623.

Thank you.

Jeff Schogol

Sender:	Lahl, Dennis /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=39FBA8EA7CD941B3A0A4F79CA3C6EE87-LAHL, DENNI (b)(6) @va.gov>
Recipient:	VHA 10P Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5098b521b1f34f8a97f74be24709d62f-VHA 10P Act <VHA10PActions@va.gov>; VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>; VHA 10P4 Communication Group /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4ba2ff9b4604547be7834a71415253c-VHA 10P4 Co <vha10p4comm@va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b)(6) @va.gov>; Strmiska, Jon G. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9872f41bf2844c8085d371e21482b635-Strmiska, J (b)(6) @va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>
Sent Date:	2019/08/21 15:28:21

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Delivered Date:	2019/08/21 15:28:22
Message Flags:	Unread

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From:	Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd.DIBOHF23SPDLT)/CN=RECIPIENTS/CN=A38D9112AD904C5A84FFC6C931693AF7-SANDIFER, E (b)(6) @va.gov>
To:	Strmiska, Jon G. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9872f41bf2844c8085d371e21482b635-Strmiska, J (b)(6) @va.gov>; VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>
CC:	VHA 10P4 Communication Group /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4ba2ff9b4604547be7834a71415253c-VHA 10P4 Co <vha10p4comm@va.gov>; VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>; VHA 10P Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5098b521b1f34f8a97f74be24709d62f-VHA 10P Act <VHA10PActions@va.gov>
Subject:	FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision
Date:	2019/06/18 15:44:29
Priority:	Normal
Type:	Note

10NC5,

10P clears the response below.

Question: Is there any more specific information that we can provide about timeline?

(b5)

V/r,

Maria Sandifer
Office of the Deputy Under Secretary for Health
for Policy and Services (10P)
Work ph: (b)(6)
Cell: (b)(6)
Email: (b)(6) @va.gov

From: Wiechers, Ilse
Sent: Tuesday, June 18, 2019 1:27 PM
To: Carroll, David (VACO) <(b)(6) @va.gov>; Strmiska, Jon G. (b)(6) @va.gov>; Ilse Wiechers (Yale) (b)(6) ; Torrise, Virginia (VHACO) <(b)(6) @va.gov>

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Cc: Daniels, Lindsay (b)(6) @va.gov>; Pomerantz, Andrew (b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Hi – I'm in office and online. I'm working on some high-level bullet points summarizing our progress and will have them up and out to folks shortly.

Ginny – you can comment on the formulary decision, but I know that the MAP/VPE is considering esketamine on the agenda of this week's meeting on Thursday morning. I was planning to use language that states (b5)
(b5)
(b5) Please edit that statement as you feel most appropriate.

Ilse

From: Carroll, David (VACO)
Sent: Tuesday, June 18, 2019 10:23 AM
To: Strmiska, Jon G. (b)(6) @va.gov>; Ilse Wiechers (Yale) (b)(6) ; Wiechers, Ilse (b)(6) @va.gov>; Torrise, Virginia (VHACO) (b)(6) @va.gov>
Cc: Daniels, Lindsay (b)(6) @va.gov>; Pomerantz, Andrew (b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Actually – Ilse responded on a similar request from Dr. Boyd. Looks like she may have something together later this afternoon.

From: Strmiska, Jon G.
Sent: Tuesday, June 18, 2019 1:17 PM
To: Ilse Wiechers (Yale) (b)(6) Wiechers, Ilse (b)(6) @va.gov>; Torrise, Virginia (VHACO) (b)(6) @va.gov>
Cc: Daniels, Lindsay (b)(6) @va.gov>; Pomerantz, Andrew (b)(6) @va.gov>; VHA 10P4P Action <vha10P4Paction@va.gov>; Carroll, David (VACO) (b)(6) @va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Ginny,

As discussed, your assistance is greatly appreciated with providing a response on this one. Ilse is out of the office until tomorrow. Please see below and provide your response by **3pm today.**

New York Times is asking when a decision will be made as to when VA will be putting Spravato in its formulary. We recently provide the response below, highlighted yellow.

Is there any more specific information that we can provide about timeline?

FDA has approved the use of intranasal esketamine for adults with treatment-resistant depression (when used in conjunction with an oral antidepressant). VA has not yet

AMERICAN OVERSIGHT

administered esketamine to any patients, and is in the process of designing a clinical implementation plan optimized for safety and efficacy.

Thanks!

Jon G. Strmiska
Business Operations Manager (10NC5)
VA Central Office – Washington, DC
Phone: *(b)(6)*
FAX: 202.495.5933

From: Dudley, Tracy
Sent: Tuesday, June 18, 2019 1:00 PM
To: VHA 10NC5 Action <VHA10NC5Action@va.gov>
Cc: VHA CO 10NC Front Office HSSs <VHACO10NCFOHSSs@va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

GOOD Afternoon

Please see below and provide your response by **3pm today.**

Thank You!
Tracy

Tracy L. Dudley
Health System Specialist
ADUSH for Clinical Operations (10NC)
(b)(6) (Direct)
(b)(6) (iPhone)

From: Greilsamer, Alan
Sent: Tuesday, June 18, 2019 12:46 PM
To: VHA 10N Action <VHA10NAction@va.gov>; VHA 10NC Action <vha10ncaction@va.gov>
Cc: VHA 10NC5 Action <VHA10NC5Action@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Good afternoon,

New York Times is asking when a decision will be made as to when VA will be putting Spravato in its formulary. We recently provide the response below.

Is there any more specific information that we can provide about timeline?

FDA has approved the use of intranasal esketamine for adults with treatment-resistant depression (when used in conjunction with an oral antidepressant). VA has not yet

AMERICAN OVERSIGHT

administered esketamine to any patients, and is in the process of designing a clinical implementation plan optimized for safety and efficacy.

Requesting a response by today (June 18) NLT 5 p.m. ET.

Thanks, Alan

From: Cashour, Curtis
Sent: Tuesday, June 18, 2019 12:38 PM
To: Greilsamer, Alan (b)(6) @va.gov>; Screen, Gina (b)(6) @va.gov>
Cc: Eason, William J. (b)(6) @va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Please let me know your recommended response to the below.

Thanks,

Curt Cashour
Press Secretary
Department of Veterans Affairs
(b)(6)
(b)(6) @va.gov
(b)(6)

From: Ben Carey (b)(6) @nytimes.com>
Sent: Tuesday, June 18, 2019 12:35 PM
To: Cashour, Curtis <(b)(6) @va.gov>
Subject: Re: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Thanks Curt, please do. Main question for now is when is decision expected..? (i.e. how much time I got?)

Ben

Sent from my iPhone

On Jun 18, 2019, at 12:22 PM, Cashour, Curtis <(b)(6) @va.gov>wrote:

Will keep you posted. Thanks, Ben.

Curt Cashour
Press Secretary
Department of Veterans Affairs
(b)(6)
(b)(6) @va.gov
(b)(6)

AMERICAN OVERSIGHT

From: Carey, Ben (b)(6) @nytimes.com>
Sent: Tuesday, June 18, 2019 11:36 AM
To: Cashour, Curtis <(b)(6) @va.gov>
Subject: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Curt Cashour-

Hello from New York. It's Ben Carey emailing. I am a reporter in science at the NY Times, I cover psych topics. I have your email from Jennifer Steinhauer, NYT reporter in DC.

I would love to hear what/ when on the VA's expected decision this week whether to put Spravato on its formulary. Keep me in the loop on this, kindly, would be good to know when decision will be made, with some notice, and anything else VA puts out on this.

We'll likely cover decision either way.

Sincerely,

Ben Carey

Sender:	Sandifer, Estella (Maria) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A38D9112AD904C5A84FFC6C931693AF7-SANDIFER, E (b)(6) @va.gov>
Recipient:	Strmiska, Jon G. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9872f41bf2844c8085d371e21482b635-Strmiska, J (b)(6) @va.gov>; VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>; VHA 10P4 Communication Group /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4ba2ff9b4604547be7834a71415253c-VHA 10P4 Co <vha10p4comm@va.gov>; VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>; VHA 10P Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5098b521b1f34f8a97f74be24709d62f-VHA 10P Act <VHA10PActions@va.gov>
Sent Date:	2019/06/18 15:44:26
Delivered Date:	2019/06/18 15:44:29

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From:	Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd.PDLT)/CN=RECIPIENTS/CN=9872F41BF2844C8085D371E21482B635-STRMISKA, J (b)(6) @va.gov>
To:	Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da (b)(6) @va.gov>
CC:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b)(6) @va.gov>; Daniels, Lindsay /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ed253196fb6b4f32aa922c90dbd05f29-Daniels, Li (b)(6) @va.gov>
Subject:	FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision
Date:	2019/06/18 15:31:26
Priority:	Normal
Type:	Note

Dave, do you clear this?

Jon G. Strmiska
Business Operations Manager (10NC5)
VA Central Office – Washington, DC
Phone:(b)(6)
FAX: 202.495.5933

From: Lahl, Dennis
Sent: Tuesday, June 18, 2019 3:28 PM
To: Torrise, Virginia (VHACO) (b)(6) @va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>; Hastings, Patricia R. (b)(6) @va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Cc: Valentino, Michael (VACO) (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) (b)(6) @va.gov>; Strmiska, Jon G. (b)(6) @va.gov>; Wiechers, Ilse (b)(6) @va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

All the below is cleared:

(b5)

Thanks. Have a great day.

Dennis

Dennis Lahl FAC-P/PM
Office of the Assistant Deputy Under Secretary for Health for

AMERICAN OVERSIGHT

Patient Care Services (10P4)
VACO PCS IT/BCAG/ISO Liaison
TMS OPCS DM
ph:(b)(6)
fax: 202-273-5483
Dennis Lahl

From: Lahl, Dennis
Sent: Tuesday, June 18, 2019 3:05 PM
To: Torrise, Virginia (VHACO) (b)(6) @va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>; Hastings, Patricia R. (b)(6) @va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Cc: Valentino, Michael (VACO) (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) (b)(6) @va.gov>; Strmiska, Jon G. (b)(6) @va.gov>; Wiechers, Ilse (b)(6) @va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Dr. Hastings,

10NC5 received the below request for input, 10P4P submitted the noted response. Submitting this for clearance to 10NC5. I've cc'd 10P Actions and 10P4 Actions for tracking purposes. Let me know if you have any questions or concerns.

Feeder Response to OMHS: PBM provides this response to support OMHS statements (Dr Wiechers) regarding implementation timeline.

Question: Is there any more specific information that we can provide about timeline?

(b5)

Thanks. Have a great day.

Dennis

Dennis Lahl FAC-P/PM
Office of the Assistant Deputy Under Secretary for Health for Patient Care Services (10P4)
VACO PCS IT/BCAG/ISO Liaison
TMS OPCS DM
ph: (b)(6)
fax: 202-273-5483
Dennis Lahl

AMERICAN OVERSIGHT

From: Torrise, Virginia (VHACO)
Sent: Tuesday, June 18, 2019 2:08 PM
To: Lahl, Dennis <(b)(6) @va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>
Cc: Valentino, Michael (VACO) <(b)(6) @va.gov>; Zacher, Jennifer L. (PBM) <(b)(6) @va.gov>; Strmiska, Jon G. <(b)(6) @va.gov>; Wiechers, Ilse <(b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Medical Advisory Panel (MAP)
VISN Pharmacy Executive (VPE)

From: Lahl, Dennis
Sent: Tuesday, June 18, 2019 2:07 PM
To: Torrise, Virginia (VHACO) <(b)(6) @va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>
Cc: Valentino, Michael (VACO) <(b)(6) @va.gov>; Zacher, Jennifer L. (PBM) <(b)(6) @va.gov>; Strmiska, Jon G. <(b)(6) @va.gov>; Wiechers, Ilse <(b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Ginny,

(b5)

Thanks. Have a great day.

Dennis

Dennis Lahl FAC-P/PM
Office of the Assistant Deputy Under Secretary for Health for Patient Care Services (10P4)
VACO PCS IT/BCAG/ISO Liaison
TMS OPCS DM
ph: (b)(6)
fax: 202-273-5483
Dennis Lahl

From: Torrise, Virginia (VHACO)
Sent: Tuesday, June 18, 2019 1:53 PM
To: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Cc: Valentino, Michael (VACO) <(b)(6) @va.gov>; Zacher, Jennifer L. (PBM) <(b)(6) @va.gov>; Strmiska, Jon G. <(b)(6) @va.gov>; Wiechers, Ilse <(b)(6) @va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Feeder Response to OMHS: PBM provides this response to support OMHS statements (Dr Wiechers) regarding implementation timeline.

AMERICAN OVERSIGHT

Question: Is there any more specific information that we can provide about timeline?

(b5) [redacted]

From: Wiechers, Ilse
Sent: Tuesday, June 18, 2019 1:27 PM
To: Carroll, David (VACO) (b)(6) @va.gov>; Strmiska, Jon G. (b)(6) @va.gov>; Ilse Wiechers (Yale) (b)(6) Torrise, Virginia (VHACO) <(b)(6) @va.gov>
Cc: Daniels, Lindsay <(b)(6) @va.gov>; Pomerantz, Andrew <(b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Hi – I'm in office and online. I'm working on some high-level bullet points summarizing our progress and will have them up and out to folks shortly.

Ginny – you can comment on the formulary decision, but I know that the MAP/VPE is considering esketamine on the agenda of this week's meeting on Thursday morning. I was planning to use language that states (b5) [redacted]
(b5) [redacted]
(b5) [redacted] Please edit that statement as you feel most appropriate.

Ilse

From: Carroll, David (VACO)
Sent: Tuesday, June 18, 2019 10:23 AM
To: Strmiska, Jon G. <(b)(6) @va.gov>; Ilse Wiechers (Yale) <(b)(6) Wiechers, Ilse (b)(6) @va.gov>; Torrise, Virginia (VHACO) (b)(6) @va.gov>
Cc: Daniels, Lindsay <(b)(6) @va.gov>; Pomerantz, Andrew <(b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Actually – Ilse responded on a similar request from Dr. Boyd. Looks like she may have something together later this afternoon.

From: Strmiska, Jon G.
Sent: Tuesday, June 18, 2019 1:17 PM
To: Ilse Wiechers (Yale) (b)(6) Wiechers, Ilse <(b)(6) @va.gov>; Torrise, Virginia (VHACO) <(b)(6) @va.gov>
Cc: Daniels, Lindsay <(b)(6) @va.gov>; Pomerantz, Andrew (b)(6) @va.gov>; VHA 10P4P Action <vha10P4Paction@va.gov>; Carroll, David (VACO) <(b)(6) @va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Ginny,

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As discussed, your assistance is greatly appreciated with providing a response on this one. Ilse is out of the office until tomorrow. Please see below and provide your response by **3pm today.**

New York Times is asking when a decision will be made as to when VA will be putting Spravato in its formulary. We recently provide the response below, highlighted yellow.

Is there any more specific information that we can provide about timeline?

FDA has approved the use of intranasal esketamine for adults with treatment-resistant depression (when used in conjunction with an oral antidepressant). VA has not yet administered esketamine to any patients, and is in the process of designing a clinical implementation plan optimized for safety and efficacy.

Thanks!

Jon G. Strmiska
Business Operations Manager (10NC5)
VA Central Office – Washington, DC
Phone: *(b)(6)*
FAX: 202.495.5933

From: Dudley, Tracy
Sent: Tuesday, June 18, 2019 1:00 PM
To: VHA 10NC5 Action <VHA10NC5Action@va.gov>
Cc: VHA CO 10NC Front Office HSSs <VHACO10NCFOHSSs@va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

GOOD Afternoon

Please see below and provide your response by **3pm today.**

Thank You!
Tracy

Tracy L. Dudley
Health System Specialist
ADUSH for Clinical Operations (10NC)
(b)(6) (Direct)
(b)(6) (iPhone)

From: Greilsamer, Alan
Sent: Tuesday, June 18, 2019 12:46 PM
To: VHA 10N Action <VHA10NAction@va.gov>; VHA 10NC Action <vha10ncaction@va.gov>
Cc: VHA 10NC5 Action <VHA10NC5Action@va.gov>; VHA CO 10B2B Media

AMERICAN OVERSIGHT

<VHACO10B2BMedia@va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Good afternoon,

New York Times is asking when a decision will be made as to when VA will be putting Spravato in its formulary. We recently provide the response below.

Is there any more specific information that we can provide about timeline?

FDA has approved the use of intranasal esketamine for adults with treatment-resistant depression (when used in conjunction with an oral antidepressant). VA has not yet administered esketamine to any patients, and is in the process of designing a clinical implementation plan optimized for safety and efficacy.

Requesting a response by today (June 18) NLT 5 p.m. ET.

Thanks, Alan

From: Cashour, Curtis
Sent: Tuesday, June 18, 2019 12:38 PM
To: Greilsamer, Alan (b)(6) @va.gov>; Screen, Gina <(b)(6) @va.gov>
Cc: Eason, William J. <(b)(6) @va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Please let me know your recommended response to the below.

Thanks,

Curt Cashour
Press Secretary
Department of Veterans Affairs
(b)(6)
(b)(6) @va.gov
(b)(6)

From: Ben Carey (b)(6) @nytimes.com>
Sent: Tuesday, June 18, 2019 12:35 PM
To: Cashour, Curtis <(b)(6) @va.gov>
Subject: Re: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Thanks Curt, please do. Main question for now is when is decision expected..? (i.e. how much time I got?)

Ben

Sent from my iPhone

AMERICAN OVERSIGHT

On Jun 18, 2019, at 12:22 PM, Cashour, Curtis <(b)(6) @va.gov>wrote:

Will keep you posted. Thanks, Ben.

Curt Cashour
Press Secretary
Department of Veterans Affairs
(b)(6)
(b)(6) @va.gov
(b)(6)

From: Carey, Ben (b)(6) @nytimes.com>
Sent: Tuesday, June 18, 2019 11:36 AM
To: Cashour, Curtis <(b)(6) @va.gov>
Subject: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Curt Cashour-

Hello from New York. It's Ben Carey emailing. I am a reporter in science at the NY Times, I cover psych topics. I have your email from Jennifer Steinhauer, NYT reporter in DC.

I would love to hear what/ when on the VA's expected decision this week whether to put Spravato on its formulary. Keep me in the loop on this, kindly, would be good to know when decision will be made, with some notice, and anything else VA puts out on this.

We'll likely cover decision either way.

Sincerely,

Ben Carey

Sender:	Strmiska, Jon G. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9872F41BF2844C8085D371E21482B635-STRMISKA, J (b)(6) @va.gov>
Recipient:	Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da (b)(6) @va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b)(6) @va.gov>; Daniels, Lindsay /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ed253196fb6b4f32aa922c90dbd05f29-Daniels, Li (b)(6) @va.gov>
Sent Date:	2019/06/18 15:31:25
Delivered Date:	2019/06/18 15:31:26

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From:	Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd.HF23SPDLT)/CN=RECIPIENTS/CN=182805D689894DA4B2D00810DA5E305C-STEWART, KA (b)(6) @va.gov>
To:	VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>
CC:	VHA CO 10NC Front Office HSSs /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcf91f73967a49c287d8747b7aee675e-VHA CO 10NC <VHACO10NCFOHSSs@va.gov>
Subject:	FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision
Date:	2019/06/20 16:02:49
Priority:	Normal
Type:	Note

Good Afternoon 10NC5,

NLT tomorrow, 6/21/19, by 9am please provide your response to the below inquiry to VHA CO 10NC Front Office HSSs.

Thank you,

Katie Stewart, MSW, LCSW
Health Systems Specialist
Office of the ADUSH for Clinical Operations (10NC)
(b)(6) (office)
(b)(6) (cell)

From: Greilsamer, Alan
Sent: Thursday, June 20, 2019 3:42 PM
To: Stewart, Katharine E. (b)(6) @va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Cc: VHA CO 10N Support Staff <VHACO10NSS@va.gov>; VHA CO 10NC Front Office HSSs <VHACO10NCFOHSSs@va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Good afternoon

VA Press Secretary is asking if we can get more specific about the question below from the NY Times. Is there a timeframe that we can provide.

"Is there any more specific information that we can provide about timeline?"

Thanks, Alan
—
Alan Greilsamer
Director, Media Relations (10B2B)

AMERICAN OVERSIGHT

Office of Communications
Veterans Health Administration
P: (b)(6)
E: (b)(6) @va.gov

From: Stewart, Katharine E. <(b)(6) @va.gov>
Date: Tuesday, Jun 18, 2019, 5:01 PM
To: Greilsamer, Alan (b)(6) @va.gov>, VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Cc: VHA CO 10N Support Staff <VHACO10NSS@va.gov>, VHA CO 10NC Front Office HSSs <VHACO10NCFOHSSs@va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Good Afternoon Alan/VHA Comms,

On behalf of 10N/10NC, Dr. Thomas O'Toole clears the below response from 10NC5 to your inquiry.

Thank you,

Katie Stewart, MSW, LCSW
Health Systems Specialist
Office of the ADUSH for Clinical Operations (10NC)
(b)(6) office)
(b)(6) (cell)

From: O'Toole, Thomas P.
Sent: Tuesday, June 18, 2019 4:56 PM
To: Stewart, Katharine E. <(b)(6) @va.gov>; VHA 10NC Clearance <VHA10NCClearance2@va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

10NC clears

From: Strmiska, Jon G.
Sent: Tuesday, June 18, 2019 3:43 PM
To: Dudley, Tracy (b)(6) @va.gov>
Cc: VHA CO 10NC Front Office HSSs <VHACO10NCFOHSSs@va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>; Wiechers, Ilse (b)(6) @va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Dr. Carroll has cleared the following response:

(b5)

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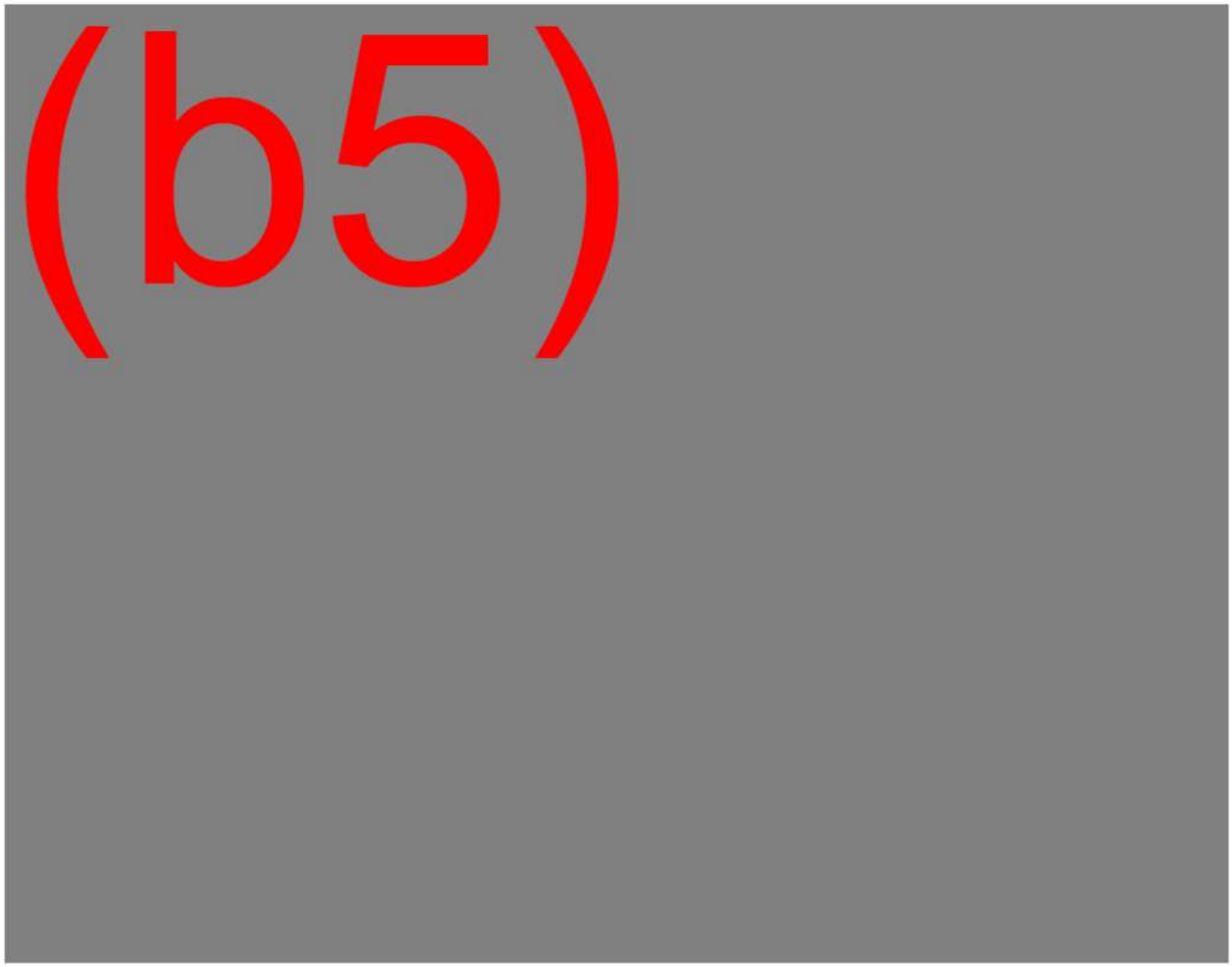

Jon G. Strmiska
Business Operations Manager (10NC5)
VA Central Office – Washington, DC
Phone: *(b)(6)*
FAX: 202.495.5933

From: Greilsamer, Alan
Sent: Tuesday, June 18, 2019 12:46 PM
To: VHA 10N Action <VHA10NAction@va.gov>; VHA 10NC Action <vha10ncaction@va.gov>
Cc: VHA 10NC5 Action <VHA10NC5Action@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

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From: Cashour, Curtis
Sent: Tuesday, June 18, 2019 12:38 PM
To: Greilsamer, Alan <(b)(6) @va.gov>; Screen, Gina (b)(6) @va.gov>
Cc: Eason, William J. <(b)(6) @va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

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Thanks,

Curt Cashour
Press Secretary
Department of Veterans Affairs
(b)(6)
(b)(6) @va.gov
(b)(6)

From: Ben Carey <(b)(6) @nytimes.com>
Sent: Tuesday, June 18, 2019 12:35 PM
To: Cashour, Curtis <(b)(6) @va.gov>
Subject: Re: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

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Ben

Sent from my iPhone

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AMERICAN OVERSIGHT

Curt Cashour
Press Secretary
Department of Veterans Affairs
(b)(6)
(b)(6) @va.gov
(b)(6)

From: Carey, Ben (b)(6) @nytimes.com>
Sent: Tuesday, June 18, 2019 11:36 AM
To: Cashour, Curtis <(b)(6) @va.gov>
Subject: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Curt Cashour-

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I would love to hear what/ when on the VA's expected decision this week whether to put Spravato on its formulary. Keep me in the loop on this, kindly, would be good to know when decision will be made, with some notice, and anything else VA puts out on this.

We'll likely cover decision either way.

Sincerely,

Ben Carey

Sender:	Stewart, Katharine E. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=182805D689894DA4B2D00810DA5E305C-STEWART, KA (b)(6) @va.gov>
Recipient:	VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>; VHA CO 10NC Front Office HSSs /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcf91f73967a49c287d8747b7aee675e-VHA CO 10NC <VHACO10NCFOHSSs@va.gov>
Sent Date:	2019/06/20 16:02:48
Delivered Date:	2019/06/20 16:02:49

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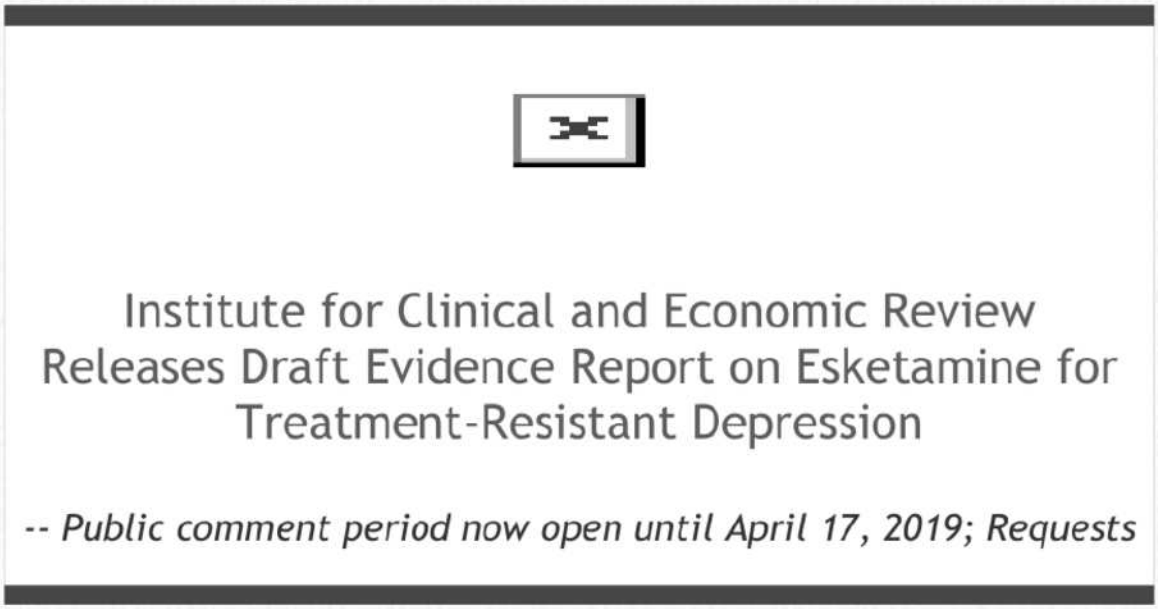
From:	Nazario, Mitchell /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2E909581B30643148BA99AB7FF79CAE0-NAZARIO, MI (b)(6) @va.gov>
To:	Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat (b)(6) @va.gov>
Subject:	FW: [EXTERNAL] ICER Releases Draft Evidence Report on Esketamine for Treatment-Resistant Depression
Date:	2019/03/25 08:17:24
Priority:	Normal
Type:	Note

Hi Matt,

In case you didn't see this.

Mitch

From: Institute for Clinical and Economic Review <info@icer-review.org>
Sent: Thursday, March 21, 2019 4:22 PM
To: Nazario, Mitchell (b)(6) @va.gov>
Subject: [EXTERNAL] ICER Releases Draft Evidence Report on Esketamine for Treatment-Resistant Depression



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to make oral comment during public meeting also being accepted --

BOSTON, March 21, 2019 - The Institute for Clinical and Economic Review (ICER) today released a Draft Evidence Report assessing the clinical effectiveness and value of esketamine (Spravato™, Janssen) for treatment-resistant depression.

This draft report will be open to public comment until 5pm ET on April 17, 2019. Based on stakeholder feedback, ICER may revise key assumptions and findings for its Evidence Report, which will be published on May 9, 2019. The Evidence Report will be subject to deliberation during a public meeting of the Midwest Comparative Effectiveness Public Advisory Council (Midwest CEPAC), one of ICER's three independent evidence appraisal committees, on May 23, 2019.

ICER is committed to engaging with all stakeholders in a thorough and transparent manner. During this review, ICER has spoken with patients, clinical experts, insurers, and manufacturers. Public comments were also accepted on a Draft Scoping Document. The current draft report incorporates input received from patients, clinicians, and other stakeholders during each of these opportunities for engagement.

Submit a Public Comment

The Draft Evidence Report and Draft Voting Questions are now open to public comment until 5 PM ET on April 17, 2019. All stakeholders are invited to submit formal comments by email to publiccomments@icer-review.org. Guidelines for submitting public comments, including formatting specifications, are available on ICER's website. ICER's Manufacturer Engagement Guide and Patient Participation Guide provide additional detail on what types of information may be most informative to the report.

ICER will review all comments and incorporate any necessary changes in the Evidence Report and Revised Voting Questions that will be posted on or about May 9, 2019. All comments and ICER's response to comments will be posted publicly along with the Evidence Report.

Register for the Public Meeting

The Evidence Report will be the subject of a public meeting of the Midwest CEPAC on May 23, 2019 in Rosemont, IL. During the meeting, the independent council will vote on key questions raised in the report. Registration for the public meeting and live webcast is now open.

Register to Make an Oral Comment

During the public meeting, there will be a limited amount of time available for interested stakeholders to make an oral comment on the report. Requests to submit oral comments must be emailed to publiccomments@icer-review.org by 5 PM ET on April 17, 2019. Individuals who wish to deliver oral comments must separately register to attend the meeting. For more information about registering for oral comment, please visit our website.

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About ICER

The Institute for Clinical and Economic Review (ICER) is an independent non-profit research institute that produces reports analyzing the evidence on the effectiveness and value of drugs and other medical services. ICER's reports include evidence-based calculations of prices for new drugs that accurately reflect the degree of improvement expected in long-term patient outcomes, while also highlighting price levels that might contribute to unaffordable short-term cost growth for the overall health care system.

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Subject:	FW: [EXTERNAL] ICER Issues Final Report and Policy Recommendations on Esketamine for Treatment-Resistant Depression
Date:	2019/06/20 19:35:10
Priority:	Normal
Type:	Note

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From: Institute for Clinical and Economic Review <info@icer-review.org>
Date: Thursday, Jun 20, 2019, 4:47 PM
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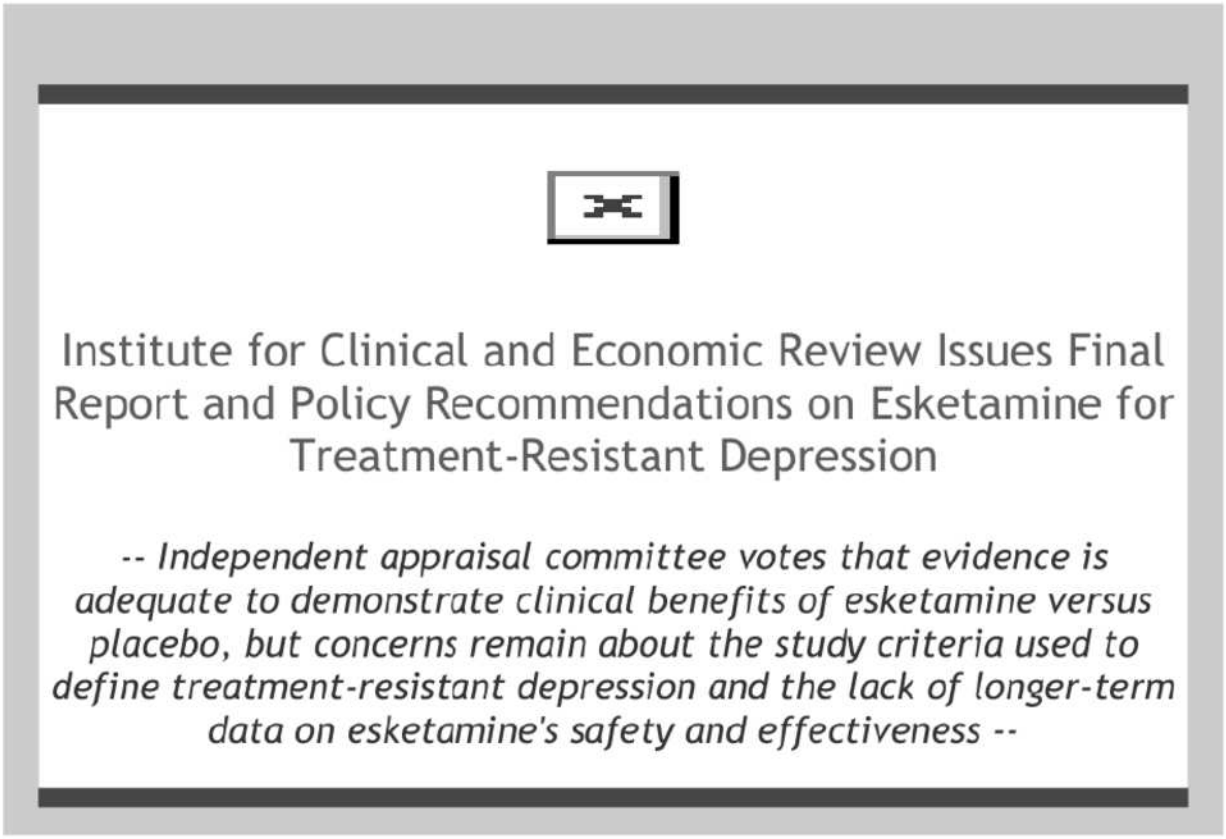

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-- Esketamine's list price would require a 25-52% discount to reach a fair value-based price benchmark, and the potential short-term budget impact associated with treating the eligible patient population leads ICER to issue an Access and Affordability Alert --

BOSTON, June 20, 2019 - The Institute for Clinical and Economic Review (ICER) today released a Final Evidence Report and Report-at-a-Glance assessing the comparative clinical effectiveness and value of esketamine (Spravato™, Janssen), a nasal spray approved by the FDA in March as a therapy for treatment-resistant depression (TRD). Esketamine is one of the two mirror-image molecules (enantiomers) that make up ketamine, an anesthetic that is commonly used off-label to treat TRD.

ICER's report was reviewed at the May 2019 public meeting of the Midwest Comparative Effectiveness Public Advisory Council (Midwest CEPAC), one of ICER's three independent evidence appraisal committees. During the meeting, the CEPAC found that the evidence demonstrated esketamine plus background antidepressant to be clinically superior to background antidepressant alone. The CEPAC members found the evidence to be insufficient to demonstrate a difference in net health benefit between esketamine and ketamine, transcranial magnetic stimulation, electroconvulsive therapy, or augmentation with olanzapine.

During their deliberation, panel members weighed the therapies' other benefits and contextual considerations. They acknowledged that esketamine is intended to care for patients with a condition of high severity and a high lifetime burden of illness, and that esketamine offers a novel mechanism of action compared to other approved treatments for TRD, which may allow successful treatment of many patients for who other available treatments have failed. Nevertheless, a majority of the panel felt that there is uncertainty about the long-term benefits and risks of esketamine, citing the lack of long-term trial evidence.

ICER's evaluation of long-term cost-effectiveness found that the fair value-based price benchmark for esketamine is between $17,700 and $25,200 per year, a range that would require a 25-52% discount from the announced list price of $32,400. Consistent with ICER's value-assessment framework, esketamine is deemed to deliver a "low value for money" because the treatment's incremental cost-effectiveness ratio, using the current list price, exceeds $175,000 per quality-adjusted life year (QALY) gained.

"Treatment-resistant forms of major depression are common and have large negative effects on patient quality of life, so new therapies are badly needed," said David Rind, MD, ICER's Chief Medical Officer. "It is hard to understand how a price exceeding usual cost-effectiveness thresholds is appropriate for a treatment that could be very widely used, particularly when that price is an order of magnitude higher than that of intravenous generic ketamine, a closely related therapy."

Affordability &Access Alert

Given that the clinical goal for uptake would exceed the potential budget impact threshold at the national level, ICER is issuing an Affordability and Access Alert as part of its final report on esketamine. Clinical experts queried at the public meeting suggested that esketamine would not be viewed as an appropriate treatment for all patients with TRD, but that roughly half of eligible patients may be offered the option during consultation with their physician.

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VA-19-1109-B-002138

However, at esketamine's current list price, only 16% of eligible Americans with TRD could receive the treatment before crossing ICER's potential budget threshold of $819 million per year. Even if esketamine's price was lowered to ICER's value-based price benchmark range for long-term cost-effectiveness, only 20-30% of all eligible patients with TRD could be treated with esketamine before exceeding the potential budget impact threshold.

The purpose of an ICER Affordability and Access Alert is to signal to stakeholders and policy makers that the amount of added health care costs associated with a new service may be difficult for the health system to absorb over the short term without displacing other needed services or contributing to rapid growth in health care insurance costs that threaten sustainable access to high-value care for all patients.

Key Policy Recommendations

Following the voting session, a policy roundtable of experts - including clinicians, patient advocates, and payer representatives - convened to discuss the implications of the evidence for policy and practice. Key recommendations stemming from the roundtable discussion include:

- • Manufacturers and researchers should conduct studies directly comparing esketamine and other treatment options using standardized research protocols and outcomes that reflect what matters most to patients; this would allow real-world, long-term assessment of comparative effectiveness.

- • Given the considerable uncertainty that remains regarding the longer-term benefits and risks of esketamine, it is reasonable for insurers and other payers to develop prior authorization criteria to ensure that patients are carefully selected and managed by clinicians with the necessary expertise to ensure appropriate care.

- • Payers should develop mechanisms to adequately compensate clinicians for the expenses associated with monitoring and delivering esketamine within the specification of the REMS program.

ICER's detailed set of policy recommendations, including considerations for establishing prior authorization criteria, is available in the Final Evidence Report.

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In case you haven't had enough esketamine for the week….

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Institute for Clinical and Economic Review Issues Final Report and Policy Recommendations on Esketamine for Treatment-Resistant Depression

-- Independent appraisal committee votes that evidence is adequate to demonstrate clinical benefits of esketamine versus placebo, but concerns remain about the study criteria used to define treatment-resistant depression and the lack of longer-term data on esketamine's safety and effectiveness --

-- Esketamine's list price would require a 25-52% discount to reach a fair value-based price benchmark, and the potential short-term budget impact associated with treating the eligible patient population leads ICER to issue an Access and Affordability Alert --

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Subject:	Follow Up: HHS Nasal Spray
Date:	2019/03/07 14:10:45
Start Date:	2019/03/08 08:30:00
End Date:	2019/03/08 09:00:00
Priority:	Normal
Type:	Appointment
Location:	VACO 802 or VANTS 1-800-767-1750 A/C 22021
Attendees:	Stone, Richard A., MD; Llorente, Maria D.; Beck, Lucille B.; Emmendorfer, Thomas (PBM); Jensen, Jon M.; Valentino, Michael (VACO); Connell, Lawrence B.; Beck, Lucille B.

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Attendees:	Stone, Richard A., MD; Llorente, Maria D.; Beck, Lucille B.; Emmendorfer, Thomas (PBM); Jensen, Jon M.; Valentino, Michael (VACO); Connell, Lawrence B.; Beck, Lucille B.

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SentVia:	Williams, Jessica D. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=007F83F1989E48888DAB9C5D712C99B4-WILLIAMS, J <(b)(6) @va.gov>
To:	Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b)(6) @va.gov>; Beck, Lucille B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=845480228a8b43e7a5fef5716ded04c2-Beck, Lucil (b)(6) @va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>; Jensen, Jon M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddeb735ace76400db5c3f10603188a14-Jensen, Jon (b)(6) @va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b)(6) @va.gov>; Connell, Lawrence B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a3e7233376344045980ad214122389f4-Connell, La <(b)(6) @va.gov>
Subject:	Follow Up: HHS Nasal Spray
Date:	2019/03/08 07:33:15
Start Date:	2019/03/08 08:30:00
End Date:	2019/03/08 09:00:00
Priority:	Normal
Type:	Schedule.Meeting.Request
Location:	VACO 802 or VANTS 1-800-767-1750 A/C 22021
Attendees:	Llorente, Maria D.; Beck, Lucille B.; Emmendorfer, Thomas (PBM); Jensen, Jon M.; Valentino, Michael (VACO); Connell, Lawrence B.

Sender:	Stone, Richard A., MD /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BD16619615D64ADEA22E45E63FF6462A-STONE, RICH (b)(6) @va.gov>; Williams, Jessica D. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=007F83F1989E48888DAB9C5D712C99B4-WILLIAMS, J (b)(6) @va.gov>
Recipient:	Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M (b)(6) @va.gov>; Beck, Lucille B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=845480228a8b43e7a5fef5716ded04c2-Beck, Lucil (b)(6) @va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b)(6) @va.gov>; Jensen, Jon M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddeb735ace76400db5c3f10603188a14-Jensen, Jon (b)(6) @va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>; Connell, Lawrence B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a3e7233376344045980ad214122389f4-Connell, La <(b)(6) @va.gov>

AMERICAN OVERSIGHT

Sent Date:	2019/03/08 07:33:08
Delivered Date:	2019/03/08 07:33:15

AMERICAN OVERSIGHT

From:	Stone, Richard A., MD /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BD16619615D64ADEA22E45E63FF6462A-STONE, RICH <(b)(6) @va.gov>
To:	Stone, Richard A., MD /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bd16619615d64adea22e45e63ff6462a-Stone, Rich (b)(6) @va.gov>; Llorente, Maria D. (b)(6) @va.gov>; Beck, Lucille B. <(b)(6) @va.gov>; Emmendorfer, Thomas (PBM) <(b)(6) @va.gov>; Jensen, Jon M. (b)(6) @va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>; Connell, Lawrence B. (b)(6) @va.gov>
Subject:	Follow Up: HHS Nasal Spray
Date:	2019/03/07 14:51:12
Start Date:	2019/03/08 08:30:00
End Date:	2019/03/08 09:00:00
Priority:	Normal
Type:	Appointment
Location:	VACO 802 or VANTS 1-800-767-1750 A/C 22021
Attendees:	Stone, Richard A., MD; Llorente, Maria D.; Beck, Lucille B.; Emmendorfer, Thomas (PBM); Jensen, Jon M.; Valentino, Michael (VACO); Connell, Lawrence B.; Beck, Lucille B.

Sender:	Stone, Richard A., MD /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BD16619615D64ADEA22E45E63FF6462A-STONE, RICH (b)(6) @va.gov>
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SentVia:	Williams, Jessica D. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=007F83F1989E48888DAB9C5D712C99B4-WILLIAMS, J (b)(6) @va.gov>
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Subject:	Follow Up: HHS Nasal Spray
Date:	2019/03/08 07:33:13
Start Date:	2019/03/08 08:30:00
End Date:	2019/03/08 09:00:00
Priority:	Normal
Type:	Schedule.Meeting.Request
Location:	VACO 802 or VANTS 1-800-767-1750 A/C 22021
Attendees:	Llorente, Maria D.; Beck, Lucille B.; Emmendorfer, Thomas (PBM); Jensen, Jon M.; Valentino, Michael (VACO); Connell, Lawrence B.

Sender:	Stone, Richard A., MD /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BD16619615D64ADEA22E45E63FF6462A-STONE, RICH (b)(6) @va.gov>; Williams, Jessica D. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=007F83F1989E48888DAB9C5D712C99B4-WILLIAMS, J (b)(6) @va.gov>
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AMERICAN OVERSIGHT

Sent Date:	2019/03/08 07:33:08
Delivered Date:	2019/03/08 07:33:13

AMERICAN OVERSIGHT

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Subject:	Follow Up: HHS Nasal Spray
Date:	2019/03/07 14:10:50
Start Date:	2019/03/08 08:30:00
End Date:	2019/03/08 09:00:00
Priority:	Normal
Type:	Appointment
Location:	VACO 802 or VANTS 1-800-767-1750 A/C 22021
Attendees:	Stone, Richard A., MD; Llorente, Maria D.; Beck, Lucille B.; Emmendorfer, Thomas (PBM); Jensen, Jon M.; Valentino, Michael (VACO); Connell, Lawrence B.; Beck, Lucille B.

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Sent Date:	2019/03/07 14:10:50

AMERICAN OVERSIGHT

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Subject:	Follow Up: HHS Nasal Spray
Date:	2019/03/07 15:35:24
Start Date:	2019/03/08 08:30:00
End Date:	2019/03/08 09:00:00
Priority:	Normal
Type:	Appointment
Location:	VACO 802 or VANTS 1-800-767-1750 A/C 22021
Attendees:	Stone, Richard A., MD; Llorente, Maria D.; Beck, Lucille B.; Emmendorfer, Thomas (PBM); Jensen, Jon M.; Valentino, Michael (VACO); Connell, Lawrence B.; Beck, Lucille B.

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Start Date:	2019/03/08 08:30:00
End Date:	2019/03/08 09:00:00
Priority:	Normal
Type:	Schedule.Meeting.Request
Location:	VACO 802
Attendees:	Llorente, Maria D.; Beck, Lucille B.; Emmendorfer, Thomas (PBM); Jensen, Jon M.

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Sent Date:	2019/03/07 14:10:47
Delivered Date:	2019/03/07 14:10:50

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AMERICAN OVERSIGHT

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To:	Stone, Richard A., MD /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bd16619615d64adea22e45e63ff6462a-Stone, Rich (b)(6) @va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M (b)(6) @va.gov>; Beck, Lucille B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=845480228a8b43e7a5fef5716ded04c2-Beck, Lucil (b)(6) @va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>; Jensen, Jon M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddeb735ace76400db5c3f10603188a14-Jensen, Jon (b)(6) @va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>; Connell, Lawrence B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a3e7233376344045980ad214122389f4-Connell, La (b)(6) @va.gov>
Subject:	Follow Up: HHS Nasal Spray
Date:	2019/03/07 15:35:24
Start Date:	2019/03/08 08:30:00
End Date:	2019/03/08 09:00:00
Priority:	Normal
Type:	Appointment
Location:	VACO 802 or VANTS 1-800-767-1750 A/C 22021
Attendees:	Llorente, Maria D.; Beck, Lucille B.; Emmendorfer, Thomas (PBM); Jensen, Jon M.; Valentino, Michael (VACO); Connell, Lawrence B.

Sender:	Stone, Richard A., MD /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BD16619615D64ADEA22E45E63FF6462A-STONE, RICH (b)(6) @va.gov>
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Subject:	Follow Up: HHS Nasal Spray
Date:	2019/03/07 14:10:49
Start Date:	2019/03/08 08:30:00
End Date:	2019/03/08 09:00:00
Priority:	Normal
Type:	Appointment
Location:	VACO 802
Attendees:	Llorente, Maria D.; Beck, Lucille B.; Emmendorfer, Thomas (PBM); Jensen, Jon M.

Follow up from Thursday's morning meeting.

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SentVia:	Howard, Kristi /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B8D0AFC371994181883D8861127791C3-HOWARD, KRI (b)(6) @va.gov>
To:	Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M (b)(6) @va.gov>; Beck, Lucille B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=845480228a8b43e7a5fef5716ded04c2-Beck, Lucil (b)(6) @va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b)(6) @va.gov>; Jensen, Jon M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddeb735ace76400db5c3f10603188a14-Jensen, Jon (b)(6) @va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>; Connell, Lawrence B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a3e7233376344045980ad214122389f4-Connell, La (b)(6) @va.gov>
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End Date:	2019/03/08 09:00:00
Priority:	Normal
Type:	Schedule.Meeting.Request
Location:	VACO 802 or VANTS 1-800-767-1750 A/C 22021
Attendees:	Llorente, Maria D.; Beck, Lucille B.; Emmendorfer, Thomas (PBM); Jensen, Jon M.; Valentino, Michael (VACO); Connell, Lawrence B.

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Sent Date:	2019/03/07 15:35:21

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Delivered Date:	2019/03/07 15:35:23

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From:	Stone, Richard A., MD /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BD16619615D64ADEA22E45E63FF6462A-STONE, RICH (b)(6) @va.gov>
To:	Stone, Richard A., MD /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bd16619615d64adea22e45e63ff6462a-Stone, Rich (b)(6) @va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M (b)(6) @va.gov>; Beck, Lucille B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=845480228a8b43e7a5fef5716ded04c2-Beck, Lucil (b)(6) @va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>; Jensen, Jon M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddeb735ace76400db5c3f10603188a14-Jensen, Jon (b)(6) @va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>; Connell, Lawrence B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a3e7233376344045980ad214122389f4-Connell, La (b)(6) @va.gov>
Subject:	Follow Up: HHS Nasal Spray
Date:	2019/03/07 14:10:51
Start Date:	2019/03/08 08:30:00
End Date:	2019/03/08 09:00:00
Priority:	Normal
Type:	Appointment
Location:	VACO 802 or VANTS 1-800-767-1750 A/C 22021
Attendees:	Llorente, Maria D.; Beck, Lucille B.; Emmendorfer, Thomas (PBM); Jensen, Jon M.; Valentino, Michael (VACO); Connell, Lawrence B.

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Location:	VACO 802 or VANTS 1-800-767-1750 A/C 22021
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SentVia:	Williams, Jessica D. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=007F83F1989E48888DAB9C5D712C99B4-WILLIAMS, J (b)(6) @va.gov>
To:	Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M (b)(6) @va.gov>; Beck, Lucille B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=845480228a8b43e7a5fef5716ded04c2-Beck, Lucil (b)(6) @va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>; Jensen, Jon M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddeb735ace76400db5c3f10603188a14-Jensen, Jon (b)(6) @va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>; Connell, Lawrence B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a3e7233376344045980ad214122389f4-Connell, La (b)(6) @va.gov>
Subject:	Follow Up: HHS Nasal Spray
Date:	2019/03/08 07:33:12
Start Date:	2019/03/08 08:30:00
End Date:	2019/03/08 09:00:00
Priority:	Normal
Type:	Schedule.Meeting.Request
Location:	VACO 802 or VANTS 1-800-767-1750 A/C 22021
Attendees:	Llorente, Maria D.; Beck, Lucille B.; Emmendorfer, Thomas (PBM); Jensen, Jon M.; Valentino, Michael (VACO); Connell, Lawrence B.

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Sent Date:	2019/03/08 07:33:08
Delivered Date:	2019/03/08 07:33:12

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Sent Date:	2019/03/07 14:10:51

AMERICAN OVERSIGHT

From:	Stone, Richard A., MD /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BD16619615D64ADEA22E45E63FF6462A-STONE, RICH (b)(6) @va.gov>
SentVia:	Williams, Jessica D. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=007F83F1989E48888DAB9C5D712C99B4-WILLIAMS, J (b)(6) @va.gov>
To:	Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M (b)(6) @va.gov>; Beck, Lucille B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=845480228a8b43e7a5fef5716ded04c2-Beck, Lucil (b)(6) @va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>; Jensen, Jon M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddeb735ace76400db5c3f10603188a14-Jensen, Jon (b)(6) @va.gov>
Subject:	Follow Up: HHS Nasal Spray
Date:	2019/03/07 14:10:51
Start Date:	2019/03/08 08:30:00
End Date:	2019/03/08 09:00:00
Priority:	Normal
Type:	Schedule.Meeting.Request
Location:	VACO 802
Attendees:	Llorente, Maria D.; Beck, Lucille B.; Emmendorfer, Thomas (PBM); Jensen, Jon M.

Sender:	Stone, Richard A., MD /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BD16619615D64ADEA22E45E63FF6462A-STONE, RICH (b)(6) @va.gov>; Williams, Jessica D. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=007F83F1989E48888DAB9C5D712C99B4-WILLIAMS, J (b)(6) @va.gov>
Recipient:	Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M (b)(6) @va.gov>; Beck, Lucille B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=845480228a8b43e7a5fef5716ded04c2-Beck, Lucil (b)(6) @va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>; Jensen, Jon M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddeb735ace76400db5c3f10603188a14-Jensen, Jon (b)(6) @va.gov>
Sent Date:	2019/03/07 14:10:47
Delivered Date:	2019/03/07 14:10:51

AMERICAN OVERSIGHT

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To:	Stone, Richard A., MD /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bd16619615d64adea22e45e63ff6462a-Stone, Rich (b)(6) @va.gov>; Llorente, Maria D. (b)(6) @va.gov>; Beck, Lucille B. (b)(6) @va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>; Jensen, Jon M. (b)(6) @va.gov>
Subject:	Follow Up: HHS Nasal Spray
Date:	2019/03/07 14:10:51
Start Date:	2019/03/08 08:30:00
End Date:	2019/03/08 09:00:00
Priority:	Normal
Type:	Appointment
Location:	VACO 802
Attendees:	Llorente, Maria D.; Beck, Lucille B.; Emmendorfer, Thomas (PBM); Jensen, Jon M.

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Sent Date:	2019/03/07 14:10:51

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From:	Stone, Richard A., MD </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BD16619615D64ADEA22E45E63FF6462A-STONE, RICH>
SentVia:	Williams, Jessica D. </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=007F83F1989E48888DAB9C5D712C99B4-WILLIAMS, J>
To:	Stone, Richard A., MD /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bd16619615d64adea22e45e63ff6462a-Stone, Rich (b)(6) @va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M (b)(6) @va.gov>; Beck, Lucille B. /o=VA/ou=VISN 05/cn=RECIPIENTS/cn=VHAWASBECKLB2 <(b) (6) @va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>; Jensen, Jon M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddeb735ace76400db5c3f10603188a14-Jensen, Jon (b)(6) @va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>; Connell, Lawrence B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a3e7233376344045980ad214122389f4-Connell, La (b)(6) @va.gov>
CC:	Beck, Lucille B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=845480228a8b43e7a5fef5716ded04c2-Beck, Lucil (b) (6) va.gov>
Subject:	Follow Up: HHS Nasal Spray
Date:	2019/03/07 14:10:45
Start Date:	2019/03/08 08:30:00
End Date:	2019/03/08 09:00:00
Priority:	Normal
Type:	Appointment
Location:	VACO 802 or VANTS 1-800-767-1750 A/C 22021
Attendees:	Stone, Richard A., MD; Llorente, Maria D.; Beck, Lucille B.; Emmendorfer, Thomas (PBM); Jensen, Jon M.; Valentino, Michael (VACO); Connell, Lawrence B.; Beck, Lucille B.

Sender:	Stone, Richard A., MD </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BD16619615D64ADEA22E45E63FF6462A-STONE, RICH>; Williams, Jessica D. </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=007F83F1989E48888DAB9C5D712C99B4-WILLIAMS, J>
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AMERICAN OVERSIGHT

	(b)(6) @va.gov>; Beck, Lucille B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=845480228a8b43e7a5fef5716ded04c2-Beck, Lucil (b)(6) @va.gov>
Sent Date:	2019/03/07 14:10:45

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Subject:	Follow Up: HHS Nasal Spray
Date:	2019/03/07 14:10:45
Start Date:	2019/03/08 08:30:00
End Date:	2019/03/08 09:00:00
Priority:	Normal
Type:	Appointment
Location:	VACO 802 or VANTS 1-800-767-1750 A/C 22021

Sender:	Stone, Richard A., MD </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BD16619615D64ADEA22E45E63FF6462A-STONE, RICH>; Williams, Jessica D. </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=007F83F1989E48888DAB9C5D712C99B4-WILLIAMS, J>
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Priority:	Normal
Type:	Appointment
Location:	VACO 802 or VANTS 1-800-767-1750 A/C 22021
Attendees:	Llorente, Maria D.; Beck, Lucille B.; Emmendorfer, Thomas (PBM); Jensen, Jon M.; Valentino, Michael (VACO); Connell, Lawrence B.

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Sent Date:	2019/03/07 14:10:50

AMERICAN OVERSIGHT

To:	Capehart, Bruce P. DURVAMC /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6866eff4e9df4a48846d056a02044c38-Capehart, B (b)(6) @va.gov>; Schreiber, Matthew A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=db4d0324bf0945f183f33816c7fd1db0-Schreiber, (b)(6) @va.gov>
Subject:	F2F meeting follow up
Date:	2019/06/21 10:01:52
Priority:	Normal
Type:	Note

Hi Bruce and Matt,

Just wanted to say Thank-You for all your efforts to get the esketamine monograph, CFU, and national protocol guidance approved.

Matthew A. Fuller, BS, Pharm.D., FASHP, BCPP
National PBM Clinical Pharmacy Program Manager – Psychiatry and Geriatrics
VHA Pharmacy Benefits Management Services (10P4P)
1st Avenue – 1 Block North of Cermak (Bldg 37)
Hines, IL 60141
(b)(6)

Recipient:	Capehart, Bruce P. DURVAMC /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6866eff4e9df4a48846d056a02044c38-Capehart, B (b)(6) @va.gov>; Schreiber, Matthew A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=db4d0324bf0945f183f33816c7fd1db0-Schreiber, (b)(6) @va.gov>
Sent Date:	2019/06/21 10:01:55
Delivered Date:	2019/06/21 10:01:52
Message Flags:	Unread Unsent

AMERICAN OVERSIGHT

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AMERICAN OVERSIGHT

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AMERICAN OVERSIGHT

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AMERICAN OVERSIGHT

From:	Emmendorfer, Thomas (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC96BB44E7AE2C94C43B55D094-EMMENDORFER (b)(6) @va.gov>
To:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>
Subject:	External communication
Date:	2019/03/11 10:02:41
Priority:	Normal
Type:	Note

https://www.spravatorems.com

SPRAVATO™ is a non-competitive N-methyl D-aspartate (NMDA) receptor antagonist indicated, in conjuction with an oral antidepressant, for the treatment for treatment-resistant depression (TRD) in adults.

Sender:	Emmendorfer, Thomas (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC96BB44E7AE2C94C43B55D094-EMMENDORFER (b)(6) @va.gov>
Recipient:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>
Sent Date:	2019/03/11 10:02:41

AMERICAN OVERSIGHT

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Esketamine Site Visits

Fall 2019

- Requesting OMHSP funding for 2 people to attend each site visit
- Schedule below serves as an example of the amount of time spent at sites. Final dates and details of which site is visited on which date TBD following coordination with local sites.
- PBM anticipates sending a representative along with us to these site visits, and will fund travel for their representative.
- Total estimated budget expenses: **$12,622**

TRIP 1: North Carolina

Tentative Dates: Sept 23 – 25 (travel days on 23rd and 26th)
Sites visited: 1) Durham VAMC, 2) Salisbury VAMC, 3) Actify Neurotherapy (non-VA private practice)
Participants: Ilse Wiechers, Hugh Myrick

Sep 23: Travel Day
AM arrival
Afternoon visit to Actify Neurotherapy site in Raleigh

Sep 24:
Visit to Durham VAMC

Sep 25
Morning drive to Salisbury VAMC
Visit Salisbury VAMC

Sep 26: Travel day

Costs

- Airfare x 1 = $500
- Ground transport = $150
- Mileage cost x 1 (RT from Charleston, SC 610 miles + Durham to Salisbury and back 206 miles x $.58) = $729
- Per diem ME&I ($61/45.75) x 2 for 4 days = $427
- Hotel in Durham ($107) x 2 x 3 nights = $642

TOTAL = $2448

AMERICAN OVERSIGHT

TRIP 2: Connecticut
Tentative Dates: Oct 2 – 5 (travel days 2nd and 5th)
Sites visited: VA Connecticut, Yale (academic affiliate, TRD clinic)
Participants: Ilse Wiechers, TBD

Oct 2: Travel Day
Arrive BDL or HVN

Oct 3
Visit VA Connecticut

Oct 4
Visit Yale

Oct 5: Travel Day

Costs

- Airfare x 2 = $1000
- Ground transport = $300
- Per diem ME&I ($61/45.75) x 2 for 4 days = $427
- Hotel in New Haven ($107) x 2 x 3 nights = $642

TOTAL = $2369

TRIP 3: NYC
Tentative dates: Oct 6-8 (travel days 6th and 8th)
Site visited: NY Harbor
Participants: Ilse Wiechers, TBD

Oct 6: Travel Day

Oct 7:
Visit NY Harbor VAMC

Oct 8: Travel Day

Costs

- Airfare x 2 = $1000
- Ground transport = $300
- Per diem ME&I ($76/57) x 2 for 3 days = $380
- Hotel in New York ($288) x 2 nights x 2 = $1152

TOTAL: $2832

AMERICAN OVERSIGHT

TRIP 4: Boston
Tentative dates: TBD
Sites visited: VA Boston, MGH (academic TRD clinic)
Participants: Ilse Wiechers, TBD

Day 1: Travel Day

Day 2:
Visit VA Boston

Day 3:
Visit MGH

Day 4: Travel Day

Costs

- Airfare x 2 = $1000
- Ground transport = $300
- Per diem ME&I ($71/53.25) x 2 for 4 days = $497
- Hotel in Boston ($273) x 3 nights x 2 = $1638

TOTAL: $3436

TRIP 5: Cleveland
Tentative dates: July 31 – Aug 2 (travel days 31st and 2nd)
Sites visited: VA Cleveland
Participants: Ilse Wiechers, TBD

July 31: Travel Day

July 1
Visit VA Cleveland

July 2: Travel Day

Estimated Costs

- Airfare x 1 = $500
- Ground transport = $150
- Mileage cost x 1 (RT from Norwalk, OH 57 miles x $.58) = $33.06
- Per diem ME&I ($66/49.50) x 2 for 3 days = $330
- Hotel in Cleveland ($131) x2 x 2 nights = $524

TOTAL: $1537

AMERICAN OVERSIGHT

To:	Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen (b)(6) @va.gov>
Subject:	esketamine question
Date:	2019/03/20 16:12:21
Priority:	Normal
Type:	Note

Jenn,

As you know, the short term esketamine trial resulting in its approval treated pt who had not adequately responded to at least two different antidepressant of adequate dose and duration. Would it be helpful

Matthew A. Fuller, BS, Pharm.D., FASHP, BCPP
National PBM Clinical Pharmacy Program Manager – Psychiatry and Geriatrics
VHA Pharmacy Benefits Management Services (10P4P)
1st Avenue – 1 Block North of Cermak (Bldg 37)
Hines, IL 60141
(b)(6)

Recipient:	Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen (b)(6) @va.gov>
Sent Date:	2019/03/20 16:12:26
Delivered Date:	2019/03/20 16:12:21
Message Flags:	Unread Unsent

AMERICAN OVERSIGHT

VA-19-1109-B-002253

Spravato® (Esketamine) Nasal Spray
Frequently Asked Questions
March 14, 2019
VA Pharmacy Benefits Management Services and Office of Mental Health and Suicide Prevention

1. Spravato® (eskatamine) nasal spray was approved by the Food and Drug Administration (FDA) on March 5, 2019, to be used in conjunction with an oral antidepressant for the treatment of depression in adults who have tried other antidepressants medicines but have not benefited from them. Is Spravato® commercially available for healthcare systems to purchase?

   ANSWER: No. Spravato® is not commercially available for healthcare systems to purchase at this time. The manufacturer estimates Spravato® will be available for healthcare systems to purchase in mid to late March 2019.

2. Since Spravato® is a nasal spray, will VA providers be able to prescribe outpatient prescriptions for VA pharmacies to dispense to the Veterans?

   ANSWER: No. Because of the risk of serious adverse outcomes resulting from possible sedation and/or dissociation caused by Spravato® administration, and the potential for abuse and misuse of the drug, it is only available through a restricted distribution system, under an FDA approved Risk Evaluation and Mitigation Strategy (REMS).

3. What are the requirements for the Spravato® FDA approved REMS?

   ANSWER:
   - Spravato® is available only through a limited distribution program that is part of the Spravato® REMS.
   - All healthcare settings and pharmacies are required to enroll in the Spravato® REMS via a designated authorized representative before they can purchase product from a distributor, dispense, or supervise administration of Spravato®.
   - All patients must be enrolled in the Spravato® REMS before they can receive Spravato®

   The Spravato® REMS Fact Sheet developed by the manufacturer is available at:
   https://www.spravatorems.com/pdfs/SPRAVATO(TM)_REMS_Fact_Sheet.pdf

4. Will Spravato® be available for VA providers to prescribe in accordance with the FDA approved REMS program when it is commercially available?

   ANSWER: Yes.

5. Has Spravato® been added to VA's National Formulary?

   ANSWER: The Spravato® formulary review will be on the May 2019 National Formulary Committee agenda. Prior to the National Formulary Committee review, VA providers will be able to prescribe Spravato® based on their clinical assessment and the individual medical needs of the Veteran.

AMERICAN OVERSIGHT

6. Is Spravato® a controlled substance?

   ANSWER: Yes. It is a Schedule III Controlled Substance.

7. Does my VA medical facility need to take any actions to enroll into the FDA approved REMS program at this time?

   ANSWER: No. Not at this time. VA Pharmacy Benefits Management (PBM) Services is working closely with the manufacturer of Spravato®. Once the manufacturer operationalizes the REMS requirements for Spravato®, PBM will collaborate with the Office of Mental Health and Suicide Prevention (OMHSP) to disseminate the information to VA medical facilities. PBM and OMHSP will provide a status update by March 18, 2019.

8. After Spravato® is administered to the patient in a medically supervised healthcare setting, what does the patient need to be monitored for?

   ANSWER: At a minimum, patients will need to be monitored with the elements of the Spravato® REMS Patient Monitoring form that is available at www.SPRAVATOrems.com. Spravato® chemical name is esketamine which is an S (+) enantiomer of ketamine and provides similar therapeutic effects to ketamine. VA PBM developed a national protocol for the use of intravenous ketamine in treatment resistant depression and severe suicidal ideation which was published in December 2017. (Ketamine Infusion for Treatment Resistant Depression). The national protocol for intravenous ketamine is consistent with the VA PBM Guidance on Off Label Prescribing of drugs that was published in August 2013 and can be accessed at: (Guidance on Off Label Prescribing).

9. What actions can VA medical facilities take now to prepare to become a certified healthcare setting?

   ANSWER: OMHSP and PBM recommend VA medical facilities review the Spravato® REMS forms available at www.SPRAVATOrems.com and the VA PBM national protocol for the use of intravenous ketamine in treatment resistant depression and severe suicidal ideation Ketamine Infusion for Treatment Resistant Depression) to ensure each VA medical facility has the necessary space and equipment to monitor after the Spravato® dose is administrated to the Veterans.

10. Do providers need to have special privileging to prescribe Spravato®?

    ANSWER: No

11. Does Spravato® require a signed informed consent?

    ANSWER: Yes. An update will be provided by OMHSP by March 18, 2019.

AMERICAN OVERSIGHT

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   - All patients must be enrolled in the Spravato® REMS before they can receive Spravato®

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   ANSWER: Yes.

5. Has Spravato® be added to VA's National Formulary?

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AMERICAN OVERSIGHT

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10. Do providers need to have special privileging to prescribe Spravato®?

    ANSWER: No

11. Does Spravato® require a signed informed consent?

    ANSWER: Yes. An update will be provided by OMHSP by March 18, 2019.

AMERICAN OVERSIGHT

Esketamine Nasal SprayNational Protocol Guidance

Frequently Asked Questions

March 14, 2019

VA Pharmacy Benefits Management Services and Office of Mental Health and Suicide Prevention

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   ANSWER:

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   - All patients must be enrolled in the Spravato® REMS before they can receive Spravato®

   The Spravato® REMS Fact Sheet developed by the manufacturer is available at: https://www.spravatorems.com/pdfs/SPRAVATO(TM)_REMS_Fact_Sheet.pdf

4. Will Spravato® be available for VA providers to prescribe in accordance with the FDA approved REMS program when it is commercially available?

   ANSWER: Yes.

Updated version may be found at PBM INTRAnet https://vaww.cmopnational.va.gov/cmop/PBM/default.aspx

AMERICAN OVERSIGHT

003260

VA-19-1109-B-002258

5. Has Spravato® be added to VA's National Formulary?

   ANSWER: The Spravato® formulary review will be on the May 2019 National Formulary Committee agenda. Prior to the National Formulary Committee review, VA providers will be able to prescribe Spravato® based on their clinical assessment and the individual medical needs of the Veteran.

6. Is Spravato® a controlled substance?

   ANSWER: Yes. It is a Schedule III Controlled Substance.

7. Does my VA medical facility need to take any actions to enroll into the FDA approved REMS program at this time?

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VA-19-1109-B-002259

Infusion for Treatment Resistant Depression) to ensure each VA medical facility has the necessary space and equipment to monitor after the Spravato® dose is administrated to the Veterans.

10. Do providers need to have special privileging to prescribe Spravato®?

    ANSWER: No

11. Does Spravato® require a signed informed consent?

    ANSWER: Yes. An update will be provided by OMHSP by March 18, 2019.

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VA-19-1109-B-002260

Esketamine Nasal SprayNational Protocol Guidance

Frequently Asked Questions

March 14, 2019

VA Pharmacy Benefits Management Services and Office of Mental Health and Suicide Prevention

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4. Will Spravato® be available for VA providers to prescribe in accordance with the FDA approved REMS program when it is commercially available?

   ANSWER: Yes.

Updated version may be found at PBM INTRAnet https://vaww.pbmnat.va.gov/sites/PBM/Pages/Home.aspx
003263
VA-19-1109-B-002261
AMERICAN OVERSIGHT

5. Has Spravato® be added to VA's National Formulary?

   ANSWER: The Spravato® formulary review will be on the May 2019 National Formulary Committee agenda. Prior to the National Formulary Committee review, VA providers will be able to prescribe Spravato® based on their clinical assessment and the individual medical needs of the Veteran.

6. Is Spravato® a controlled substance?

   ANSWER: Yes. It is a Schedule III Controlled Substance.

7. Does my VA medical facility need to take any actions to enroll into the FDA approved REMS program at this time?

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Infusion for Treatment Resistant Depression) to ensure each VA medical facility has the necessary space and equipment to monitor after the Spravato® dose is administrated to the Veterans.

10. Do providers need to have special privileging to prescribe Spravato®?

    ANSWER: No

11. Does Spravato® require a signed informed consent?

    ANSWER: Yes. An update will be provided by OMHSP by March 18, 2019.

AMERICAN OVERSIGHT

VA-19-1109-B-002263

Department of Veterans Affairs
Veterans Health Administration
Pharmacy Benefits Management Service
1st Avenue-1 Block North of Cermak Road
Building 37 Room 139 | Hines, IL 60141

1. Spravato® (eskatamine) nasal spray was approved by the Food and Drug Administration (FDA) on March 5, 2019, to be used in conjunction with an oral antidepressant for the treatment of depression in adults who have tried other antidepressants medicines but have not benefited from them. Is Spravato® commercially available for healthcare systems to purchase?

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AMERICAN OVERSIGHT

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AMERICAN OVERSIGHT

This spreadsheet will calculate estimated pharmaceutical costs for esketamine use.
Edit only the gray cells. All other cells will automatically recalculate.
The TRD percentage is from ICER draft report on esketamine, p 81.
This TRD estimate is for all MDD, not recurrent MDD.
ICD-10 diagnoses F32.xx (MDD, Single Episode) and F33.xx (MDD, Recurrent)
Updates:
3/29/19

- added Read Me tab
- changed initial dose in 84mg to 56mg
- added option for number of patients per year
- added VISN-level data on F33.xx diagnoses

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Esketamine cost projection
pharmaceutical cost only

	weight	row sum	Month 1	2	3	4	5	6	7	8	9	10	11	12
Initial Dosing														
56mg	*0.33*	*$ 7,080*	$ 4,720	$ 2,360										
84mg	*0.67*	*$ 10,325*	$ 6,785	$ 3,540										
Maintenance Dosing														
56mg weekly	*0.142*	*$ 23,600*			$ 2,360	$ 2,360	$ 2,360	$ 2,360	$ 2,360	$ 2,360	$ 2,360	$ 2,360	$ 2,360	$ 2,360
84 mg weekly	*0.287*	*$ 35,400*			$ 3,540	$ 3,540	$ 3,540	$ 3,540	$ 3,540	$ 3,540	$ 3,540	$ 3,540	$ 3,540	$ 3,540
56 mg biweekly	*0.188*	*$ 11,800*			$ 1,180	$ 1,180	$ 1,180	$ 1,180	$ 1,180	$ 1,180	$ 1,180	$ 1,180	$ 1,180	$ 1,180
84mg biweekly	*0.382*	*$ 17,700*			$ 1,770	$ 1,770	$ 1,770	$ 1,770	$ 1,770	$ 1,770	$ 1,770	$ 1,770	$ 1,770	$ 1,770

Annual cost range:	Maintenance Dose Frequency			
	Weekly		Biweekly	
	56mg	84mg	56mg	84mg
Initial 56mg	$ 30,680	$ 42,480	$ 18,880	$ 24,780
Initial 84mg	$ 33,925	$ 45,725	$ 22,125	$ 28,025

Weighted Annual Cost, per veteran:	$ 31,745	*Dose weighting from clinical trial data as reported in ICER analysis*
Weighted Annual Cost, all VHA	$ 326,885,585	
Cost per 28mg dose	$ 295	*(current AWP)*
Veteran acceptance rate	15%	*enter percentage of veterans with Treatment Resistant Depression who start esketamine*
Mean months of esketamine	12.0	*enter average number of months a veteran takes esketamine*
Include age 65+?	no	*yes/no*
Single Episode and Recurrent MDD?	no	*yes/no; no will limit the patient population to only Recurrent Major Depression*
Percent MDD defined as TRD	13.6%	*enter percentage of Major Depression defined as "Treatment-Resistant Depression"*
Veterans with recurrent MDD	68,648	*all VHA, FY18 from VSSC Outpatient Cube with ICD-10 F33.XX*

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Report 1

Filter Selection: (VA Outpatient)

Unique Patients by VISN (Facility District) on columns; and Date (DXDate), ICD (Diagnosis) and Age (Age) on rows sub-setted by VA Outpatient

				1V01	1V02	1V04	1V05	1V06	2V07	2V08	2V09	3V10	3V12	3V15	4V16	4V17	4V19	5V20	5V21	5V22	3V23
				1	2	4	5	6	7	8	9	10	12	15	16	17	19	20	21	22	23
FY18	(ICD10)F32	Unique Patients	<25	179	266	195	110	376	392	446	178	400	411	128	268	463	225	228	224	549	153
			25-34	1,954	2,415	2,552	1,416	3,392	4,557	4,775	2,106	4,763	2,357	1,633	3,203	5,328	2,689	2,714	2,802	5,058	1,947
			35-44	1,969	2,422	2,921	1,839	4,071	5,437	5,650	2,461	4,495	2,397	1,870	4,179	6,460	3,085	2,717	2,552	4,918	2,216
			45-54	2,209	2,546	3,547	2,347	5,291	7,598	6,912	3,552	6,304	2,872	2,324	5,327	6,248	3,048	2,731	2,652	4,653	2,619
			55-64	3,252	4,013	5,179	2,786	5,965	8,385	9,749	4,134	7,908	3,832	2,975	6,168	6,608	3,510	3,460	4,036	5,791	3,207
			65-74	4,531	4,485	6,093	3,127	5,486	6,851	10,045	5,038	10,126	4,940	4,187	6,925	6,529	4,519	4,223	4,765	6,925	4,798
			75-84	1,668	1,489	1,639	891	1,506	1,543	3,633	1,220	2,586	1,567	1,201	1,808	1,807	1,218	1,198	1,496	2,001	1,758
			85+	1,164	1,192	947	537	658	663	2,056	634	1,441	1,041	739	820	701	522	485	693	959	1,150
			Unknown									1									
	(ICD10)F33	Unique Patients	<25	177	302	197	158	516	499	521	241	452	326	227	403	583	347	304	252	729	222
			25-34	3,057	3,180	3,094	2,412	6,315	7,159	6,282	3,935	6,439	3,559	3,231	6,680	8,592	5,466	4,490	4,030	8,928	3,852
			35-44	3,369	3,584	3,697	3,401	7,717	9,570	8,355	4,642	6,686	3,959	3,934	8,687	10,876	6,606	5,204	4,402	9,560	4,529
			45-54	3,720	3,924	4,696	4,321	9,950	13,202	10,484	6,673	8,887	4,640	4,623	10,763	10,659	6,596	5,623	4,619	9,304	5,204
			55-64	6,084	6,225	7,130	5,437	12,286	15,727	16,237	8,440	12,554	6,761	6,614	12,938	11,538	8,107	7,714	7,052	12,862	7,238
			65-74	8,325	6,967	8,677	6,615	11,622	14,469	17,879	10,489	16,124	9,179	8,601	16,137	11,979	10,283	9,917	8,742	16,428	10,651
			75-84	2,100	1,733	1,857	1,321	2,111	2,463	4,675	1,962	2,897	1,928	1,727	2,940	2,410	2,247	2,243	1,996	3,703	2,515
			85+	989	929	769	441	635	654	2,059	631	1,061	789	650	905	681	766	665	705	1,272	1,074
			Unknown		1																
			All VHA Total																		
Total, all VHA, F32,xx, all ages				436473	16926	18828	23073	13053	26745	35426	43266	19323	38023	19417	15057	28698	34144	18816	17756	19220	30854	17848
Total, all VHA, F32.xx, excluding 65+				286249	9563	11662	14394	8498	19095	26369	27532	12431	23870	11869	8930	19145	25107	12557	11850	12266	20969	10142
Total, all VHA, F33.xx, all ages				766354	27821	26844	30117	24106	51152	63743	66492	37013	55100	31141	29607	59453	57318	40418	36160	31798	62786	35285
Total, all VHA, F33.xx, excluding 65+				504767	16407	17215	18814	15729	36784	46157	41879	23931	35018	19245	18629	39471	42248	27122	23335	20355	41383	21045

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From:	Wiechers, Ilse /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0C7B1428D9E4233A641F125C5B6FC4F-WIECHERS, I (b)(6) @va.gov>
To:	Myrick, Donald L. (Hugh) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ffec881db4394259b082b76436cdc904-Myrick, Don (b)(6) @va.gov>; Shiroma, Paulo R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cae9fb698bb245669c11a3564784e24e-Shiroma, Pa (b)(6) @va.gov>; McGuire, Marsden H. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29e9d648c29f4885828c10446fdd7379-McGuire, Ma (b)(6) @va.gov>; Drexler, Karen MD (Atlanta) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c456a9bf391415bb4bdb9b6f88bdf45-Drexler, Ka (b)(6) @va.gov>; Pomerantz, Andrew /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29a9288df9a34e84bddfd00cde79f11b-Pomerantz, (b)(6) @va.gov>; Katz, Ira R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=65f4e28aa7574641932c29fed7c0b4b8-Katz, Ira R (b)(6) @va.gov>; Yoon, Gihyun /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aec946e46a224f4ea66ce2078a8115d3-Yoon, Gihyu (b)(6) @va.gov>; Mathew, Sanjay (HOU) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=67422a5cc3904b40bff8fca2b9cd1b48-Mathew, San (b)(6) @va.gov>; Mohamed, Somaia /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=37831d1786914522b90bb85b2a8e1441-Mohamed, So (b)(6) @va.gov>; Ranganathan, Mohini /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a929509685bd4ad2895c66775c05d7b5-Ranganathan (b)(6) @va.gov>; Krystal, John /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3d5500f300d74e0dba7f8b30a5b42f02-Krystal, Jo (b)(6) @va.gov>; Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat (b)(6) @va.gov>; Cunningham, Fran /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=613f0d8e535d46af95fed310f100dcbc-Cunningham, (b)(6) @va.gov>; Czekanski, Elizabeth R /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aee7f346873e4a84a863e6c1d28bac48-Czekanski, (b)(6) @va.gov>; Wells, Daina L. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2256099a3577421182c5516b56f40815-Wells, Dain (b)(6) @va.gov>; Schafer, David W. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=973c61b80ecf454db7d41d84e7c0e5d4-Schafer, Da (b)(6) @va.gov>; Buyck, David W SAMVAMC /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=843f993026ff420d954994c4fd003f8b-Buyck, Davi (b)(6) @va.gov>; Gibson, Carri-Ann M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c2724a4ca7d14b64b204647e837eaa96-Gibson, Car <Carri-(b)(6) @va.gov>; Burgard, Jesse, VHAV10 /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec2d7ce69d5948b6a01e6f285def5e99-Burgard, Je (b)(6) @va.gov>; Landreth, Edward S. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=958d788ebb18486399bf7a8a19fde302-Landreth, E (b)(6) @va.gov>; Kuo, Irving /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4cf261f46b1a4dad979c0574a6ba90c6-Kuo, Irving (b)(6) @va.gov>;

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Indest, David W (Portland) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=88f2b44132574f0cb18c81f22e510497-Indest, Dav
(b)(6) @va.gov>;
Drexler, Michael /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e10af3d4ce04d558cd5db0d376086f1-Drexler, Mi
(b)(6) @va.gov>;
Kilgore, Heath M /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90dc4cf50df2413bbc05adc92feea138-Kilgore, He
(b)(6) @va.gov>;
Bradley, John /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ca871d111a945a5a95a24e049aa5b79-Bradley, Jo
(b)(6) @va.gov>;
Petrakis, Ismene /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d11f785ba09d4495bf181c8665cc7e72-Petrakis, I
(b)(6) @va.gov>;
Leinbach, Jonathan E DURVAMC /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e9f36c898fc246d4bce7481a6432bd7a-Leinbach, J
(b)(6) @va.gov>;
Cooper, Marc A. SBYVAMC /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=601f7783e51e4cd5b77fe484244bca91-Cooper, Mar
(b)(6) @va.gov>;
Shorter, George Wiley /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=130c7b26133844fdb48963618cef1a1e-Shorter, Ge
(b)(6) @va.gov>;
Hosanagar, Avinash /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd0a6edbab5545afad67a25bb681199e-Hosanagar,
(b)(6) @va.gov>;
Konicki, P. Eric (VHACLE) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f92e0dd164c74dda9e7b53c5a83818c5-Konicki, Er
(b)(6) @va.gov>;
Juergens, Timothy /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6b13c091863a4a6d87ad2e2768eb4587-Juergens, T
(b)(6) @va.gov>;
Marsh, Laura (HOU) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=25c6587b8e8b425badb999aa06fee879-Marsh, Laur
(b)(6) @va.gov>;
Markman, Jesse D /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4286eae3f7c645508e9ebd4a37eeaa77-Markman, Je
(b)(6) @va.gov>;
McQuaid, John R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a6c17ce5787e486c8bd8b962c5d794a0-McQuaid, Jo
(b)(6) @va.gov>;
Torres-Sena, Lorraine M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8008d1cadb56431ba2f3a5aefd07852c-Torres-Sena
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Guze, Barry H. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6e1141be97be49c09258f5d56766a5e1-Guze, Barry
(b)(6) @va.gov>;
Holsinger, Tracey DURVAMC /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5f5d2d5c18444d6b9bef3b91343f3cd-Holsinger,
(b)(6) @va.gov>;
Brown, Thomas W. SBYVAMC /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=519c14650eb547ff997b2cdcd4424ecb-Brown, Thom
(b)(6) @va.gov>;
Bruijnzeel, Dawn /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d1cf1b6b0aaa4c1096649a3e969f9665-Bruijnzeel,
(b)(6) @va.gov>;
Salow, Marci VHABHS /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab3a0697fe7b4a7bb929f984583ad13c-Salow, Marc
(b)(6) @va.gov>;
Narayana, Sampath (VISN1) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98f8f110ecf440c38d1ad1aaf873fd83-Narayana, S
(b)(6) @va.gov>;
Borysiuk, Lydia /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95be5aa72a36464c8b0e4b8953673bc0-Borysiuk, L
(b)(6) @va.gov>;

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	Coombs, Stephen J. VISN 6 /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a1e036602964fac81fedf5498358f68-Coombs, Ste (b)(6) @va.gov>; Holland, Jon Todd DURVAMC /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0c13758fc3724462aa5e74ecb0416a0f-Holland, J. (b)(6) @va.gov>; Norem, Brett SBYVAMC /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=46b8a61fc56c46ff88d1dc6d980979ad-Norem, Bret (b)(6) @va.gov>; Justice, Keri M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=49446622754a44329f9465e88a172124-Justice, Ke (b)(6) @va.gov>; Itebejac, Ivan S. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8ea7279e6e9043d394ce89972a6152d2-Itebejac, I (b)(6) @va.gov>; Ekola, Timothy A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc6d34dd314948a8829ce59e77ecedf7-Ekola, Timo (b)(6) @va.gov>; Neff, Melissa VHAV10 /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2531b80e4493471aa43935843c7efc6c-Neff, Melis (b)(6) @va.gov>; Heimann, Timothy M. (VHACLE) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=efc4c9f8f050498581072306ab590474-Heimann, Ti (b)(6) @va.gov>; Leslie, Donna M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5c658dca625d48eba1d7be8efb4caa5c-Leslie, Don (b)(6) @va.gov>; Wilcox, Andrew J. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7cfa7156ebef44e995b72c7d93ed7e09-Wilcox, And (b)(6) @va.gov>; McMaster-Baxter, Nicole L. (HOU) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4ca99c7a2e64733b5d63a37196ccae7-McMaster-Ba (b)(6) @va.gov>; Hawkins, Jason B. (V16) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f569492d23e4f728896042aeb741999-Hawkins, Ja (b)(6) @va.gov>; Chantelois, Eric P /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec3b9dc56d564260889b3406c7019ec6-Chantelois, (b)(6) @va.gov>; LaDue, Brenda (V20) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e1dd346fefa7472ca42c13026324d67d-LaDue, Bren (b)(6) @va.gov>; Dare, Donna C. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9da97c4829ac4b79b2eefe7ef4a7a844-Dare, Donna (b)(6) @va.gov>; Mambourg, Scott VHAREN /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1cc0e02a3f9c4b748574199266262b10-Mambourg, S (b)(6) @va.gov>; Evans, Winston F. (Frank) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afed6e1406174710a563ac0ebddf0acb-Evans, Wins (b)(6) @va.gov>; Foster, Julie /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0d279c8333b46908f96add8e5cad9e4-Foster, Jul (b)(6) @va.gov>
CC:	Mohamed, Somaia (b)(6) ; (b)(6)
Subject:	Esketamine Clinical Implementation Workgroup meeting
Date:	2019/06/19 16:38:38
Start Date:	2019/06/05 14:00:00
End Date:	2019/06/05 15:00:00
Priority:	Normal
Type:	Schedule.Meeting.Request

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Location:	Skype Meeting
Attendees:	Myrick, Donald L. (Hugh); Shiroma, Paulo R.; McGuire, Marsden H.; Drexler, Karen MD (Atlanta); Pomerantz, Andrew; Katz, Ira R.; Yoon, Gihyun; Mathew, Sanjay (HOU); Mohamed, Somaia; Ranganathan, Mohini; Krystal, John; Fuller, Matthew A. (PBM); Cunningham, Fran; Czekanski, Elizabeth R; Wells, Daina L.; Schafer, David W.; Buyck, David W SAMVAMC; Gibson, Carri-Ann M.; Burgard, Jesse, VHAV10; Landreth, Edward S.; Kuo, Irving; Indest, David W (Portland); Drexler, Michael; Kilgore, Heath M; Bradley, John; Petrakis, Ismene; Leinbach, Jonathan E DURVAMC; Cooper, Marc A. SBYVAMC; Shorter, George Wiley; Hosanagar, Avinash; Konicki, P. Eric (VHACLE); Juergens, Timothy; Marsh, Laura (HOU); Markman, Jesse D; McQuaid, John R.; Torres-Sena, Lorraine M.; Guze, Barry H.; Holsinger, Tracey DURVAMC; Brown, Thomas W. SBYVAMC; Bruijnzeel, Dawn; Salow, Marci VHABHS; Narayana, Sampath (VISN1); Borysiuk, Lydia; Coombs, Stephen J. VISN 6; Holland, Jon Todd DURVAMC; Norem, Brett SBYVAMC; Justice, Keri M.; Itebejac, Ivan S.; Ekola, Timothy A.; Neff, Melissa VHAV10; Heimann, Timothy M. (VHACLE); Leslie, Donna M.; Wilcox, Andrew J.; McMaster-Baxter, Nicole L. (HOU); Hawkins, Jason B. (V16); Chantelois, Eric P; LaDue, Brenda (V20); Dare, Donna C.; Mambourg, Scott VHAREN; Evans, Winston F. (Frank); Foster, Julie; Mohamed, Somaia; (b)(6)

Sender:	Wiechers, Ilse /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0C7B1428D9E4233A641F125C5B6FC4F-WIECHERS, I (b)(6) @va.gov>
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Coombs, Stephen J. VISN 6 /o=ExchangeLabs/ou=Exchange Administrative Group
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Holland, Jon Todd DURVAMC /o=ExchangeLabs/ou=Exchange Administrative Group
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Justice, Keri M. /o=ExchangeLabs/ou=Exchange Administrative Group
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Neff, Melissa VHAV10 /o=ExchangeLabs/ou=Exchange Administrative Group
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Heimann, Timothy M. (VHACLE) /o=ExchangeLabs/ou=Exchange Administrative Group
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Wilcox, Andrew J. /o=ExchangeLabs/ou=Exchange Administrative Group
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McMaster-Baxter, Nicole L. (HOU) /o=ExchangeLabs/ou=Exchange Administrative Group
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LaDue, Brenda (V20) /o=ExchangeLabs/ou=Exchange Administrative Group
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Mambourg, Scott VHAREN /o=ExchangeLabs/ou=Exchange Administrative Group

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CC:	Mohamed, Somaia (b)(6) (b)(6)
Subject:	Esketamine Clinical Implementation Workgroup meeting
Date:	2019/06/19 16:38:38
Start Date:	2019/06/05 14:00:00
End Date:	2019/06/05 15:00:00
Priority:	Normal
Type:	Schedule.Meeting.Request

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Location:	Skype Meeting
Attendees:	Myrick, Donald L. (Hugh); Shiroma, Paulo R.; McGuire, Marsden H.; Drexler, Karen MD (Atlanta); Pomerantz, Andrew; Katz, Ira R.; Yoon, Gihyun; Mathew, Sanjay (HOU); Mohamed, Somaia; Ranganathan, Mohini; Krystal, John; Fuller, Matthew A. (PBM); Cunningham, Fran; Czekanski, Elizabeth R; Wells, Daina L.; Schafer, David W.; Buyck, David W SAMVAMC; Gibson, Carri-Ann M.; Burgard, Jesse, VHAV10; Landreth, Edward S.; Kuo, Irving; Indest, David W (Portland); Drexler, Michael; Kilgore, Heath M; Bradley, John; Petrakis, Ismene; Leinbach, Jonathan E DURVAMC; Cooper, Marc A. SBYVAMC; Shorter, George Wiley; Hosanagar, Avinash; Konicki, P. Eric (VHACLE); Juergens, Timothy; Marsh, Laura (HOU); Markman, Jesse D; McQuaid, John R.; Torres-Sena, Lorraine M.; Guze, Barry H.; Holsinger, Tracey DURVAMC; Brown, Thomas W. SBYVAMC; Bruijnzeel, Dawn; Salow, Marci VHABHS; Narayana, Sampath (VISN1); Borysiuk, Lydia; Coombs, Stephen J. VISN 6; Holland, Jon Todd DURVAMC; Norem, Brett SBYVAMC; Justice, Keri M.; Itebejac, Ivan S.; Ekola, Timothy A.; Neff, Melissa VHAV10; Heimann, Timothy M. (VHACLE); Leslie, Donna M.; Wilcox, Andrew J.; McMaster-Baxter, Nicole L. (HOU); Hawkins, Jason B. (V16); Chantelois, Eric P; LaDue, Brenda (V20); Dare, Donna C.; Mambourg, Scott VHAREN; Evans, Winston F. (Frank); Foster, Julie; Mohamed, Somaia; (b)(6)

This invitation is for the monthly call of the Esketamine Clinical Implementation Workgroup. Initial participants will include the National Workgroup members and teams from the Round 1 Early Adopter sites. Ideally, Early Adopter sites will have representation on the call from Mental Health, Pharmacy, and Nursing. We encourage as many members of the front-line staff and providers engaged in esketamine treatment as well as facility leadership to participate in these calls. Participation by VISN MH and Pharmacy teams is also welcome.

Initial invites are being sent to MH and Pharmacy service line leads and POC at Early Adopter sites, as well as VISN CMHOs and VPEs for the associated VISNs. ***Please forward to additional staff and providers at your sites, as appropriate***.

The call will occur on the **first Wed @ 11 am PT / 2 pm ET**, tentatively through the end of calendar year 2019, with additional calls based on assessment of need and group discussion. ***Please use Skype*** to join for audio and for shared desktop functionality (link and call in # below).

Please contact Dr. Ilse Wiechers (b)(6) @va.gov) with any questions.

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A Word to the Wise About Intranasal Esketamine

Alan F. Schatzberg, M.D.

Rarely has there been so much anticipation for a new antidepressant as has been seen for intranasal esketamine, the putatively more effective enantiomer of ketamine. This reflects the exposure given to studies on the off-label intravenous use of racemic mixture ketamine for refractory depression and its ensuing availability via ketamine clinics and infusion centers. Intranasal esketamine represents a novel way of administering the agent and is the subject of the report in this issue by Popova et al. (1).

This pivotal phase 3 study demonstrated rapid separation (by 24–48 hours) for esketamine plus antidepressant compared with placebo plus antidepressant, with continued separation with repeated administration up to 28 days. Esketamine was administered twice weekly for 4 weeks. This trial was presented as part of the recent approval of esketamine by the U.S. Food and Drug Administration (FDA) for refractory depression. During that process, a number of worrisome findings were revealed that should give potential users some pause and call for a concise framework for assessing the risk-benefit balance for using this formulation of ketamine.

The phase 3 program included three pivotal trials, and in only the Popova et al. study was there a statistically significant separation from placebo on the primary endpoint. In the other two trials, mean differences in change scores were similar to those in this report but did not attain statistical significance. The effect size in the Popova et al. study was 0.30, that is, in the mild range. With the use of saline as a control for esketamine, the reader should have cause to wonder, with a small effect and a rather limited control comparison, whether efficacy has been truly demonstrated. The control condition produced little in the way of side effects similar to those of esketamine, although some individuals seemed to experience dissociation with placebo. Moreover, as demonstrated in Figure 1 in the article, the difference was seen early and was maintained throughout the trial, but there was no further gain in advantage beyond the initial separation.

The study design in this development program called for an antidepressant to be started at the same time as esketamine or placebo. Since the patients were treated with the combination of an active antidepressant plus either esketamine or placebo, the data make one wonder whether one really needs to continue esketamine beyond initial use. Why not use it only once or twice for 1 or 2 weeks rather than twice weekly for 4 weeks? This question needs to be considered in the context of what ketamine is—an anesthetic agent that has been abused in this country and elsewhere in various formulations. A recent report on a rodent study points out that continued use of ketamine maintains and extends its acute neuronal spine–producing effects to produce stronger interneuron communication, suggesting that some continued use is necessary to maintain biological effects (2). But how much and for how long in humans? The package insert for the drug in refractory depression currently recommends twice-weekly administration for 4 weeks, once weekly for 4 weeks, and then, beyond 8 weeks, once weekly or once every 2 weeks, aiming for the least frequent dosing to maintain response or remission.

Our group has reported in this journal (3) that the acute antidepressant effects of ketamine are blocked when the patient is pretreated with oral naltrexone, indicating that ketamine's antidepressant effects are mediated by mu opioid agonism. We could not determine whether the effect was a release of endogenous opioids or some binding to the mu opioid receptor. Also, our results did not rule out that NMDA antagonism may be needed for maintaining the response (3). The opioid properties may explain the drug's abusability and raise concerns regarding liability with longer-term use.

> Do we have a real sense of how long and how often to prescribe [intranasal esketamine]? It's not entirely clear.

The drug's opioid properties need to be considered when considering how best to use it. A release of endogenous opioids by ketamine has been reported by Pacheco et al. (4) in a rodent pain study where antinociception was blocked by the mu opioid receptor antagonist naloxone, and this mechanism may be unique for ketamine. At first glance, that release would suggest a risk of developing tachyphylaxis and risk of withdrawal symptoms. But ketamine has been reported to reduce the risk of tolerance with opioids (5) and, at anesthetic doses, to reduce postsurgery opioid use, likely through its NMDA antagonism effects (6). Thus, this unique pharmacology may not be a problem with "continued intermittent" use. Indeed, it was recently reported that endogenous and synthetic opioids behave

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differently at the Golgi membrane levels (7), and that may explain differences in risk. At any rate, further studies, both in animals and humans, are needed to understand the opioid effects of ketamine.

Reasons for concern, however, rest with the known abusability of ketamine in humans, and these issues were raised in an earlier commentary on ketamine in this journal (8). They are reinforced by the data in the FDA's Briefing Document (9), in which the manufacturer reported on a drug relapse prevention/discontinuation study where patients were treated with ketamine plus antidepressant for 16 weeks and then tapered to once per week to once per 2 weeks before being randomized to continuing treatment with antidepressant plus ketamine or antidepressant plus placebo. The study was used as a second positive trial to support proof of efficacy, which, as previously noted (8), is a somewhat unusual application in proof of efficacy. Patients assigned to placebo showed significantly greater relapse rates by 2 weeks, which is a much shorter time frame than other discontinuation studies with known antidepressants where patients are actually taken off all drugs and differences in relapse are observed by 1 month or more (8). Relapse rates on discontinuing esketamine reached 40% by 3–4 months even though patients were receiving known antidepressants. This raises the question as to whether patients should be receiving esketamine for even longer periods—or would that be even more risky? What is more worrisome than this rapid relapse coming off even less frequent esketamine administration were the three suicides that occurred 4–20 days after the last dose of esketamine (there were none in the placebo group). Two of the patients who died by suicide showed no previous signs of suicidal activity during the study, either at baseline or at the last visit. This suggests a protracted withdrawal reaction, as has been reported with opioids, and one that is different from the more physical withdrawal symptoms seen acutely with opioids (10).

Given the rapid relapse and potential suicide risk, it is hard to know what to recommend to clinicians. Should they really continue to use the agent beyond an acute course? For how long? In whom? Unfortunately, the long-term discontinuation study that demonstrates efficacy may not be the best paradigm for a drug of abuse where coming off the drug may be more important and informative than the period when taking it. The FDA Briefing Document (9, p. 42) states, in regard to the suicides, that "given the small number of cases, the severity of the patients' underlying illness, and the lack of a consistent pattern among these cases, it is difficult to consider these deaths as drug-related." This appears misguided. Discontinuation reactions can certainly be due to the drug even though patients are not taking them at that time. Unfortunately, when one approaches ketamine as another antidepressant rather than a drug of abuse, this type of trap is easy to fall into, and in the end, such mistakes can be catastrophic. We have witnessed four decades of supposedly new and safer opioids that have turned out often to be, if anything, even more abusable and lethal. The FDA has asked the company to track patients for 3 years, and these data should help. In addition, the restricted distribution limits patients' access to the drug to approved medical settings, with patients observed for side effects for 2 hours.

So, where are we? Intranasal esketamine represents an easier method of administration than intravenous administration of ketamine. Do we have clear evidence of efficacy? Maybe? How strong is the efficacy? Apparently mild. Do we have a real sense of how long and how often to prescribe it? It's not entirely clear. If patients lose response, should we increase the frequency of administration? This could be problematic. Can coming off the drug be problematic? Data suggest that it could be an issue. Taken together, there are more questions than answers with intranasal esketamine, and care should be exercised in its application in clinical practice. Only time will tell how useful it will be. Still, the agent could be helpful to many patients with refractory depression, and efforts to develop rapidly acting agents for severely depressed patients need to be applauded.

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Esketamine (SPRAVATO)
National Drug Monograph
May 2019

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

The purpose of VA PBM Services drug monographs is to provide a focused drug review for making formulary decisions. Updates will be made when new clinical data warrant additional formulary discussion. The Product Information or other resources should be consulted for detailed and most current drug information.

FDA Approval Information

Description/Mechanism of Action

Esketamine is the S-enantiomer of racemic ketamine, a non-selective, non-competitive antagonist of the N-methyl-D-aspartate (NMDA) receptor, an ionotropic glutamate receptor. The mechanism by which esketamine exerts its antidepressant effect is unknown.

Indication(s) Under Review in This Document

- Esketamine is indicated, in conjunction with an oral antidepressant, for the treatment of treatment-resistant depression (TRD) in adults[1]

Dosage Form(s) Under Review

- Nasal Spray: 28 mg of esketamine per device. Each nasal spray device delivers two sprays. Each spray is 14 mg for a total delivered dose of 28 mg of esketamine over two sprays.

REMS

- SPRAVATO REMS; see Other Considerations for additional REMS information.

Special Handling

- **Restricted Distribution:** Esketamine will be self-administered under the direct supervision of a health care provider in a certified medical facility. Esketamine will not be dispensed directly to Veterans for use at home.

Postmarketing Requirements[32]

- Conduct a 3-year open-label safety study to characterize the long-term effects of esketamine on cognitive function and urinary symptoms. Ongoing trial TRD 3008 will be adapted to meet this requirement.
- To further characterize the potential risk of increasing thyroid stimulating hormone levels, analyze biobank samples taken at screening and predose on Days 1, 8, 25 or early withdrawal visits from patients who participated in the TRD3001 and TRD3002 Phase 3 studies.
- Conduct a study to evaluate the efficacy of esketamine monotherapy for the treatment of treatment-resistant depression. The study design must be agreed to by the FDA prior to initiating the study.

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Executive Summary

Efficacy

- The efficacy of esketamine was evaluated in three short-term (four-week) clinical trials (TRANSFORM-1,-2,-3) and one longer-term maintenance-of-effect trial (SUSTAIN-1). In the three short-term studies, patients were randomized to receive esketamine or a placebo nasal spray. All patients in these studies started a new oral antidepressant at the time of randomization and the new antidepressant was continued throughout the trials. The primary efficacy measure was the change from baseline on the Montgomery-Asberg Depression Rating Scale (MADRS) total score at the end of the 4-week double-blind induction phase.
- In one of the short-term studies, esketamine demonstrated statistically significant effect compared to placebo on the severity of depression. The two other short-term trials did not meet the pre-specified statistical tests for demonstrating effectiveness. In the longer-term maintenance-of-effect trial, patients in stable remission or with stable response who continued treatment with esketamine plus an oral antidepressant experienced a statistically significantly longer time to relapse of depressive symptoms than patients on placebo nasal spray plus an oral antidepressant.
- Most of esketamine's treatment difference compared to placebo was observed at 24 hours. The difference between the groups generally remained over the 28-day study but did not appear to increase over time. The positive short-term trial also demonstrated a significant placebo effect in the control arm from 24 hours that lasted until the study end point of 28 days.
- The Institute for Clinical and Economic Review (ICER) considers esketamine's evidence as "promising but inconclusive".[31]

Safety

- Boxed Warning: Sedation, dissociation, abuse and misuse, and suicidal thoughts and behaviors.

Other Considerations

- Quality of evidence is moderate. Long-term efficacy and safety data are lacking

Projected Place in Therapy

- **Potential Place in Therapy Based on the Evidence**. Esketamine may be considered for patients with TRD based on one positive short-term trial. However, esketamine nasal inhaler was only compared to a placebo inhaler and only one of three short-term studies showed a statistically significant effect compared to placebo on the severity of depression. The subgroup analysis of short-term studies (TRANSFORM-1 and -2) does not support the acute use of esketamine in males with TRD.
- Those patients in stable remission or with stable response who continued treatment with esketamine plus an oral antidepressant experienced a statistically significantly longer time to relapse of depressive symptoms than patients on placebo nasal spray plus an oral antidepressant based on the longer-term maintenance-of-effect trial (SUSTAIN-1). However, the faster rate of relapse in those patients who were randomized to placebo nasal spray plus and oral antidepressant could reflect functional unblinding, with subjects realizing that they are

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no longer on esketamine after switching to placebo. Further, the subgroup analysis of the maintenance-of-effect-trial does not support the use of esketamine in male stable remitters

- **Potential VA Place in Therapy**. Esketamine may be considered for adult patients without contraindications who have treatment resistant depression and have not responded to multiple formulary alternatives. Older Veterans (≥ 65 years of age) should not be considered candidates for esketamine given the non-significant efficacy data in this patient population.

Background

Purpose for Review

Esketamine is the S-enantiomer of racemic ketamine, a non-selective, non-competitive antagonist of the N-methyl-D-aspartate (NMDA) receptor. It is indicated, in conjunction with an oral antidepressant, for the treatment of TRD in adults. The purpose of this monograph is to review the efficacy and safety of esketamine for formulary decision-making purposes.

Issues to Be Determined

- Does the product offer efficacy advantages over alternative drug therapies?
- Does the product offer safety advantages over alternative drug therapies?
- What is the product's place in therapy?
- Formulary status?
- CFU?

Other Therapeutic Options

There is no standard definition and no standard treatment for treatment-resistant depression. The definition in the esketamine trials utilized for its approval is: a patient with MDD and in the current depressive episode, had not responded adequately to at least two different antidepressants of adequate dose and duration.

Treatment strategies for the management of TRD include augmentation with second generation antipsychotics, lithium, a second antidepressant (combination therapy), thyroid hormone, monoamine oxidase inhibitors (MAOIs), psychotherapy (cognitive behavior therapy), repetitive transcranial magnetic stimulation (rTMS), and electroconvulsive therapy.[33]

Alternative treatments at the same step in therapy for TRD are listed in the table 1 below (source, UpToDate[1]).[2]

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Table 1. Formulary and nonformulary alternatives for the management of major depression in patients resistant to standard treatment. *

Drug	Indication	Formulary	Other consideration
Olanzapine and fluoxetine	TRD	No	Combination product; can use individual formulary agents to approximate combination dosage
Quetiapine	Adjunctive tx in pts with inadequate response to AD of MDD	Yes	
Aripiprazole	Adjunctive tx of MDD	Yes	
Brexpiprazole	Adjunctive tx of MDD	No	NMDA receptor activity[26]
Risperidone	Adjunctive tx in combo with AD for TRD	Yes	Off label[3,4,25]
Olanzapine	Adjunctive tx of MDD	Yes	Off label[5,25]; risk of weight gain and metabolic disturbances
Lithium	AD augmentation	Yes	Off label[6]
Thyroid (T3 or T4)	AD augmentation	Yes	Off label[7,8,9]
Ziprasidone	AD augmentation	Yes	Off label[10,25]
AD combinations	AD augmentation	Yes	Add a second AD from a different class[11,12]

* AD=antidepressant, tx=treatment, MDD=major depressive disorder

Dosing and Administration

- Esketamine must be administered under the direct supervision of a healthcare provider. A treatment session consists of nasal administration of esketamine and post-administration observation under supervision.
    - Blood pressure assessed before and after treatment
    - Avoid food for at least 2 hours before administration and avoid drinking liquids at least 30 minutes prior to administration.
    - Administer nasal corticosteroid or nasal decongestant at least one hour before esketamine for patients requiring these treatments
    - During and after administration observe patient for at least 2 hours until they are safe to leave
    - Instruct patient not to engage in potentially hazardous activities (driving a motor vehicle or operating machinery) until the next day after a restful sleep.
- Administer esketamine in conjunction with an oral antidepressant.
- The recommended dosage for esketamine is shown in Table 2. Dosage adjustments should be made based on efficacy and tolerability. Evidence of therapeutic benefit should be evaluated at the end of the induction phase to determine need for continued treatment.

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- Esketamine is for nasal use only. The nasal spray device delivers a total of 28 mg of esketamine. To prevent loss of medication, do not prime the device before use. Use 2 devices (for a 56 mg dose) or 3 devices (for an 84 mg dose), with a 5-minute rest between use of each device.

Table 2: Recommended dosage for esketamine[1]

Induction Phase	**Weeks 1-4**	**Dosage**
	Administer twice per week	Day 1 starting dose: 56 mg Subsequent doses: 56 mg or 84 mg
Maintenance Phase		
	Weeks 5-8	
	Administer once weekly	56 mg or 84 mg
	Week 9 and after	
	Administer every 2 weeks or once weekly	56 mg or 84 mg

Efficacy (FDA Approved Indications)

Literature Search Summary

A literature search was performed on PubMed/Medline (March 2019) and the Cochrane Register of Controlled Trials (March 2019) using the search terms *esketamine and Spravato*. The search was limited to studies performed in humans and published in the English language. Reference lists of review articles and the manufacturer's Academy of Managed Care Pharmacy (AMCP) dossier[13] were checked for relevant clinical trials. All randomized clinical trials (RCTs), controlled clinical trials, and long-term (≥ 1 year) observational studies were included. Study results were also searched for from the FDA Medical Review(s)[14] and clinicaltrials.gov for Study 1; NCT02418585 and Study 2; NCT02493868

Review of Efficacy

- The efficacy of esketamine was evaluated in three short-term (four-week) clinical trials (TRANSFORM-1, -2, -3) and one longer-term maintenance-of-effect trial (SUSTAIN-1). In the three short-term studies, patients were randomized to receive esketamine or a placebo nasal spray. All patients in these studies started a new oral antidepressant at the time of randomization and the new antidepressant was continued throughout the trials. The newly initiated daily oral antidepressant (duloxetine, escitalopram, sertraline, or extended-release venlafaxine) was determined by the investigator based on patient's prior treatment history; the newly initiated oral antidepressant was an SSRI in 32% of patients and an SNRI in 68% of patients. The primary efficacy measure was the change from baseline on the Montgomery-Asberg Depression Rating Scale (MADRS) total score at the end of the 4-week double-blind induction phase.

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- Patients were 18 to <65 years old with treatment-resistant depression (TRD). TRD defined as: in the current depressive episode, the patient had not responded adequately to at least two different antidepressants of adequate dose and duration.
- Patients were randomized to receive twice weekly doses of intranasal esketamine (flexible dose; 56 mg or 84 mg) or intranasal placebo.
- Patients had a median age of 47 years (range 19 to 64 years) and were 62% female, 93% Caucasian, and 5% Black.
- In one of the short-term studies (TRANSFORM-2), esketamine demonstrated statistically significant effect compared to placebo on the severity of depression. The two other short-term trials (TRANSFORM-1 and TRANSFORM-3) did not meet the pre-specified statistical tests for demonstrating effectiveness. Note that in the TRANSFORM-1 trial (Table 3) two p values are listed for the fixed dose esketamine groups. The reason for this is that the prespecified statistical analysis plan employed a fixed-sequence testing procedure to control the Type-I error rate. The esketamine 84-mg arm was prespecified as the first group to be tested, as it was the higher dose. Because the change from baseline on MADRS was not significantly different between the 84-mg treatment group and the placebo group (p=0.088), the testing sequence stopped here, and the 56-mg treatment group could not be formally analyzed.
- In an exploratory analysis of TRANSFROM-1, subjects in the esketamine 56-mg arm did experience greater improvement in depressive symptoms as measured by the MADRS than patients in the placebo group (p = 0.011). However, the study was not positive based on the prespecified analysis plan.
- In the longer-term maintenance-of-effect trial (SUSTAIN-1), patients in stable remission or with stable response who continued treatment with esketamine plus an oral antidepressant experienced a statistically significantly longer time to relapse of depressive symptoms than patients on placebo nasal spray plus an oral antidepressant.
- The faster rate of relapse in (SUSTAIN-1) could reflect functional unblinding, with subjects realizing that they were no longer on esketamine after switching to placebo. Dissociation and sedation with esketamine generally do not dissipate over time. Subjects who have all been exposed to open-label esketamine for at least 16 weeks may be able to notice the difference soon after being switched to placebo.

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Table 3. Change from Baseline in MADRS Total Score at Week 4[31]

Trial	Treatment group	N	Mean baseline score (SD)	Change from BL to week 4 (SD)	LS Mean difference (95% CI)	P-value	Effect Size
TF-1	Placebo+AD	113	37.5 (6.2)	-14.8 (15.1)	-		
	ESK 56 mg + AD	115	37.4 (4.8)	-19.0 (13.9)	-4.1 (-7.67, -0.49)	0.011	
	ESK 84 mg + AD	114	37.8 (5.6)	-18.8 (14.1)	-3.2 (-6.88, 0.45)	0.088	
TF-2	Placebo nasal spray + oral AD	109	37.3 (5.7)	-15.8 (13.6)	_		_
	ESK (56 mg or 84 mg) + oral AD	114	37.0 (5.7)	-19.8 (13.9)	-4.0 (-7.3, -0.6)	0.020	0.29
TF-3	Placebo +AD	65	34.8 (6.4)	-6.3 (8.9)	-		
	ESK (56 mg or 84 mg) + oral AD	72	35.5 (5.9)	-10.0 (12.7)	-3.6 (-7.2, 0.07)	0.059	

MADRS: Montgomery-Asberg Depression Rating Scale, TF: TRANSFORM study, ESK: esketamine, AD: antidepressant, SD: standard deviation, LS Mean: least-squares mean difference estimated using mixed model for repeated measures (MMRM), CI: confidence interval

Note: TF-1 and TF-2=adults 18-64 years. TF-3= adults ≥65 years

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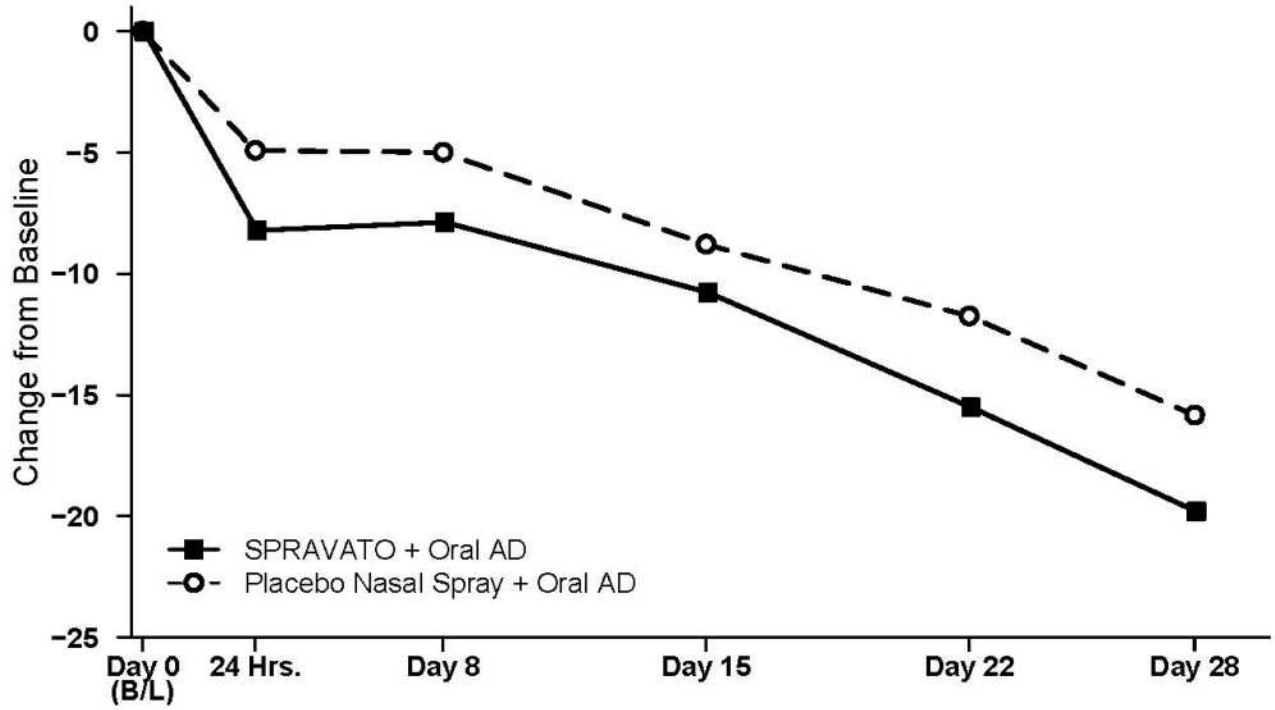
Figure 1. Least Squares Mean Change from Baseline in MADRS Total Score Over Time in Patients with TRD in Study 1* (Full Analysis Set) – MMRM Analysis[1]



NOTE: MADRS sustained response Day 2+: esketamine 8% vs placebo 5% p=0.161[30]

Table 4. Clinical Response and Remission (MADRS)*[30]

Trial	Treatment group	N	Response rate, %	NNT	Remission rate, %	NNT
TF-1	Placebo+AD	113	39		31	
	ESK 56 mg + AD	115	54	7	36	20
	ESK 84 mg + AD	114	53	7	39	13
TF-2	Placebo nasal spray + oral AD	109	52		31	
	ESK (56 mg or 84 mg) + oral AD	114	69	6	53	5
TF-3	Placebo +AD	65	13		7	
	ESK (56 mg or 84 mg) + oral AD	72	27	7	18	9

AD: antidepressant, TF: TRANSFORM study, ESK: esketamine, MADRS: Montgomery-Åsberg Depression Rating Scale, Response: ≥ 50% improvement, Remission: ≤12 MADRS, *statistical significance could not

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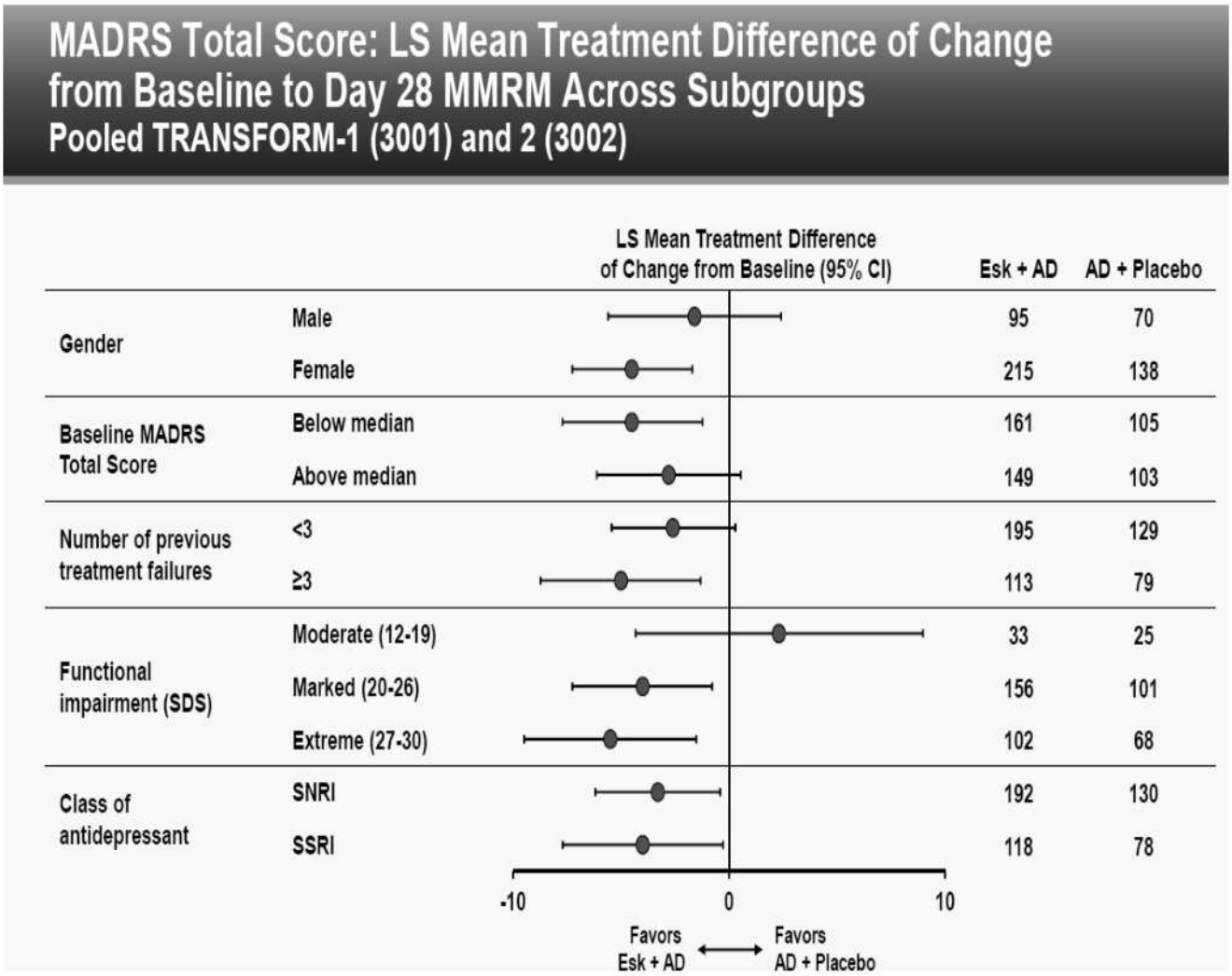
be formally tested due to a previously statistically insignificant endpoint in the fixed testing sequence or were not controlled for multiplicity

Table 5. Acute treatment subgroup analysis[34]



MADRS: Montgomery-Asberg Depression Rating Scale, LS: least square, MMRM: mixed model for repeated measures

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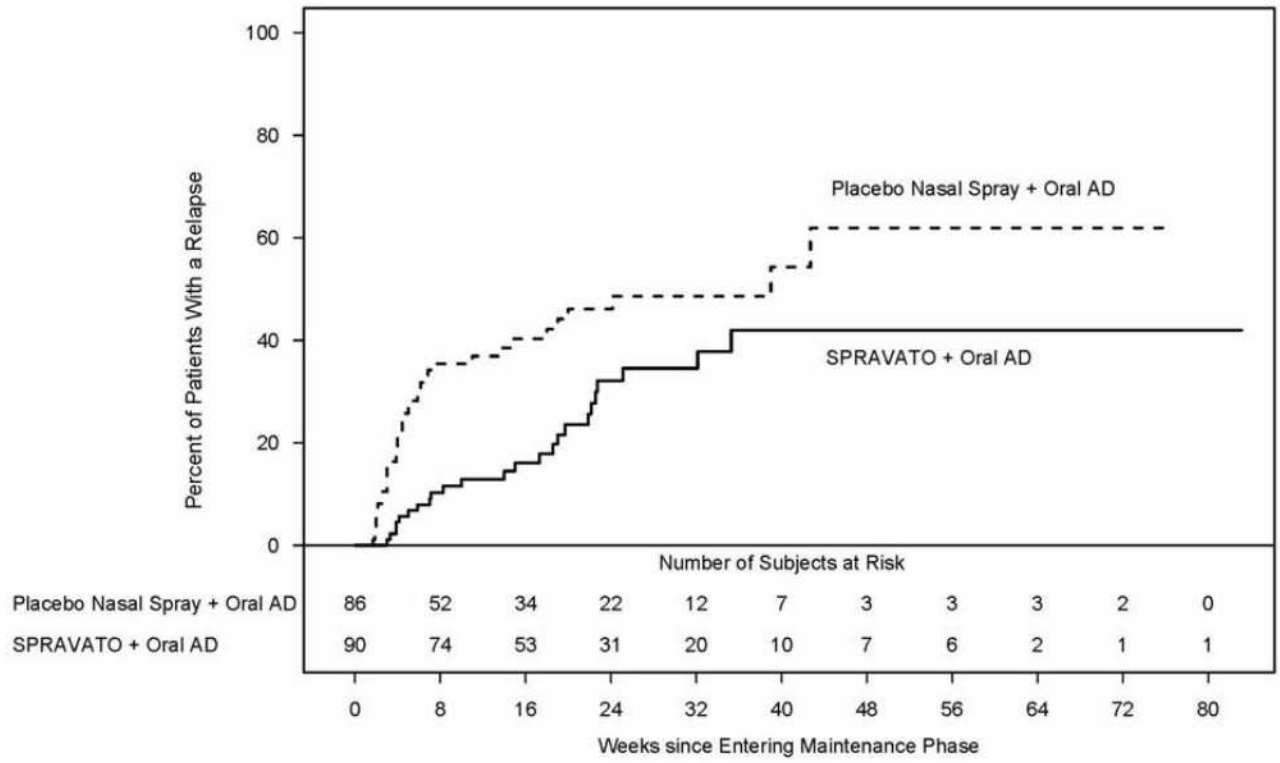
Figure 2. Time to Relapse in Patients with TRD in Stable Remission in Study (stable remission = MADRS total score ≤ 12 for at least 3 of the last 4 weeks)[1]



The median number of days to relapse in stable remitters who received placebo was 273 days. The estimated hazard ratio (95% CI) of esketamine + oral AD relative to placebo nasal spray + oral AD based on weighted estimates was 0.49 (95% CI: 0.29, 0.84).

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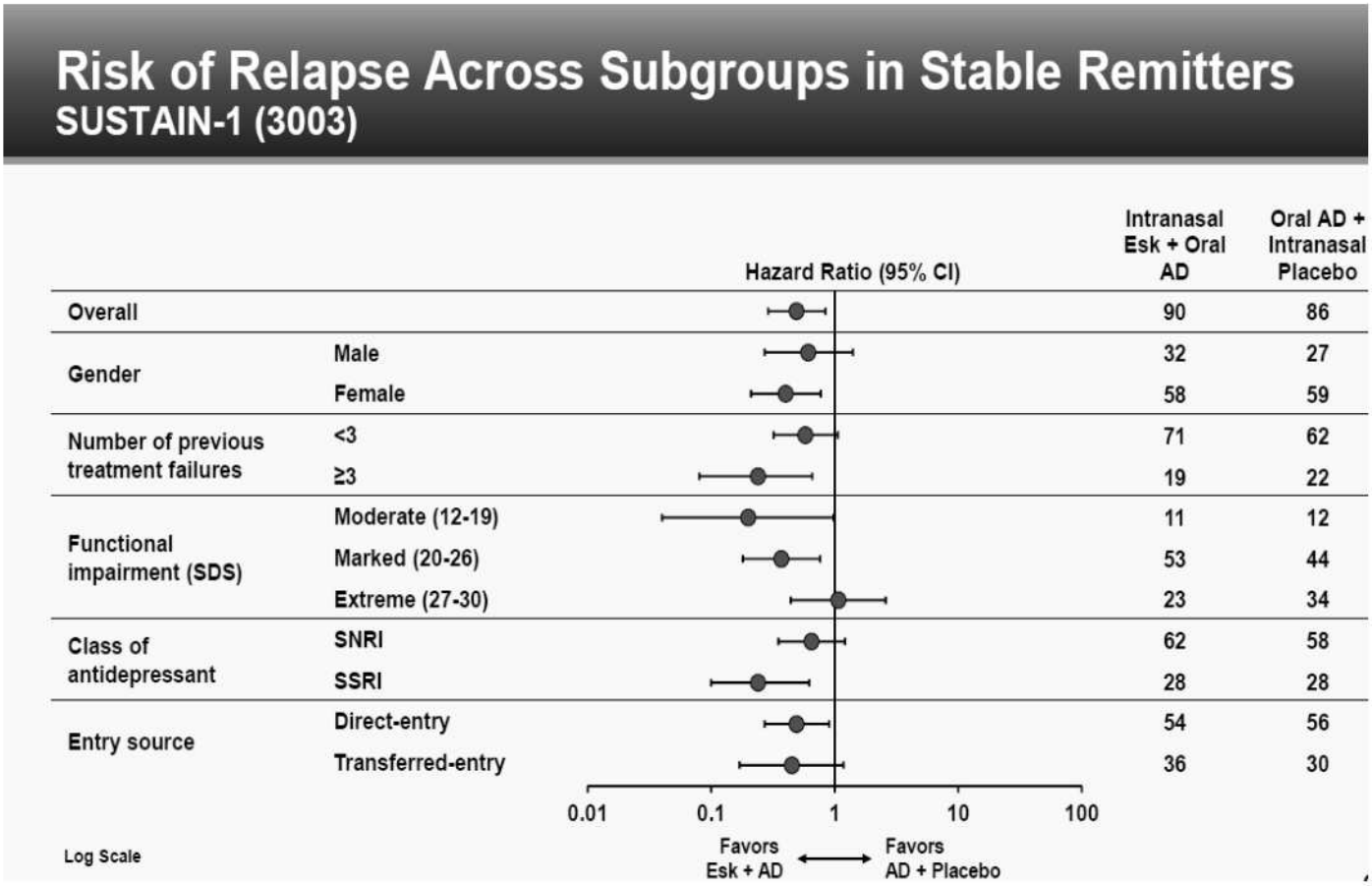
Table 6. Relapse subgroup analysis[34]



Potential Off-Label Use

This section is not intended to promote any off-label uses. Off-label use should be evidence-based. See VA PBM-MAP and Center for Medication Safety's Guidance on Off-label Prescribing *(available on the VA PBM Intranet site).*

- Non "treatment-resistant" depression, suicidality, bipolar depression, PTSD and pain

Safety

- For more detailed information, refer to the prescribing information.[1]

Boxed Warnings: Sedation, dissociation, abuse and misuse, and suicidal thoughts and behaviors

- **Sedation**
  - Patients are at risk for sedation after administration of esketamine.
- **Dissociation**

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  - Patients are at risk for dissociative or perceptual changes after administration of esketamine.
  - Because of the risks of sedation and dissociation, patients must be monitored for at least 2 hours at each treatment session, followed by an assessment to determine when the patient is considered clinically stable and ready to leave the healthcare setting.
- **Abuse and Misuse**
  - Esketamine has the potential to be abused and misused (especially in patients with Substance Use Disorder). Consider the risks and benefits of prescribing esketamine prior to use in patients at higher risk of abuse. Monitor patients for signs and symptoms of abuse and misuse.
  - Because of the risks of serious adverse outcomes resulting from sedation, dissociation, and abuse and misuse, esketamine is only available through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the SPRAVATO REMS.
- **Suicidal Thoughts and Behaviors**
  - Antidepressants increased the risk of suicidal thoughts and behavior in pediatric and young adult patients in short-term studies. Closely monitor all antidepressant-treated patients for clinical worsening, and for emergence of suicidal thoughts and behaviors. Esketamine is not approved for use in pediatric patients.

Contraindications

- Esketamine is contraindicated in patients with:
  - Aneurysmal vascular disease (including thoracic and abdominal aorta, intracranial, and peripheral arterial vessels) or arteriovenous malformation.
  - History of intracerebral hemorrhage.
  - Hypersensitivity to esketamine, ketamine, or any of the excipients.

Warnings / Precautions

- Sedation
- Dissociation
- Abuse and Misuse
- Suicidal thoughts and behaviors in adolescents and young adults
- Increase in blood pressure
- Cognitive impairment
- Impaired ability to drive and operate machinery
- Ulcerative or interstitial cystitis
- Embryo-fetal toxicity

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Adverse Reactions

Table 7. Adverse Reactions Occurring in ≥2% of TRD Patients Treated with esketamine + Oral AD at Any Dose and at a Greater Rate than Patients Treated with Placebo Nasal Spray + Oral AD[1]

	Esketamine + Oral AD	Placebo + Oral AD
	N=346	N=222
Tachycardia	6 (2%)	1 (0.5%)
Vertigo	78 (23%)	6 (3%)
Constipation	11 (3%)	3 (1%)
Diarrhea	23 (7%)	13 (6%)
Dry mouth	19 (5%)	7 (3%)
Nausea	98 (28%)	19 (9%)
Vomiting	32 (9%)	4 (2%)
Feeling abnormal	12 (3%)	0 (0%)
Feeling drunk	19 (5%)	1 (0.5%)
Blood pressure increased	36 (10%)	6 (3%)
Dizziness	101 (29%)	17 (8%)
Dysarthria	15 (4%)	0 (0%)
Dysgeusia	66 (19%)	30 (14%)
Headache	70 (20%)	38 (17%)
Hypoesthesia	63 (18%)	5 (2%)
Lethargy	37 (11%)	2 (1%)
Mental impairment	11 (3%)	2 (1%)
Sedation	79 (23%)	21 (9%)
Tremor	12 (3%)	2 (1%)
Anxiety	45 (13%)	14 (6%)
Dissociation	142 (41%)	21 (9%)
Euphoric mood	15 (4%)	2 (1%)
Insomnia	29 (8%)	16 (7%)
Pollakiuria	11 (3%)	1 (0.5%)
Nasal discomfort	23 (7%)	11 (5%)
Oropharyngeal pain	9 (3%)	5 (2%)
Throat irritation	23 (7%)	9 (4%)
Hyperhidrosis	14 (4%)	5 (2%)

Serious Adverse Reactions[30]

- Death -six, all in esketamine-treated subjects (NNH=69); three deaths were by suicide.
- Sedation, dissociation and abuse and misuse (Boxed warning)

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Table 8. Other serious adverse events[30] (NNH=38)

Study	TF-1		TF-2		TF-3	
	Placebo	ESK	Placebo	ESK	Placebo	ESK
Subjects	113	231	109	115	65	72
Depression	1	6	0	0	0	1
Suicidal ideation	1	4	0	0	0	0
Traffic accident/death	0	0	0	1	0	0
Hip fracture	0	0	0	0	0	1
Cerebral hemorrhage	0	0	0	1	0	0

TF: TRANSFORM study, ESK: esketamine

Discontinuations Due to Adverse Reactions

- Esketamine plus oral AD 4.6% vs 1.4% for placebo nasal spray plus oral AD (short term studies)
- Esketamine plus oral AD 2.6% vs 2.1% for placebo nasal spray plus oral AD (long-term study)

Safety Considerations

- Sedation was reported in 2 ways in the clinical studies: adverse events reports (table 7) and by using the Modified Observer's Assessment of Alertness/Sedation Scale (MOAA/s)
    - Based on the MOAA/s 49%-61% of patients treated with esketamine developed sedation
    - 0.3% experience loss of consciousness
- Dissociation was evaluated by adverse event reports (table75) and the Clinician-Administered Dissociative States Scale (CADSS) questionnaire.
    - Based on the CADSS, 61%-75% of patients treated with esketamine developed dissociative or perceptual changes.
- Increase in blood pressure
    - The mean placebo-adjusted increases in systolic and diastolic blood pressure (SBP and DBP) over time were about 7 to 9 mmHg in SBP and 4 to 6 mmHg in DBP at 40 minutes post-dose and 2 to 5 mmHg in SBP and 1 to 3 mmHg in DBP at 1.5 hours post-dose in patients receiving esketamine plus oral antidepressants

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Table 9. Increases in Blood Pressure in Double-blind, Randomized-controlled, Short-term Trials of esketamine + Oral AD Compared to Placebo Nasal Spray + Oral AD in the Treatment of TRD[1]

	Patients < 65 yrs.		Patients ≥65 yrs.	
	Esketamine + oral AD	Placebo + oral AD	Esketamine + oral AD	Placebo + oral AD
	N=346	N=222	N=72	N=65
SBP				
≥180 mmHG	9 (3%)	-	2 (3%)	1 (2%)
≥ 40 mmHG increase	29 (8%)	1 (0.5%)	12 (17%)	1 (2%)
DBP				
≥110 mmHG	13 (4%)	1 (0.5%)	-	-
≥ 25 mmHG increase	46 (13%)	6 (3%)	10 (14%)	2 (3%)

Drug Interactions

Drug-Drug Interactions

- CNS depressants (benzodiazepines, opioids, alcohol) – may increase sedation; monitor
- Psychostimulants (amphetamines, methylphenidate, modafinil) – may increase blood pressure; monitor
- Monoamine Oxidase Inhibitors – may increase blood pressure; monitor

Special Populations (Adults)

Elderly

- The efficacy of esketamine for the treatment of treatment resistant depression in patients ≥65 years of age was evaluated in a 4-week, randomized, double-blind study comparing intranasal esketamine plus a newly initiated oral antidepressant compared to intranasal placebo plus a newly initiated oral antidepressant.[1] At the end of 4 weeks there was no significant difference between groups on the primary efficacy endpoint of change from baseline to week 4 on the MADRS.
- 194/1601 (12%) of the patients in Phase 3 clinical studies were ≥ 65 years of age and 25 (2%) were ≥ 75 years of age. No overall differences in safety profile were observed between those patients ≥ 65 and those < 65 years of age.
- Mean esketamine Cmax and AUC values were higher in the elderly patients compared with non-elderly patients.

Pregnancy

- Esketamine is not recommended during pregnancy

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Lactation

- Esketamine is present in human milk. Breastfeeding is not recommended.

Renal Impairment

- There is no clinical experience with esketamine spray in patients on hemodialysis.

Hepatic Impairment

- The mean esketamine AUC and $t_{1/2}$ values were higher in patients with moderate hepatic impairment compared to those with normal hepatic function. Esketamine has not been studied in patients with severe hepatic impairment (Child-Pugh class C). Use in this population is not recommended

Risk Evaluation

As of March 20, 2019

Sentinel Event Advisories

- None
- Sources: ISMP, FDA, TJC

Look-alike / Sound-alike Error Potential

	Comments

Look-alike/sound-alike error potentials

NME Drug Name	Lexi-Comp	First DataBank	ISMP	Clinical Judgment
esketamine	None	None	None	Ketamine Imipramine
SPRAVATO™ treatment-resistant depression Nasal Spray	None	None	None	Pravachol Yosprala Spiriva

- High alert medication: The Institute for Safe Medication Practices (ISMP) includes this medication among its list of drug classes which have a heightened risk of causing significant patient harm when used in error.
- Lexi-Comp, First Databank, and ISMP Confused Drug Name List)
- *Note: The list provided is not all-inclusive. Other medications may be mistaken due to various LASA similarities.*

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Other Considerations

FDA Concerns During Deliberations (https://lowninstitute.org/news/esketamine-nears-fda-approval-prompting-both-excitement-and-concern/)

- FDA experts gave an overall strong recommendation for approving esketamine, with 14 voting yes, two voting no, and one abstaining. However, a few reviewers, as well as some other researchers, questioned the low standard of evidence provided by Johnson & Johnson on the drug's effectiveness and safety.
- The agency's "gold standard" for formal approval is two positive, well-controlled studies. However, J&J presented just one positive short-term trial and a positive randomized maintenance trial.

Risk Evaluation and Mitigation Strategy (REMS)

- Esketamine is available only through a restricted program called the SPRAVATO REMS
  - Patients must be enrolled in the SPRAVATO REMS Program prior to administration.
  - REMS requires the prescriber and the patient to both sign a Patient Enrollment Form that clearly states that the patient understands they should make arrangements to safely leave the health care setting to get home and that the patient should not drive or use heavy machinery for the rest of the day on which they receive the drug.
  - Esketamine must be dispensed with a patient Medication Guide that outlines the drug's uses and risks.
  - Esketamine must be administered under the direct observation of a healthcare provider.
  - Patients must be monitored by a healthcare provider for at least 2 hours after administration of esketamine.

Drug Administration Issues

- Esketamine will be self-administered under the direct supervision of a health care provider in a certified medical facility. Esketamine will not be dispensed directly to Veterans for use at home.
- A secondary efficacy endpoint, MADRS sustained response Day 2+, was not different between esketamine (8%) and placebo (5%), p=0.161. If the patient does not respond to nasal esketamine after one week, discontinuation should be considered.

Storage and Handling

- Esketamine is a Schedule III controlled substance

Special Monitoring Requirements

- Blood pressure assessment before, during, and after treatment.
- During and after administration observe the patient for sedation and dissociation for at least 2 hours until they are safe to leave.
- Monitor for signs of abuse and misuse.
- Monitor for clinical worsening, and for emergence of suicidal thoughts and behaviors.

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Projected Place in Therapy

- MDD, a common psychiatric condition that causes significant disability and disease burden, has been estimated to occur in 17 million people or 7.1% of adults in the United States who experienced at least one major depressive episode in 2017.[15,16]
- Symptoms of depression overlap with medical and other psychiatric disorders making proper diagnosis imperative.
- Approximately one in three patients with depression are considered "treatment resistant." [20]
- There is no standard definition of treatment resistant depression.
- TRD refers to a major depressive episode with an inadequate response to therapy of adequate dosing and duration.[17]
- The failure of two or more trials of antidepressant monotherapies are commonly considered TRD, but the number of trials has not been standardized and some drug trials include patients with failure of one or more trials.[18,19]
- Practice guidelines are dated.[27-29]
- The definition for TRD utilized in the esketamine trials garnering its approval was: a patient with MDD and in the current depressive episode, had not responded adequately to at least two different antidepressants of adequate dose and duration.
- Esketamine is approved for use, in conjunction with an oral antidepressant, for the treatment of TRD in adults
- **Potential Place in Therapy Based on the Evidence**. Esketamine may be considered for patients with TRD based on one positive short-term trial. However, esketamine nasal inhaler was only compared to a placebo inhaler and only one of three short-term studies showed a statistically significant effect compared to placebo on the severity of depression. The subgroup analysis of short-term studies (TRANSFORM-1 and -2) does not support the acute use of esketamine in males with TRD.
- Those patients in stable remission or with stable response who continued treatment with esketamine plus an oral antidepressant experienced a statistically significantly longer time to relapse of depressive symptoms than patients on placebo nasal spray plus an oral antidepressant based on the longer-term maintenance-of-effect trial (SUSTAIN-1). However, the faster rate of relapse in those patients who were randomized to placebo nasal spray plus and oral antidepressant could reflect functional unblinding, with subjects realizing that they are no longer on esketamine after switching to placebo. Further, the subgroup analysis of the maintenance-of-effect-trial does not support the use of esketamine in male stable remitters
- **Quality of Evidence and External Validity to VA Population.** Moderate-quality evidence. Two short-term trials did not meet the pre-specified statistical tests for demonstrating effectiveness. The patient population studied (median age of 47 years, 62% female, 93% Caucasian, and 5% Black) is not representative of the VA population. Long-term efficacy and safety data are lacking. The subgroup analyses of both short-term studies and the maintenance-of-effect trial do not support the use of esketamine in male patients with TRD.
- **Potential VA Place in Therapy.** Esketamine may be considered for adult patients without contraindications who have treatment resistant depression and have not responded to multiple

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formulary alternatives. Older Veterans (≥ 65 years of age) should not be considered candidates for esketamine given the non-significant efficacy data in this patient population.

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Updated version may be found at PBM INTERnet or PBM INTRAnet

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Prepared May 2019. Contact person: Matthew A. Fuller, PharmD, BCPP, National PBM Clinical Pharmacy Program Manager – Pharmacy Benefits Management Services (10P4P)

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Appendix A. GRADEing the Evidence

Evidence was rated using the GRADE method, as described in Appendix Table 1.

Appendix Table 1 Quality of Evidence Descriptions

Quality of Evidence	Description
High	Evidence includes consistent results from well-designed, well-conducted studies in representative populations that directly assess effects on health outcomes (2 consistent, higher-quality randomized controlled trials or multiple, consistent observational studies with no significant methodological flaws showing large effects).
Moderate	Evidence is sufficient to determine effects on health outcomes, but the number, quality, size, or consistency of included studies; generalizability to routine practice; or indirect nature of the evidence on health outcomes (1 higher-quality trial with > 100participants; 2 higher-quality trials with some inconsistency; 2 consistent, lower-quality trials; or multiple, consistent observational studies with no significant methodological flaws showing at least moderate effects) limits the strength of the evidence.
Low	Evidence is insufficient to assess effects on health outcomes because of limited number or power of studies, large and unexplained inconsistency between higher-quality studies, important flaws in study design or conduct, gaps in the chain of evidence, or lack of information on important health outcomes.

Please refer to Qaseem A, et al. The development of clinical practice guidelines and guidance statements of the American College of Physicians: Summary of Methods. Ann Intern Med 2010;153:194-199.

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Esketamine (SPRAVATO)
Criteria for Use
May 2019

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

See the VA National PBM-MAP-VPE Monograph on this drug at the *PBM INTERnet* or *PBM INTRAnet* site for further information.

Exclusion Criteria

If the answer to **ANY** item below is met, then the patient should **NOT** receive esketamine.

- ☐ Hypersensitivity to esketamine, ketamine, or any of the excipients.
- ☐ Aneurysmal vascular disease (including thoracic and abdominal aorta, intracranial, and peripheral arterial vessels) or arteriovenous malformation.
- ☐ History of intracerebral hemorrhage.
- ☐ History of seizures
- ☐ Current or recent (within 30 days) delirium.
- ☐ Current uncontrolled hypertension (systolic blood pressure >140 mm Hg or diastolic blood pressure > 90 mm Hg).
- ☐ Severe cardiac decompensation (Class IV heart failure or unstable angina).
- ☐ Severe hepatic impairment (Child-Pugh class C).
- ☐ Current or previous interstitial or ulcerative cystitis.
- ☐ Active suicidal ideation.
- ☐ Comorbid psychiatric condition is present (schizophrenia, schizoaffective disorder, MDD with psychotic symptoms, bipolar disorder, obsessive-compulsive disorder, intellectual disability, autism, cluster B personality disorder, or a major neurocognitive disorder diagnosis).
- ☐ History of non-response to ketamine, esketamine, or ECT.
- ☐ History of VNS or deep brain stimulation in current episode of depression.
- ☐ Current or previous abuse of ketamine or esketamine.
- ☐ Clinical evidence for current substance abuse except tobacco use (e.g. confirmed UDS).
- ☐ Current barbiturate, cannabis or opioid use.
- ☐ Current moderate or severe substance use disorder (SUD).
- ☐ Pregnancy (known pregnancy or positive pregnancy test).
- ☐ Patient is breastfeeding.

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Inclusion Criteria

The answers to **ALL** of the following must be fulfilled in order to meet criteria.

- ☐ All REMS requirements have been met.
- ☐ Adults <65 years of age with current diagnosis of unipolar major depressive disorder by DSM-5.
- ☐ The patient did not achieve remission from at least four adequate therapeutic trials (dose and duration) of antidepressants, either alone or in combination with evidence-based psychotherapy, and in the current episode of depression is experiencing moderate to severe depressive symptomatology based on a depression rating scale within the last 30 days. At least two trials must include an antidepressant augmented with an additional agent (e.g. antipsychotic, second antidepressant, lithium, or thyroid supplementation).
- ☐ Antidepressant treatment trials are considered unsuccessful if the patient has not responded to at least 6 weeks of an antidepressant at half maximum dose or greater.
- ☐ The patient has been considered for electroconvulsive therapy (ECT).
- ☐ The patient has started and is currently receiving a new antidepressant that has not previously failed in the current depressive episode.
- ☐ A psychiatrist has evaluated the patient and determined and documented in the patient's medical records that the patient qualifies for esketamine treatment.
- ☐ The prescriber is a psychiatrist.
- ☐ The patient agrees to stay and be monitored for at least two hours after esketamine administration and agrees not to drive or operate heavy machinery/equipment and not to make major financial or legal decisions for the remainder of the day in which esketamine is administered.
- ☐ The patient or their legal representative can provide signed informed consent.
- ☐ The patient has an adult who can accompany him/her and assist with transportation, or another method of safe transport has been arranged and documented.

For women of childbearing potential

- ☐ Pregnancy should be excluded prior to receiving esketamine and the patient provided contraceptive counseling on potential risks vs. benefits of taking esketamine if patient were to become pregnant.

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Dosage and Administration

Induction Phase	Weeks 1-4	Dosage
	Administer twice per week	Day 1 starting dose: 56 mg Subsequent doses: 56 mg or 84 mg
Maintenance Phase		
	Weeks 5-8	
	Administer once weekly	56 mg or 84 mg
	Week 9 and after	
	Administer every 2 weeks or once weekly	56 mg or 84 mg

Discontinuation Criteria

- If the patient does not respond to nasal esketamine after one week, discontinue.
    - An adequate response is defined as a 50% or greater decline in the depression rating scale score from baseline.
- If a woman taking esketamine becomes pregnant, the drug should be stopped, and the patient counseled about the risk to the fetus.
- If the patient has a positive urine drug screen for specified drugs of abuse (cannabinoids, barbiturates, methadone, opioids, cocaine, phencyclidine, and amphetamine/methamphetamine), while receiving esketamine, then discontinue esketamine.
- Discontinue if signs/symptoms of new or recurrent substance use disorder emerge and refer to SUD specialty care.

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Monitoring

- The REMS Patient Monitoring/Esketamine Safety Form shall be completed after every treatment session and submitted to VAMedSAFE online (esketamine safety InfoPath link) or via fax (1-708-786-xxxx).
- Blood pressure assessment before, during, and prior to discharge.
- During and after administration observe the patient for sedation and dissociation for at least 2 hours until they are safe to leave with a safe method of transport.
- Monitor for signs of abuse and misuse of any substance.
- Monitor for clinical worsening, and for emergence of psychosis, suicidal thoughts and behaviors.

Issues for Consideration

- Patients prescribed a benzodiazepine, a non-benzodiazepine sedative hypnotic or a monoamine oxidase inhibitor are eligible to receive esketamine; however, it is advised that concurrent use while receiving esketamine may cause sedation or blood pressure changes.
- Carefully review prior to use of esketamine, patients who are less than 6 months in remission from Substance Use Disorder. Review Prescription Drug Monitoring Program (PDMP).
- May cause fetal harm. Consider pregnancy planning and prevention in females of reproductive potential.

Prepared: May 2019. Contact: Matthew A. Fuller, Pharm.D., BCPP, National Clinical Pharmacy Program Manager, VA Pharmacy Benefits Management Services 10P4P

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From:	Zacher, Jennifer L. (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9027C425646E4DE8A7D196908016331B-ZACHER, JEN <(b)(6) @va.gov>
To:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b)(6) @va.gov>
Subject:	Call With J&J
Date:	2019/06/26 17:03:45
Priority:	Normal
Type:	Note

Hi Mike,

I had a follow up call with J&J today, because they alluded to me that they were hearing conflicting information from the VISNs, and they wanted to clarify (email attached).

When I got on the call, I asked them who they had been hearing from within the VISNs, as none of our formulary decisions had been announced yet, and they retreated and told me that their questions had come from the media reports on this topic and that no one from VA had been in communication with them related to Spravato.

I gave them an overview of the discussion during the VPE/MAP meeting, including the CFU edits, protocol development, MUE, etc. I advised them that I could send a copy of the CFU and protocol once they were publicly posted this week. I also informed them that the decision had been made to keep this drug non-formulary. They were advised that this drug will be added to our non-promotable list. I explained that the decision was made because this drug has safety concerns and requires a lot of infrastructure to be in place to be used appropriately and that we wanted to work through that internally and make sure that the messaging was clear until we got everything in place. They were advised that the VPE/MAP committee would revisit periodically and determine if it was appropriate to keep the drug non-promotable or not.

They had several questions about what non-promotable means, and if that status applied to unsolicited requests for education. I explained that if a provider requests educational information, the local Chief of Pharmacy MUST approve that interaction to occur, and that if approved, it had to be medical personnel having the interaction (versus part of the sales team). I also advised them that discussing anything with

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VA providers related to VA outside of the VA (i.e. at the university office across the street) as a means to circumvent the Chief of Pharmacy was not appropriate. They also asked if the non-promotable status would impact anything that they had been working on with Ilse or my team, and I advised that it would not.

At the end of the call, they stated that they were intending to put a TPR in place to reduce the cost of the drug by 5% off WAC. In the private sector, they are offering a "rebate" of 5% off WAC for commercial patients and they want to make it equitable so that they are offering the same type of discount to VA, so they are intending to do a straight TPR effective ASAP through 9/6/2019. They sent this as a compromise after we reviewed their initial offer (attached) and determined that it wasn't likely feasible for VA to meet the purchase volumes in the letter based on our implementation plan, as they were only going to make that offer through 7/31/2019. They asked that I assist in getting the modification expedited through FSS, and I did commit that I would attempt to do that. I just saw the modification come through, and here are the new prices:

Spravato 2X28mg: Current price: $437.34, new TPR price through 9/6/19: $407.84
Spravato 3X28mg: Current price $656.03, new TPR price through 9/6/2019: $611.78

They indicated that they may have further questions once they inform their senior leadership, but wanted to make sure you were in the loop as to what the conversation was. Let me know if questions.
JZ

Jennifer L. Zacher, PharmD, BCPP
Associate Chief Consultant – Formulary Management
VA Pharmacy Benefits Management Services
(b)(6)
(b)(6) @va.gov

Sender:	Zacher, Jennifer L. (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (EXDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9027C425646E4DE8A7D196908016331B-ZACHER, JEN (b)(6) @va.gov>

AMERICAN OVERSIGHT

Recipient:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>
Sent Date:	2019/06/26 17:03:44
Delivered Date:	2019/06/26 17:03:45
From:	(b) (6) (b)(6)
To:	Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen (b)(6) @va.gov>
CC:	(b) (6) [SCGUS] (b)(6)
Subject:	[EXTERNAL] Connect request
Date:	2019/06/25 13:57:26
Priority:	Normal
Type:	Note

Hi Jennifer,

Good afternoon, I hope you are doing well.

We have a couple of topics that have been brought forward from your VISN's that we would like to discuss with you in order to be aligned with VA direction.

I realize this is a bit out of our typical cadence of touch points, but in this instance It would be helpful to hear directly from you, since a number of key decisions need to be aligned with your overall direction.

If you could let me know what times would work for you, our team will accommodate our calendar accordingly. If possible since July 4th is next week could we connect by Friday of this week?

Thanks,



National Federal Team - Strategic Customer Group

Johnson &Johnson Health Care Systems

AMERICAN OVERSIGHT

T: (b)(6) - https://www.jnj.com/heroes : Johnson &Johnson Supports Our Troops &Veterans

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Sent from iPad

Sender:	(b) (6) (b)(6)
Recipient:	Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen (b)(6) @va.gov>; (b) (6) (b)(6)
Sent Date:	2019/06/25 13:56:39
Delivered Date:	2019/06/25 13:57:26

AMERICAN OVERSIGHT

(b5)

AMERICAN OVERSIGHT

(b5)

AMERICAN OVERSIGHT

(b5)

AMERICAN OVERSIGHT

From:	Lowe, Joette /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2CDA61A196F849548A246B80455099D9-LOWE, JOETT (b)(6) @va.gov>
To:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>
Subject:	Automatic reply: VA to make new nasal spray drug available for treatment-resistant depression
Date:	2019/03/19 17:16:23
Priority:	Normal
Type:	Note.Rules.OofTemplate.Microsoft

I am out of the office until Thursday, March 21, 2019 on travel. I will be reading e-mail sporadically during this time and you may reach me at (b) (6) for urgent matters.

Sender:	Lowe, Joette /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2CDA61A196F849548A246B80455099D9-LOWE, JOETT (b)(6) @va.gov>
Recipient:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>
Sent Date:	2019/03/19 17:16:21
Delivered Date:	2019/03/19 17:16:23
Message Flags:	Unread

AMERICAN OVERSIGHT

From:	Emmendorfer, Thomas (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC96BB44E7AE2C94C43B55D094-EMMENDORFER (b)(6) @va.gov>
To:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>
Subject:	Automatic reply: SVAC-Majority Inquiry for Info re: Esketamine
Date:	2019/06/21 14:21:05
Priority:	Normal
Type:	Note.Rules.OofTemplate.Microsoft

I am currently out of the office and will return on 7/1/2019. If it is an emergency, please call (b) (6) (b) (6)

Sender:	Emmendorfer, Thomas (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC96BB44E7AE2C94C43B55D094-EMMENDORFER (b)(6) @va.gov>
Recipient:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>
Sent Date:	2019/06/21 14:21:03
Delivered Date:	2019/06/21 14:21:05
Message Flags:	Unread

AMERICAN OVERSIGHT

From:	Zacher, Jennifer L. (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9027C425646E4DE8A7D196908016331B-ZACHER, JEN ·(b)(6) @va.gov>
To:	Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M (b)(6) @va.gov>
Subject:	Automatic reply: Successful first dose of esketamine in VHA
Date:	2019/06/18 11:58:23
Priority:	Normal
Type:	Note.Rules.OofTemplate.Microsoft

I will be out of the office 6/18/19-6/20/19 with limited access to emails.

Please call either (b) (6) if you need immediate assistance.

Sender:	Zacher, Jennifer L. (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9027C425646E4DE8A7D196908016331B-ZACHER, JEN ·(b)(6) @va.gov>
Recipient:	Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M (b)(6) @va.gov>
Sent Date:	2019/06/18 11:58:22
Delivered Date:	2019/06/18 11:58:23
Message Flags:	Unread

AMERICAN OVERSIGHT

From:	Oshinski, Renee /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=56925A4F59DF47D19FCCEB5E7C270BC0-OSHINSKI, R (b)(6) @va.gov>
To:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>
Subject:	Automatic reply: Spravato Info
Date:	2019/08/22 13:30:33
Priority:	Normal
Type:	Note.Rules.OofTemplate.Microsoft

Ms Tammy Czarnecki is the Acting DUSHOM. Please contact Annette Field with any questions or concerns.

Sender:	Oshinski, Renee /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=56925A4F59DF47D19FCCEB5E7C270BC0-OSHINSKI, R (b)(6) @va.gov>
Recipient:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>
Sent Date:	2019/08/22 13:30:32
Delivered Date:	2019/08/22 13:30:33
Message Flags:	Unread

AMERICAN OVERSIGHT

From:	Beck, Lucille B. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=845480228A8B43E7A5FEF5716DED04C2-BECK, LUCIL (b)(6) @va.gov>
To:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>
Subject:	Automatic reply: Spravato Info
Date:	2019/08/26 08:22:42
Priority:	Normal
Type:	Note.Rules.OofTemplate.Microsoft

I am out of the office from 8/25-30 with no e-mail access.
Please contact Cassandrwa Law for assistance at (b)(6) (b)(6) @va.gov or Sonya Skinker at (b)(6) (b)(6) @va.gov, for assistance.

Sender:	Beck, Lucille B. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=845480228A8B43E7A5FEF5716DED04C2-BECK, LUCIL (b)(6) @va.gov>
Recipient:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>
Sent Date:	2019/08/26 08:22:41
Delivered Date:	2019/08/26 08:22:42
Message Flags:	Unread

AMERICAN OVERSIGHT

From:	Boyd, Teresa D. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F6886A7D555A43E0BEE23C1E40E1C234-BOYD, TERES (b)(6) @va.gov>
To:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>
Subject:	Automatic reply: Spravato Info
Date:	2019/08/26 08:22:42
Priority:	Normal
Type:	Note.Rules.OofTemplate.Microsoft

I will be on annual leave August 26th-August 30th, returning to the office on September 3rd. I will have very limited connectivity or access to email. Please contact Christine Going, my Executive Assistant at (b)(6) for assistance. Alan Bernstein is the acting Deputy ADUSH for Clinical Operations and will be covering in my absence. Have a great week and restful and safe Labor Day.

Sender:	Boyd, Teresa D. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F6886A7D555A43E0BEE23C1E40E1C234-BOYD, TERES (b)(6) @va.gov>
Recipient:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>
Sent Date:	2019/08/26 08:22:41
Delivered Date:	2019/08/26 08:22:42
Message Flags:	Unread

AMERICAN OVERSIGHT

From:	Howard, Kristi /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B8D0AFC371994181883D8861127791C3-HOWARD, KRI (b)(6) @va.gov>
To:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>
Subject:	Automatic reply: Spravato Info
Date:	2019/08/26 08:22:42
Priority:	Normal
Type:	Note.Rules.OofTemplate.Microsoft

I will be out of the office on travel until Monday, September 9th. If you need assistance, please email VHA USH Meeting Requests at vhaushmeetingrequests@va.gov or call (b)(6) If you need something urgent please contact Jennifer L. Adams.

Have a great day!

Kristi Howard
Mobile: (b)(6)

Sender:	Howard, Kristi /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B8D0AFC371994181883D8861127791C3-HOWARD, KRI (b)(6) @va.gov>
Recipient:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>
Sent Date:	2019/08/26 08:22:41
Delivered Date:	2019/08/26 08:22:42
Message Flags:	Unread

AMERICAN OVERSIGHT

From:	Zacher, Jennifer L. (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9027C425646E4DE8A7D196908016331B-ZACHER, JEN (b)(6) @va.gov>
To:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b)(6) @va.gov>
Subject:	Automatic reply: Spravato A word to the Wise
Date:	2019/06/18 11:35:37
Priority:	Normal
Type:	Note.Rules.OofTemplate.Microsoft

I will be out of the office 6/18/19-6/20/19 with limited access to emails.

Please call either (b)(6) if you need immediate assistance.

Sender:	Zacher, Jennifer L. (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9027C425646E4DE8A7D196908016331B-ZACHER, JEN (b)(6) @va.gov>
Recipient:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>
Sent Date:	2019/06/18 11:35:36
Delivered Date:	2019/06/18 11:35:37
Message Flags:	Unread

AMERICAN OVERSIGHT

From:	Drexler, Karen MD (Atlanta) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9C456A9BF391415BB4BDB9B6F88BDF45-DREXLER, KA (b)(6) @va.gov>
To:	Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da (b)(6) @va.gov>
Subject:	Automatic reply: Spravato 10N memo materials - full packet for final review
Date:	2019/03/15 12:31:38
Priority:	Normal
Type:	Note.Rules.OofTemplate.Microsoft

I am currently out of the office without access to e-mail. For urgent matters, please contact Dr. Jennifer Burden. Thank you!

Sender:	Drexler, Karen MD (Atlanta) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9C456A9BF391415BB4BDB9B6F88BDF45-DREXLER, KA (b)(6) @va.gov>
Recipient:	Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da (b)(6) @va.gov>
Sent Date:	2019/03/15 12:31:38

AMERICAN OVERSIGHT

From:	Wiechers, Ilse /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0C7B1428D9E4233A641F125C5B6FC4F-WIECHERS, I (b)(6) @va.gov>
To:	Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da (b)(6) @va.gov>
Subject:	Automatic reply: SME Needed for Spravato® (esketamine)
Date:	2019/03/18 13:50:35
Priority:	Normal
Type:	Note.Rules.OofTemplate.Microsoft

Hello -

I am out of the office on Monday, March 18th. I will respond to your email upon my return.

Best,
Ilse Wiechers

Sender:	Wiechers, Ilse /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0C7B1428D9E4233A641F125C5B6FC4F-WIECHERS, I <(b)(6) @va.gov>
Recipient:	Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da (b)(6) @va.gov>
Sent Date:	2019/03/18 13:50:34
Delivered Date:	2019/03/18 13:50:35

AMERICAN OVERSIGHT

From:	Pomerantz, Andrew /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=29A9288DF9A34E84BDDFD00CDE79F11B-POMERANTZ, (b)(6) @va.gov>
To:	Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat (b)(6) @va.gov>
Subject:	Automatic reply: Need input on IV ketamine to IN esketamine conversion guidance
Date:	2019/06/10 15:37:54
Priority:	Normal
Type:	Note.Rules.OofTemplate.Microsoft

I will be traveling and in meetings all week. will be on email from time to time. If this is urgent please text my cell (b)(6)

Sender:	Pomerantz, Andrew /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=29A9288DF9A34E84BDDFD00CDE79F11B-POMERANTZ, (b)(6) @va.gov>
Recipient:	Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat (b)(6) @va.gov>
Sent Date:	2019/06/10 15:37:53
Delivered Date:	2019/06/10 15:37:54
Message Flags:	Unread

AMERICAN OVERSIGHT

From:	Dantzler, Anne /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2F5ACD16706148918BA6B1552B149061-DANTZLER, A (b)(6) @va.gov>
To:	Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat (b)(6) @va.gov>
Subject:	Automatic reply: Need input on IV ketamine to IN esketamine conversion guidance
Date:	2019/06/10 15:37:49
Priority:	Normal
Type:	Note.Rules.OofTemplate.Microsoft

I am out of the office from Friday 06/07/2019 as of 4:30 p.m. until my return on Monday 06/17/2019. For questions regarding my inpatients, please call (b)(6) and ask for the covering Prescriber. Please contact Dr. Ma at (b)(6) or Dr. Festin at (b)(6) or send them an email or leave a voicemail for me at (b)(6) if you have questions regarding ECT. Dr. Ma is covering ECT and ketamine referrals in my absence.

Sender:	Dantzler, Anne /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2F5ACD16706148918BA6B1552B149061-DANTZLER, A (b)(6) @va.gov>
Recipient:	Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat (b)(6) @va.gov>
Sent Date:	2019/06/10 15:37:48
Delivered Date:	2019/06/10 15:37:49
Message Flags:	Unread

AMERICAN OVERSIGHT

From:	Glassman, Peter A. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90608D43EF14423DB308FB6C71ED750B-GLASSMAN, P <(b)(6) @va.gov>
To:	Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat <(b)(6) @va.gov>
Subject:	Automatic reply: Nasal spray depression drug may be riskier than first thought
Date:	2019/06/12 09:57:25
Priority:	Normal
Type:	Note.Rules.OofTemplate.Microsoft

Hello. I will be out of the office until Thursday the 13th. Thank you for your patience in getting back to you.

Sender:	Glassman, Peter A. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90608D43EF14423DB308FB6C71ED750B-GLASSMAN, P <(b)(6) @va.gov>
Recipient:	Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat <(b)(6) @va.gov>
Sent Date:	2019/06/12 09:57:24
Delivered Date:	2019/06/12 09:57:25
Message Flags:	Unread

AMERICAN OVERSIGHT

From:	Zacher, Jennifer L. (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9027C425646E4DE8A7D196908016331B-ZACHER, JEN (b)(6) @va.gov>
To:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>
Subject:	Automatic reply: Nasal spray depression drug may be riskier than first thought
Date:	2019/06/11 16:30:35
Priority:	Normal
Type:	Note.Rules.OofTemplate.Microsoft

I will be out of the office 6/11/19-6/12/19 with limited access to emails.

Please call either (b)(6) if you need immediate assistance.

Sender:	Zacher, Jennifer L. (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9027C425646E4DE8A7D196908016331B-ZACHER, JEN (b)(6) @va.gov>
Recipient:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b)(6) @va.gov>
Sent Date:	2019/06/11 16:30:35
Message Flags:	Unread

AMERICAN OVERSIGHT

From:	Zacher, Jennifer L. (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9027C425646E4DE8A7D196908016331B-ZACHER, JEN (b)(6) @va.gov>
To:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>
Subject:	Automatic reply: Initial press re PBM esketamine decisions
Date:	2019/06/21 17:19:35
Priority:	Normal
Type:	Note.Rules.OofTemplate.Microsoft

I will be out of the office 6/24/19 with limited access to emails.

Please call either (b)(6) if you need immediate assistance.

Sender:	Zacher, Jennifer L. (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9027C425646E4DE8A7D196908016331B-ZACHER, JEN (b)(6) @va.gov>
Recipient:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>
Sent Date:	2019/06/21 17:19:34
Delivered Date:	2019/06/21 17:19:35
Message Flags:	Unread

AMERICAN OVERSIGHT

From:	Boyd, Teresa D. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F6886A7D555A43E0BEE23C1E40E1C234-BOYD, TERES (b)(6) @va.gov>
To:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>
Subject:	Automatic reply: Initial press re PBM esketamine decisions
Date:	2019/06/21 17:19:35
Priority:	Normal
Type:	Note.Rules.OofTemplate.Microsoft

I will be off-site for an all-day sequester today, June 21st. I will be back in the office on Monday, June 24th. Please contact my EA, Christine Going, at (b)(6) for any needs and coverage (Alan Bernstein). I will have limited time for email today. Any urgent needs, please text me at (b)(6) (b)(6) Sorry to have missed you and have a good weekend.

Sender:	Boyd, Teresa D. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F6886A7D555A43E0BEE23C1E40E1C234-BOYD, TERES (b)(6) @va.gov>
Recipient:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>
Sent Date:	2019/06/21 17:19:34
Delivered Date:	2019/06/21 17:19:35
Message Flags:	Unread

AMERICAN OVERSIGHT

From:	McGuire, Marsden H. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=29E9D648C29F4885828C10446FDD7379-MCGUIRE, MA (b)(6) @va.gov>
To:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>
Subject:	Automatic reply: Initial press re PBM esketamine decisions
Date:	2019/06/21 17:19:35
Priority:	Normal
Type:	Note.Rules.OofTemplate.Microsoft

I am away from the office on Friday, June 21st and until noon on Monday, June 24th. During this time, I will only be accessing emails intermittently. For any issues requiring immediate attention, please contact the VHA 10NC5 Action Team. Thank you.

Sender:	McGuire, Marsden H. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=29E9D648C29F4885828C10446FDD7379-MCGUIRE, MA (b)(6) @va.gov>
Recipient:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>
Sent Date:	2019/06/21 17:19:34
Delivered Date:	2019/06/21 17:19:35
Message Flags:	Unread

AMERICAN OVERSIGHT

From:	Pomerantz, Andrew /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=29A9288DF9A34E84BDDFD00CDE79F11B-POMERANTZ, (b)(6) @va.gov>
To:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>
Subject:	Automatic reply: Initial press re PBM esketamine decisions
Date:	2019/06/21 17:19:35
Priority:	Normal
Type:	Note.Rules.OofTemplate.Microsoft

I will be traveling and in meetings during the week of June 24-28. if this cannot wait as long as 24 hours please call or text me (b)(6)

Sender:	Pomerantz, Andrew /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=29A9288DF9A34E84BDDFD00CDE79F11B-POMERANTZ, (b)(6) @va.gov>
Recipient:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>
Sent Date:	2019/06/21 17:19:34
Delivered Date:	2019/06/21 17:19:35
Message Flags:	Unread

AMERICAN OVERSIGHT

From:	Cunningham, Fran /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=613F0D8E535D46AF95FED310F100DCBC-CUNNINGHAM, (b)(6) @va.gov>
To:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>
Subject:	Automatic reply: Initial press re PBM esketamine decisions
Date:	2019/06/21 17:19:35
Priority:	Normal
Type:	Note.Rules.OofTemplate.Microsoft

I am currently out of the office and will return Monday, June 24th. For urgent issues please call Nikia Griffith at (b)(6) or Tom Frankowicz at (b)(6)

Sender:	Cunningham, Fran /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=613F0D8E535D46AF95FED310F100DCBC-CUNNINGHAM, (b)(6) @va.gov>
Recipient:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>
Sent Date:	2019/06/21 17:19:34
Delivered Date:	2019/06/21 17:19:35
Message Flags:	Unread

AMERICAN OVERSIGHT

From:	Cunningham, Fran /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=613F0D8E535D46AF95FED310F100DCBC-CUNNINGHAM, (b)(6) @va.gov>
To:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>
Subject:	Automatic reply: HHS bought a nasal spray for depression - DRAFT News Release - REVISED
Date:	2019/03/15 10:31:01
Priority:	Normal
Type:	Note.Rules.OofTemplate.Microsoft

I am currently out of the office and will return Monday, March 18th. For urgent issues please call Nikia Griffith at (b)(6) or Tom Frankowicz at (b)(6)

Sender:	Cunningham, Fran /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=613F0D8E535D46AF95FED310F100DCBC-CUNNINGHAM, (b)(6) @va.gov>
Recipient:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>
Sent Date:	2019/03/15 10:31:00
Delivered Date:	2019/03/15 10:31:01
Message Flags:	Unread

AMERICAN OVERSIGHT

From:	Law, Cassandra M. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F888D507D6C54EB5A92FC44199EB5838-LAW, CASSAN (b)(6) @va.gov>
To:	Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da (b)(6) @va.gov>
Subject:	Automatic reply: HHS bought a nasal spray for depression - DRAFT News Release
Date:	2019/03/12 12:36:56
Priority:	Normal
Type:	Note.Rules.OofTemplate.Microsoft

I am out of the office in training this week. Please contact VHA 10P4 actions for issues related to Patient Care Services. I will be reading email intermittingly and will return to the office Friday, March 15, 2019.

Thank you very much, Cassie

Sender:	Law, Cassandra M. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F888D507D6C54EB5A92FC44199EB5838-LAW, CASSAN (b)(6) @va.gov>
Recipient:	Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da (b)(6) @va.gov>
Sent Date:	2019/03/12 12:36:55
Delivered Date:	2019/03/12 12:36:56

AMERICAN OVERSIGHT

From:	Boyd, Teresa D. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F6886A7D555A43E0BEE23C1E40E1C234-BOYD, TERES (b)(6) @va.gov>
To:	Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da (b)(6) @va.gov>
Subject:	Automatic reply: HHS bought a nasal spray for depression - DRAFT News Release
Date:	2019/03/12 10:56:35
Priority:	Normal
Type:	Note.Rules.OofTemplate.Microsoft

I will be out of the office on travel Tuesday and Wednesday, March 12-13th - returning to the office on the 14th. Dr. Chris Saslo, Acting Deputy ADUSH for Clinical Operations, will be covering in my absence. He may be reached at (b)(6) or through Shamika Johnson at 10NC. I will have limited access to email during the day. Sorry to have missed you and look forward to catching up.

Sender:	Boyd, Teresa D. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F6886A7D555A43E0BEE23C1E40E1C234-BOYD, TERES (b)(6) @va.gov>
Recipient:	Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da (b)(6) @va.gov>
Sent Date:	2019/03/12 10:56:34
Delivered Date:	2019/03/12 10:56:35

AMERICAN OVERSIGHT

From:	Valentino, Michael (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO, (b)(6) @va.gov>
To:	Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da (b)(6) @va.gov>
Subject:	Automatic reply: HHS bought a nasal spray for depression - DRAFT News Release
Date:	2019/03/12 12:36:57
Priority:	Normal
Type:	Note.Rules.OofTemplate.Microsoft

I am currently away from the office and will return on Monday, March 18, 2019. If you need immediate assistance please contact one of the following PBM staff:

Tom Emmendorfer at (b)(6) @va.gov and (b)(6) for VA Central Office PBM issues,
Jennifer Zacher at (b)(6) @va.gov and (b)(6) for Drug Formulary issues;
Mario Franchi at (b)(6) @va.gov and (b)(6) for CMOP and Emergency Pharmacy issues;
Ron Nosek at (b)(6) @va.gov and (b)(6) for Meds-by-Mail issues;
Ginny Torrise at (b)(6) @va.gov and (b)(6) for Clinical Pharmacy issues;
Lynn Sanders at (b)(6) @va.gov and (b)(6) for Pharmacy Re-Engineering and Clinical Informatics Issues; and
Christa Stoiber at (b)(6) @va.gov and (b)(6) for Administrative issues.

You may also send an e-mail to "pbm.consultants@med.va.gov" to reach the entire group. MV

Sender:	Valentino, Michael (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO, (b)(6) @va.gov>
Recipient:	Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da (b)(6) @va.gov>
Sent Date:	2019/03/12 12:36:56
Delivered Date:	2019/03/12 12:36:57

AMERICAN OVERSIGHT

From:	Law, Cassandra M. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F888D507D6C54EB5A92FC44199EB5838-LAW, CASSAN (b)(6) @va.gov>
To:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>
Subject:	Automatic reply: HHS bought a nasal spray for depression
Date:	2019/03/08 11:02:28
Priority:	Normal
Type:	Note.Rules.OofTemplate.Microsoft

I am currently out of the office and am sorry to have missed you. Please contact Dr. Jane Kim or Ms. Chantelle Bartch for issues related to Patient Care Services or 10P4 Actions for email assistance. I will return to the office on Monday, March 11, 2019.

Thank you very much, Cassie

Sender:	Law, Cassandra M. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F888D507D6C54EB5A92FC44199EB5838-LAW, CASSAN (b)(6) @va.gov>
Recipient:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>
Sent Date:	2019/03/08 11:02:28
Message Flags:	Unread

AMERICAN OVERSIGHT

From:	Pomerantz, Andrew /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=29A9288DF9A34E84BDDFD00CDE79F11B-POMERANTZ, (b)(6) @va.gov>
To:	Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat (b)(6) @va.gov>
Subject:	Automatic reply: HHS bought a nasal spray for depression
Date:	2019/03/07 16:09:09
Priority:	Normal
Type:	Note.Rules.OofTemplate.Microsoft

I will be in meeting all day Thursday. Back in office the afternoon of Friday, March 8. If this cannot wait as long as 24 hours, leave a message on my cell 802-280-5681

Sender:	Pomerantz, Andrew /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=29A9288DF9A34E84BDDFD00CDE79F11B-POMERANTZ, (b)(6) @va.gov>
Recipient:	Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat (b)(6) @va.gov>
Sent Date:	2019/03/07 16:09:08
Delivered Date:	2019/03/07 16:09:09
Message Flags:	Unread

AMERICAN OVERSIGHT

From:	Zacher, Jennifer L. (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9027C425646E4DE8A7D196908016331B-ZACHER, JEN (b)(6) @va.gov>
To:	Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M (b)(6) @va.gov>
Subject:	Automatic reply: HHS bought a nasal spray for depression
Date:	2019/03/06 23:03:10
Priority:	Normal
Type:	Note.Rules.OofTemplate.Microsoft

I will be on VA travel from 2/25-3/1/19, 3/4-3/7/19, and 3/11-3/15/19 with only intermittent access to email during those times. I will only be responding to urgent emails while on travel.

Please call either (b)(6) if you need immediate assistance that cannot wait until I return to the office on 3/18/19.

Sender:	Zacher, Jennifer L. (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9027C425646E4DE8A7D196908016331B-ZACHER, JEN (b)(6) @va.gov>
Recipient:	Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M (b)(6) @va.gov>
Sent Date:	2019/03/06 23:03:08
Delivered Date:	2019/03/06 23:03:10
Message Flags:	Unread

AMERICAN OVERSIGHT

From:	Zacher, Jennifer L. (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9027C425646E4DE8A7D196908016331B-ZACHER, JEN (b)(6) @va.gov>
To:	Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da (b)(6) @va.gov>
Subject:	Automatic reply: HHS bought a nasal spray for depression
Date:	2019/03/07 09:38:49
Priority:	Normal
Type:	Note.Rules.OofTemplate.Microsoft

I will be on VA travel from 2/25-3/1/19, 3/4-3/7/19, and 3/11-3/15/19 with only intermittent access to email during those times. I will only be responding to urgent emails while on travel.

Please call either (b)(6) if you need immediate assistance that cannot wait until I return to the office on 3/18/19.

Sender:	Zacher, Jennifer L. (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9027C425646E4DE8A7D196908016331B-ZACHER, JEN (b)(6) @va.gov>
Recipient:	Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da (b)(6) @va.gov>
Sent Date:	2019/03/07 09:38:48
Delivered Date:	2019/03/07 09:38:49

AMERICAN OVERSIGHT

From:	Zacher, Jennifer L. (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9027C425646E4DE8A7D196908016331B-ZACHER, JEN (b)(6) @va.gov>
To:	Jensen, Jon M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddeb735ace76400db5c3f10603188a14-Jensen, Jon (b)(6) @va.gov>
Subject:	Automatic reply: HHS bought a nasal spray for depression
Date:	2019/03/06 19:34:41
Priority:	Normal
Type:	Note.Rules.OofTemplate.Microsoft

I will be on VA travel from 2/25-3/1/19, 3/4-3/7/19, and 3/11-3/15/19 with only intermittent access to email during those times. I will only be responding to urgent emails while on travel.

Please call either (b)(6) if you need immediate assistance that cannot wait until I return to the office on 3/18/19.

Sender:	Zacher, Jennifer L. (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9027C425646E4DE8A7D196908016331B-ZACHER, JEN (b)(6) @va.gov>
Recipient:	Jensen, Jon M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddeb735ace76400db5c3f10603188a14-Jensen, Jon (b)(6) @va.gov>
Sent Date:	2019/03/06 19:34:40
Delivered Date:	2019/03/06 19:34:41

AMERICAN OVERSIGHT

From:	Valentino, Michael (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO, (b)(6) @va.gov>
To:	Jensen, Jon M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddeb735ace76400db5c3f10603188a14-Jensen, Jon (b)(6) @va.gov>
Subject:	Automatic reply: HHS bought a nasal spray for depression
Date:	2019/03/06 17:40:52
Priority:	Normal
Type:	Note.Rules.OofTemplate.Microsoft

I am currently away from the office and will return on Monday, March 11, 2019. If you need immediate assistance please contact one of the following PBM staff:

Tom Emmendorfer at (b)(6) @va.gov and (b)(6) for VA Central Office PBM issues,
Jennifer Zacher at (b)(6) @va.gov and (b)(6) for Drug Formulary issues;
Mario Franchi at (b)(6) @va.gov and (b)(6) for CMOP and Emergency Pharmacy issues;
Ron Nosek at (b)(6) @va.gov and (b)(6) for Meds-by-Mail issues;
Ginny Torrise at (b)(6) @va.gov and (b)(6) for Clinical Pharmacy issues;
Lynn Sanders at (b)(6) @va.gov and 202-266-4631 for Pharmacy Re-Engineering and Clinical Informatics Issues; and
Christa Stoiber at Christa.Stoiber@va.gov and (b)(6) for Administrative issues.

You may also send an e-mail to "pbm.consultants@med.va.gov" to reach the entire group. MV

Sender:	Valentino, Michael (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO, (b)(6) @va.gov>
Recipient:	Jensen, Jon M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddeb735ace76400db5c3f10603188a14-Jensen, Jon (b)(6) @va.gov>
Sent Date:	2019/03/06 17:40:52

AMERICAN OVERSIGHT

From:	Carroll, David (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=95E14EBD3B6745C8952A823B04DABFF5-CARROLL, DA (b)(6) @va.gov>
To:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>
Subject:	Automatic reply: esketamine updates for week of June 3rd
Date:	2019/06/10 08:05:40
Priority:	Normal
Type:	Note.Rules.OofTemplate.Microsoft

I am away from the office until Wednesday 6/12/19. Please contact VHA10NC5Action@va.gov with any urgent concerns.

Sender:	Carroll, David (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=95E14EBD3B6745C8952A823B04DABFF5-CARROLL, DA (b)(6) @va.gov>
Recipient:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>
Sent Date:	2019/06/10 08:05:39
Delivered Date:	2019/06/10 08:05:40
Message Flags:	Unread

AMERICAN OVERSIGHT

From:	Fuller, Matthew A. (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=62D9CBB23B184CACB98895776E36A471-FULLER, MAT (b)(6) @va.gov>
To:	Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M (b)(6) @va.gov>
Subject:	Automatic reply: esketamine updates
Date:	2019/06/20 14:26:38
Priority:	Normal
Type:	Note.Rules.OofTemplate.Microsoft

I am currently out of the office. I will return to the office on Friday June 21st. If urgent attention is needed please leave me a message at (b)(6)

Sender:	Fuller, Matthew A. (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=62D9CBB23B184CACB98895776E36A471-FULLER, MAT (b)(6) @va.gov>
Recipient:	Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M (b)(6) @va.gov>
Sent Date:	2019/06/20 14:26:36
Delivered Date:	2019/06/20 14:26:38
Message Flags:	Unread

AMERICAN OVERSIGHT

From:	Emmendorfer, Thomas (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC96BB44E7AE2C94C43B55D094-EMMENDORFER (b)(6) @va.gov>
To:	Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M (b)(6) @va.gov>
Subject:	Automatic reply: esketamine updates
Date:	2019/06/20 14:26:37
Priority:	Normal
Type:	Note.Rules.OofTemplate.Microsoft

I am currently out of the office and will return on 6/20/2019. If it is an emergency, please call (b)(6) (b)(6)

Sender:	Emmendorfer, Thomas (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC96BB44E7AE2C94C43B55D094-EMMENDORFER (b)(6) @va.gov>
Recipient:	Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M (b)(6) @va.gov>
Sent Date:	2019/06/20 14:26:36
Delivered Date:	2019/06/20 14:26:37
Message Flags:	Unread

AMERICAN OVERSIGHT

From:	Zacher, Jennifer L. (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9027C425646E4DE8A7D196908016331B-ZACHER, JEN (b)(6) @va.gov>
To:	Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat (b)(6) @va.gov>
Subject:	Automatic reply: esketamine question
Date:	2019/03/25 11:30:02
Priority:	Normal
Type:	Note.Rules.OofTemplate.Microsoft

(b)(6)

Please call either (b)(6) if you need immediate assistance.

Sender:	Zacher, Jennifer L. (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9027C425646E4DE8A7D196908016331B-ZACHER, JEN (b)(6) @va.gov>
Recipient:	Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat (b)(6) @va.gov>
Sent Date:	2019/03/25 11:30:02
Message Flags:	Unread

AMERICAN OVERSIGHT

From:	Zacher, Jennifer L. (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9027C425646E4DE8A7D196908016331B-ZACHER, JEN (b)(6) @va.gov>
To:	Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat (b)(6) @va.gov>
Subject:	Automatic reply: Esketamine Community of Practice call tomorrow @ 2 pm ET
Date:	2019/06/12 08:48:02
Priority:	Normal
Type:	Note.Rules.OofTemplate.Microsoft

I will be out of the office 6/11/19-6/12/19 with limited access to emails.

Please call either (b)(6) if you need immediate assistance.

Sender:	Zacher, Jennifer L. (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9027C425646E4DE8A7D196908016331B-ZACHER, JEN (b)(6) @va.gov>
Recipient:	Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat (b)(6) @va.gov>
Sent Date:	2019/06/12 08:48:01
Delivered Date:	2019/06/12 08:48:02
Message Flags:	Unread

AMERICAN OVERSIGHT

Department of Veterans Affairs

Consent for Clinical Treatment/Procedure

A. IDENTIFICATION

1. Patient name, Social Security Number and Date of Birth:

Name: Last, First, Middle	Social Security Number	Date of Birth

2. Decision-making capacity:

☐ The patient HAS decision-making capacity (skip to item 3).

☐ The patient DOES NOT HAVE decision-making capacity. Enter surrogate name and relationship to the patient. (If the patient's surrogate is not established or available, refer to Handbook 1004.1 for guidance.)

Name: Last, First, Middle	Relationship

3. Name of the treatment(s)/procedure(s):

patient-administered intranasal esketamine

4. Part of the body on which the treatment/procedure will be performed: (Correct site includes the correct side [i.e., left or right] and the precise anatomical part, such as a specific finger. DO NOT ABBREVIATE.)

nostrils

5. Practitioner obtaining consent:

Name: Last, First, Middle

6. Supervising practitioner: (if applicable)

Name: Last, First, Middle

7. Additional practitioner(s) performing or supervising the treatment/procedure: (if not listed above)

B. INFORMATION ABOUT THE TREATMENT/PROCEDURE

8. Reason for the treatment/procedure (diagnosis, condition, or indication):

treatment-resistant major depressive disorder

9. Brief description of the treatment/procedure:

You will take esketamine nasal spray yourself, under the supervision of a healthcare provider in a healthcare setting. Your healthcare provider will give you full instructions on use of the device. You will place the device in a nostril and press the plunger while breathing in through the nose. You will rest in a semi-reclined position for 5 minutes, then repeat based on dose. You will remain in the healthcare setting for 2 hours of monitoring.

10. Potential benefits of the treatment/procedure:

Possible benefits of esketamine may include: •Improved symptoms of depression •Less anxiety •Better quality of sleep •Reduced negative thoughts •Reduction or elimination of suicidal thoughts and urges

11. Known risks and side effects of the treatment/procedure: (Include potential problems related to recuperation.)

•Sleepiness(sedation)•fainting•feeling disconnected from yourself, your thoughts, feelings, space & time(dissociation)•dizziness•nausea/vomiting•spinning sensation•anxiety•blood pressure increase•feeling drunk•lack of energy•numbness•risk for abuse and physical and psychological dependence or addiction•bladder problems•problems thinking clearly•increased risk of suicidal thoughts or actions•full list available (see SPRAVATO Prescribing Information)

AMERICAN OVERSIGHT

12. Alternatives to the treatment/procedure:

•Continued treatment with other antidepressants or combinations of medications •Electroconvulsive Therapy •Transcranial Magnetic Stimulation •Admission to the hospital for psychiatric treatment (These alternatives are not direct substitutes for esketamine treatment and require additional criteria to be utilized)

13. Anesthesia / Moderate Sedation (CHECK ONE):

☒ Neither anesthesia nor moderate sedation will be used in this treatment/procedure.

☐ **Moderate sedation will be used**. Medications will be administered to decrease anxiety and discomfort during the treatment/procedure. These medications will be administered by a qualified practitioner. Patient response to some of these medications varies. Patients are expected to remain aware and responsive during the treatment or procedure. Minor risks of moderate sedation include temporary amnesia or forgetfulness and drowsiness. Moderate sedation can interfere with your ability to drive, operate machinery, or make important decisions for up to 24 hours. Medications used for moderate sedation can cause allergic reactions, respiratory depression (this is when your breathing slows down and may stop), low blood pressure, and a slow or irregular heart beat. In rare instances these complications can cause death. Tell your health care team if you do not want to receive moderate sedation.

☐ **Anesthesia will be administered.** A member of the anesthesia care team will visit you before your treatment to discuss the type(s) of anesthesia you may need and to give you more information about anesthesia. It may become necessary to alter your anesthesia care plan after this discussion. Devices may be applied to your body and placed in your veins and arteries to monitor you during your anesthesia. All forms of anesthesia involve some risk. Minor (not life-threatening) risks include: nausea, vomiting, and pain where an injection is given. Although rare, severe complications include: injury to blood vessels, drug reactions, bleeding, blood clots, loss of sensation or limb function, infection, paralysis, stroke, brain damage, heart attack, and death.

Here is a basic description of the major types of anesthesia including their risks in addition to those described above:

General anesthesia involves drugs that are injected into the bloodstream or breathed into the lungs. A tube or other device may be inserted into your airway to help you breathe. The expected benefit is that you will be totally unconscious and you will not feel pain during the procedure. Additional risks include: injury to the teeth, throat, eyes, or lung. In less than one case in a thousand, patients may be aware of activities during their surgery.

Spinal or epidural analgesia/anesthesia involves a drug being injected through a needle or catheter placed into the spinal canal. The expected benefit is a temporary decreased feeling in the area of surgical incision, allowing surgery to proceed without pain. Additional risks include: headache, backache, convulsions, persistent weakness and or numbness, abnormal heart rhythms, and incomplete pain relief during the operation that may require general anesthesia.

Major/minor nerve block involves a drug being injected near nerves providing loss or reduction of sensation and movement to the area. The expected benefit is a temporary loss of feeling and/or movement of a specific limb or area of your body. Additional risks include: convulsions, persistent weakness and or numbness, and incomplete pain relief during the operation that may require general anesthesia.

Monitored anesthesia care involves monitoring of the heart and lungs to make sure that they are functioning adequately during your procedure. A local anesthetic will be injected to prevent pain, and the anesthesia care provider may use drugs to help you relax, and lessen any pain. You may remain conscious throughout your procedure, or you may be given medications that will make you unconscious. The expected benefit is that you will be comfortable during your operation with a minimum amount of anesthesia. This may result in a shorter stay in the hospital. Additional risks include: incomplete pain relief during the operation that may require additional anesthesia. Convulsions from the injected drug are a rare but serious complication.

14. Blood products (CHECK ONE)

☒ It is not expected that blood products will be used in this treatment/procedure.

It is anticipated that blood products may be needed in this treatment/procedure and:

☐ I CONSENT to the use of blood products during this treatment/procedure if they are needed to improve my overall condition or save my life. I understand that my consent for use of blood products is valid during the treatment/procedure and during the recovery period after the treatment/procedure. My provider will determine when this recovery period ends. I will be asked again for my consent for use of blood products if this consent form expires, my treatment plan changes, or if blood products are needed for a reason that is unrelated to this treatment/procedure. I understand that common risks of using blood products include (but are not limited to) infection or irritation where the needle is placed, fever, chills, and skin rashes. Other rare but more serious complications may occur such as allergic reactions, heart failure due to fluid overload, acute pulmonary edema (fluid leaking into the lungs), shock, or death. I also understand that transfusions of blood or blood products involve a small risk of transmission of diseases such as Hepatitis B (1 in 137,000), Hepatitis C (1 in 1,000,000), and HIV/AIDS (1 in 1,900,000). There is also a small risk of bacterial infection when blood products are transfused. Alternatives to blood or blood products may be available if my health, time, and procedure permit. These alternatives may include auto-donation (using my own previously donated blood) and intra-operative salvage (my own blood collected during surgery). In addition, medications may be used to reduce the need for blood products. (Please note exceptions to consent in the “Comments” section of the consent form.)

☐ I DO NOT CONSENT to the use of blood products and I do not wish them to be used even if it is determined that they are needed to improve my overall condition or save my life. Alternatives to blood or blood products may be available if my health, time, and procedure permit. These alternatives may include auto-donation (using my own previously donated blood) and intra-operative salvage (my own blood collected during surgery). In addition, medications may be used to reduce the need for blood products.

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15. Additional information

VA hospitals are teaching facilities, and trainees may participate in or observe this treatment/procedure. In certain circumstances, the presence of a vendor representative (company representative) is important to the success of the procedure. Prior to the procedure the representative will sign an agreement to strictly adhere to VA's privacy rules. The representative may provide technical advice but will not physically participate in the procedure. The representative will be closely monitored by the VA treatment team.

16. Comments

I understand: 1)I should make arrangements to safely leave the healthcare setting and get home 2) I should not drive or use heavy machinery for the rest of the day on which I receive SPRAVATO 3) I should contact my doctor if I believe I have a side effect or reaction

C. SIGNATURES

Practitioner obtaining consent:

- All relevant aspects of the treatment/procedure and its alternatives (including no treatment) have been discussed with the patient **(or surrogate) in language that s/he could understand. This discussion included the nature, indications, benefits, risks, side effects, and likelihood of success of each alternative.**
- The patient (or surrogate) demonstrated comprehension of the discussion.
- I have given the patient (or surrogate) an opportunity to ask questions.
- I did not use threats, inducements, misleading information, or make any attempt to coerce the patient/surrogate to consent to this **treatment/procedure.**
- I have offered the patient (or surrogate) the opportunity to review a printed copy of the consent form.

Signature _____ Date and Time _____

Patient or surrogate:

- Someone has explained this treatment/procedure and what it is for.
- Someone has explained how this treatment could help me and things that could go wrong.
- Someone has told me about other treatments/procedures that might be done instead, and what would happen if I have no **treatment.**
- Someone has answered all my questions.
- I know that I may refuse or change my mind about having this treatment/procedure. If I do refuse or change my mind, I will not **lose my health care or any other VA benefits.**
- I have been offered the opportunity to read the consent form.
- I choose to have this treatment/procedure.

Signature _____ Date and Time _____

Witnesses: No witness is required if the patient or surrogate signs their name. Two witnesses are required only when the patient's signature is indicated with an "X" or some other identifying mark.

Witness name (please print) _____

Signature _____ Date and Time _____

Witness name (please print) _____

Signature _____ Date and Time _____

AMERICAN LEGALNET

Attachment B

Spravato® Risk Evaluation and Mitigation Strategy (REMS) Healthcare Setting Certification Guidance

- The Spravato® REMS can be accessed at www.SPRAVATOrems.com.

- The goal of the REMS is to mitigate the risks of serious adverse outcomes resulting from sedation and dissociation caused by Spravato® administration, and abuse and misuse of Spravato® by:
    - Ensuring that Spravato® is only dispensed and administered to patients in a medically supervised healthcare setting that monitors these patients
    - Ensuring pharmacies and healthcare settings that dispense Spravato® are certified
    - Ensuring that each patient is informed about the serious adverse outcomes resulting from sedation and dissociation and need for monitoring
    - Enrollment of all patients in the REMs (registry) to further characterize the risks and support safe use
    - The Spravato® REMS Fact Sheet developed by the manufacturer is available at: https://www.spravatorems.com/pdfs/SPRAVATO(TM)_REMS_Fact_Sheet.pdf

- Guidance on Spravato® REMS Pharmacy certification will be distributed by Pharmacy Benefits Management (PBM) Services by established communication pathways for all FDA approved REMS.

- Each VAMC should designate the Mental Health Service Line Chief or the Chief of Psychiatry as the Authorized Representative for the Healthcare Setting certification.

- The Authorized Representative should review forms and materials available on the Spravato® REMS webpage listed above, and then complete and submit the Spravato® REMS Healthcare Setting Enrollment Form to the REMS as per instructions provided on the form (https://www.spravatorems.com/pdfs/SPRAVATO(TM)_REMS_Healthcare_Setting_Enrollment_Form.pdf).

- For the question: “Does your healthcare setting intend to purchase Spravato® from a specialty distributor (i.e., buy and bill)?” please respond NO.

- Prior to a VA provider ordering the medication, all patients must be enrolled in the Spravato® REMS (https://www.spravatorems.com/pdfs/SPRAVATO(TM)_REMS_Patient_Enrollment_Form.pdf)

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- All patients must be counseled on the need for REMS enrollment, monitoring, and risks of sedation and dissociation, abuse and misuse, and changes in vital signs prior to receiving Spravato®. Please see Attachment C for guidance language for use in providing informed consent for patients prescribed Spravato®. A signed copy of this document should be scanned into a patient's medical record until iMed consent processes become available.

- A Patient Monitoring Form must be submitted to the Spravato® REMS for every patient within 7 calendar days following administration of every dose https://www.spravatorems.com/pdfs/SPRAVATO(TM)_REMS_Patient_Monitoring_Form.pdf .

- Further guidance beyond the information above and what is currently provided by the Spravato® REMS website on clinical processes and procedures for dispensing and administration of Spravato® will be forthcoming from OMHSP and PBM.

AMERICAN OVERSIGHT

Spravato® (Esketamine) Nasal Spray
Frequently Asked Questions
March 14, 2019
VA Pharmacy Benefits Management Services and Office of Mental Health and Suicide Prevention

1. Spravato® (eskatamine) nasal spray was approved by the Food and Drug Administration (FDA) on March 5, 2019, to be used in conjunction with an oral antidepressant for the treatment of depression in adults who have tried other antidepressants medicines but have not benefited from them. Is Spravato® commercially available for healthcare systems to purchase?

   ANSWER: No. Spravato® is not commercially available for healthcare systems to purchase at this time. The manufacturer estimates Spravato® will be available for healthcare systems to purchase in mid to late March 2019.

2. Since Spravato® is a nasal spray, will VA providers be able to prescribe outpatient prescriptions for VA pharmacies to dispense to the Veterans?

   ANSWER: No. Because of the risk of serious adverse outcomes resulting from possible sedation and/or dissociation caused by Spravato® administration, and the potential for abuse and misuse of the drug, it is only available through a restricted distribution system, under an FDA approved Risk Evaluation and Mitigation Strategy (REMS).

3. What are the requirements for the Spravato® FDA approved REMS?

   ANSWER:
   - Spravato® is available only through a limited distribution program that is part of the Spravato® REMS.
   - All healthcare settings and pharmacies are required to enroll in the Spravato® REMS via a designated authorized representative before they can purchase product from a distributor, dispense, or supervise administration of Spravato®.
   - All patients must be enrolled in the Spravato® REMS before they can receive Spravato®

   The Spravato® REMS Fact Sheet developed by the manufacturer is available at:
   https://www.spravatorems.com/pdfs/SPRAVATO(TM)_REMS_Fact_Sheet.pdf

4. Will Spravato® be available for VA providers to prescribe in accordance with the FDA approved REMS program when it is commercially available?

   ANSWER: Yes.

5. Has Spravato® be added to VA's National Formulary?

   ANSWER: The Spravato® formulary review will be on the May 2019 National Formulary Committee agenda. Prior to the National Formulary Committee review, VA providers will be able to prescribe Spravato® based on their clinical assessment and the individual medical needs of the Veteran.

AMERICAN OVERSIGHT

VA-19-1109-B-002384

6. Is Spravato® a controlled substance?

   ANSWER: Yes. It is a Schedule III Controlled Substance.

7. Does my VA medical facility need to take any actions to enroll into the FDA approved REMS program at this time?

   ANSWER: No. Not at this time. VA Pharmacy Benefits Management (PBM) Services is working closely with the manufacturer of Spravato®. Once the manufacturer operationalizes the REMS requirements for Spravato®, PBM will collaborate with the Office of Mental Health and Suicide Prevention (OMHSP) to disseminate the information to VA medical facilities. PBM and OMHSP will provide a status update by March 18, 2019.

8. After Spravato® is administered to the patient in a medically supervised healthcare setting, what does the patient need to be monitored for?

   ANSWER: At a minimum, patients will need to be monitored with the elements of the Spravato® REMS Patient Monitoring form that is available at www.SPRAVATOrems.com. Spravato® chemical name is esketamine which is an S (+) enantiomer of ketamine and provides similar therapeutic effects to ketamine. VA PBM developed a national protocol for the use of intravenous ketamine in treatment resistant depression and severe suicidal ideation which was published in December 2017. (Ketamine Infusion for Treatment Resistant Depression). The national protocol for intravenous ketamine is consistent with the VA PBM Guidance on Off Label Prescribing of drugs that was published in August 2013 and can be accessed at: (Guidance on Off Label Prescribing).

9. What actions can VA medical facilities take now to prepare to become a certified healthcare setting?

   ANSWER: OMHSP and PBM recommend VA medical facilities review the Spravato® REMS forms available at www.SPRAVATOrems.com and the VA PBM national protocol for the use of intravenous ketamine in treatment resistant depression and severe suicidal ideation Ketamine Infusion for Treatment Resistant Depression) to ensure each VA medical facility has the necessary space and equipment to monitor after the Spravato® dose is administrated to the Veterans.

10. Do providers need to have special privileging to prescribe Spravato®?

    ANSWER: No

11. Does Spravato® require a signed informed consent?

    ANSWER: Yes. An update will be provided by OMHSP by March 18, 2019.

AMERICAN OVERSIGHT

Spravato® (Esketamine) Nasal Spray
Frequently Asked Questions
March 14, 2019
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   - All patients must be enrolled in the Spravato® REMS before they can receive Spravato®.

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   https://www.spravatorems.com/pdfs/SPRAVATO(TM)_REMS_Fact_Sheet.pdf

4. Will Spravato® be available for VA providers to prescribe in accordance with the FDA approved REMS program when it is commercially available?

   ANSWER: Yes.

5. Has Spravato® been added to VA's National Formulary?

   ANSWER: The Spravato® formulary review will be on the May 2019 National Formulary Committee agenda. Prior to the National Formulary Committee review, VA providers will be able to prescribe Spravato® based on their clinical assessment and the individual medical needs of the Veteran.

AMERICAN OVERSIGHT

VA-19-1109-B-002386

6. Is Spravato® a controlled substance?

   ANSWER: Yes. It is a Schedule III Controlled Substance.

7. Does my VA medical facility need to take any actions to enroll into the FDA approved REMS program at this time?

   ANSWER: No. Not at this time. VA Pharmacy Benefits Management (PBM) Services is working closely with the manufacturer of Spravato®. Once the manufacturer operationalizes the REMS requirements for Spravato®, PBM will collaborate with the Office of Mental Health and Suicide Prevention (OMHSP) to disseminate the information to VA medical facilities. PBM and OMHSP will provide a status update by March 18, 2019.

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10. Do providers need to have special privileging to prescribe Spravato®?

    ANSWER: No

11. Does Spravato® require a signed informed consent?

    ANSWER: Yes. An update will be provided by OMHSP by March 18, 2019.

AMERICAN OVERSIGHT

From:	Christopher, Melissa L (VHASDC) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A542DAAD1277489FB77C0B3D08454521-CHRISTOPHER (b)(6) @va.gov>
To:	Grana, Andrea /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1a8a304ae1514d6189c1a802b232fb7f-Phillips, A (b)(6) @va.gov>
CC:	Wells, Daina L. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2256099a3577421182c5516b56f40815-Wells, Dain (b)(6) @va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen (b)(6) @va.gov>; Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat (b)(6) @va.gov>
Subject:	Accreditation of Esketamine Enduring Material to Support TRD updates
Date:	2019/06/26 14:07:44
Priority:	Normal
Type:	Note

Andrea,
Given your training experience in June with EES, I am wondering if we may have an opportunity to produce in concert with other PBM colleagues enduring materials for training on Esketamine in TMS. We are exploring options for this and I'd like to leverage your skill workshop information from EES to figure out how we may want to proceed to support efforts on education on this topic. Would you be able to set up a time to share more details on process and work effort it will take to develop various types of CE topics we do as a program office with myself and other program mangers on our team. I'd like to get a better understanding of our options before we offer a specific partnership opportunity with others working on this topic.

Melissa L.D. Christopher, PharmD

Associate Chief Consultant, Pharmacy Benefits Management Service
National Director, VA PBM Academic Detailing Service
Phone: (b)(6) San Diego CA
Email: (b)(6) @va.gov
ADS Inquiry and Request Portal
Academic Detailing Sharepoint Site
VA Academic Detailing Service Public Website
Academic Detailing Service Email Group: PharmacyAcademicDetailingProgram@va.gov

Suicide Prevention is Everyone's Business. #BeThere.
If you, or someone you know are in crisis, please call the National Suicide Prevention Lifeline at 1-800-273-TALK (8255) or contact the Crisis Text Line by texting TALK to 741741.

AMERICAN OVERSIGHT

Veterans in crisis, or their friends or family, can call the Veterans Crisis Line for confidential support 24 hours a day, seven days a week, 365 days a year at 1-800-273-8255 **and Press 1**, chat online at VeteransCrisisLine.net/Chat, or text to **838255**.

The information transmitted is intended only for the person or entity to which it is addressed and may contain confidential and/or privileged material. Any review, retransmission, dissemination or other use of, or taking of any action in reliance upon this information by persons or entities other than the intended recipient is prohibited. If you received this in error, please contact the sender and delete the material from computer.

Sender:	Christopher, Melissa L (VHASDC) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A542DAAD1277489FB77C0B3D08454521-CHRISTOPHER (b)(6) @va.gov>
Recipient:	Grana, Andrea /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1a8a304ae1514d6189c1a802b232fb7f-Phillips, A (b)(6) @va.gov>; Wells, Daina L. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2256099a3577421182c5516b56f40815-Wells, Dain (b)(6) @va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen (b)(6) @va.gov>; Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat (b)(6) @va.gov>
Sent Date:	2019/06/26 14:07:44

AMERICAN OVERSIGHT

From:	Llorente, Maria D. </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F5C91F577D894BD9A0F09305DB34DD4F-LLORENTE, M>
To:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer *(b)(6)* @va.gov>
Subject:	Accepted: Spravato FAQ
Date:	2019/03/12 12:16:38
Start Date:	2019/03/12 15:00:00
End Date:	2019/03/12 16:00:00
Priority:	Normal
Type:	Schedule.Meeting.Resp.Pos
Location:	Skype Meeting

Sender:	Llorente, Maria D. </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F5C91F577D894BD9A0F09305DB34DD4F-LLORENTE, M>
Recipient:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer *(b)(6)* @va.gov>
Sent Date:	2019/03/12 12:16:37
Delivered Date:	2019/03/12 12:16:38

AMERICAN OVERSIGHT

From:	Llorente, Maria D. </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F5C91F577D894BD9A0F09305DB34DD4F-LLORENTE, M>
To:	Emmendorfer, Thomas (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC96BB44E7AE2C94C43B55D094-EMMENDORFER (b)(6) @va.gov>
Subject:	Accepted: Spravato FAQ
Date:	2019/03/12 12:16:35
Start Date:	2019/03/12 15:00:00
End Date:	2019/03/12 16:00:00
Priority:	Normal
Type:	Schedule.Meeting.Resp.Pos.SilentResponse
Location:	Skype Meeting

Sender:	Llorente, Maria D. </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F5C91F577D894BD9A0F09305DB34DD4F-LLORENTE, M>
Recipient:	Emmendorfer, Thomas (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC96BB44E7AE2C94C43B55D094-EMMENDORFER (b)(6) @va.gov>
Sent Date:	2019/03/12 12:16:35

AMERICAN OVERSIGHT

From:	Wiechers, Ilse /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0C7B1428D9E4233A641F125C5B6FC4F-WIECHERS, I (b)(6) @va.gov>
To:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>
Subject:	Accepted: Spravato FAQ
Date:	2019/03/12 10:57:14
Start Date:	2019/03/12 15:00:00
End Date:	2019/03/12 16:00:00
Priority:	Normal
Type:	Schedule.Meeting.Resp.Pos
Location:	Skype Meeting

Sender:	Wiechers, Ilse /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0C7B1428D9E4233A641F125C5B6FC4F-WIECHERS, I (b)(6) @va.gov>
Recipient:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>
Sent Date:	2019/03/12 10:57:12
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AMERICAN OVERSIGHT

From:	Llorente, Maria D. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F5C91F577D894BD9A0F09305DB34DD4F-LLORENTE, M (b)(6) @va.gov>
SentVia:	Beasley, Mary (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=36A878CF4A524E6FA76340749E3DE6D2-BEASLEY, MA (b)(6) @va.gov>
To:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>
Subject:	Accepted: Spravato FAQ
Date:	2019/03/12 11:02:31
Start Date:	2019/03/12 15:00:00
End Date:	2019/03/12 16:00:00
Priority:	Normal
Type:	Schedule.Meeting.Resp.Pos
Location:	Skype Meeting

Sender:	Llorente, Maria D. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F5C91F577D894BD9A0F09305DB34DD4F-LLORENTE, M (b)(6) @va.gov>; Beasley, Mary (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=36A878CF4A524E6FA76340749E3DE6D2-BEASLEY, MA (b)(6) @va.gov>
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Sent Date:	2019/03/12 11:02:29
Delivered Date:	2019/03/12 11:02:31

AMERICAN OVERSIGHT

From:	Llorente, Maria D. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F5C91F577D894BD9A0F09305DB34DD4F-LLORENTE, M (b)(6) @va.gov>
To:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>
Subject:	Accepted: Spravato FAQ
Date:	2019/03/12 12:16:39
Start Date:	2019/03/12 15:00:00
End Date:	2019/03/12 16:00:00
Priority:	Normal
Type:	Schedule.Meeting.Resp.Pos
Location:	Skype Meeting

Sender:	Llorente, Maria D. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F5C91F577D894BD9A0F09305DB34DD4F-LLORENTE, M (b)(6) @va.gov>
Recipient:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>
Sent Date:	2019/03/12 12:16:37
Delivered Date:	2019/03/12 12:16:39

AMERICAN OVERSIGHT

From:	Llorente, Maria D. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F5C91F577D894BD9A0F09305DB34DD4F-LLORENTE, M (b)(6) @va.gov>
SentVia:	Beasley, Mary (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=36A878CF4A524E6FA76340749E3DE6D2-BEASLEY, MA (b)(6) @va.gov>
To:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>
Subject:	Accepted: Spravato FAQ
Date:	2019/03/12 11:02:31
Start Date:	2019/03/12 15:00:00
End Date:	2019/03/12 16:00:00
Priority:	Normal
Type:	Schedule.Meeting.Resp.Pos
Location:	Skype Meeting

Sender:	Llorente, Maria D. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F5C91F577D894BD9A0F09305DB34DD4F-LLORENTE, M (b)(6) @va.gov>; Beasley, Mary (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=36A878CF4A524E6FA76340749E3DE6D2-BEASLEY, MA (b)(6) @va.gov>
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Sent Date:	2019/03/12 11:02:29
Delivered Date:	2019/03/12 11:02:31

AMERICAN OVERSIGHT

From:	Wiechers, Ilse /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0C7B1428D9E4233A641F125C5B6FC4F-WIECHERS, I (b)(6) @va.gov>
To:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>
Subject:	Accepted: Spravato FAQ
Date:	2019/03/12 10:57:14
Start Date:	2019/03/12 15:00:00
End Date:	2019/03/12 16:00:00
Priority:	Normal
Type:	Schedule.Meeting.Resp.Pos
Location:	Skype Meeting

Sender:	Wiechers, Ilse /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0C7B1428D9E4233A641F125C5B6FC4F-WIECHERS, I (b)(6) @va.gov>
Recipient:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>
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AMERICAN OVERSIGHT

From:	Emmendorfer, Thomas (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC96BB44E7AE2C94C43B55D094-EMMENDORFER>
To:	Boyd, Teresa D. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F6886A7D555A43E0BEE23C1E40E1C234-BOYD, TERES (b)(6) @va.gov>
Subject:	Accepted: SPRAVATO
Date:	2019/03/08 11:03:02
Start Date:	2019/03/08 14:30:00
End Date:	2019/03/08 15:00:00
Priority:	Normal
Type:	Schedule.Meeting.Resp.Pos.SilentResponse
Location:	VACO Room 818

Sender:	Emmendorfer, Thomas (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC96BB44E7AE2C94C43B55D094-EMMENDORFER>
Recipient:	Boyd, Teresa D. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F6886A7D555A43E0BEE23C1E40E1C234-BOYD, TERES (b)(6) @va.gov>
Sent Date:	2019/03/08 11:03:02

AMERICAN OVERSIGHT

From:	Emmendorfer, Thomas (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC96BB44E7AE2C94C43B55D094-EMMENDORFER>
To:	Boyd, Teresa D. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F6886A7D555A43E0BEE23C1E40E1C234-BOYD, TERES (b)(6) @va.gov>
Subject:	Accepted: SPRAVATO
Date:	2019/03/08 11:03:02
Start Date:	2019/03/08 14:30:00
End Date:	2019/03/08 15:00:00
Priority:	Normal
Type:	Schedule.Meeting.Resp.Pos
Location:	VACO Room 818

Sender:	Emmendorfer, Thomas (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC96BB44E7AE2C94C43B55D094-EMMENDORFER>
Recipient:	Boyd, Teresa D. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F6886A7D555A43E0BEE23C1E40E1C234-BOYD, TERES (b)(6) @va.gov>
Sent Date:	2019/03/08 11:03:01
Delivered Date:	2019/03/08 11:03:02

AMERICAN OVERSIGHT

From:	Jensen, Jon M. </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DDEB735ACE76400DB5C3F10603188A14-JENSEN, JON>
To:	Stone, Richard A., MD /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BD16619615D64ADEA22E45E63FF6462A-STONE, RICH (b)(6) @va.gov>
Subject:	Accepted: PBM Nasal Spray Follow-Up
Date:	2019/03/11 15:50:30
Start Date:	2019/04/01 11:00:00
End Date:	2019/04/01 11:30:00
Priority:	Normal
Type:	Schedule.Meeting.Resp.Pos.SilentResponse
Location:	VACO 802 or VANTS 1-800-767-1750 A/C 22021

Sender:	Jensen, Jon M. </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DDEB735ACE76400DB5C3F10603188A14-JENSEN, JON>
Recipient:	Stone, Richard A., MD /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BD16619615D64ADEA22E45E63FF6462A-STONE, RICH (b)(6) @va.gov>
Sent Date:	2019/03/11 15:50:30

AMERICAN OVERSIGHT

From:	Llorente, Maria D. </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F5C91F577D894BD9A0F09305DB34DD4F-LLORENTE, M>
To:	Stone, Richard A., MD /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bd16619615d64adea22e45e63ff6462a-Stone, Rich (b)(6) @va.gov>
Subject:	Accepted: PBM Nasal Spray Follow-Up
Date:	2019/03/20 12:36:28
Start Date:	2019/04/08 11:30:00
End Date:	2019/04/08 12:00:00
Priority:	Normal
Type:	Schedule.Meeting.Resp.Pos
Location:	VACO 802 or VANTS 1-800-767-1750 A/C 22021

Sender:	Llorente, Maria D. </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F5C91F577D894BD9A0F09305DB34DD4F-LLORENTE, M>
Recipient:	Stone, Richard A., MD /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bd16619615d64adea22e45e63ff6462a-Stone, Rich (b)(6) @va.gov>
Sent Date:	2019/03/20 12:36:27
Delivered Date:	2019/03/20 12:36:28

AMERICAN OVERSIGHT

From:	Llorente, Maria D. </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F5C91F577D894BD9A0F09305DB34DD4F-LLORENTE, M>
To:	Stone, Richard A., MD /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BD16619615D64ADEA22E45E63FF6462A-STONE, RICH (b)(6) @va.gov>
Subject:	Accepted: PBM Nasal Spray Follow-Up
Date:	2019/03/20 12:36:24
Start Date:	2019/04/08 11:30:00
End Date:	2019/04/08 12:00:00
Priority:	Normal
Type:	Schedule.Meeting.Resp.Pos.SilentResponse
Location:	VACO 802 or VANTS 1-800-767-1750 A/C 22021

Sender:	Llorente, Maria D. </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F5C91F577D894BD9A0F09305DB34DD4F-LLORENTE, M>
Recipient:	Stone, Richard A., MD /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BD16619615D64ADEA22E45E63FF6462A-STONE, RICH (b)(6) @va.gov>
Sent Date:	2019/03/20 12:36:24

AMERICAN OVERSIGHT

From:	Fuller, Matthew A. (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=62D9CBB23B184CACB98895776E36A471-FULLER, MAT>
To:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b)(6) @va.gov>
Subject:	Accepted: Ilse <> Matthew re esketamine
Date:	2019/03/21 14:09:00
Start Date:	2019/03/22 14:00:00
End Date:	2019/03/22 14:30:00
Priority:	Normal
Type:	Schedule.Meeting.Resp.Pos

Sender:	Fuller, Matthew A. (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=62D9CBB23B184CACB98895776E36A471-FULLER, MAT>
Recipient:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b)(6) @va.gov>
Sent Date:	2019/03/21 14:09:11
Delivered Date:	2019/03/21 14:09:00

AMERICAN OVERSIGHT

From:	Fuller, Matthew A. (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=62D9CBB23B184CACB98895776E36A471-FULLER, MAT>
To:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b)(6) @va.gov>
Subject:	Accepted: Ilse <> Matthew re esketamine
Date:	2019/03/21 14:09:00
Start Date:	2019/03/22 14:00:00
End Date:	2019/03/22 14:30:00
Priority:	Normal
Type:	Schedule.Meeting.Resp.Pos

Sender:	Fuller, Matthew A. (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=62D9CBB23B184CACB98895776E36A471-FULLER, MAT>
Recipient:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b)(6) @va.gov>
Sent Date:	2019/03/21 14:09:11
Delivered Date:	2019/03/21 14:09:00

AMERICAN OVERSIGHT

From:	Emmendorfer, Thomas (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC96BB44E7AE2C94C43B55D094-EMMENDORFER>
To:	Stone, Richard A., MD /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BD16619615D64ADEA22E45E63FF6462A-STONE, RICH (b)(6) @va.gov>
Subject:	Accepted: Follow Up: HHS Nasal Spray
Date:	2019/03/07 14:12:03
Start Date:	2019/03/08 08:30:00
End Date:	2019/03/08 09:00:00
Priority:	Normal
Type:	Schedule.Meeting.Resp.Pos.SilentResponse
Location:	VACO 802

Sender:	Emmendorfer, Thomas (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC96BB44E7AE2C94C43B55D094-EMMENDORFER>
Recipient:	Stone, Richard A., MD /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BD16619615D64ADEA22E45E63FF6462A-STONE, RICH (b)(6) @va.gov>
Sent Date:	2019/03/07 14:12:03

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To:	Stone, Richard A., MD /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BD16619615D64ADEA22E45E63FF6462A-STONE, RICH (b)(6) @va.gov>
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Recipient:	Stone, Richard A., MD /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BD16619615D64ADEA22E45E63FF6462A-STONE, RICH (b)(6) @va.gov>
Sent Date:	2019/03/07 14:12:02

AMERICAN OVERSIGHT

From:	Valentino, Michael (VACO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO,>
To:	Stone, Richard A., MD /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bd16619615d64adea22e45e63ff6462a-Stone, Rich (b)(6) @va.gov>
Subject:	Accepted: Follow Up: HHS Nasal Spray
Date:	2019/03/08 07:50:14
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End Date:	2019/03/08 09:00:00
Priority:	Normal
Type:	Schedule.Meeting.Resp.Pos.SilentResponse
Location:	VACO 802 or VANTS 1-800-767-1750 A/C 22021

Sender:	Valentino, Michael (VACO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO,>
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Sent Date:	2019/03/08 07:50:14

AMERICAN OVERSIGHT

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To:	Stone, Richard A., MD /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bd16619615d64adea22e45e63ff6462a-Stone, Rich *(b)(6)* @va.gov>
Subject:	Accepted: Follow Up: HHS Nasal Spray
Date:	2019/03/08 07:50:17
Start Date:	2019/03/08 08:30:00
End Date:	2019/03/08 09:00:00
Priority:	Normal
Type:	Schedule.Meeting.Resp.Pos
Location:	VACO 802 or VANTS 1-800-767-1750 A/C 22021

Sender:	Valentino, Michael (VACO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO,>
Recipient:	Stone, Richard A., MD /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bd16619615d64adea22e45e63ff6462a-Stone, Rich *(b)(6)* @va.gov>
Sent Date:	2019/03/08 07:50:15
Delivered Date:	2019/03/08 07:50:17

AMERICAN OVERSIGHT

From:	Jensen, Jon M. </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DDEB735ACE76400DB5C3F10603188A14-JENSEN, JON>
To:	Stone, Richard A., MD /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bd16619615d64adea22e45e63ff6462a-Stone, Rich *(b)(6)* @va.gov>
Subject:	Accepted: Follow Up: HHS Nasal Spray
Date:	2019/03/08 08:27:35
Start Date:	2019/03/08 08:30:00
End Date:	2019/03/08 09:00:00
Priority:	Normal
Type:	Schedule.Meeting.Resp.Pos.SilentResponse
Location:	VACO 802 or VANTS 1-800-767-1750 A/C 22021

Sender:	Jensen, Jon M. </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DDEB735ACE76400DB5C3F10603188A14-JENSEN, JON>
Recipient:	Stone, Richard A., MD /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bd16619615d64adea22e45e63ff6462a-Stone, Rich *(b)(6)* @va.gov>
Sent Date:	2019/03/08 08:27:35

AMERICAN OVERSIGHT

VETERANS HEALTH ADMINISTRATION

Informational Briefing on VA's Formulary Management and the Esketamine Review

Presentation for: House and Senate Veterans Affairs CommitteesPresented by: Maria Llorente, MD, Acting Assistant Deputy Under Secretary for Health for Patient Care Services
Michael Valentino, R.Ph., MHSA, Chief Consultant, Pharmacy Benefits Management ServicesDate of briefing: Month, date, 2019 (TBD)

Formulary Management Objectives

- Promote a culture of medication safety Promote appropriate drug therapy; discourage inappropriate drug therapyPromote evidence-based formulary decisions, not preference-based decisionsReduce geographic variability in drug utilization across the VA systemPromote portability and uniformity of the drug benefitOperate an economically sustainable drug benefit

Formulary Overview

- The VA National Formulary (VANF) is the sole drug formulary used in VAEvolved from 173 individual drug formularies in 1995 to a single formulary in 2009VA medical facilities and VISNs still have formulary committees to conduct traditional Pharmacy & Therapeutics committee work with the EXCEPTION of adding or removing drugs from the formulary Integrated non-formulary request processVA's "non-formulary" designation is the same as the "formulary, prior authorization" designation seen in other health care systemsHigh-quality evidence drives decision-making

Formulary Overview (cont.)

- Drug safety is VA's highest priorityDrug effectiveness is VA's second priorityCost is only a consideration after a drug has demonstrated acceptable safety and effectiveness VANF Committee responsibilitiesUpdating and maintaining the VANFAdding drugs, removing drugs, developing evidence-based guidance, standardization contractingMonitoring utilizationData collection and reviewIntervention when indicated (access issues, over/under utilization)Adverse Drug Event monitoringContract adherence

Formulary Management Infrastructure

- VA Medical Advisory PanelVISN Pharmacist Executives CommitteeVA Clinical Subject Matter ExpertsVA Pharmacy Benefits Management (PBM)Facilitation roleRegional (VISN) Pharmacy &Therapeutics (P&T) CommitteesOversight role for Local committeesAdvisory role for the national formulary committeesLocal (VAMC) P&T CommitteesImplementation of VANF initiatives

Formulary Management Process Decisions

VANF Committees

- Medical Advisory Panel (MAP)15 practicing VA physicians*12 PBM clinical pharmacist specialists1 VISN Pharmacist Executive memberVISN Pharmacist Executives Committee (VPE)18 pharmacists1 DoD pharmacist and 1 IHS pharmacist (non-voting)1 MAP memberMeetingsMonthly 2-hour conference calls with each group Quarterly 2-day face-to-face meetings (MAP and VPE)Consensus decision-making

**** Currently 2 of the 15 MAP physicians are practicing VA psychiatrists***

New Molecular Entity (NME) Review*

- NME stepwise review process:NME is approved by the FDAPBM staff complete a literature search, review materials submitted to FDA for approval and draft formulary documentsThe draft documents are presented to VPE/MAP committeesChanges are incorporated as neededThe draft review is disseminated widely to field-based VA clinical staff for commentComments are presented to VPE/MAP committeesChanges are incorporated if warranted by the evidenceVA National Formulary decisionFormulary status is determinedNational criteria for use is developed when indicatedNational monitoring process is developed when indicated

**** An NME is defined as a drug that contains an active ingredient that has not been previously approved by the FDA nor marketed in the U.S.***

Esketamine (Spravato) Review

2019 Milestones

- 5 March: Esketamine nasal inhalation was approved by the FDA with an indication for Treatment-Resistant Depression and to be used in conjunction with an oral antidepressant11-12 March: Product overview presented to internal clinical groups (Chief Medical Officers, Mental Health Leads, VISN Pharmacist Executives)15 March: Frequently Asked Questions distributed to field-based staff18 March: Memo issued to the field with instructions about how to obtain Risk Evaluation and Mitigation Strategy (REMS)* certification as required by the FDA

**** A Risk Evaluation and Mitigation Strategy (REMS) is a drug safety program that the U.S. Food and Drug Administration (FDA) can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks. REMS are designed to reinforce medication use behaviors and actions that support the safe use of that medication. While all medications have labeling that informs health care stakeholders about medication risks, only a few medications require a REMS.*** ***https://www.fda.gov/drugs/drug-safety-and-availability/risk-evaluation-and-mitigation-strategies-rems***

2019 Milestones (cont.)

- 19 March: VA issued an esketamine press release19 March: Esketamine became available in the U.S. pharmaceutical supply chain25 March: A Clinical Implementation Workgroup was formed to develop guidance13-15 May: The esketamine monograph, draft Criteria for Use and field comments were presented to the VPEs and MAP for review and discussion on conference callsAfter discussion, the issue was tabled for the June face-to-face meetingFormulary documents were revised based on feedback from the field and MAP/VPEsDocuments were developed in collaboration with the Office of Mental Health

2019 Milestones (cont.)

- 20 June: Based on careful review of available evidence, the MAP and VPEs voted to:Designate Esketamine as a non-formulary drugIt will be made available with an approved prospective reviewApprove evidence-based prescribing guidanceEstablish an ongoing clinical monitor to assess the drug's safety and effectiveness in the Veteran populationProvide clear and consistent messaging to VA providers

VETERANS HEALTH ADMINISTRATION

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Presentation for: House and Senate Veterans Affairs CommitteesPresented by: Michael Valentino, R.Ph., MHSA, Chief Consultant, Pharmacy Benefits Management ServicesDate of briefing: Month, date, 2019 (TBD)

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Formulary Overview (cont.)

- Drug safety is the first priorityDrug effectiveness is the second priorityCost is only considered after safety & effectivenessVANF Committee responsibilitiesUpdating and maintaining the VANFAdding drugs, removing drugs, developing evidence-based guidance, standardization contractingMonitoring utilizationData collection and reviewIntervention when indicated (access issues, over/under utilization)Adverse Drug Event monitoringContract adherence

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- NME approved by the FDAPBM staff complete literature search and draft review Draft review presented to VPE/MAP committeesChanges incorporatedDisseminated widely to field-based clinical staff for commentComments presented to VPE/MAP committeesChanges incorporated if warrantedVA National Formulary decisionNational criteria for use developed when indicatedNational monitoring process developed when indicated

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Milestones (cont.)

- May: Esketamine monograph, draft Criteria for Use and field-comments presented to the VPEs and MAPIssue tabled for June face-to-face meetingDocument revision based on feedback from the field and MAP/VPEsMaterials developed in collaboration with the Office of Mental Health June: Based on careful review of available evidence, the MAP and VPEs voted to:Designate Esketamine as a non-formulary drugWill be available with an approved prospective reviewIssue evidence-based prescribing guidanceEstablish an ongoing clinical monitor to assess the drug's safety and effectiveness in the Veteran populationMake the drug "non-promotable" by the manufacturerProvide education to VA providers with clear messaging

Milestones (cont.)

- Future Actions: Request the manufacturer enter into a risk-share agreement with VAPossibly reimburse VA for the cost of the drug for non-respondersTiered discount Etc.

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Milestones (cont.)

- Future Actions: Request the manufacturer enter into a risk-share agreement with VAPossibly reimburse VA for the cost of the drug for non-respondersTiered discount Etc.

From:	Spivak Melinger, Michelle B. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5CCBEF35430140308BCAF818ADD099E0-SPIVAK MELI (b)(6) @va.gov>
To:	VHA CO ELT Clips /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=47d7fa1e81c441ae95fcb118d95107d8-VHA CO ELT <VHACOELTClips@va.gov>
Subject:	24 August Veterans Affairs Media Summary and News Clips
Date:	2019/08/24 09:08:54
Priority:	Normal
Type:	Note

Good Morning,

Significant VHA-related news in this morning's clips includes the following stories:

Politico reports the EHR update project "faces significant delays" and the joint Federal Electronic Health Record Modernization Office is not yet up-and-running.

U.S. News and World Report and several other media outlets are reporting on an investigation into the death of retired Army Sgt. Felix Kirk McDermott at the Louis A. Johnson VA Medical Center in Clarksburg, West Virginia. McDermott's daughter is suing VA claiming the 82-year-old was wrongly injected with a fatal dose of insulin in April 2018. The autopsy report from the Armed Forces Medical Examiner declared the death a homicide.

Another *U.S. News and World Report* story says Richard Ojeda, former Democratic state senator and one-time presidential candidate, filed suit against VA indicating his West Virginia congressional campaign was derailed by a Department of Veterans Affairs employee who's charged with leaking medical records.

Stories in *The Atlantic* and *Government Executive* indicate the President will authorize the purchase "a lot" of the drug esketamine, a derivative of a hallucinogen asserted to be of benefit to veterans with PTSD and depression.

Military.com reports on the opening of a VA Research Center on Burn Pit related illnesses.

Significant

1. • - Politico: $16B veterans' health project hits major snag Link
2. • - U.S. News &World Report (AP): Ojeda Says Medical Records Leak Derailed Congressional Bid Link
3. • - U.S. News &World Report (AP): Politicians Seek Answers on Veteran's Death at VA Hospital Link

1.4 - The Atlantic: Trump Orders 'a Lot' of Ketamine for Depressed Veterans Link
1.5 - Military.com: After Mandate from Congress, VA Opens Research Center for Burn Pit-Related Illnesses Link
1.6 - Military Times: House chairman calls for nationwide veterans hospital stand-down to bolster suicide prevention training Link
1.7 - Government Executive: Trump Told the VA to Order 'a Lot' of Ketamine for Vets Link

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1.8 - Government Executive: 'I'm Just Baffled': Internal Emails Show Career VA Employees Frustrated by Influence of Mar-a-Lago Outsiders Link
1.9 - The Exponent Telegram: Claim: Death of Vietnam vet at Louis A. Johnson VA Medical Center in Clarksburg, WV, was homicide; 9 or 10 other suspicious deaths Link
1.10 - The Morehead News: Veterans take center stage during Trump visit Link

Neutral/Positive
2.1 - Reuters: VA facilities offering cochlear implants to vets are few and far between Link
2.2 - Politico: Ruling in Oklahoma opioids lawsuit imminent Link
2.3 - Medscape: PAs Fight for Right to Follow Patients Into Hospice Link
2.4 - The Seattle Times: Prizes for sobriety: As Washington meth use rises, this treatment is one of few that works Link
2.5 - Orlando Sentinel: New hepatitis C cases increasing in Florida; local doctor helps treat uninsured Link
2.6 - WMUR (ABC-9, Video): Buttigieg unveils mental health plan in NH visit Link
*2.7 - WEAU (NBC-13, Video): Starting in October, the Tomah VA Medical Center will be smoke-free Link
2.9 - The Register-Herald: Governor hands over keys to 13 new VA vans Link
2.11 - WFVX (FOX-22, Video): New director for VA Maine Healthcare System Link
2.12 - American Press: VA programs help local veterans Link
2.19 - GovernmentCIO: VA Focuses on New AI Initiatives Link
3.1 - KIMT (CBS-3, Video): Rochester Welcomes New VA Clinic Link
6.2 - FOX News: (Video): President Trump signs executive order to cancel student loan debt for disabled veterans Link
6.3 - Military.com: Trump Signs Bill Protecting Disability Payments for Veterans Who Declare Bankruptcy Link
6.4 - The San Diego Union-Tribune: Homeless veterans take center stage at bipartisan congressional hearing in San Diego Link
7.2 - Patch.com (West Chester): Chester County VA Center Wins EPA Award For Waste Diversion Link

Negative
2.8 - MedCity News: Documents reveal conflict between VA and unelected Trump advisors Link
2.10 - The News-Review: DeFazio calls on federal agencies to help Roseburg VA with staffing problems Link
2.14 - The Journal: Claim: Clarksburg VAMC patients died under suspicious circumstances Link
2.16 The Intelligencer (Wheeling News-Register): W.Va. Woman Files Claim Against Clarksburg VA Over Father's 'Suspicious' Death Link
2.16 - 2.18 - West Virginia Record: Ojeda says his VA medical records were stolen, wants answers from government Link
4.1 - FierceHealthcare: VA's paper health records digitization backlog is 5 miles high, VA OIG says Link
5.1 - Connecting Vets: A report shows VA failures may have led to veteran suicide. Congressman calls for 'stand-down.' Link
6.6 - WVIR (NBC-29, Video): Homeless Veteran in Greene Co. Seeking Support, Wants to Investigate VA Link

*VHA Comms supported this query.

Sender:	Spivak Melinger, Michelle B. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

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	(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5CCBEF35430140308BCAF818ADD099E0-SPIVAK MELI (b)(6) @va.gov>
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VA Secretary's Stand-Up Brief28 August 2019

Executive SummaryCoverage of the claim that one Veteran, and perhaps 10 others, died of homicide at the Clarksburg VAMC surged as Tier 1 outlets across the country picked up the story.

Storyline	Outlets	Analysis	Trend	Priority
Up to 11 deceased Veterans wrongfully injected with insulin at Clarksburg VAMC	*USA Today*, *AP*, *Exponent Telegram*, *CNN*, *FOX News*, *CBS News*, *WCHS (ABC)*	Reporting generally reiterated previous coverage with the addition of a statement by IG Missal that his office is working with federal law enforcement to investigate the allegations of potential wrongdoing. *USA Today* and *CNN* cited spokesman Wesley Walls as saying the person of interest is not a current employee and included his previously reported statements. *CBS News* likewise reported the Department as saying the investigation does "not involve any current employees." *Exponent Telegram* published a detailed article in which it claimed VA has not been "forthcoming" as to whether the person of interest is an employee, and has not answered questions about the number of sentinel events reported at the facility. It said Mr. Walls sent a statement saying VA is "cooperating fully" with the IG's investigation and referred additional questions to the IG's office.	**Sustained**	Service
Study examines effectiveness of Suicide prevention treatments	*HealthDay*, *Medical Xpress*	These outlets covered a new review that points to effective treatments that can reduce suicide risk, saying the review has been used to update Suicide prevention guidelines at the Department. The researchers reportedly examined nonpharmacologic and pharmacologic interventions to prevent Suicide and found that cognitive behavioral therapy (CBT) and dialectical behavior therapy (DBT) both showed modest benefit in reducing suicidal thoughts, and CBT was shown to reduce suicide attempts. They further reported that Ketamine and lithium reduced suicide rates compared to placebo, but noted that the studies had limited information on any harms that might be associated with these drugs.	**Emerged**	Suicide

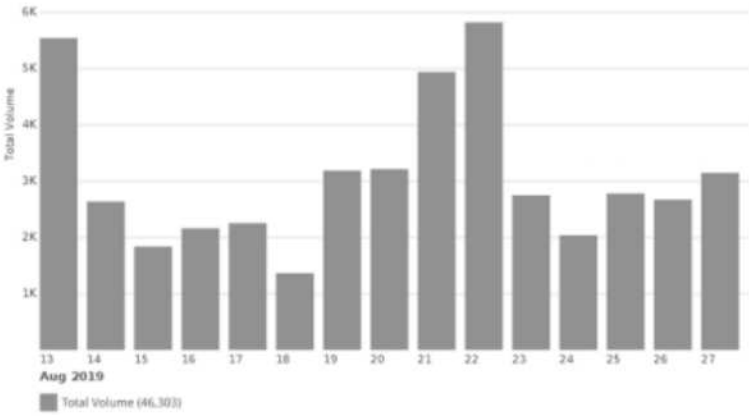
AMERICAN OVERSIGHT

VA Secretary's Stand-Up Brief28 August 2019

Social Media TakeawayActivity related to Mar-a-Lago and Spravato declined, and Suicide sustained as users engaged with posts calling for a nationwide Suicide stand-down.

Key PointsPhilanthropist @pulte wrote the top tweet requesting donations for a Veteran whose, "VA pension does not cover bills" (1.2k+ retweets).In the second top tweet, @SpeakerPelosi called for a nationwide stand-down on Suicide (540+ retweets). @RepMarkTakano's post asking all members of Congress to join in the call for a Suicide stand-down was in seventh position (60+ retweets).In the third and fourth posts, @RedTRaccoon and CNN Breaking News (@cnnbrk) wrote about the "suspicious deaths" at the Clarksburg VA (140+ and 110+ retweets, respectively).Veteran @JoeKristol quoted the 21 Aug. CBS News story on Dr. Levy being charged in the deaths of 3 Veterans and called the situation "infuriating and tragic" (90+ retweets. This was the fifth top post.@RepThomasMassie's 25 Aug. post on the red flag law that results in Veterans being prohibited from owning firearms dropped from second to sixth position (60+ additional retweets, 990+ total).@HollieWolfen's 24 Aug. post and @Liz_Llorente's 26 Aug. post on Spravato elicited some additional user engagement (50+ retweets each). These were the eighth and ninth top tweets, respectively.

Twitter and Facebook Volume: 13 August – 27 August



Notable Social Media Items

Platform	Item	Relevance
Twitter	@pulte	21% of Volume
Twitter	Suicide	20% of Volume
Facebook	Disabled Marine veteran climbs Mt. Timpanogos with the help of a fellow veteran	1k+ Reactions, 350+ Shares, 110+ Comments since 26 Aug.
YouTube	CBS Evening News: Feds investigating 10 more deaths at VA hospital	1.7k+ Views

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VA-19-1109-B-002497

VA Secretary's Stand-Up Brief28 August 2019

Omaha World-Herald: VA in midst of unprecedented building boom across Nebraska and western Iowa (25 August, Steve Liewer, 1.3M uvm; Omaha, NE) Colorful stained glass is now installed along the hallway joining the Omaha VA Hospital with its new ambulatory care center, adding a decorative touch to the $86 million facility that is slated for completion next spring. The three-story clinic will add seven primary care clinics, five operating rooms and a specialized women's clinic and give a modern look and feel to a medical center that opened in 1950. Hyperlink to Above Chico Enterprise-Record: Editorial: Veterans clinic a welcome addition (27 August, 101k uvm; Chico, CA)Today is a momentous day, with the new Veterans Affairs Outpatient Clinic opening in Chico.It's not just that Chico gets something new. It's that the new availability of extra services for veterans is long warranted. And it's certainly a feather in Chico's cap. The state of the art facility off Bruce Road in east Chico means a lot to a population that has sacrificed a lot. Hyperlink to Above Columbia Missourian: Columbia veteran hospital named 'leader' in LGBTQ healthcare (27 August, Mariana Labbate, 94k uvm; Columbia, MO)Truman Veterans' Hospital was designated Tuesday as a leader in "LGBTQ Healthcare Equality" by the Human Rights Campaign. The veterans hospital received the designation along with 405 other hospitals across the country. The hospital was evaluated using the Human Rights Campaign's Healthcare Equality Index, which measures how well hospitals' policies and practices support both LGBTQ patients and employees. Hyperlink to Above Commercial-News: Reaching Out To Vets: VA director reaches out to vets (27 August, Mary Wicoff, 10k uvm; Danville, IL)Shawn Branksy, new director of the Veterans Affairs Illiana Health Care System, believes in the power of optimism. "We have challenges and also have a lot of opportunities," he said. "How do we capitalize on the opportunities?" Quoting former Secretary of State Colin Powell about optimism being contagious, he hopes to instill that attitude in his staff and veterans. Hyperlink to Above GovernmentCIO: Reforming End-User Operations is a VA IT Focus (27 August, Adam Patterson, Washington, DC)The Department of Veterans Affairs is focusing on broad-scale renovation of its deployment capacities, according to Executive Director of End-User Operations Dewaine Beard. Following 23 years of service to the VA, Beard was officially appointed director of the 3,500-person team responsible for requisitions and deployment of end-user technology in April 2019. Hyperlink to Above

AMERICAN OVERSIGHT

Veterans Affairs Media Summary and News Clips

27 August 2019

1. Top Stories

1.1 - KIVI (ABC-6, Video): #FINDINGHOPE: US Secretary of VA works to open mental health dialogue in the armed forces (26 August, Madeline White, 111k uvm; Nampa, ID)
The national tragedy of veteran suicide has been a main concern for US Secretary of Veterans Affairs Robert Wilkie since his appointment to the job. During his recent visit to Boise, he sat down for an exclusive TV interview with 6 On Your Side's Madeline White.

Hyperlink to Above

1.2 - CBS News (Video): Inside a suicide prevention call center for veterans responding to 1,700 calls each day (26 August, Dean Reynolds, 30.2M uvm; New York, NY)
The Departments of Defense and Veterans Affairs are holding a conference in Nashville this week aimed at preventing suicides. A hotline launched in 2007 has answered more than 3.5 million calls, sending emergency help to nearly 100,000 people. At the Veterans Crisis Line in Canandaigua, New York, the calls come in all day and night. Every day, 1,700 calls come in from veterans on the brink. CBS News was given rare access to the Veterans Affairs responders and their life-saving conversations.

Hyperlink to Above

1.3 - ABC News (Video): Could a new drug treat veterans with severe depression? President Trump thinks so (27 August, Dr. Lauren Kelly and Elizabeth Mclaughlin, 22.2M uvm; New York, NY)
At a veterans event in Kentucky last week, President Donald Trump touted what he called an "incredible" new drug he says could help American veterans struggling with depression. The drug, called esketamine and marketed as Spravato, was produced by Johnson & Johnson subsidiary Janssen Pharmaceuticals and billed as a breakthrough treatment for patients who have not responded to other antidepressants.

Hyperlink to Above

1.4 - Military.com: The VA Removed a Vet's High-Risk Label. The Patient Died by Suicide. What Went Wrong? (26 August, Richard Sisk, 4.3M uvm; San Francisco, CA)
Again and again, teams at the Department of Veterans Affairs' San Diego Health Care System reached out to and helped a troubled veteran battling suicidal thoughts and substance abuse who frequently missed appointments or broke off contact. The efforts were not enough. The veteran was found dead in July 2018; the San Diego Medical Examiner's Office ruled the death a suicide by asphyxiation.

Hyperlink to Above

1.5 - The Daily Signal: VA Lifts Ban on Bibles in Move to Support Religious Freedom (26 August, Fred Lucas, 1.1M uvm; Washington, DC)
As a kid, Veterans Affairs Secretary Robert Wilkie recalls, he visited a VA hospital at Christmastime. “One of my fondest memories growing up, we used to sing Christmas carols at the VA hospital in Fayetteville, North Carolina,” Wilkie told The Daily Signal, sitting in a 10th-floor office at VA headquarters on Vermont Avenue Northwest, overlooking the White House.

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Hyperlink to Above

1.6 - Nextgov: **Veterans Affairs Launches Digital National Cemetery** (26 August, Brandi Vincent, 339k uvm; Washington, DC)
The Veterans Affairs Department's National Cemetery Administration developed and launched an online memorial platform—Veterans Legacy Memorial—to honor millions of veterans interred in national cemeteries across America. Deemed a "digital national cemetery," the new resource leverages technology and prioritizes security to boost community engagement and preserve the memories of those who served.

Hyperlink to Above

1.7 - Las Vegas Sun: **At VA, we protect those who protected us** (26 August, Sec. Robert Wilkie, 180k uvm; Henderson, NV)
Cpl. Orlando Camacho, Lt. Kenneth Frazier and officer Miguel Calderon didn't know they would save lives when they woke up Aug. 12 and reported to the Jesse Brown VA Medical Center in Chicago. The three members of the Veterans Affairs Police were on duty when shots were fired just outside the VA's doors. As alarms blared and people flooded 911 with calls, Camacho, Frazier and Calderon waded past panicked people toward a man with a rifle in his hand who entered the building.

Hyperlink to Above

1.8 - The Exponent Telegram: **Sen. Manchin: VA officials assure 'person of interest' in homicide no longer in contact with veterans in VA hospital** (26 August, Matt Harvey, 133k uvm; Clarksburg, WV)
A person of interest in 11 suspicious deaths at the Louis A. Johnson VA Medical Center — one of those deaths a confirmed homicide — "is no longer in any contact with veterans at the facility," U.S. Sen. Joe Manchin said Monday in a news release.

Hyperlink to Above

1.9 - Healthcare IT News: **OIG audit: Massive backlog in digitizing VHA medical records** (26 August, Nathan Eddy, 64k uvm; Chicago, IL)
Veterans Health Administration medical facilities are facing an enormous challenge as they scan and enter medical documentation into patients' electronic health records, according to an audit from the Office of the Inspector General for the Department of Veterans Affairs.

Hyperlink to Above

1.10 - WDTV (CBS-5, Video): **Update: Veteran speaks out about his time at the Louis A. Johnson VA Medical Center** (26 August, 32k uvm; Bridgeport, WV)
5 News spoke with local veteran, Ken Warman about his experience at the Clarksburg VA Medical Center. "That facility, I hate to tell you. Worst facility I have ever been to. Hands down, of all the states I have been to. Hands down the worst. I have been treated the worst," said Warman.

Hyperlink to Above

2. Improving Customer Service

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2.1 - Military Times: **Unable to sue the Army for medical malpractice, this retired soldier is now fighting the VA for benefits** (26 August, Meghann Myers, 1.7M uvm; Vienna, VA)
Retired Sgt. 1st Class Barbara Ospina is partially paralyzed, in debilitating pain and confined to a wheelchair for almost all of her day. Her condition is the result of malpractice at the hands of hands of military medicine, according to claims she made to the Department of Veterans Affairs, but she is paying out of pocket for a caregiver to help her bathe, dress and prepare meals, because the VA has denied her request for caregiver assistance.

Hyperlink to Above

2.2 - Military Times: **Did VA hospital leaders ignore recalls on faulty medical equipment?** (26 August, Leo Shane III, 1.7M uvm; Vienna, VA)
Staffers at a Florida-based Veterans Affairs hospital say leadership ignored a medical equipment recall for weeks — even after a patient's life was endangered — despite repeated warnings their inaction violated health and safety norms.

Hyperlink to Above

2.3 - KDKA (CBS-2, Video): **Family Of Westmoreland County Veteran Files Federal Tort Claims Act Following Stay At West Virginia VA Hospital** (25 August, Pam Surano, 1.3M uvm; Pittsburgh, PA)
A federal tort claims act has been initiated by the family of a Vietnam veteran whose death at a VA hospital promoted a homicide investigation. Retired Sergeant Felix McDermott died April 8, 2018, at the Loius A. Johnson VA Medical Center in Clarksburg, West Virginia after he was injected with a fatal dose of insulin while at the center, a lawsuit says.

Hyperlink to Above

2.4 - WREG (CBS-3): **Longtime Memphis pain doctor reprimanded for prescription issues** (26 July, Stacy Jacobson, 605k uvm; Memphis, TN)
The Tennessee Department of Health has reprimanded a Memphis pain management and addiction doctor for his prescribing practices. The state put Dr. Douglas Jones' license to practice on probation and banned him from owning or operating pain management clinics.

Hyperlink to Above

2.5 - Becker's Hospital Review: **Staff members claim VA hospital ignored medical equipment recall** (26 August, 593k uvm; Chicago, IL)
Staff members claim leadership ignored a medical equipment recall for weeks at the James A. Haley Veterans' Hospital in Tampa, Fla., according to the Military Times. Becton Dickinson, an IV tubing manufacturer, recalled its tubing equipment on May 6. The VA hospital failed to recall the tubing for weeks, even after the equipment endangered a patient on July 31, staff members said. The patient received too much medication due to what nurses claim was malfunctioning IV equipment.

Hyperlink to Above

2.6 - WINK (CBS-11, Video): **Veteran patients missing appointments, Cape VA clinic lacking resources** (26 August, Jack Lowenstein, 348k uvm; Fort Myers, FL)

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The U.S. Department of Veteran Affairs in Cape Coral says it is unable to provide transportation services to doctor appointments from its clinic due to lack of volunteers and donations that help provide necessary resources. Vietnam Bubba Schneider is someone who depends on these services for his health. He reflected on his time in the war overseas when we spoke to him.

Hyperlink to Above

2.7 - WBIR (NBC-10, Video): Veteran hopes toolbox gift will help other veterans transition back to life after deployment (25 August, Sean Franklin, 464k uvm; Knoxville, TN)
A wounded combat veteran from East Tennessee received a way to find his purpose in life after serving. A simple gift of a toolbox has helped him and others transition from the Army. More than a hundred soldiers filled the Knoxville Convention Center this weekend, learning how to make a transition from deployment to life back home.

Hyperlink to Above

2.8 - Idaho Statesman: Letters to the editor (26 August, Richard L. Barrett, 392k uvm; Boise, ID)
VA THANKS. Kudos to Boise VA Medical Center Director's superb staff and many thanks to Secretary of Veterans Affairs Director Robert Wilkie for giving those folks the recognition they so richly deserve.

Hyperlink to Above

2.9 - WMAZ (CBS-13, Video): Dublin VA going smoke free October 1st (26 August, Wanya Reese, 281k uvm; Macon, GA)
The Carl Vinson VA Medical Center plans to go smoke free starting in the fall, but some veterans have mixed opinions about the ban. Some say it will help, while others think it won't, but regardless of what they think the smoking ban will go into effect at the center starting in October. "I started smoking in the Navy, because that was really the only time I had the opportunity to take a break," Christopher Anderson said.

Hyperlink to Above

2.10 - MetroNews: Clarksburg VA death ruled homicide; VA investigating more possible victims (27 August, Hoppy Kercheval, 242k uvm; Charleston, WV)
On the morning of April 9, 2018, Felix McDermott died at the Louis A. Johnson VA Medical Center in Clarksburg. The retired Army Sergeant and Vietnam Veteran was 82 years old and had several health issues, including aspiration pneumonia. However, his condition was improving, and his death shocked his family.

Hyperlink to Above

2.11 - MetroNews: Autopsy: Vietnam veteran was not diabetic but died of insulin injection (26 August, Brad McElhinny, 242k uvm; Charleston, WV)
An autopsy report for a Vietnam veteran who died suspiciously at the Veterans Affairs Medical Center concludes that the man — who was not diabetic — was injected with a fatal amount of insulin. The autopsy uses clinical language to describe horror. "This case represents the administration of unprescribed insulin to a non-hyperglycemic, non-diabetic patient in a hospital setting," the report states.

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Hyperlink to Above

2.12 - WJET (ABC-24, Video): Erie VA Medical Center goes tobacco free (26 August, 73k uvm; Erie, PA)
Erie VA Medical Center will soon be tobacco free. According to the Medical Center Director, the new rule will also apply to all of their community based outpatient clinics. The director said the reasoning for this is to create a healthier environment for anyone who comes in contact with the center.

Hyperlink to Above

2.13 - Citizen Tribune: Group buys van to transport patients to VA clinic (26 August, Shawn Singleton, 64k uvm; Morristown, TN)
Veterans who receive care at the Morristown VA Clinic now have a new way to make their specialized appointments on time. The Jerry Alvis Disabled American Veterans Chapter 59 recently purchased a new van to transport disabled veterans to James H. Quillen Mountain Home VA Medical Center in Johnson City. Veterans from Hamblen, Hawkins, Grainger and Jefferson counties will be eligible for the transportation service.

Hyperlink to Above

2.14 - The Journal Gazette: Five questions for Brett P. Reistad. National commander, American Legion (26 August, 56k uvm; Fort Wayne, IN)
Are people surprised to learn your organization has been around for 100 years? How and when did the American Legion come to be headquartered in Indianapolis? Some people are surprised, but I think most people are aware that we've been around for quite some time. Depending on their age, some may recall how we were such strong advocates for those returning from World War II (just as our founders were for the WWI vets).

Hyperlink to Above

2.15 - Federal Computer Week: Congratulations to the 2019 Rising Stars (26 August, Troy K. Schneider, 46k uvm; Vienna, VA)
Each year, the Rising Star Awards recognize individuals who are early in their federal IT careers yet already are having an outsized impact. The women and men listed below have been selected both for their accomplishments over the past year and for their leadership potential in this community.

Hyperlink to Above

2.16 - Colorado Politics: VA appoints new director of Eastern Colorado Health Care System (26 August, Caitlin Curley, 57k uvm; Denver, CO)
The U.S. Department of Veterans Affairs is bringing on a new director for its Aurora-based Eastern Colorado Health Care System. Michael Kilmer, formerly the medical center director for the Western Colorado system in Grand Junction, will replace Sallie Houser-Hanfelder, who retired in May.

Hyperlink to Above

2.17 - Manistee News Advocate: Volunteers needed for veteran transportation service (26 August, Jane Bond, 1k uvm; Manistee, MI)

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A new vehicle is taking local veterans to their medical appointments, but Eric Sullivan of the local Disabled American Veterans (DAV) chapter is looking for more volunteers to drive it. As the ride coordinator for the DAV Manistee chapter, Sullivan spends most of his time organizing free transportation for retired soldiers to Veterans Affairs (VA) medical centers in locations like Traverse City, Cadillac, Wyoming and Saginaw.

Hyperlink to Above

3. Business Transformation

3.1 - The Virginian-Pilot: **Editorial: Veterans clinic a welcome addition to region** (27 August, 1.1M uvm; Norfolk, VA)
Sens. Mark Warner and Tim Kaine have been working for years to accelerate the painfully slow process of getting a new VA outpatient clinic open in Hampton Roads. Faced with reports of veterans having long, frustrating waits for care at VA facilities, Congress has approved leases for 28 new medical facilities around the country, including one in Hampton Roads and one in Fredericksburg.

Hyperlink to Above

3.2 - KCRG (ABC-9, Video): **Dubuque VA clinic open to patients starting Monday** (26 August, 505k uvm; Cedar Rapids, IA)
Veterans in Dubuque will now have access to the city's new VA clinic. The new clinic opened earlier this month inside a portion of the former K-Mart building off Highway 20. t's more than four times the space of the current clinic, offering new services like radiology, physical therapy, and expanded mental health services.

Hyperlink to Above

4. DOD Cooperation / Electronic Health Records / MISSION Act Implementation

4.1 - FedScoop: **Backlog of VA medical records awaiting digitization is 5 miles tall** (26 August, Billy Mitchell, 48k uvm; Washington, DC)
Across the country at Department of Veterans Affairs medical facilities, there's a massive backlog of documents waiting to be scanned and digitized that, if stacked, would stand more than 5 miles tall. For reference, that's taller than 18 Empire State Buildings. It's just 2,000 feet short of the peak of Mount Everest.

Hyperlink to Above

4.2 - Health Data Management: **OIG: VHA's document scanning backlog puts patients at risk** (27 August, Greg Slabodkin, 41k uvm; Chicago, IL)
Veterans Health Administration facilities are woefully behind when it comes to scanning and entering medical documentation into patients' electronic health records. According to an audit by the VA's Office of Inspector General, the agency found significant backlogs across the VHA, potentially putting patient care at risk because of a lack of timely and accurate EHR documentation.

Hyperlink to Above

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4.3 - Delaware Public Media (Audio): **Delaware VA officials discuss new patient health care access rules** (26 August, Sarah Mueller, 11k uvm; Dover, DE)
State Veterans Affairs officials discussed what's working and what's not with the newly-implemented VA Mission Act Monday. Congresswoman Lisa Blunt Rochester hosted a roundtable at the Wilmington VA Medical Center to hear about June's roll out of new patient rules. The VA Mission Act expands access to outside medical providers for veterans who have long drives or face long waits at VA facilities.

Hyperlink to Above

4.4 - HIT Infrastructure: **VHA's Lax Health Information Management Created 5-Mile-High Backlog** (26 August, Fred Donovan, 7k uvm; Danvers, MA)
The Veterans Health Administration's (VHA) poor health information management of medical record scanning has produced a paper record backlog of 600,000 documents, or a stack of paper more than five miles high, concluded a recent audit by the Department of Veterans Affairs' (VA) Office of Inspector General (OIG).

Hyperlink to Above

5. Suicide Prevention

5.1 - Becker's Hospital Review: **House chairman calls for national stand-down at VA hospitals for suicide prevention training** (26 August, Anne-Marie Kommers, 593k uvm; Chicago, IL)
The chairman of the House Veterans' Affairs Committee called for a one-day halt to all nonessential work at VA medical centers to allow staff to focus on suicide prevention policies, according to The Marine Corps Times. The call comes after an Aug. 22 inspector general report found numerous safety issues related to staffing, employee training and risk mitigation at West Palm Beach (Fla.) VA Medical Center, where a patient died by suicide in early 2019.

Hyperlink to Above

5.2 - Federal News Network (Audio): **House VA Committee chair calls for agencywide stand-down to address veteran suicide** (26 August, Eric White, 238k uvm; Washington, DC)
The head of the House Veterans Affairs Committee wants all hands on deck to address veteran suicide. Rep. Mark Takano (D-Calif.) is calling for The Department of Veterans Affairs to hold a nationwide suicide stand-down within the next 15 days, so every leadership executive, administrator, nurse, doctor, and employee across the agency understands how to identify veterans in crisis and get them the help they need.

Hyperlink to Above

5.3 - The Augusta Chronicle: **Family of veteran treated at Augusta VA who killed self files negligence suit** (26 August, Sandy Hodson, 133k uvm; Augusta, GA)
The family of a Gulf War veteran who killed himself after suffering for years with post traumatic stress disorder has filed suit against the federal government, alleging his VA doctors were negligent. Raymond Georgia Green died from a self-inflicted gunshot Jan. 10, 2017. His widow, Michele Green, and children Na'Kesha Green, Raven Simon Green-Harris, Raymond George Green Jr., and Dontair Wilson filed the federal lawsuit seeking $4 million in damages Aug. 8.

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Hyperlink to Above

5.4 - St. Cloud Times: **Suicide rates among women veterans continue to rise** (26 August, Patricia Wilson, 125k uvm; Saint Cloud, MN)
The Department of Veterans Affairs April 2019 press release that suicide rates among women veterans are going up and the suicide rate for women veterans was nearly twice the rate of non-veteran women should come as no surprise.

Hyperlink to Above

6. Women Veterans / Homelessness / Benefits / Cemeteries

6.1 - The Hill: **Here's why Congress must close the '90/10 loophole' in veterans' education** (26 August, Wesley Wilson, 18.4M uvm; Washington, DC)
For years, veteran advocates and lawmakers have worked to close the widely-known 90/10 loophole that for-profit schools use to target veterans unethically. This year, 37 veteran service organizations and lawmakers have banded together to make closing the loophole a real possibility. Unfortunately, organizations such as the Reserve Officers Association (ROA) are getting in the way of progress by defending for-profit schools and incorrectly promulgating veteran advocates' arguments.

Hyperlink to Above

6.2 - WCPO (ABC-9, Video): **Despite ban, Cincinnati VA Medical Center continues to support transgender troops** (27 August, Craig McKee, 680k uvm; Cincinnati, OH)
Lesbian, gay, bisexual and transgender people have served in the United States military for as long as there's been one. Edicts from the White House — like the bygone "Don't Ask, Don't Tell" and President Donald Trump's current ban on transgender troops — can't change that. And they don't change the responsibility of the United States Department of Veterans Affairs, according to Cincinnati VA psychologist Connie Boehner.

Hyperlink to Above

6.3 - WKYC (NBC-3): **Local son, fiancee hold special wedding ceremony to include ailing father** (25 August, 611k uvm; Cleveland, OH)
Most people dream of their parents being a part of their wedding day. But as many people come to understand due to health risks and deaths, it's not always possible. In an effort to avoid that scenario, a local man held a special wedding service at Cleveland's VA Medical Center Sunday.

Hyperlink to Above

6.4 - Villages-News.com: **Rollout for $10 million monument plan at Florida National Cemetery taking place in The Villages** (26 August, 195k uvm; Lady Lake, FL)
The rollout for a $10 million venture to bring a series of monuments to Florida National Cemetery will be announced this week in The Villages. The Joint Veterans Support Committee (JVSC) is working to bring the Freedom Memorial Plaza to the national cemetery. It will be located near the entrance to the Bushnell facility, will encompass two-plus acres and will be inner-connected by sidewalks.

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Hyperlink to Above

7. Other

7.1 - FOX News: Presidential administrations from both sides like to spend, but then again, so do most Americans (26 August, Chad Pergram, 73.9M uvm; New York, NY)
Eat your veggies. Take your vitamins. Hit the gym. Eliminate alcohol and caffeine. Everyone knows how to stay healthy. Yet we don't like carrots and kale. We forget our Centrum. We go to happy hour with friends after work and skip the cardio class. This is human nature. Who wouldn't rather eat goodies then pound away a few hours at the gym?

Hyperlink to Above

7.2 - U.S. News & World Report (HealthDay): Staying Optimistic Might Lengthen Your Life, Study Shows (26 August, Alan Mozes, 23.3M uvm; Washington, DC)
An upbeat view of life may increase your odds for living to a ripe old age, new research suggests. The finding stems from a look at optimism and longevity among nearly 70,000 women and 1,400 men. It builds on earlier research linking higher levels of optimism to lower risks of chronic illness and premature death.

Hyperlink to Above

7.3 - U.S. News & World Report (AP): Former Trump Official to Helm Florida Republican Party (26 August, 23.3M uvm; Washington, DC)
Florida's Republican Party has named Peter O'Rourke, a former acting secretary of the U.S. Department of Veterans Affairs under the Trump administration, as its new executive director. O'Rourke is widely seen as a loyalist for President Donald Trump. In its announcement Monday, the party said O'Rourke would help the party deliver Florida for Trump's re-election.

Hyperlink to Above

7.4 - Politico: Former VA official 'hand-picked' by Trump to lead Florida GOP (26 August, Matt Dixon, 14.4M uvm; Arlington, VA)
In a surprise move, Peter O'Rourke, a former top official at the U.S. Department of Veterans Affairs and an ally of President Donald Trump, will take over leadership of the Republican Party of Florida, the latest development in a party power struggle going into the 2020 presidential election.

Hyperlink to Above

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1. Top Stories

1.1 - KIVI (ABC-6, Video): #FINDINGHOPE: US Secretary of VA works to open mental health dialogue in the armed forces (26 August, Madeline White, 111k uvm; Nampa, ID)

BOISE, Idaho — FULL STORY ON 6 ON YOUR SIDE MONDAY AT 10 P.M.:

The national tragedy of veteran suicide has been a main concern for US Secretary of Veterans Affairs Robert Wilkie since his appointment to the job. During his recent visit to Boise, he sat down for an exclusive TV interview with 6 On Your Side's Madeline White.

Since October of last year, every veteran who has come into the VA has received a mental health screening, according to Wilkie. He said they have now screened almost 1 million veterans— but their oversight continues in some who are struggling.

“We follow closely 3,000 of them because we believe that they could be a danger to themselves or to others," said Wilkie.

When it comes to preventing mental crises and suicide in veterans, Wilkie says stigmas need to be broken earlier on.

“It’s a cultural phenomenon that needs to be addressed when that young American first enters the military," said Wilkie.

He said, in the military, mental health issues weren’t always taken seriously.

“In my father’s day, the notion that anyone would express concern or anxiety while in uniform, would have been treated as a one-way ticket out of the service. Well that was fine in a draftee force-- its’ not fine in an all-volunteer force, nor is it helpful for the combat effectiveness of the armed forces.”

He said he’s working to create changes that he hopes will have impacts on generations to come.

“When I was under Secretary of Defense, working for General [James] Mattis, we started the program when people are in boot camp, they start being told about the signs of mental health problems— even something simple like anxiety," said Wilkie.

Through actions of this nature, he hopes to spread awareness on how to identify warning signs.

“They can see it in their comrades, they can see it in themselves, and they keep telling themselves throughout their career, 'It’s alright to go see the chaplain.' It’s alright to tell us, and that attitude then becomes part of the mindset once that individual comes into VA"

And those mental health screenings at the VA are one way Wilkie says his intention to open dialogue on mental health is taking form.

“So, it’s a cultural change that’s been slow and coming— but it is coming," said Wilkie.

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If you or someone you know is exhibiting warning signs or having thoughts of suicide, text or call the Idaho Suicide Prevention Hotline at (208) 398-4357 to get 24/7 confidential help from professionals.

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1.2 - CBS News (Video): Inside a suicide prevention call center for veterans responding to 1,700 calls each day (26 August, Dean Reynolds, 30.2M uvm; New York, NY)

For immediate help if you are in a crisis, call the toll-free National Suicide Prevention Lifeline at 1-800-273-TALK (8255), available 24 hours a day, seven days a week. All calls are confidential.

Canandaigua, New York — The Departments of Defense and Veterans Affairs are holding a conference in Nashville this week aimed at preventing suicides. A hotline launched in 2007 has answered more than 3.5 million calls, sending emergency help to nearly 100,000 people.

At the Veterans Crisis Line in Canandaigua, New York, the calls come in all day and night. Every day, 1,700 calls come in from veterans on the brink. CBS News was given rare access to the Veterans Affairs responders and their life-saving conversations.

Twenty veterans take their lives every day in America, or 6,000 a year. Personal finances, broken relationships and loneliness are all factors.

Responder Terrence Davis, a Navy veteran himself, said he always tries to answer by the second ring.

"It's highly stressful. Just knowing that you have someone else's life in your hands," Davis said.

Former Sergeant Danny O'Neel knows that feeling. Santa Cruz, California, may be a long way from the battlefield, but for him and his men, Sadr City, Iraq, is close by.

"It was hell on Earth. It was the most dangerous place at the time," O'Neel said.

In 2006, his unit lost nine men in the fighting. But back home, 14 have died at their own hands.

"The guys started isolating and drinking and doing things that they thought were helping them cope. And it, and it led to depression and suicide," he said.

O'Neel, who attempted suicide in 2012, today describes it as the new enemy with isolation as its accomplice. It's why he now arranges surfing reunions for his fellow warriors.

"When we're together, we feel that sense of family, that sense of a team that we miss," O'Neel said. "I've heard that the Pacific has no memory. For me, that's powerful because I can take Iraq out there and I can give it to the ocean. And I don't have to carry it around anymore."

Back in New York, the VA's responders are also trying to lift that burden — one call at a time.

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1.3 - ABC News (Video): Could a new drug treat veterans with severe depression? President Trump thinks so (27 August, Dr. Lauren Kelly and Elizabeth Mclaughlin, 22.2M uvm; New York, NY)

At a veterans event in Kentucky last week, President Donald Trump touted what he called an "incredible" new drug he says could help American veterans struggling with depression.

The drug, called esketamine and marketed as Spravato, was produced by Johnson & Johnson subsidiary Janssen Pharmaceuticals and billed as a breakthrough treatment for patients who have not responded to other antidepressants.

The Food and Drug Administration approved Spravato in March, although some uncertainties remain about its effectiveness, risks and long term effects, according to experts.

However, those concerns were absent when the president ordered the Department of Veterans Affairs last week to purchase it and "get as much as it as you can from Johnson & Johnson."

"It really has an incredible effect for a lot of people," Trump told an audience at the AMVETS National Convention in Louisville, Kentucky, on Wednesday.

In light of the burden of severe depression among veterans and the alarming rate of suicide -- with 20 veterans dying each day by suicide -- Trump is not the only one who feels the imperative of a timely solution.

What is Spravato?
Spravato is a nasal spray based on the drug ketamine, which has been used as an anesthetic for over half a century since its introduction in the 1960s and has played an emerging role in the treatment of chronic pain and treatment-resistant depression by doctors.

Typically given in IV form, ketamine was reformulated as Spravato for people with treatment-resistant depression, and it boasts quicker and easier delivery with fewer side effects.

A series of clinical trials have shown that the drug, when given in conjunction with a typical antidepressant, such as a selective serotonin reuptake inhibitor, can improve people's depressive symptoms.

Results in one out of three randomized controlled trials used by the FDA to fast-track the drug showed positive efficacy, but the size of the drug's impact on depressive symptoms has been critiqued. In the study used by the FDA, there was just a 4-point improvement in depression symptoms on a 60-point scale used by some clinicians to measure depression.

"The clinical trials of esketamine were completely underwhelming," said Dr. Wesley Boyd, psychiatrist at Cambridge Health Alliance and an assistant professor of psychiatry at Harvard Medical School who was not involved in the studies.

"I'm open to giving esketamine consideration, but given the data we have and its high cost, there are other drugs and therapies we can maximize first," he added.

Boyd cautioned about trials supported by the pharmaceutical industry, like the one used for Spravato, though it is not uncommon for pharmaceutical companies to sponsor trials. Two trials

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that had positive results used by the FDA in their approval of Spravato were funded and conducted by Janssen.

Another refrain among experts is that there is too little data to assess the medication's long term effects, including potential harms, and it has not shown to be efficacious in treating individuals over the age of 65 -- a population of particular relevance to the veteran community. It was also mainly tested in white people.

Long-term studies and reporting of adverse events associated with the use of the drug are ongoing.

A treatment for America's veterans?
Despite the limited research on esketamine, the FDA green-lighted Spravato because there's been a long-standing need for more effective treatments for treatment-resistance depression, which is considered a life-threatening condition, according to the FDA.

Used in conjunction with oral antidepressants, Spravato is administered by medical professionals who are required to monitor a patient for two hours after receiving treatment. Possible side effects of the drug include sedation, nausea and increased blood pressure.

Additionally, black box warnings include the risk of drug abuse and suicide in pediatric and young adult patients. While suicide warnings are seen with other antidepressants, Boyd notes that box warnings are not generic, saying, "A box warning would have to be a result of people during clinical trials who experienced suicidal thinking while taking the drug."

Although, severely depressed people may already have suicidal thoughts before starting treatment, he added.

"I applaud VA efforts to get good treatments into the hands of veterans -- not just the hottest treatment, but the whole menu of options" said Dr. Jonathan Avery, director of Addiction Psychiatry at Weill Cornell Medical College who completed his training at the VA but was not involved in the clinical trials for Spravato. "There's a lot of hope for esketamine, but we should be sure the VA is equipped with all the well-studied medications and psycho-social treatments that we have, including cognitive behavioral therapy."

In response to mounting rates of suicide among veterans, the VA has reformed its guidelines to reflect new data on best practices for screening, evaluating and treating veterans with increased suicide risks.

New recommendations suggest a combination of medication and cognitive behavioral therapy with routine medical visits, frequent outreach, and a "safety" or "crisis response" plan for those at greatest risk. The recommendations also address "lethal means" safety, including restricting people's access to firearms, poisons, medications and installing barriers to prevent jumping from lethal heights.

Getting Spravato to veterans
A VA advisory panel in June decided the use of Spravato would require justification prior to use -- an authorization not unusual for an expensive and powerful new drug.

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Still, Spravato is now available to veterans enrolled in VA care "based on an individualized treatment plan developed by their provider in collaboration with the veteran," a VA spokesperson said.

The department has developed guidelines for Spravato's use "to promote thoughtful patient selection and safe administration practices."

VA Secretary Robert Wilkie, who described Spravato as in its "opening stages" during a Fox News interview on Thursday, said the drug is being used by veterans under the supervision of anesthesiologists at the VA who can monitor any side effects patients experience after taking the drug.

The VA spokesperson told ABC News that the department will continue to monitor the drug's use "to more fully understand its relative safety and effectiveness as compared to other available treatments. Based on this information, the VA may revise its clinical guidance and formulary status if warranted."

Trump pushes Spravato
While there is excitement in the medical community about the promise of Spravato, the president's public promotion of the drug's prescription for veterans has raised eyebrows.

The Center for Public Integrity, a nonprofit investigative news organization, reported in June that Trump was pushing VA officials for quicker adoption of Spravato, and, according to Bloomberg News, the president personally offered to help the VA negotiate purchases of the drug from Janssen.

Trump's ambassador to the United Kingdom Robert Wood "Woody" Johnson IV is the great-grandson of the co-founder of Johnson & Johnson and heir to the "consumer products fortune," owning over 1.5 million shares in the company, according to Bloomberg.

Johnson donated $1 million to Trump's inaugural campaign and was nominated to the ambassadorship in 2017.

Prior to departing for Louisville on Wednesday, the president said the VA would get Spravato "at a very good cost." But hours later at the AMVETS event, he suggested Johnson & Johnson should give the drug to the department for "free" because they "have done so well in this country and they have made so much money."

Janssen spokesperson Kaitlin Meiser told ABC News, "We have not had any conversations with President Trump regarding Spravato."

"Information regarding contracts with payers, including the VA, is proprietary," Meiser said, but "the VA is offered the lowest price in the country."

The VA also declined to say how much the purchase of Spravato would cost the department.

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1.4 - Military.com: **The VA Removed a Vet's High-Risk Label. The Patient Died by Suicide. What Went Wrong?** (26 August, Richard Sisk, 4.3M uvm; San Francisco, CA)

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Again and again, teams at the Department of Veterans Affairs' San Diego Health Care System reached out to and helped a troubled veteran battling suicidal thoughts and substance abuse who frequently missed appointments or broke off contact.

The efforts were not enough. The veteran was found dead in July 2018; the San Diego Medical Examiner's Office ruled the death a suicide by asphyxiation.

Prompted by charges from an anonymous caller, the VA's Office of Inspector General (OIG) investigated the circumstances of the death and issued a report earlier this month titled: "Alleged Deficiencies in Mental Health Care Prior to a Death by Suicide at the VA San Diego Healthcare System, California."

The anonymous caller who claimed that the veteran was "turned away" by the VA could not be reached by the IG's office to back up the accusations.

"The OIG inspection team attempted to contact the complainant by telephone, certified mail, and electronic mail; however, the complainant did not respond," the report states.

The 27-page IG report found procedural "deficits" in how the San Diego VA dealt with the veteran, but stopped short of leveling blame.

The IG's detailed report offered penetrating insight into a case that is emblematic of the challenges faced by the VA health care system. As VA staff serve nine million veterans each year, they must contend with what officials have described as an "epidemic" of suicides among veterans.

The challenges become even more acute, the IG report shows, when the veteran misses appointments, rejects treatment plans or sporadically ignores attempts at outreach.

The investigation was conducted to assess whether the VA failed to provide mental health care to a patient who subsequently died by suicide. Ultimately, investigators did not substantiate claims that the VA failed to provide mental health care when the patient sought help, according to the report.

"The OIG found that the suicide risk assessment of the patient was adequate" and complied with the standards of the Veterans Health Administration and the San Diego system's requirements, the report states.

Still, there were serious shortcomings. Investigators identified the move to deactivate the patient’s flag in medical records noting a high risk for suicide as a concern. The suicide prevention coordinator at the hospital removed the veteran from the high-risk list "without contacting the patient" or "consulting the patient's treatment team," the report states.

The veteran remained off the list even after failing to show up for mental health services for more than two months.

Patients are supposed to be added to the high-risk list so VA staff members can track those veterans closely, making efforts to reach them when they miss or cancel appointments, agency guidelines state.

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The IG made two recommendations for improving procedures and documentation at the San Diego VA based on a case that could serve as a valuable example for systemic improvements.

Investigations of such deaths often center on what the VA did, or didn't do, to assist the veteran, although statistics show that about 14 of the 20 veterans who die daily by suicide never have any contact with the department.

"It seems like the VA did a lot of things correctly" based on the IG report, said Navy Reserve Cmdr. Jeremy Butler, CEO of Iraq and Afghanistan Veterans of America. "But it's not a totally clean bill of health."

Butler called the issue of veteran suicide "a national emergency."

"We realize the VA can't do everything," he said, but he questioned the removal of the veteran in the San Diego case from the high-risk list.

Butler said the San Diego suicide case underlined the need for the VA to engage in more outreach to veterans, either by the department itself or through local and state partners when veterans become difficult to contact.

VA Secretary Robert Wilkie has repeatedly cited curbing the veteran suicide rate as the "top clinical priority" for the system's 170 hospitals and more than 1,100 clinics nationwide.

In March, President Donald Trump signed an executive order creating a cabinet-level task force that he pledged would "mobilize every level of American society" to address the crisis of suicides among veterans.

The death of the veteran in San Diego, and the report of the IG on the circumstances, illustrate how difficult the task will be.

Early Warning Signs
The veteran in this case, who was identified only as the "patient" due to privacy rules, was younger than 30 at the time of death.

The veteran's gender and military branch were not disclosed, but investigators found the individual "first experienced depressive symptoms including insomnia and thoughts of suicide during high school but did not seek treatment at that time."

Just a month after joining the military in 2013, the patient met with a counselor and was "feeling really depressed," the report states, but chose not to start medication until the summer of 2014 for fear that it might interfere with training.

The patient was then prescribed two antidepressant medications and a sleep aid. The patient's first contact with the VA came in the spring of 2017, after leaving the military.

"During that visit, the patient complained of periodic thoughts of self-harm," the report adds. "The patient asked to restart psychiatric medications, and the primary-care provider prescribed an antidepressant."

The investigation goes on to detail several contacts and visits to the VA by the patient, though it notes the veteran's follow-up on advice or treatment suggestions was sporadic.

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In the initial visit to the VA, the patient described "chronic passive suicidal ideation" and recounted an attempt while in the military. The patient ultimately stopped the attempt and called a suicide hotline, the report states.

A VA social worker drew up a risk assessment in which the patient reported researching methods of suicide on the internet. The social worker estimated the patient's risk of suicide to be "moderate/ambivalent," but the patient did not think a safety plan would be useful and declined to complete one.

Then followed meetings with a VA psychiatrist and psychologist in which the patient would ask for changes in medication and admit to substance abuse while refusing treatment for it. The patient also met with a private psychologist under the VA's "Choice" program for private-care options.

Rescheduled Appointments
In the summer of 2017, after the patient rescheduled appointments multiple times, the VA psychiatrist called the patient.

"The patient reported intrusive thoughts of suicide" and spoke of planning to discuss them with the VA Choice provider, but also "denied active suicidal ideation, intent, or plans," the report states.

The psychiatrist called the patient's Choice provider less than a week later. They agreed that, although the patient did not meet criteria for inpatient psychiatric admission, the patient was at long-term elevated risk for self-harm, according to the report.

"During a follow-up psychiatric visit four days later, the patient admitted to a suicide attempt in mid-summer of 2017," the report continues.

This attempt was also stopped by the patient after about a minute, the report states.

There was more back and forth between the VA and the patient on recommendations for treatment and medication, many of which the patient ignored, according to the report.

In early 2018, the VA psychiatrist reached out to the patient following a missed appointment. The patient said that two weeks prior while at an airport, they sent a photo to a friend showing an apparent self-strangulation attempt, and then turned the phone off, the report states.

The friend contacted the patient's family, who called airport security.

"The patient said that the police spoke with the patient upon landing but did not detain the patient," according to the report.

Three days after the phone call, it adds, the patient agreed to an intensive outpatient program referral, but declined the psychiatrist's offers for substance abuse treatment or restarting psychiatric medication.

"After the patient missed the next appointment, the psychiatrist contacted the system emergency department social worker, who called police and requested a health and welfare check," it continues.

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"During the health and welfare check, the patient expressed passive thoughts of death but did not meet criteria for inpatient admission," the report states. "The patient agreed to follow up with the outpatient providers the following week but did not."

After multiple calls to the patient without a response, the VA psychiatrist called the patient's mother and left a voice message. The patient's mother called back and said that she was speaking with the patient twice a week and was appreciative of staff concern, the report states.

Suicide Risk Flag Deactivated

In late winter 2017, a VA suicide prevention coordinator, or SPC, contacted the patient, who reported "decreased depression, and decreased frequency and intensity of suicidal thoughts."

"The SPC changed the patient's suicide risk assessment to moderate/ambivalent," and after additional calls, the patient's suicide risk flag was deactivated in late spring of 2018, the report states.

However, in the summer of 2018, the patient went to the VA emergency room with thoughts of suicide, according to the report.

The patient was evaluated by a second-year psychiatry resident, who "described the patient as 'pleasant, engaging, and jovial at times,' despite the patient's self-report of feeling suicidal for the prior two days after a fight with a friend," the report states.

The patient denied symptoms consistent with major depressive disorder, investigators found, including changes in appetite, energy or concentration, but admitted having fleeting thoughts of suicide most days of the week.

"The resident offered the patient voluntary psychiatric admission for stabilization, but the patient declined," the report states. "The patient stated that the conversation with the resident had improved the patient's mood and the patient now felt safe to return home with a roommate."

The resident decided that the patient did not meet the criteria for involuntary admission or "warrant psychiatric inpatient admission at that time," according to the report.

"The resident assessed the patient's short-term risk of suicide as low," but "acknowledged that the patient's long-term risk of suicide was elevated given the patient's history of chronic suicidality and other mental health conditions," the report adds.

The staff psychiatrist at the hospital co-signed the resident's consultation note about four hours after the patient left, the report states, and the resident added the outpatient psychiatrist, outpatient psychologist and lead suicide prevention coordinator to the note.

Several days later, the outpatient psychiatrist attempted to contact the patient by phone and left a voice message asking the patient to return to care. A psychiatry medical support assistant later attempted to phone the patient but was unsuccessful, according to the report.

The medical support assistant then sent a letter to the patient "that encouraged the patient to call to schedule an appointment and noted that there would be no further attempts to schedule an appointment," the report adds.

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"The patient expired two days after the medical support assistant sent the letter," the report states. "The Deputy Medical Examiner reported the patient's cause of death as asphyxia [suffocation] and manner of death as suicide."

In response to questions from Military.com, the IG office said that the detailed analysis of an individual case could point the way to improvements in suicide prevention.

"It is hoped that the identification of failures in a specific case will lead to lessons learned across the VA system of care," the office said in a statement.

In its response, the VA's San Diego Health Care System thanked the IG for the "thorough review of the circumstances involving this tragic veteran suicide which occurred in July 2018," but did not refer to any "failures."

"We appreciate their confirmation that there were no deficiencies in the care of the veteran provided by our mental health providers or our emergency department, or in the supervision of the resident physician staff who also participated in the veteran's care," Cynthia Butler, public affairs director for the San Diego VA, said in a statement.

On the subject of red flags for high-risk patients, Butler said, "We are also working with the VA Office of Mental Health and Suicide Prevention to assure that consistent processes are developed and implemented for the management of flags alerting staff to the presence of veterans who may be at higher risk for suicide."

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1.5 - The Daily Signal: VA Lifts Ban on Bibles in Move to Support Religious Freedom (26 August, Fred Lucas, 1.1M uvm; Washington, DC)

As a kid, Veterans Affairs Secretary Robert Wilkie recalls, he visited a VA hospital at Christmastime.

“One of my fondest memories growing up, we used to sing Christmas carols at the VA hospital in Fayetteville, North Carolina,” Wilkie told The Daily Signal, sitting in a 10th-floor office at VA headquarters on Vermont Avenue Northwest, overlooking the White House.

“Something as simple and as decent as that was being stopped,” he said. “With the support of the president, we just said enough is enough.”

Wilkie grew up at Fort Bragg, the son of an Army artillery commander. He himself served in both the Navy and Air Force reserves, and as a Pentagon official.

Since becoming VA secretary a little more than a year ago, he has returned to North Carolina.

“I was in my hometown. We have a beautiful chapel in the old VA hospital. And I walked in and there were no Bibles,” the secretary said. “It had been stripped of the symbols of religion.”

The VA revised directives to permit religious literature, symbols, and displays at agency facilities following a string of incidents in recent years in which individual medical centers banned

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Christmas carols and a Christmas tree, chapels removed Bibles, and chaplains faced restraints on religious expression.

Generally, the VA had inconsistent policies across the country.

Officials designed the changes to protect the religious freedom of veterans and their families.

The new guidelines, which went into effect last month, referred to the recent Supreme Court ruling allowing a cross-shaped memorial to World War I dead to continue standing on public land in Bladensburg, Maryland.

The high court's decision highlighted the important role that religious symbols plays in the lives of Americans and their consistency with constitutional principles.

"The military culture has been part of my being, an important part of what I believe," Wilkie told The Daily Signal. "I've seen the effects of combat, both in uniform and out of uniform."

That military culture in which he grew up, Wilkie said, also prioritizes the "ability of our troops to worship, their right to worship, their right to have access to chaplains, and to be free to celebrate their faith." He added:

Now, moving over to VA, I consider the spiritual well-being of our veterans, their spiritual health, to be just as important as the medical competence and technical competence of our doctors and nurses. They should have that fundamental right available to them to access chaplains, to access their Bibles.

The new guidelines call for "inclusion in appropriate circumstances of religious content in publicly accessible displays at VA facilities," and allow "patients and their guests to request and be provided religious literature, symbols and sacred texts during visits to VA chapels and during their treatment at VA."

The guidelines also allow the VA to accept donations of religious literature, cards, and symbols at its facilities, and to distribute them to VA patrons "under appropriate circumstances."

"Under the old regime, you couldn't have those outward symbols," Wilkie said. "You could not have religious texts in the chapels unless you brought them. The chaplains could not walk the halls seeking people to talk with. There had to be a specific request."

The allowed literature may include the Bible, the Quran, the Talmud, or any other religious text, VA officials noted.

Still, the policy faces opposition.

"The VA's actions undermine our Constitution, which intentionally establishes a secular government in order to preserve religious freedom, a right enjoyed by individuals," Sam Grover, associate counsel for the Freedom From Religion Foundation, wrote in a letter to Wilkie objecting to the standards.

"Were the VA truly concerned about protecting the religious freedom of veterans, it could simply do what the Constitution prescribes and keep its facilities free from government-endorsed religion," Grover wrote.

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Wilkie said he doesn't anticipate litigation over the policy because it is based on the recent Supreme Court ruling.

"What Justice [Neil] Gorsuch said in the Maryland cross case was absolutely on target," Wilkie said. "Because you might be offended doesn't give you standing to stop other people from worshiping. For me, this is not only a military issue. It's a religious liberty issue, and one that is vitally important to those we serve."

The high court's ruling should reaffirm the VA's policy, said Emilie Kao, director of the DeVos Center for Religion and Civil Society at The Heritage Foundation.

"On the heels of the Supreme Court's 7-2 decision that reaffirmed the Constitution's protection of the tradition of public displays of religious monuments, symbols, and practices, the U.S. Department of Veterans Affairs took a much-needed step to clarify that religious symbols as well as spiritual and pastoral care are welcome at VA facilities," Kao told The Daily Signal.

"Millions of soldiers from different religious backgrounds have relied upon their faith and gained encouragement from religious literature, symbols, and displays," Kao continued. "No member of the military should have to hide their faith when they put on a uniform. Nor should our public square be devoid of religious symbols."

In January, the Manchester Veterans Affairs Medical Center in New Hampshire removed a Bible on display at a "Missing Man" table after a secular group, the Military Religious Freedom Foundation, objected.

The Bible had been carried by a prisoner of war from World War II, but the group said some veterans had complained about its display.

After receiving new complaints about its removal, hospital officials restored the Bible the following month. In May, however, a Vietnam veteran sued to have the Bible removed.

"A Bible that was owned by a survivor in the Battle of the Bulge had to be put under lock and key because several people unknown had complained that this was an affront to them," Wilkie said, adding:

It's incongruous to me [because] we send our young people to some pretty rough places. The notion that someone who would have been in those situations is so offended by the sight of a Bible that he wants to sue and deprive his comrades of that comfort is just beyond the pale.

In late 2015, a VA clinic in Salem, Virginia, initially blocked a Christmas tree from the premises, stating in a letter to employees that "trees have been deemed to promote the Christian religion and will not be permitted in any public areas this year."

The clinic reversed course in late November after public pushback, and allowed the Christmas tree.

In January 2014, then-House Veterans Affairs Chairman Jeff Miller, R-Fla., wrote then-VA Secretary Eric Shinseki, citing a VA medical center in Augusta, Georgia, that banned high school Christmas carolers.

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Miller also wrote that VA officials in Iowa City, Iowa, had told the American Legion not to hand out gifts if the wrapping paper said “Merry Christmas” and a VA hospital in Dallas had refused a delivery of handwritten Christmas cards from schoolchildren because they included the words “Merry Christmas” and “God Bless You.”

Such matters are important beyond individuals’ freedom of religion, affecting the health of veterans in the VA’s care, Wilkie said.

“The issue of Christmas carols is about simple courtesy, the ability to make people smile at a time in their lives when they are in a hospital for whatever reason, for groups to come in and spread comfort,” he said. “Emotional sustenance is absolutely something that we should be allowing, not standing in the way of.”

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1.6 - Nextgov: **Veterans Affairs Launches Digital National Cemetery** (26 August, Brandi Vincent, 339k uvm; Washington, DC)

The Veterans Affairs Department’s National Cemetery Administration developed and launched an online memorial platform—Veterans Legacy Memorial—to honor millions of veterans interred in national cemeteries across America. Deemed a “digital national cemetery,” the new resource leverages technology and prioritizes security to boost community engagement and preserve the memories of those who served.

“It is first and foremost a memorialization tool to enhance and extend the national cemetery experience beyond the physical boundaries of the national cemetery and create something so that veterans, family members, friends, students, history buffs—whoever—can then connect with that veteran tradition, keep community and share memories whenever the moment strikes them,” Veterans Legacy Program Manager Bryce Carpenter told Nextgov Monday.

To Carpenter, an Army veteran who also has experience working in academia, the development of the tool was “personally and professionally powerful.” As an academic leading students in various research, Carpenter frequently searched for better resources to inspire the sorts of questions he encouraged them to ask, often to no avail.

In 2017, Carpenter was working for VA’s legacy program at Florida National Cemetery where he was engaging with students and professors from the University of Central Florida. He had a panoramic view of many of the agency’s stakeholders—students, professors, teachers, veterans, family members, civil war actors and others—and was inspired to create one digital product that could serve all of NCA’s customers, and ultimately, its mission.

“Our agency has a statutory mission to memorialize all veterans in perpetuity,” he said. “So through VLM, we can use this as a way to make sure that people can access the stories of all 3.7 million veterans in our national cemeteries, which go back through the Civil War, and even to the Revolution, to make sure that the story of every single veteran is not forgotten.”

The public can use the interactive site to search for any veterans who are buried in the 136 cemeteries that NCA manages. Every veteran interred has their own memorial page on the site. Individuals can access it for information about grave whereabouts, as well as basic details about the veterans’ lives and service. Carpenter said the agency’s goal is for people to use it to find

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new information about veterans they know about as well as study veterans that they don't know. He also hopes it will motivate teachers to engage their students and incorporate veteran history into their lesson plans in new and exciting ways.

"So many different perspectives in American history can be accessed through the veteran experience," he said.

For insights on how to build a site that customers would use, Carpenter and the development team met with veterans across many generations and a variety of other stakeholders for feedback and inspiration during the development process. They engaged directly with the Defense Department's survivors forum, educators in academia and organizations like the Tragedy Assistance Program For Survivors to learn what they'd want most from an online memorial site. He expects to incorporate those interactions and further feedback going forward.

"Just through that process alone we know that with more feedback we are going to get better information with which we can further refine the product so that we can serve our public with greater intentionality," he said.

The site will see a variety of future enhancements, as well. Carpenter said it eventually likely will offer users the ability to interact with others over comments, upload photos and access historical documents via VLM. He also emphasized how security and privacy were a major priority throughout the site's creation.

"The security and privacy standards right now are the highest for any public-facing government website," he said. "What we want to provide under the security and the neutrality of the VA brand is 100% assurance that our veterans and all of our customers know that their data is safe, it's being used for nothing other than memorialization and there's actually no way to access any personally identifiable information."

Ultimately, Carpenter said he hopes the platform helps unite diverse groups of veterans and allows them to connect and share memories about "battle buddies" they may have lost. He also hopes to inspire people across the country to learn more about America's history through streamlined information about those who fought on the frontlines.

"One of the things we often talk about in the Veterans Legacy Program is that we are striving to make sure that all veterans are honored for their service—not just high ranking officers or war heroes that have been decorated with medals of honor and things like that—but everybody who played a part and everybody who wore a uniform," he said. "And so hopefully this is a way for people to really access some of those stories of service."

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1.7 - Las Vegas Sun: **At VA, we protect those who protected us** (26 August, Sec. Robert Wilkie, 180k uvm; Henderson, NV)

Cpl. Orlando Camacho, Lt. Kenneth Frazier and officer Miguel Calderon didn't know they would save lives when they woke up Aug. 12 and reported to the Jesse Brown VA Medical Center in Chicago.

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The three members of the Veterans Affairs Police were on duty when shots were fired just outside the VA's doors. As alarms blared and people flooded 911 with calls, Camacho, Frazier and Calderon waded past panicked people toward a man with a rifle in his hand who entered the building.

All three drew their firearms and ordered him to drop the rifle. The suspect complied and was quickly handcuffed.

Less than a minute after the call went out, it was all over. VA Police had their man without firing a shot, and no one was hurt.

It's an incredible success story at a time when we continue to wake up to news of violence across the nation. Our hearts break when these tragedies occur, but when our first responders run toward danger and prevent tragedies as these three VA Police officers did that day, our hearts swell with pride.

On behalf of the entire VA family, I thank Camacho, Frazier and Calderon for their prompt, measured and heroic response.

The incident is just the latest point of pride for the VA Police, a family of 4,700 that works around the clock to ensure the safety and security of our medical centers and national cemeteries.

The origins of this police force date back to President Abraham Lincoln's time — they have been working alongside veterans for more than 150 years now, although their role has changed over the years.

The VA Police do more than just protect veterans, families and visitors from outsiders, they are also specially trained to ensure veterans are not a harm to themselves. Suicide prevention is our top clinical priority, and the decision to put our police through rigorous training on how to de-escalate potentially violent situations is a testament to our all-hands-on-deck approach to this issue.

Just months ago, a veteran on a VA campus in Atlanta threatened to take his life. VA Police officer Alonzo Pitmon found the veteran in a car in the parking lot, and repeated to the veteran, "I am here to help you and not hurt you."

This potential victim was taken into custody unharmed, thanks to Pitmon and others.

These officers undergo specialized training at the VA Law Enforcement Training Center in Arkansas, where they are taught "veteran-centered policing," which focuses on resolving incidents in a respectful manner that's designed to ensure the maximum level of safety for anyone in one of our medical centers. They learn to de-escalate situations through apprehension techniques that minimize the amount of force officers use to gain control over these situations.

Our officers also have another edge — many are veterans themselves, and have deeper insight into the sorts of challenges that our veteran patients and their families are facing.

This nation has a duty to understand and treat mental health disorders that lead to violence against others and the tragedy of suicide. As a start, we need discussions at all levels about the

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value of life, and we must have a plan beyond hoping we can save people by making the equivalent of a last-second diving catch.

We are making important strides in that direction, particularly when it comes to addressing the issue of veteran suicide. Meantime, those VA officers in Chicago, Atlanta and elsewhere have our eternal thanks for engaging in situations in which there is only time to act, not plan, and for fearlessly serving as our last line of defense against the unthinkable.

Robert Wilkie is the secretary of Veterans Affairs. He wrote this for InsideSources.com.

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1.8 - The Exponent Telegram: **Sen. Manchin: VA officials assure 'person of interest' in homicide no longer in contact with veterans in VA hospital** (26 August, Matt Harvey, 133k uvm; Clarksburg, WV)

CLARKSBURG — A person of interest in 11 suspicious deaths at the Louis A. Johnson VA Medical Center — one of those deaths a confirmed homicide — "is no longer in any contact with veterans at the facility," U.S. Sen. Joe Manchin said Monday in a news release.

Later in the day, Wesley Walls, chief of public affairs and community relations service at the Medical Center, issued a statement, saying the "allegations of potential misconduct you may have heard about in media reports do not involve any current Louis A. Johnson VA Medical Center employees."

Manchin spoke with Department of Veterans Affairs Secretary Robert Wilkie and the VA hospital's director, Dr. Glenn Snider, according to the release.

"I was ... assured by both Secretary Wilkie and Dr. Snider that the person of interest is no longer in any contact with veterans at the VA facility," Manchin said in the statement. "These crimes shock the conscience, and I'm still appalled they were not only committed, but that our veterans, who have sacrificed so much for our country, were the victims.

"As a member of the Senate Veterans Affairs Committee, I will do everything in my power to investigate these accusations and get to the bottom of what happened. These families and loved ones deserve answers as soon as possible, and I will make sure they get them," said Manchin, D-W.Va.

Manchin also said he "made sure to talk to Secretary Wilkie and Dr. Snider to make sure that their investigation into these deaths is accurate and thorough."

According to the statement from the Medical Center's Walls, "immediately upon discovering these serious allegations, Louis A. Johnson VA Medical Center leadership brought them to the attention of VA's inspector general while putting safeguards in place to ensure the safety of each and every one of our patients."

"The department informed the staffs of Senators Capito and Manchin and Rep. McKinley of these allegations August 7, 2018, and they are aware of the ongoing investigation," Walls wrote in an email. "VA is cooperating fully with the inspector general's ongoing investigation, and for additional questions, we refer you to them."

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Meanwhile, a Veterans Affairs Office of Inspector General report from 2018 found staff at the Louis A. Johnson VA Medical Center hasn't consistently applied criteria that would identify sentinel events.

Sentinel events are incidents or conditions that result "in patient death, permanent harm, severe temporary harm, or intervention required to sustain life," according to the report.

The review covered the period of Sept. 21, 2015, through May 7, 2018. On that date, an unannounced week-long site visit started. During that review period, inspectors discovered what they believed to be six "sentinel" events that were unreported.

The report was released last October, the same time that the body of retired Army Sgt. Felix Kirk McDermott, a patient who died at the VA hospital, was exhumed. A subsequent autopsy ruled McDermott's death a homicide, saying he was given insulin even though he wasn't a diabetic, and none was prescribed for him.

Up to 10 other deaths are suspicious and are believed to have occurred in the same manner," according to a notice of claim filed on behalf of McDermott's estate by Charleston attorney Tony O'Dell.

The report last October by the VA Office of Inspector General also found that hospital "managers did not follow local policy for single identified sentinel events and disclose relevant information to the patient or the patient's representative. The OIG noted that the Facility has opportunities to improve identification of events that require disclosure and sentinel event identification, tracking and reporting."

According to the claim filed by O'Dell on behalf of Melanie Proctor, McDermott's daughter from Ellenboro and the administrator of his estate, the VA Office of the Inspector General ordered McDermott's remains exhumed Oct. 23, 2018, and they were sent to Dover Air Force Base for an autopsy "because of the suspicious manner of Mr. McDermott's death."

"During its investigation, VA investigators advised Melanie Proctor ... that there was evidence that nine or ten other patients of the Louis A. Johnson VA Medical Center had been wrongfully injected with insulin in their abdomen, thereby causing their deaths," O'Dell wrote. "Ms. Proctor was further advised that her father was one of the last known victims."

The autopsy "confirmed investigators' suspicions that Ret. Army Sgt. McDermott had received an exogenous insulin shot in the left side of his abdomen," the claim states. "That finding was consistent with the clinical history of profound hypoglycemic event that occurred the morning of April 9, 2018.

"The autopsy report confirmed that Ret. Army Sgt. McDermott was not a diabetic and had no history of oral hypoglycemic use or previous insulin administration," O'Dell wrote. "The autopsy report also confirmed there were no hospital orders for the administration of insulin. The autopsy report noted that despite Ret. Army Sgt. McDermott's pre-existing health issues, he was showing clear improvement in his medical condition when he was negligently, wrongfully, or intentionally injected with insulin."

The claim contends that employees at the medical center "were aware of each of the unexpected and suspicious deaths."

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The claim, which serves as an official six-month notice of a coming lawsuit, seeks monetary damages of $1 million for personal injury and $5 million for wrongful death, as well as funeral expenses and other costs.

O'Dell said his law office is currently seeking out the families of the other patients who may have died the same way.

McDermott, who also had lived in Ruffs Dale, Pennsylvania, retired as a sergeant after a 20-year career in the Army, during which he was deployed to Vietnam, then served in the Pennsylvania National Guard and also worked as a truck driver.

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1.9 - Healthcare IT News: OIG audit: Massive backlog in digitizing VHA medical records
(26 August, Nathan Eddy, 64k uvm; Chicago, IL)

Veterans Health Administration medical facilities are facing an enormous challenge as they scan and enter medical documentation into patients' electronic health records, according to an audit from the Office of the Inspector General for the Department of Veterans Affairs.

WHY IT MATTERS
Based on provided data, the audit team calculated that VHA medical facilities have a cumulative medical document backlog equivalent to more than five miles of stacked paper, with nearly 600,000 individual electronic document files dating back to October 2016.

The backlog has built up in part because VHA staff had not been scanning and entering documents into the electronic medical record system in a timely manner, though the report also noted staffing shortages have contributed to the challenge.

Further complicating the situation, the audit found, was the fact that when medical facility staff scan medical documentation, they are not always performing the appropriate reviews and monitoring to assess the overall quality and legibility of the scanned documents.

This means the VHA must work to improve the management of scanning activities, including importing, indexing and legibility checks, and should also establish and implement a training program for those in charge of the scanning and indexing in medical facilities.

The audit also recognized the scale of the problem, noting specific backlog details such as descriptions of the documents, the size of the backlog and age of unscanned records are not consistently addressed as part of the OIG's inventory.

Another major challenge described in the report was the discovery that the eight medical facilities visited did not consistently follow training policy, and training by the health information management staff varied from site to site.

The audit recommended the VHA implement standardized quality assurance monitoring procedures and ensure original medical records are retained until it has been verified that those quality assurance standards have been met.

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THE LARGER TREND
The OIG audit comes as the VA is undergoing a massive push toward digitalization. In June, the Department of Defense and the VA announced the creation of a special office to help centralize decision making as the VA makes its multibillion-dollar electronic health records upgrade.

But just this past week, Politico reported that the VA's modernization effort is already encountering roadblocks that could delay the project for six months or more.

ON THE RECORD
“The VHA needs to improve its supervision and medical facilities’ management to ensure medical documents are accurately scanned and indexed,” the OIG report noted.

“During audit team site visits, neither the chiefs of HIM nor their designees responsible for supervising scanning activities always had direct knowledge of the scanning processes and backlog information within their facilities,” auditors said.

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1.10 - WDTV (CBS-5, Video): Update: Veteran speaks out about his time at the Louis A. Johnson VA Medical Center (26 August, 32k uvm; Bridgeport, WV)

CLARKSBURG, W.Va. (WDTV) -- 5 News spoke with local veteran, Ken Warman about his experience at the Clarksburg VA Medical Center.

"That facility, I hate to tell you. Worst facility I have ever been to. Hands down, of all the states I have been to. Hands down the worst. I have been treated the worst," said Warman.

According to a 2018 report by the Department of Veteran's Affairs Office of the Inspector General, officials found one sentinel event at the medical center. A sentinel event is defined by the report as a "incident or condition that results in patient death, permanent harm, severe temporary harm, or intervention required to sustain life."

Originally, inspectors found six cases that appeared to meet the criteria for sentinel events, however, after discussing with facility managers, those cases were re-evaluated.

Inspectors also found a presence of "organizational risk factors - [noted as] lack of identification, tracking, and reporting of sentinel events and disclosure of adverse events."

The report notes that these risk factors could contribute to "future issues of noncompliance and/or lapses in patient safety."

UPDATE 08/26/19 @ 1:03 p.m.
U.S. Senator Joe Manchin's office say he spoke with the Department of Veterans Affairs Secretary Robert Wilkie and Louis A. Johnson VA Medical Center Director Dr. Glenn Snider Monday about the ongoing investigation into the suspicious deaths being investigated at VAMC. One of the up to 11 deaths was ruled a homicide.

“Today I made sure to talk to Secretary Wilkie and Dr. Snider to make sure that their investigation into these deaths is accurate and thorough. I was also assured by both Secretary Wilkie and Dr. Snider that the person of interest is no longer in any contact with Veterans at the

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VA facility," said Manchin. "These crimes shock the conscience and I'm still appalled they were not only committed but that our Veterans, who have sacrificed so much for our country, were the victims."

Manchin says he will do everything in his power to investigate and get to the bottom of what happened.

"These families and loved ones deserve answers as soon as possible and I will make sure they get them," said Manchin.

The claim filed by Tiano O'Dell says that retired Army Sergeant Felix McDermott died of low blood sugar after he received a fatal dose of insulin in April.

The claim says McDermott's death was ruled a homicide after an autopsy was completed.

UPDATE 08/23/19
A claim filed by Tiano O'Dell law firm says that retired Army Sergeant Felix McDermott received a fatal dose of insulin while a patient at the Louis A. Johnson VA Medical Center.

According to the claim obtained by 5 News, first reported by the Clarksburg Exponent-Telegram, McDermott was admitted to the VAMC on April 6, 2018. He died of hypoglycemia, or severe low blood sugar, on April 9, 2018. He was 82.

The claim states that employees never told McDermott's family how he died. He was buried 4 days later.

On Oct. 23, 2018, McDermott's remains were exhumed and sent to the Dover Air Force Base for an autopsy and investigation.

The autopsy completed February 2019 confirmed that McDermott was not a diabetic and that he was showing improvement in his medical condition when was injected with insulin.

The autopsy ruled McDermott's death a homicide.

The claim also states that nine or 10 other patients died of severe low blood sugar before McDermott's death.

Tony O'Dell is the family's lawyer.

"It's all very disturbing that people who served our country were being killed either extremely negligently, grossly negligently, or intentionally, and nobody has done anything about it," O'Dell said.

The claim says the VAMC breached its duty and was negligent in several ways.

The claim says their client, the estate of McDermott, is seeking damages of up to $5 million for wrongful death, $1 million for personal injuries and expenses for the funeral and other costs.

"Each time one of these deaths happened, they have an obligation to run at the ground to find out what happened, why it happened, how it could be prevented," O'Dell said.

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McDermott was a Vietnam Veteran who served for 20 years before retiring.

U.S. Senators Joe Manchin and Shelley Moore-Capito released statements about the claim.

“This news is sickening and troubling," Capito said. My office has reached out to the VA to learn more details, and I will do everything I can to make sure this is fully investigated.”

5 news reached out to Congressman David McKinely's office for a statement.

“Congressman McKinley is aware of an ongoing investigation at Clarksburg by the Veterans Administration Office of the Inspector General," said McKinely's Communications Director Amanda Hyman "We hope to get more answers about this situation as that investigation progresses.”

The full claim is attached to the right of this article.

ORIGINAL STORY
U.S. Senator Joe Manchin release a statement on a claim filed by Tiano O'Dell law firm that one of the up to 11 suspicious deaths being investigated at the Louis A Johnson VA Medical Center has been ruled a homicide.

“This report is shocking and if accurate, I am appalled that these crimes were not only committed but that our Veterans, who have sacrificed so much for our country, were the victims. As a member of the Senate Veterans Affairs Committee I will do everything in my power to investigate these accusations and get to the bottom of what happened. These families and loved ones deserve answers as soon as possible and I will make sure they get them,” Senator Manchin said.

The claim states that the other nine or ten suspicious deaths are also expected to be a homicide.

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2. Improving Customer Service

2.1 - Military Times: **Unable to sue the Army for medical malpractice, this retired soldier is now fighting the VA for benefits** (26 August, Meghann Myers, 1.7M uvm; Vienna, VA)

Retired Sgt. 1st Class Barbara Ospina is partially paralyzed, in debilitating pain and confined to a wheelchair for almost all of her day. Her condition is the result of malpractice at the hands of hands of military medicine, according to claims she made to the Department of Veterans Affairs, but she is paying out of pocket for a caregiver to help her bathe, dress and prepare meals, because the VA has denied her request for caregiver assistance.

What began as a treatable birth defect turned into a dislocated neck and a stroke that went undetected for days, according to records provided to Military Times. Had that initial surgery taken place at a civilian hospital, Ospina, 29, would be able to seek damages. But the Feres Doctrine, a 1950 Supreme Court decision, prevents her from suing the Defense Department for service-connected illness or injury.

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“Her story represents the egregious conduct, consistent lack of care and malpractice at the hands of Wright-Patterson Air Force Base,” her attorney, Natalie Khawam of the Tampa, Florida- and D.C.-based Whistleblower Law Firm, told Military Times on Tuesday.

For now, the hope is that a bill in Congress will allow Ospina, a mother of a young son, and veterans like her to seek compensation for alleged medical mistakes that they claim have altered their lives forever.

“This case is an example of how flawed the system is, and why it’s time for change,” Khawam said.

Ospina was a public affairs noncommissioned officer for 5th Special Forces Group at Fort Campbell, Kentucky, when she started experiencing headaches, tingling and numbness in her limbs and occasional blurred vision, according to an appeal letter her husband wrote to the VA in 2017, after she was denied access to their caregiver program.

She thought perhaps she’d been injured during combatives training with her unit in early 2013, Khawam said. After making repeated requests for an MRI, the scan showed a deformity known as a “type I Chiari malformation” — essentially, her skull was putting pressure on her cerebellum, forcing it down into her spinal column.

On April 16, 2013, Ospina and her family traveled to Wright Patterson Air Force Base, Ohio, for a surgery to repair the malformation. The risks included hemorrhage, stroke or infection.

According to her husband’s statement in her VA claim appeal, her treatment there nearly killed her.

“The VA is claiming Barb’s condition is the result of ‘an Illness or Medical Condition,’ specifically Arnold Chiari 1 Malformation, and not from an ‘injury,’ "her husband wrote in her VA appeal, which was also denied. “Her current condition is due to INJURIES sustained from medical malpractice that occurred by a military Neurosurgeon, military nurses, and the overall horrible care she received at Wright-Patterson Air Force Base.”

Johnny Van Winkle, a spokesman for the base. declined to comment on the allegations, citing the Health Insurance Portability and Accountability Act of 1996, which prevents medical providers from disclosing a patient’s medical records.

As she began recovery, Fitzsimmon’s left eye was swollen shut and her head was leaning toward her left shoulder, Khawam said.

Her VA disability rating documents confirms that she suffers from a paralyzed cranial nerve and blindness on her left side.

“The lack of care continues when Barb is admitted for an MRI of her head and is ordered to lay flat without oxygen for an hour,” she said. “This is despite Barb crying and stating she cannot breathe without her oxygen.”

Following the MRI, she was intubated — put on a ventilator to help her breathe, preventing her from eating on her own or speaking — for a month.

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In the VA claims appeal, her husband wrote that on April 21, medical staff informed the family Ospina had suffered a stroke.

Further, he wrote wrote to the VA, the stroke went undetected for more than a day, “even though Barbara was supposed to be receiving hourly neuro checks.”

“This led to extensive brain damage and almost to her death,” he added.

She was transferred to Miami Valley Hospital in nearby Dayton, Ohio, where she had surgery to remove part of her skull, to relieve the pressure on her brain the following day.

“It is not until June 2014 that the family learned her neck had been dislocated during the Chiari surgery,” Khawam said, when they visited Northwestern Memorial Hospital in Chicago for a consult on her continuing pain and paralysis.

There, a neurosurgeon told Ospina that her dislocated neck would be “extremely rare” if it wasn’t done negligently.

Further, Ospina’s husband wrote, the Northwestern surgeon told them he believed the stroke was the result of the dislocation, which had created a tear in the inner lining of her vertebral artery, where a clot formed and blocked blood flow to her brain.

Jenny Nowatzke, a spokeswoman for the hospital, confirmed that Ospina had been a patient of Dr. Nader Dahdelah.

“This is not from Arnold Chiari: this is from the neurosurgeon dislocating Barbara’s neck at C1-C2 during surgery,” her husband wrote. “Not only did he injure Barbara’s neck, but he did not tell anyone."

In August of 2014, she had the removed skull portions replaced by a ceramic device, and in November, another surgery to fuse her neck.

A line-of-duty investigation found that Ospina had been permanently disabled by her medical condition, allowing her to retire in July 2016.

A month later, the VA denied her access to its caregiver program, which would provide a up to $30,000 a year so that a family member could take care of her full-time. Ospina continues to suffer from paralysis and chronic pain, her husband wrote, and spends most of her time of her time in a wheelchair.

Serious injury, according to the VA, includes “traumatic brain injury, psychological trauma, or other mental disorder, incurred or aggravated in the line of duty in the active military, naval, or air service on or after September 11, 2001, that renders the veteran or servicemember in need of personal care services,” spokeswoman Susan Carter told Military Times.

“Barb is left to pay for her own caregiver out of her VA disability paycheck,” Khawam said.

If Ospina had been originally operated on in a civilian hospital, she would have been able to sue her medical providers for the alleged negligence that led to her dislocated neck, and the pain, paralysis and loss of quality of life that followed.

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“This is another example of why the Feres Doctrine needs to be changed,” Khawam said. “Our troops and veterans deserve much better, especially after they proudly served our country.”

Feres, originally designed to protect DoD from lawsuits due to battlefield injuries, also applies to what goes on at home. Since its inception, numerous service members have suffered illness, injury and death without being able to hold care providers accountable.

The issue has circulated throughout the military community for years, but on April 30, Rep. Jackie Speier, D-California, introduced a law into the most recent National Defense Authorization bill, exempting medical malpractice from Feres.

Dubbed the SFC Richard Stayskal Military Medical Accountability Act of 2019, it would allow service members of their families to sue the United States damages following the personal injury or death of a service member because of “negligent or wrongful act or omission” stemming from health care, as well as investigations or clinical trials.

It’s named for a Green Beret facing terminal lung cancer that went unreported by Army doctors. He and others testified before the House Armed Services Committee in April about the breadth and depth of malpractice service members have faced.

“When doctors fail to perform or woefully misread tests, when nurses botch routine procedures, when clinicians ignore and disregard pain, service members deserve their day in court,” Speier, the chairwoman of the House Armed Services Committee’s personnel subcommittee, said in April.

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2.2 - Military Times: **Did VA hospital leaders ignore recalls on faulty medical equipment?**
(26 August, Leo Shane III, 1.7M uvm; Vienna, VA)

Staffers at a Florida-based Veterans Affairs hospital say leadership ignored a medical equipment recall for weeks — even after a patient’s life was endangered — despite repeated warnings their inaction violated health and safety norms.

But officials at the James A. Haley Veterans' Hospital in Tampa said their week they have removed all of the faulty items without any harm to patients, dismissing concerns that proper procedures were not followed.

It’s unclear whether the dispute is isolated to the single VA medical center or indicative of larger problems with recall alerts throughout the nation’s veterans hospital system. Department of Veterans Affairs officials in Washington, D.C. referred all questions to local hospital officials.

At issue is a July 31 incident where a patient at the Tampa medical center received too much prescribed medication because of what nurses described as malfunctioning IV equipment. Tubing designed to slowly drip out fluids into the patient’s bloodstream instead allowed a rush of medication all at once. In a grievance filed with facility leadership, staff said a medical disaster was avoided only because nurses on duty quickly diagnosed and responded to the problem.

But in a statement to Military Times, hospital leadership said that “no patient harm” occurred and praised medical personnel on staff for quickly identifying the problem. They also said an

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internal review found no specific equipment malfunctions but did uncover some system parts that were on recall lists.

Dennis McLain, head of the facility's National Nurses United chapter, said the manufacturer of the IV tubing (BD, headquartered in New Jersey) issued an urgent recall of the equipment two weeks earlier, instructing hospitals to "destroy all products" found in their inventory.

"Since this issue may lead to flow inaccuracies through the pumping cycle process, this may result in an over-infusion and the potential for serious patient injury or death, depending on the type of medication that is being delivered," the July 18 recall notice states.

In the grievance, McClain said the Tampa site continued not only overlooked that notice but also continued to use the faulty tubing for weeks after the July 31 incident, even after the union filed its formal complaints in early August.

Leadership issued a response this week (after Military Times inquiries on the matter) stating that "after speaking with the manufacturer today to ensure compliance with the recall, staff received additional clarification on tubing products affected" and that now "all affected IV tubing found at the facility is being replaced immediately."

Identifying the parts is difficult once it is in use, hospital officials said in their response to the union grievance, because they lack clear model numbers and identification markers once taken out of packaging.

Identifying the parts is difficult once it is in use, hospital officials said in their response to the union grievance, because they lack clear model numbers and identification markers once taken out of packaging.

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2.3 - KDKA (CBS-2, Video): Family Of Westmoreland County Veteran Files Federal Tort Claims Act Following Stay At West Virginia VA Hospital (25 August, Pam Surano, 1.3M uvm; Pittsburgh, PA)

CHARLESTON, W. Va. (KDKA) — A federal tort claims act has been initiated by the family of a Vietnam veteran whose death at a VA hospital promoted a homicide investigation.

Retired Sergeant Felix McDermott died April 8, 2018, at the Loius A. Johnson VA Medical Center in Clarksburg, West Virginia after he was injected with a fatal dose of insulin while at the center, a lawsuit says.

He was admitted three days before his death because he developed aspiration pneumonia.

McDermott, a Westmoreland County native, received an insulin shot in the left side of his abdomen, was not diabetic and had no history of insulin use, an autopsy revealed.

His death was ruled a homicide, and the VA investigators have a person of interest in the death.

McDermott's remains were exhumed and flown to the Dover Air Force Base for the autopsy in October 2018.

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The family's attorney, Tony O'Dell, said the McDermotts entrusted their father — a 20-year army veteran — in the care of the center.

O'Dell provided KDKA with a legal document sent to the hospital, claiming the 82-year-old may not have been the only victim.

"Our understanding is that there have been several patients, nine or 10, who had died under similar circumstances," O'Dell said.

O'Dell said the findings from the autopsy were negligent and preventable.

The suit is seeking damages of up to $5 million for wrongful death, $1 million for personal injuries and expenses for funeral costs.

The claim states that employees at the hospital never told McDermott's family how he died.

O'Dell explained the federal tort claims process involves putting the government on notice for six months before a lawsuit can be filed.

He fully expects the families of the other potential victims to retain attorneys as well.

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2.4 - WREG (CBS-3): Longtime Memphis pain doctor reprimanded for prescription issues
(26 July, Stacy Jacobson, 605k uvm; Memphis, TN)

The Tennessee Department of Health has reprimanded a Memphis pain management and addiction doctor for his prescribing practices.

The state put Dr. Douglas Jones' license to practice on probation and banned him from owning or operating pain management clinics.

Jones has been licensed in Tennessee since 1987.

In 2012, the Tennessee Medical Association posted this photo of Jones meeting with other doctors and state lawmakers. He's wearing a white coat with red writing that lists his specialties: "addiction medicine" and "pain management."

That's exactly the type of work that got him in trouble with the state starting around the same time.

In the order from the Tennessee Department of Health, officials said Dr. Jones treated patients for pain management between 2008 and 2016. He ran his own clinic in this Park Avenue office building during much of that time.

But, according to the board that regulates doctors, Jones did not meet standards of care for most of his patients.

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The allegations read like a list of what not to do as a doctor: prescribing controlled substances “without conducting a physical exam” or “formulating a treatment plan" and giving prescriptions to patients with a history of addiction and suicide attempts without any kind of mental health screening.

WREG analyzed federal statistics for opioid prescriptions in 2015, when records show he was the director of the Park Avenue clinic. Jones ranked in the top 15 percent of opioid prescribers in Tennessee, with more than 35 percent of his prescriptions being for an opioid.

WREG went to Jones’ East Memphis home. When a woman answered the door, we told her who we were and why we were looking for Dr. Doug Jones.

"We’re covering how his license was put on probation," reporter Stacy Jacobson said.

She promptly shut the door.

But neighbors confirmed Dr. Doug Jones lived at the home.

WREG also confirmed Jones lived at the home by spotting his white lab coat in the backseat of an Acura sedan parked outside. It was the same lab coat from the TMA photo on Facebook.

The back of the car also had piles of documents: research and even patient reports left out for anyone to see.

Neighbors said Dr. Jones’ messy car may be an indicator of his work.

But one of the names on those records was Felicia Price with a home address less than four miles away on Southern Avenue.

We found Felicia Price and told her how we knew about her.

“You’re kidding," Price said. "I don’t like that because I don’t know what it’s doing back there. Why would he have it open in the backseat of his car?”

In fact, WREG spoke with Parke Morris, an attorney who handles a lot of patient rights issues. Morris said Jones could be in big trouble.

"Extremely unprofessional. Violation of federal law and outrageous," he said, referencing the Health Insurance Portability and Accountability Act. "The records indicate you’re supposed to protect not only the treatment given, but their name, identifying information, date of birth and their social. This is no different than him leaving these records out in a waiting room for anyone to see."

Price, the patient, was also concerned because she didn't remember Dr. Jones, though she did know another doctor listed on paperwork in his backseat.

“I remember the last name. He did see me at Baptist,” Price said.

She was alarmed to hear about Jones’s license probation and other issues.

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"It's a good thing, so it should be done," she said. "People get operated on, they prescribe stuff, then they get addicted to it. Sometimes it gets to be so bad."

"There's a growing emphasis to discipline these doctors who are writing scripts for anything, for pain medication without an examination," Morris said.

A spokesperson for the Memphis Veterans Affairs Medical Center said Jones worked at the hospital from 1998 until 2008.

Methodist and VA officials said he does not have privileges anymore at their hospital.

Representatives for Baptist Hospital confirmed he still has privileges at their hospital.

Jones' practitioner profile with the Tennessee Department of Health states he has privileges at Saint Francis Hospital. Representatives did not respond to our repeated requests to confirm.

Jones faces fines up to $90,000 in the case.

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2.5 - Becker's Hospital Review: **Staff members claim VA hospital ignored medical equipment recall** (26 August, 593k uvm; Chicago, IL)

Staff members claim leadership ignored a medical equipment recall for weeks at the James A. Haley Veterans' Hospital in Tampa, Fla., according to the Military Times.

Becton Dickinson, an IV tubing manufacturer, recalled its tubing equipment on May 6. The VA hospital failed to recall the tubing for weeks, even after the equipment endangered a patient on July 31, staff members said. The patient received too much medication due to what nurses claim was malfunctioning IV equipment.

Officials at the hospital said they have removed all the faulty equipment and no patients were harmed. An internal review revealed some recalled equipment was involved in the July 31 incident, but hospital leadership said there were no equipment malfunctions. All recalled equipment has now been replaced, they said.

Staff members affiliated with National Nurses United have asked the Department of Veterans Affairs' inspector general to investigate whether the hospital followed proper procedures in complying with the recall. The VA has promised to inspect all equipment at the facility.

The VA did not respond to Becker's request for comment.

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2.6 - WINK (CBS-11, Video): **Veteran patients missing appointments, Cape VA clinic lacking resources** (26 August, Jack Lowenstein, 348k uvm; Fort Myers, FL)

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The U.S. Department of Veteran Affairs in Cape Coral says it is unable to provide transportation services to doctor appointments from its clinic due to lack of volunteers and donations that help provide necessary resources.

Vietnam Bubba Schneider is someone who depends on these services for his health. He reflected on his time in the war overseas when we spoke to him.

“We did what had to do,” Schneider said.

Schneider was on the front lines as a machine gun operator when he was 19 years old. Now, he suffers from several medical conditions, stemming from his experience on active duty. He worries he won’t make it to his appointments without help from the local VA clinic.

“I have problems getting dizzy, blacking out and falling,” Schneider said. “So now I have the chance to go to someone that can help me, but I can’t get there.”

The clinic said it only has one van that goes to Labelle, where Schneider lives, which picks up about half a dozen vets. Meanwhile, veterans like Schneider have waited months to see a doctor. He has an appointment Wednesday, but he doesn’t know if he will make it there.

“It has several of us in a turmoil that don’t drive trying to figure out how are we going to get to our appointments,” Schneider said.

Because of its lack of resources, the VA clinic said it can’t take veteran patients to appointments the clinic itself scheduled for them, something the clinic said it has always worked with veterans on.

To volunteer or donate to the local clinic, visit U.S. Department of Veteran Affairs.

“It would be an extremely sad thing for us not being cared for after what we did for our country,” Schneider said. “And we get pushed on the side of the road.”

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2.7 - WBIR (NBC-10, Video): Veteran hopes toolbox gift will help other veterans transition back to life after deployment (25 August, Sean Franklin, 464k uvm; Knoxville, TN)

A wounded combat veteran from East Tennessee received a way to find his purpose in life after serving.

A simple gift of a toolbox has helped him and others transition from the Army.

More than a hundred soldiers filled the Knoxville Convention Center this weekend, learning how to make a transition from deployment to life back home.

And retired Army Sergeant Lyle Allen knows exactly how that process works.

He has dedicated his life to serving others.

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"I'm a medically retired Army veteran, Purple Heart recipient," Allen said. "I got injured in Iraq in 2004."

Now, he has something that serves him.

"Yeah, somebody gave back to me, that's for sure," he said, looking down at his toolbox.

Allen laid out all $400 worth of tools in his new toolbox.

It was a way the Knoxville Vet Center employee helped welcome back members of the 278th Armored Cavalry Regiment at their Post-Deployment event Sunday.

"When a veteran gets back, they have to find a purpose," Allen said.

It's that purpose that drives the non-profit organization called Resources Exchange Association, based out of North Carolina.

Allen just sent them his information.

"I was impressed when I got the box," Allen said. "I went on their website and three weeks later there was a box at my doorstep."

A toolbox--a simple gift the program sends to veterans.

And Allen has the perfect way to put it to use.

It's his 1969 Red Ford Mustang--sitting in his garage and waiting to hit the road.

"This is actually giving us a purpose to get back out there, trying to keep busy," Allen said. "Because everyone has their own niche in life that keeps them going. So working with my hands and stuff is definitely one of them."

He said it's hard for veterans to get used to being home.

"The transition can be difficult," Allen said.

That's why he hopes the toolbox will help him serve those who have served this country.

"Just having different resources out there that people really don't know about, and just finding those resources for other veterans, to make their transition a lot better than mine," Allen said.

For more information about the Knoxville Vet Center, head to its website.

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2.8 - Idaho Statesman: **Letters to the editor** (26 August, Richard L. Barrett, 392k uvm; Boise, ID)

[…]

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VA THANKS
Kudos to Boise VA Medical Center Director's superb staff and many thanks to Secretary of Veterans Affairs Director Robert Wilkie for giving those folks the recognition they so richly deserve.

Richard L. Barrett, Boise

[…]

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2.9 - WMAZ (CBS-13, Video): Dublin VA going smoke free October 1st (26 August, Wanya Reese, 281k uvm; Macon, GA)

DUBLIN, Ga. — The Carl Vinson VA Medical Center plans to go smoke free starting in the fall, but some veterans have mixed opinions about the ban.

Some say it will help, while others think it won't, but regardless of what they think the smoking ban will go into effect at the center starting in October.

"I started smoking in the Navy, because that was really the only time I had the opportunity to take a break," Christopher Anderson said.

Anderson says spending days at sea helped him pick up a habit.

"They say it calms you down, it gives you an immediate rush of Nicotine," Anderson said.

He says it's the rush that kept him going.

"Two men talking with cigarettes in their hand," he said.

But starting October 1, the Carl Vinson VA Medical Center is going smoke free campus wide.

"If we can limit, reduce, or eliminate smoking, I think employees and veterans are going to be a lot healthier," Associate Director for the center Jay DeWorth said.

DeWorth says the VA will host free classes to help vets quit.

"What is new is we are going to be offering employees some of these same resources, classes to stop smoking if they choose to stop smoking, and also some medications," Deworth said.

He says these resources will be available to make sure all six area clinics are ready to go smoke free by October 1.

"And it is going to be a journey to get them not to smoke on our campus, but also to stop smoking all together," Deworth said.

Anderson says even with the new rule, he realizes it is going to be tough to quit.

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"I just think I'm going to have, to have the willpower and the proper mindset to throw the packs away, you know?" Anderson said.

You can find class details below.

Tobacco Cessation Classes: Classes usually meet one hour a week for five weeks. You can contact the following locations to confirm dates and times.

- Dublin Campus: Every Wednesday at 2 p.m. on 15A, and every Thursday at 2 p.m. on 10B for DOM in-patients only
- Tele-Health at all CBOC locations (Albany, Tifton, Brunswick, Macon, Milledgeville, and Perry): Every Friday at 1:15 p.m.

For more information, call Health Promotion Disease Prevention Program Manager Jennifer Johnson, BSN RN at 1-800-595-5229. Dial #1, then the extension 304.

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2.10 - MetroNews: **Clarksburg VA death ruled homicide; VA investigating more possible victims** (27 August, Hoppy Kercheval, 242k uvm; Charleston, WV)

On the morning of April 9, 2018, Felix McDermott died at the Louis A. Johnson VA Medical Center in Clarksburg. The retired Army Sergeant and Vietnam Veteran was 82 years old and had several health issues, including aspiration pneumonia.

However, his condition was improving, and his death shocked his family.

“No answers were given to the family at all,” said attorney Tony O’Dell, who represents McDermott’s relatives. “They really were left in the dark. He (McDermott) took a sudden turn. They didn’t know what to think. They were surprised.”

Another shock came later when the Veterans Administration contacted McDermott’s family for permission to exhume his body to conduct an autopsy after reports of other suspicious deaths at the Clarksburg VA.

The autopsy revealed the most stunning news of all; McDermott, who was not diabetic, had been given an insulin injection in the abdomen the morning of his death. He died of severe hypoglycemia. Deputy Medical Examiner Dr. Paul Uribe concluded, “Based on the investigative and autopsy findings, the manner of death is a homicide.”

O’Dell said the family wants answers. “We don’t know whether this is just an unbelievably incompetent person, which is hard to believe, or if someone is doing this willfully to people who have served our country,” O’Dell told me on Talkline Monday.

McDermott may not have been the only victim. O’Dell claims in his filing that prior to April, 2018, nine or ten patients at the Clarksburg VA “had died unexpectedly as a result of unexplained severe hypoglycemia” due to wrongful injections of insulin.

West Virginia Senator Joe Manchin, who is a member of the Senate Committee on Veterans’ Affairs, said on Talkline Monday that he has spoken with Veterans Affairs Secretary Robert

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Wilkie and Clarksburg VA Medical Center Director Dr. Glenn Snider to try to find out what happened.

Manchin said the investigation by the VA's Office of Inspector General has focused on an individual, who has not been identified. Manchin said he was assured by both Wilkie and Snyder that "the person of interest is no longer in any contact with veterans at the VA facility." There's no word of any criminal charges against anyone yet.

The investigation has gone on for months, and Manchin said despite his position on the Veterans' committee, he didn't find out about it until the story was first reported in the Clarksburg Exponent newspaper last week.

"It's very upsetting that it has taken this long for us to have gotten any kind of news," he said.

Wesley Walls, a spokesman for the hospital, said in a prepared statement that the hospital responded promptly when the allegations were discovered and put safeguards in place "to ensure the safety of each and every one of our patients."

Walls added that the hospital is cooperating with the investigation and the allegations of misconduct "do not involve any current Louis A. Johnson Medical Center employees."

Assurances that an unidentified "person of interest" no longer has access to patients at the Clarksburg VA is the bare minimum of information that patients, families and the public are entitled to. The fact that an autopsy, which was completed six months ago, determined McDermott was the victim of a homicide is alarming, and it is horrific to think there may have been nine or ten additional victims.

VA investigators have already acknowledged to McDermott's daughter, Melanie Proctor, that her father was the last known victim of these suspicious deaths as a result of wrongful insulin injections. There's been plenty of time for an investigation. A full accounting of exactly what happened to those veterans is long overdue.

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2.11 - MetroNews: **Autopsy: Vietnam veteran was not diabetic but died of insulin injection**
(26 August, Brad McElhinny, 242k uvm; Charleston, WV)

An autopsy report for a Vietnam veteran who died suspiciously at the Veterans Affairs Medical Center concludes that the man — who was not diabetic — was injected with a fatal amount of insulin.

The autopsy uses clinical language to describe horror.

"This case represents the administration of unprescribed insulin to a non-hyperglycemic, non-diabetic patient in a hospital setting," the report states.

"Based on the investigative and autopsy findings, the manner of death is homicide."

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The death of 82-year-old retired U.S. Army Sgt. Felix McDermott is drawing attention from the public, as well as West Virginia's congressional delegation, including senators Shelley Moore Capito and Joe Manchin.

Manchin said he spoke today with leaders with the U.S. Department of Veterans Affairs, as well as leadership at the VA hospital in Clarksburg.

A statement put out by Manchin's office made reference to a total of 11 suspicious deaths at the VA hospital.

"These crimes shock the conscience and I'm still appalled they were not only committed but that our veterans, who have sacrificed so much for our country, were the victims," Manchin stated.

McDermott's family has filed a claim over his death with the U.S. Department of Veterans Affairs.

McDermott's family was told by VA investigators that nine or ten additional patients of the Louis A. Johnson VA Medical Center had been given fatal injections of insulin, according to the claim.

"We don't know whether this is just an unbelievably incompetent person, which is hard to believe, or if someone is doing this willfully to people who have served our country," said Tony O'Dell, a Charleston lawyer who is representing McDermott's family.

McDermott was a Vietnam veteran who retired after 20 years of U.S. Army Service. He later served as a member of the Pennsylvania National Guard.

He was admitted for treatment at the VA Medical Center in Clarksburg on April 9, 2018 because he had choked on some food and developed aspiration pneumonia.

At first, his health improved.

Then, on April 9, 2018, his condition plummeted. He couldn't catch his breath. A fingerstick blood glucose test showed that he had critically low blood sugar.

The situation was so critical that his family was called in.

"All of a sudden they're called in the early morning hours. He's taken this sudden turn for the worse," O'Dell said on MetroNews' "Talkline.

By 9 a.m., McDermott was dead.

"Really, no answers were given to the family at all. They really were just left in the dark. He took a sudden turn. They didn't know what to think. They were surprised."

McDermott was buried on April 13, 2018.

The family grieved as time passed. After a few months, the family was asked for permission to exhume McDermott's body.

The exhumation occurred Oct. 23, 2018, and McDermott's remains were sent to the Dover Air Force Base for autopsy.

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The resulting autopsy report confirmed that McDermott was not diabetic and had no history of oral hypoglycemic use or previous insulin administration. The autopsy report also confirmed there were no hospital orders for the administration of insulin.

Yet, the autopsy identified a subcutaneous insulin injection site on the left side of his abdomen.

The report concluded that McDermott "died of exogenous insulin administration."

"If the medical examiner's conclusion is correct," the family's claim against the VA states, "Felix Kirk McDermott was murdered while he was in the care and custody of the Louis A. Johnson VA Medical Center despite the VAMC being on notice of previous wrongful injections."

Wesley Walls, who leads public affairs and community relations services at the medical facility, told MetroNews on Monday the allegations do not involve any current employees.

"Immediately upon discovering these serious allegations, Louis A. Johnson VA Medical Center leadership brought them to the attention of VA's inspector general while putting safeguards in place to ensure the safety of each and every one of our patients," he said.

Walls added Manchin's office was made aware of the allegations on Aug. 7, 2018, as were Capito's office and the staff of Rep. David McKinley, R-W.Va.

"VA is cooperating fully with the inspector general's ongoing investigation, and for additional questions we refer you to them," he concluded.

Manchin, who had spoken today with officials, said the investigation has identified a suspect. Manchin said that person was "removed immediately from any patient care."

"I did find out – the hospital did everything they could do when they found the person of suspicion," Manchin said on MetroNews' "Talkline." "They have secured and feel confident everything in the world is done for their patients."

He added, "There has been concern that they're looking into all the patients that person might have been in contact with."

Manchin expressed disappointment that the public just learned of the situation even though McDermott's death was a year ago.

"It's very upsetting that it has taken this long for us to have gotten any kind of news," Manchin said.

The claim by McDermott's family does not conclude whether the insulin injection was negligence or intentional.

O'Dell, the attorney, says the family is experiencing "total betrayal."

"Put yourself in that position where it's your father and someone may have purposefully killed that person," he said.

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2.12 - WJET (ABC-24, Video): **Erie VA Medical Center goes tobacco free** (26 August, 73k uvm; Erie, PA)

Erie VA Medical Center will soon be tobacco free.

According to the Medical Center Director, the new rule will also apply to all of their community based outpatient clinics.

The director said the reasoning for this is to create a healthier environment for anyone who comes in contact with the center.

In order to make this an easier transition, they are offering different outlets to help veterans and employees quit smoking.

"We know that this is not an easy thing to kick a habit, so we want to make sure that they feel fully supported. Overall we know the dangerous affects of smoke," said John Gennaro, Medical Center Director.

The tobacco free policy will go into effect on October 1.

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2.13 - Citizen Tribune: **Group buys van to transport patients to VA clinic** (26 August, Shawn Singleton, 64k uvm; Morristown, TN)

Veterans who receive care at the Morristown VA Clinic now have a new way to make their specialized appointments on time.

The Jerry Alvis Disabled American Veterans Chapter 59 recently purchased a new van to transport disabled veterans to James H. Quillen Mountain Home VA Medical Center in Johnson City. Veterans from Hamblen, Hawkins, Grainger and Jefferson counties will be eligible for the transportation service.

"There are vets who are disabled and can't drive to Johnson City (for their appointments)," said Steve Totino, a volunteer driver and Marine Corps veteran. "That's the idea behind the new van."

"(The van) looks nice," said Phillip Armstrong, a volunteer driver from Bean Station. "Rides nicer (than the old van) too."

The 2019 Ford van replaced an older van that reached the mileage threshold. The new van was purchased through the national chapter with funds raised through local donations stemming from the DAV's annual "Forget Me Not" drive for Mother's Day. The VA and DAV will share maintenance duties on the vehicle.

"The old van is in service now," said Raymond Shockley, commander of Chapter 59, which was named for former commander Alvis, who lost his battle with cancer last year. "Once our vans

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exceed 250,000 miles, we replace them. We leave the van (at the Morristown clinic) and our volunteers give rides to Mountain Home."

"We are very grateful for this donation. This van replaces an older one that had reached nearly 150,000 miles," said Mike Kromoff, chief of voluntary services at James H. Quillen VA Medical Center. "The new one has been on the road for nearly two weeks now, and has already helped numerous veterans come to their appointments here at the medical center. We appreciate our partners at the DAV as we continue taking care of our veterans."

Jerry Barnard, an Army veteran who serves as a volunteer driver, and the scheduling coordinator for the DAV, said veterans should schedule rides to their appointments in Johnson City as early as possible, but the process is very simple.

"It's not too bad. It's pretty simple. You just have to keep the paperwork right," he said. "(Veterans) call us and tell us what time and day their appointments are scheduled. Then I call the drivers."

In addition to the Mother's Day fundraiser, DAV members also reached out to nonprofits from all four of the counties representative – as well as private citizens – for donations. Jerry Lane, an Air Force veteran from Morristown, said while his role is important, the organization received a great deal of assistance from people in their service area.

"I helped collect the money and kept it in order," said Lane, who is the treasurer for Chapter 59. "A great deal of credit goes to the community. We were able to raise $35,000 in donations to buy the van outright."

The DAV is still collecting donations for a new van for the Rogersville VA clinic. Members meet on the second Tuesday of each month at the Golden Corral on West Andrew Johnson Highway in Morristown. Interested donors can contact 312-6549.

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2.14 - The Journal Gazette: Five questions for Brett P. Reistad. National commander, American Legion (26 August, 56k uvm; Fort Wayne, IN)

1 - Are people surprised to learn your organization has been around for 100 years? How and when did the American Legion come to be headquartered in Indianapolis?

Some people are surprised, but I think most people are aware that we've been around for quite some time. Depending on their age, some may recall how we were such strong advocates for those returning from World War II (just as our founders were for the WWI vets). After World War II, people wondered if America would return to another Great Depression since so many of the returning service members would be searching for jobs. Yet, it was the American Legion that drafted in 1944 what would become the greatest social legislation ever passed by the U.S. Congress – the original GI Bill. It not only made higher education possible for millions of veterans, it made home ownership possible through low-cost guaranteed mortgages. It is responsible for the building of many middle-class communities throughout the country.

There is a funny story about Indianapolis winning the bid to become the home of the American Legion National Headquarters. Minneapolis was the site of the American Legion's first national

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convention and a strong contender to be the home of our headquarters. However, during the convention, which was held in November, temperatures dipped to 11 degrees and a snowstorm arrived. ... Indianapolis was chosen instead, and Washington, D.C., finished second in the voting.On June 4, 1924, ground was broken at777 N. Meridian St. in Indianapolis for our first permanent national headquarters. ...

2 - The challenges facing veterans returning from the conflicts of the 21st century must be quite different from those facing those who served in the world wars. Are young veterans today drawn to the American Legion the way earlier generations of servicemen and servicewomen were?

I think as people learn more about how the American Legion is making a difference in the lives of veterans and their families, the draw becomes greater. Many people serving in the military don't even think of themselves as veterans until they get out of the service and start reflecting on their past. But we consider those serving on active duty as veterans from the first day they enter basic training or boot camp. Also, younger veterans have many priorities ... . But as they learn about our many programs and see that we are here to assist them, they often decide to become members of our American Legion Family. We hope they join us, but even if they don't, we will vigorously advocate for their quality-of-life benefits.

... Due to medical advances and better evacuation methods, many veterans are surviving battlefield wounds that would have killed them if they had served in previous wars. But as a result, we have to find better and more comprehensive treatments ... . But even though technology and cultures change, veterans have a bond that transcends generations. ... They all understand service and sacrifice.

3 - Is America doing enough today for those who served?

We could always do more. Many veterans suffered disabilities from environmental exposures and contaminations that are still not covered today. I think about the service members who cleaned radioactive waste from Enewetak Atoll in the 1970s. Others served in places where they were sickened because of contaminated water. But many good things are happening. Vietnam veterans who were exposed to Agent Orange while serving on ships off that country's coast are finally getting benefits to compensate for their illnesses. VA health care is excellent, overall, but ... there have been enormous backlogs for those trying to access it. Today, we are seeing greater accountability and veterans who can't get into VA for various reasons can more easily opt for private-sector care. In short, America can never fully “do enough” for people who put their lives on the line, but VA is getting much better both in quality of care and responsiveness.

4 - Your 101st convention began in Indianapolis Friday and runs through Thursday. What event or aspect of this year's celebration are you most excited about?

... I'm excited about the job fair we are conducting to help veterans obtain employment and start businesses. I'm excited about our American Legion Family gathering and having the opportunity to ... bond as we discuss ways to improve the lives of veterans and their families. I'm excited about all of our speakers. The fact that the vice president of the United States, secretary of State, secretary of Veterans Affairs and members of Congress are taking the time from their busy schedules to be with us shows us the respect that America's leaders and the American public has not just for veterans but for the American Legion.

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5 - It's easy for us to acknowledge the immense debt we owe those who have served – but harder, perhaps, to repay it. What's the best way for Americans to honor our veterans?

... If you're an employer, hire veterans. You could volunteer at a VA Medical Center or place flags at veterans graves during Memorial Day, Veterans Day or frankly any day. If you are a son, grandson, wife, daughter or mother of a veteran, you could help support veterans by joining our American Legion Family. For more information, visit legion.org

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2.15 - Federal Computer Week: Congratulations to the 2019 Rising Stars (26 August, Troy K. Schneider, 46k uvm; Vienna, VA)

Each year, the Rising Star Awards recognize individuals who are early in their federal IT careers yet already are having an outsized impact. The women and men listed below have been selected both for their accomplishments over the past year and for their leadership potential in this community.

These awards are part of our larger Government Innovation Awards program. A joint effort of FCW, GCN, Washington Technology and Defense Systems, these awards also recognize the companies supporting the government's transformation and the most innovative technology initiatives across the public sector.

The Public Sector Innovation winners were announced today as well; the 2019 Industry Innovators will be revealed in the coming days. You can learn more about the overall Government Innovation Awards here.

We'll be running full profiles of the 2019 Rising Stars this fall, and the winners will be honored in person at the Nov. 7 Government Innovation Awards dinner. Until then, here's a quick salute this year's winners — 21 individuals we're confident you'll be hearing about for years to come:

Brecken W. Auchterlonie
Business Development Manager
SAIC

Kevin E. Brisley
Manpower Analyst / Senior Human Resources Manager
Command, Control, Communications and Cyber Systems Directorate, U.S. Transportation Command

Kaitlin I. Bulavinetz
Managing Director
Washington Cyber Roundtable

Will Cahoe
Projects Coordinator, 10x
General Services Administration

Gilberto Castro
Global Networking Manager

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Georgetown University

David Catanoso
Director, Enterprise Cloud Solutions Office, Dept of Veterans Affairs
Department of Veteran Affairs

Taylor K. Chott
Data Scientist
CACI

Anna Cordrey
Deputy Program Manager
NASA

Mahtab Emdadi
Regional Sales Director
Dell Technologies

Omid Ghaffari-Tabrizi
Acquisitions Lead
Centers of Excellence, General Services Administration

Ryan V. Hendricks
USA Performance Product Development Supervisor
Office of Personnel Management
Dr. Leonie Heyworth
Director of Synchronous Telehealth, VHA Office of Connected Care/ Telehealth Services,
Department of Veterans Affairs
Veterans Health Administration, Department of Veterans Affairs

Michelle Johnson
Communications Manager, Senior Research Analyst
Section 809 Panel, Defense Acquisition University

Samer Madarani
Partner Account Director - Partnership Development
Dovel Technologies

Ellen Nadeau
Deputy Manager, Privacy Framework
National Institute of Standards and Technology

Lt. Jason A. Pawlak
Cyber Battle Captain
U.S. Transportation Command

Jonathan Riksen
Associate Partner & Client Leader
IBM

Christopher Rorvig

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Senior Consultant, Consulting Services
CGI Federal

Blake M. Scates
Digital Program Manager
Department of Veterans Affairs

Robert G. Sheldon
Head of Technology Strategy, Public Sector
CrowdStrike

Travis Sorensen
CEO
Oddball, Inc.

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2.16 - Colorado Politics: VA appoints new director of Eastern Colorado Health Care System (26 August, Caitlin Curley, 57k uvm; Denver, CO)

The U.S. Department of Veterans Affairs is bringing on a new director for its Aurora-based Eastern Colorado Health Care System.

Michael Kilmer, formerly the medical center director for the Western Colorado system in Grand Junction, will replace Sallie Houser-Hanfelder, who retired in May.

The Eastern Colorado system covers more than 44,000 square miles through Colorado and Western Kansas, with a main hospital adjacent to the University of Colorado Anschutz Medical Campus in Aurora, according to a VA release Monday.

“We are excited to bring Mr. Kilmer on board as the new Director of VA Eastern Colorado Health Care System,” said Ralph Gigliotti, Veterans Integrated Service Network (VISN) 19 Director.

“Mr. Kilmer’s sound leadership qualities and proven experience will be valuable assets for the facility, the employees and volunteers, and most importantly, for the Veterans we are honored to serve.”

2. - Manistee News Advocate: Volunteers needed for veteran transportation service (26 August, Jane Bond, 1k uvm; Manistee, MI)

MANISTEE COUNTY — A new vehicle is taking local veterans to their medical appointments, but Eric Sullivan of the local Disabled American Veterans (DAV) chapter is looking for more volunteers to drive it.

As the ride coordinator for the DAV Manistee chapter, Sullivan spends most of his time organizing free transportation for retired soldiers to Veterans Affairs (VA) medical centers in locations like Traverse City, Cadillac, Wyoming and Saginaw.

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“This is a dire need service because we have a lot of elderly and disabled veterans that can’t drive themselves,” said Sullivan. “It’s a way for people to serve their country so-to-speak and provide a service to our veterans.”

The new Ford Flex van replaces an older model which has accumulated over 200,000 miles of wear and tear.

Sullivan said the Ford Flex was chosen for this program because they are all-wheel drive vehicles which seat seven.

“Because of our service range and location, we need all wheel drive vehicles or else we won’t be able to drive in the winter safely,” he said.

Two other vehicles in the DAV fleet are also nearing the 200,000 mile mark. Sullivan expects that they will be replaced in time for next summer.

Although the need for this service has remained constant, the number of volunteers has declined drastically. Since April, the shuttle service has lost three volunteers: two with health issues and one that moved away from the area.

“That’s our biggest hurdle, the critical need is for drivers,” said Sullivan.

The Manistee DAV relies on just four volunteers attending to veterans spread across five counties: Lake, Manistee, Mason, Osceola and Wexford.

Between March and July, DAV volunteers made 120 trips accounting for 23,704 miles traveled.

“The VA has valued DAV hours of volunteer service at nearly $34.7 million annually — making it an indispensable resource for veterans and a cost-effective solution for the VA,” said Brett Robbins, an Army veteran serving as a communications specialist detailed to the Department of Veterans Affairs.

According to Sullivan, the decline in volunteers has resulted in cutbacks within their program.

“Because there are very few volunteer drivers we have had to cut the number of counties served from Manistee,” he said. “We are no longer able to take veterans to the Detroit VA Hospital because of the shortage of drivers.”

Pat Vuksanovic is the local DAV’s longest serving volunteer, having driven with the organization since 2015. She volunteers on a regular basis, often making multiple stops every week.

Vuksanovic values the time she spends with the veterans she drives.

“Some days are early because of morning appointments — you go to their home, pick them up and take them where they need to go,” she said. “You get to know them. I have a lot that I’ve taken multiple times and you become friends with them. We don’t always talk war stories, but you get to talk personally.”

Vuksanovic hopes that veterans and other civic-minded community members will volunteer their time.

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"We want to get people who just want to do a little something when they can," she said. "It's very educational and it's out of the goodness of your heart to be able to take someone to an appointment that they need to be physically better."

Requirements for volunteering

• Pass a physical and background check;

• Possess a valid state driver's license and clean driving record; and

• Possess personal auto liability insurance.

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3. Business Transformation

3.1 - The Virginian-Pilot: Editorial: Veterans clinic a welcome addition to region (27 August, 1.1M uvm; Norfolk, VA)

THE NEW STEVEN A. Cohen Military Family Clinic at The Up Center in Virginia Beach is a welcome and necessary addition to the services offered to veterans and military families in Hampton Roads.

Virginia's first facility in the national Cohen Veterans Network, the clinic is expected to help more than 500 people in its first year and will offer a comprehensive range of services, including treatment for stress, anxiety, depression and post-traumatic stress disorder.

It will help veterans and their families with the often-difficult transition to civilian life, including couple's therapy. People in crisis will be able to get help immediately — the clinic offers transportation and remote treatment through high-tech options — and will provide care at little or no cost as needed.

The demand for health and mental health services among veterans is substantial. Much remains to be done in the effort to provide adequate facilities, so that those who serve can get the help they need when they need it.

That is especially true in Hampton Roads, with its heavy concentration of military bases, service members, retired veterans and so many military families.

The military actions that began nearly 20 years ago in response to the 9/11 attacks have never ended. Nearly 3 million troops have served in combat zones, facing dangers, injuries and traumatic experiences. Families have endured the strains of long separation.

All that takes its toll. Estimates are that as many as 40 percent of those who serve in these conditions have some sort of mental health problem when they return home. And, despite years of efforts to change the culture, many of them still feel some hesitant to talk about their problems and seek help.

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If veterans don't have easy access to a facility that works with veterans, they are even less likely to seek help. And if they face a long wait before they can see a physician or therapist, things only get worse.

Suicide is a serious problem among veterans, and it's on the rise among younger veterans. Department of Veterans Affairs statistics say the suicide rate for veterans is 1.5 times greater than among those who have not served in the military. In 2016, 14 percent of all adults who died by suicide in the United States were veterans, even though fewer than 8 percent of Americans have served. By some estimates, about 20 veterans across the country kill themselves on any given day.

Family members generally learn to watch out for the warning signs of depression or other mental distress. Here in Hampton Roads, we all would do well to be aware and offer a sympathetic ear or a helping hand when we can.

The Cohen clinic will be an invaluable help in those situations as well, providing crisis services and other care as needed regardless of one's ability to pay.

Additionally, it's good that Virginia's lawmakers continue to champion veterans' causes in Congress. That includes Rep. Elaine Luria, a Navy veteran who represents Virginia Beach and other parts of Hampton Roads, who is building on the work of her predecessor, former Navy SEAL Scott Taylor.

Sens. Mark Warner and Tim Kaine have been working for years to accelerate the painfully slow process of getting a new VA outpatient clinic open in Hampton Roads. Faced with reports of veterans having long, frustrating waits for care at VA facilities, Congress has approved leases for 28 new medical facilities around the country, including one in Hampton Roads and one in Fredericksburg.

When it becomes reality, the new one in Hampton Roads should help veterans here have easier, prompter access to primary care, mental health and other services. The leases were approved in 2017, but the current timeline projects the two facilities in Virginia won't open until 2023.

Those who serve in the nation's military do what their country asks of them, when it asks. That service takes its toll on them and their families. The nation should make every effort to give veterans support and help when they need it.

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3.2 - KCRG (ABC-9, Video): Dubuque VA clinic open to patients starting Monday (26 August, 505k uvm; Cedar Rapids, IA)

DUBUQUE, Iowa (KCRG) - Veterans in Dubuque will now have access to the city's new VA clinic.

The new clinic opened earlier this month inside a portion of the former K-Mart building off Highway 20.

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It's more than four times the space of the current clinic, offering new services like radiology, physical therapy, and expanded mental health services.

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4. DOD Cooperation / Electronic Health Records / MISSION Act Implementation

4.1 - FedScoop: **Backlog of VA medical records awaiting digitization is 5 miles tall** (26 August, Billy Mitchell, 48k uvm; Washington, DC)

Across the country at Department of Veterans Affairs medical facilities, there's a massive backlog of documents waiting to be scanned and digitized that, if stacked, would stand more than 5 miles tall.

For reference, that's taller than 18 Empire State Buildings. It's just 2,000 feet short of the peak of Mount Everest.

Since 2014, the VA has allowed veterans to seek care outside of its facilities under the Veterans Access, Choice and Accountability Act. When that happens, those non-VA facilities generate records and send them, often as paper copies, to the VA to be integrated digitally with a veteran's electronic health record.

Veterans have visited community providers — as the non-VA facilities are called — for more than 70 million appointments and counting, each time creating at least one new medical document to send to the VA and integrate into an EHR.

According to a new inspector general's report, "[s]ignificant medical documentation backlogs have occurred VHA-wide in part because VA medical facility staff did not scan documentation and enter electronic medical records into patients' EHRs in a timely manner." The result is a "backlog of paper documentation that measured approximately 5.15 miles high and contained at least 597,000 individual electronic document files dating back to October 2016."

To make things worse, this could just be the tip of the digitization iceberg. As of June, the MISSION Act allows veterans to see a more expanded network of community providers. With that, there's "the potential to significantly increase the volume of documentation VA medical facilities will receive from outside providers for scanning, as well as any related backlog," the IG says.

The IG based its calculation on self-reported "data provided by the eight facilities visited and the 78 facilities interviewed." And there's probably quite a bit more than that, as the "totals do not include facilities that lacked quantifiable measures for their backlogs (i.e., those without paper document or electronic file calculations, such as facilities that only noted the age of the oldest document without calculating quantity)."

The paper pileup stems from the lack of "adequate oversight or resources to support the mission of medical document scanning and indexing for quality patient care," the IG said.

"Inaccurate EHRs put patients at risk and compromise continuity of care because accurate medical diagnoses and treatment depend on complete and current documentation," the report

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concludes. “VHA needs to improve supervision and management of scanning activities to ensure medical documents are indexed to patients’ EHRs in a timely manner. This will help ensure veterans receive appropriate, thorough, and timely care.”

The backlog provides yet another layer of challenges the VA faces in developing an effective modernized electronic health records system. The department has struggled for decades to provide a system that will interoperate with the Department of Defense’s, so transitioning service members can access their files when they become veterans.

However, the VA has made progress in recent years, signing a contract with Cerner estimated to be worth $16 billion to develop a modernized system that should work seamlessly with DOD’s Cerner-based system. The VA also touted a “major milestone” this summer, saying it migrated 78 billion health records, including vital signs, lab tests and others from its legacy systems to the new EHR.

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4.2 - Health Data Management: **OIG: VHA’s document scanning backlog puts patients at risk** (27 August, Greg Slabodkin, 41k uvm; Chicago, IL)

Veterans Health Administration facilities are woefully behind when it comes to scanning and entering medical documentation into patients’ electronic health records.

According to an audit by the VA’s Office of Inspector General, the agency found significant backlogs across the VHA, potentially putting patient care at risk because of a lack of timely and accurate EHR documentation.

“Based on data provided by the eight facilities visited and the 78 facilities interviewed, the audit team calculated that as of July 19, 2018, VA medical facilities had a cumulative medical documentation backlog of paper documentation that measured approximately 5.15 miles high and contained at least 597,000 individual electronic document files dating back to October 2016,” states OIG’s report.

In addition, auditors revealed that “when medical facility staff scan medical documentation, they are not always performing the appropriate reviews and monitoring to assess the overall quality and legibility of the scanned documents.”

While VHA facility directors are responsible for establishing policies and processes to ensure all duties associated with health record scanning are conducted in a timely manner, OIG concluded that staffing shortages were a factor in medical documentation backlogs.

“Staffing levels should be proportional to the volume of scanning to be completed; however, staffing levels and productivity standards varied significantly among the facilities reviewed, even between facilities with comparable veteran populations, demonstrating that VHA facility directors are not consistently assessing staffing needs based on scanning demand,” according to auditors.

OIG warned that what could make an already bad situation worse is last year’s enactment of the VA Maintaining Internal Systems and Strengthening Integrated Outside Networks (MISSION)

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Act, which is meant to consolidate the VA's community care programs into a new, streamlined and more efficient Veterans Community Care Program.

"The MISSION Act has the potential to significantly increase the volume of documentation VA medical facilities will receive from outside providers for scanning, as well as any related backlog," added auditors.

To address these shortcomings, OIG made nine recommendations to the VHA in three areas—define and promptly reduce backlogs; assess staffing resources to account for scanning demand; and develop monitoring roles, controls and procedures.

VHA concurred with all of OIG's recommendations and submitted what auditors described as "acceptable" corrective action plans.

"The OIG will monitor implementation of planned actions and will close the recommendations when VA provides sufficient evidence demonstrating progress in addressing the issues identified," concluded auditors.

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4.3 - Delaware Public Media (Audio): Delaware VA officials discuss new patient health care access rules (26 August, Sarah Mueller, 11k uvm; Dover, DE)

State Veterans Affairs officials discussed what's working and what's not with the newly-implemented VA Mission Act Monday.

Congresswoman Lisa Blunt Rochester hosted a roundtable at the Wilmington VA Medical Center to hear about June's roll out of new patient rules.

The VA Mission Act expands access to outside medical providers for veterans who have long drives or face long waits at VA facilities. It also gives vets a new ability to go to community urgent care facilities instead of VA clinics.Vince Kane said he believes the VA gives veterans better primary care and mental health care than private medical care providers.

Terry Baker, with Vietnam Veterans of America, said he likes the urgent care provision because vets can get minor issues addressed locally.

But Baker said more veterans need access to dental care coverage.

"A guy that's here and he's 90 percent disabled, but he's not "100 percent," he doesn't get dental care," Baker said. "I'm service-connected, I don't get dental care. I have to go to the outside, deal with a doctor out there."

He takes issue with state lawmakers expanding dental services to people on Medicaid - although he acknowledges Congress would have to approve changes to dental coverage for veterans.

Blunt Rochester said her takeaway is the act is working, but challenges remain.

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“Another thing that I think we heard about was the whole issue of medical shortages," she said. "Here we are expanding options for veterans, but if there are no people to actually provide the services, it’s a moot point.”

Delaware’s shortages of some medical providers are leading to lengthy wait times for some veterans.

Staff from the VA Community Based Outpatient Clinic in Georgetown say vets in Sussex County can wait up to eight months for an outside dermatology appointment. A veteran in Southern Delaware may wait up to a year to see a gastrointestinal specialist.

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4.4 - HIT Infrastructure: VHA’s Lax Health Information Management Created 5-Mile-High Backlog (26 August, Fred Donovan, 7k uvm; Danvers, MA)

The Veterans Health Administration’s (VHA) poor health information management of medical record scanning has produced a paper record backlog of 600,000 documents, or a stack of paper more than five miles high, concluded a recent audit by the Department of Veterans Affairs’ (VA) Office of Inspector General (OIG).

To address the backlog, OIG recommended that VHA improve the management of document scanning activities and ensure related resources and staffing are adequate. In addition, VHA should train personnel who are scanning and indexing the document on the proper procedures to improve quality assurance monitoring.

“These actions are necessary to help ensure veterans receive appropriately informed quality care in a timely manner,” the audit stressed.

Several recent laws have made it easier for veterans to be treated by third-party providers, who send paper medical records to the VA to add to the electronic health records. Since 2014, more than 70 million appointments with non-VA providers have been conducted.

“Incorporating these non-VA medical documents into the patients’ EHRs is critical to supporting patient care because it contributes to more complete, accurate, and readily accessible health records that guide clinicians’ decisions,” the audit stressed.

For the audit, OIG visited eight VA medical facilities and interviewed personnel from 78 other medical facilities.

The OIG related that VHA’s health information management staff conducts an annual inventory on the status of information management operations to decide on future training needs and to identify facilities that need technical assistance.

This annual inventory does not examine specific document backlog information, such as description of documents, size of the backlog at each facility, and/or the age of unscanned medical records, the audit related.

In addition, the VA health information management leaders and the VA medical facility staff do not use the annual inventory to advise facility on how to prevent document backlogs.

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While health information management personnel have authority in creating policy, it is the VHA facility directors who are tasked with enforcing that policy.

This divided authority, along with staffing shortages and poor training, has contributed to the document backlog, the audit concluded.

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5. Suicide Prevention

5.1 - Becker's Hospital Review: House chairman calls for national stand-down at VA hospitals for suicide prevention training (26 August, Anne-Marie Kommers, 593k uvm; Chicago, IL)

The chairman of the House Veterans' Affairs Committee called for a one-day halt to all nonessential work at VA medical centers to allow staff to focus on suicide prevention policies, according to The Marine Corps Times.

The call comes after an Aug. 22 inspector general report found numerous safety issues related to staffing, employee training and risk mitigation at West Palm Beach (Fla.) VA Medical Center, where a patient died by suicide in early 2019.

"We appreciate the Office of Inspector General's oversight, which focuses on an event that occurred in March 2019," the VA told Becker's following the report's release. "We continue to reinforce education to all staff and maintain suicide prevention as a priority."

Nearly 30 veterans have died from suicide at VA medical centers since 2017.

The VA did not respond to Becker's request for comment on the chairman's call for a national stand-down.

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5.2 - Federal News Network (Audio): House VA Committee chair calls for agencywide stand-down to address veteran suicide (26 August, Eric White, 238k uvm; Washington, DC)

The head of the House Veterans Affairs Committee wants all hands on deck to address veteran suicide. Rep. Mark Takano (D-Calif.) is calling for The Department of Veterans Affairs to hold a nationwide suicide stand-down within the next 15 days, so every leadership executive, administrator, nurse, doctor, and employee across the agency understands how to identify veterans in crisis and get them the help they need. There were three veteran suicides in five days on VA property back in April, and a recent VA inspector general report found there was a series of leadership failures at the West Palm Beach VA Medical Center which lead to a patient committing suicide in a secure psychiatric ward back in March. (House Veterans Affairs Committee)

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Veterans Affairs has a backlog of paper medical records that measures over five miles high. The VA inspector general said medical facility staff have struggled to quickly and accurately scan and enter patient documents into electronic health records. The department hasn't ensured the information in the documents is legible and accurate. The IG said VA should first address staffing shortages to help the department manage and improve its medical records backlog. (Department of Veterans Affairs Office of Inspector General)

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5.3 - The Augusta Chronicle: Family of veteran treated at Augusta VA who killed self files negligence suit (26 August, Sandy Hodson, 133k uvm; Augusta, GA)

The family of a Gulf War veteran who killed himself after suffering for years with post traumatic stress disorder has filed suit against the federal government, alleging his VA doctors were negligent.

Raymond Georgia Green died from a self-inflicted gunshot Jan. 10, 2017. His widow, Michele Green, and children Na'Kesha Green, Raven Simon Green-Harris, Raymond George Green Jr., and Dontair Wilson filed the federal lawsuit seeking $4 million in damages Aug. 8.

According to the lawsuit, Green was stationed at the National Training Center in Fort Irwin between 1994 and 1995. The fort is in the Mojave Desert in California. Green, a tank mechanic, witnessed a tank explosion that killed several servicemen. For years he suffered nightmares and flashbacks, according to the lawsuit. Green retired in 2006.

From 2011 Green was treated for depression at Charlie Norwood VA Medical Center. In April 2016 his primary care psychiatric care provider changed his medication to treat insomnia, anxiety, nightmares and flashbacks, according to the lawsuit.

On Nov. 14, 2016, Green's wife and daughter contacted social workers at the VA Center because he was having auditory and visual hallucinations, according to the lawsuit. He was exhibiting delusional behavior and extreme paranoia and refused to leave his bedroom, stopped attending classes and cancelled a major medical appointment, which had had never done before, the lawsuit contends.

In response to the Green family's concern, his treating physicians responded they couldn't have Green involuntarily admitted to an emergency room or mental health facility, the lawsuit alleges. Two months later, Green was dead. A review of his medical records at the VA revealed that between July and November 2016 Green didn't fill most of his prescriptions and had not visited a psychiatrist since April.

The Green family contends the medical staff was negligent and deviated from the standard of care in not ensuring Green received adequate follow-up psychiatric examination and treatments with careful monitoring of his prescription intake. The lawsuit includes an affidavit by Dr. Moustafa Shafey, chairman of the psychiatry department at CentraState Medical Center in Freehold, N.J., who considered Green's care negligent.

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There are 20 million veterans in the U.S. , and only about 30 percent seeks medical treatment at VA centers, according to the Department of Veterans Affairs. Since 2005, about 20 veterans commit suicide every day.

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5.4 - St. Cloud Times: **Suicide rates among women veterans continue to rise** (26 August, Patricia Wilson, 125k uvm; Saint Cloud, MN)

The Department of Veterans Affairs April 2019 press release that suicide rates among women veterans are going up and the suicide rate for women veterans was nearly twice the rate of non-veteran women should come as no surprise.

Women are becoming the fastest-growing veteran group and will probably rise to 15% by 2035. The VA further indicates that it is devising a national strategy to prevent veteran suicide.

“Sexual trauma is a significant risk factor for suicide,” according to former RAND researcher Rajeev Ramchand, now senior vice president of Cohen Veterans Network. Ramchand’s three years of intensive research and study concluded that women veterans “who screen positive for military sexual trauma have a higher risk of dying by suicide than those who don’t.”

The VA states that one in four women who have served or who are still serving in the military have experienced sexual trauma. Ramchand said that number is likely low because of “the stigma and possible consequences associated with reporting military sexual trauma.”

Ramchand has it right. Many women I have worked with in the military and those who are now my sister veterans have spent years in a secret, private hell because they know their families, friends and other veterans will tend to blame them for what happened. Women on active duty are very cautious to not report sexual assault to their commanders, as they do not want to jeopardize their careers.

The RAND Corporation conducted an intensive survey in 2014 of every military installation in the United States, including all Navy vessels to determine the extent of MST (Military Sexual Trauma), and released a comprehensive list of the “most dangerous” ones where a military woman can expect to be assaulted.

To cite just one example, the following Army bases were listed as leaders in MST involving women: Fort Huachuca, Arizona; Osan Base, Korea; Fort Drum, New York; Okinawa, Japan; and Fort Riley, Kansas.

It is stunning to read this list and realize that the VA is still behind the curve on reaching the “hidden and invisible women veterans” who struggle daily to deal with what has happened to them.

The recent St. Cloud VA Women’s Expo on Aug. 17 was a perfect example of lack of innovation and use of updated material.

What I and other women I spoke with who attended this expo were hoping for was to hear perhaps how money might have been approved to completely update the Women’s Clinic and

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bring more female providers. We were told not to expect much happening in that regard for at least two years.

Instead of having speakers who were excited about new ways to improve the situation for women veterans, we were treated to an afternoon of “art therapy,” painting clay fish and teapots while VA employees read 10-year-old statistics from their slide presentations. And they wonder why turnout at their events are so low?

In fairness, the VA employees are not completely to blame. After all, there is no solid, settled leadership at the top of the St. Cloud VA Medical Center.

For the past two years the St. Cloud VA has had a succession of acting directors, but cannot seem to find a candidate to elevate to the position of director. There are 11 other VA Medical Centers in the U.S. dealing with the same problem.

United States Secretary of Veterans Affairs Robert Wilkie is so busy patting himself on the back that I fear he may dislocate his shoulder and is not exactly the epitome of leadership.

Wilkie has again turned down the American Legion’s request to go ahead and start early processing of Blue Water Navy Claims, stating the VA has until January 1, 2020 to BEGIN the process. Heaven forbid you might take the initiative and forge ahead, Mr. Secretary!

Meanwhile my sister veterans continue to try to stay invisible and find their way through the maze of MST. These women have served with honor and distinction and need to have confidence that if they come forward that they will receive the help they have earned.

Self-destruction is terrible option, but we are losing these women because they are deciding that the shame and fear that MST has brought to their lives will never end. They make the decision that the pain of dying is better than one more day of the pain of living with MST.

This is the opinion of Patricia Wilson, a veteran and a resident of St. Cloud. Her column appears on the fourth Tuesday of the month.

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6. Women Veterans / Homelessness / Benefits / Cemeteries

6.1 - The Hill: **Here's why Congress must close the '90/10 loophole' in veterans' education**
(26 August, Wesley Wilson, 18.4M uvm; Washington, DC)

For years, veteran advocates and lawmakers have worked to close the widely-known 90/10 loophole that for-profit schools use to target veterans unethically. This year, 37 veteran service organizations and lawmakers have banded together to make closing the loophole a real possibility. Unfortunately, organizations such as the Reserve Officers Association (ROA) are getting in the way of progress by defending for-profit schools and incorrectly promulgating veteran advocates' arguments.

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ROA claims advocates push to close the 90/10 loophole with interests of curtailing competition between the for-profit and not-for-profit sectors; this is not true. Here is why Congress should close the 90/10 loophole.

Created under the Higher Education Act Amendments of 1998, the 90/10 rule mandated that proprietary institutions must derive 10 percent of their revenue from non-federal sources. The legislative intent was to combat waste and fraud, not default rates. Despite originating from taxpayer pockets, G.I. Bill payments do not count as federal dollars under the rule. Because of this, for-profit schools are incentivized to target veterans and their benefits.

According to the American Economic Journal, for-profit institution tuition rates often mirror the amount of money they would receive in per-student federal aid subsidies. With tuition set at a profit-maximizing rate, for-profits can "strategically" recruit G.I. Bill-eligible students.

This strategy explains why for-profit schools received the largest amount of G.I. Bill dollars. Between 2009 and 2017, eight of the top 10 recipients of G.I. Bill dollars were for-profit institutions — collecting a whopping $34 billion. Six of those eight schools have come under fire in state and federal lawsuits (most of them multiple times) for predatory recruitment and fraud.

For example, in 2015, the University of Phoenix (the top recipient of G.I. Bill dollars) was sued by two university employees when they were asked to misrepresent information to recruit veterans. The recruiters claimed they "were trained to lie to students about their future employment prospects." Unfortunately, similar stories are commonplace. The VA has received 2,000 complaints against for-profit institutions — more than any other type of school.

Accusations of fraud and recruitment malpractice caused proprietary giants such as ITT Tech and Corinthian College to close their doors permanently — leaving 7,000 student veterans without degrees and G.I. Bill benefits. Fortunately, provisions of the new Forever G.I. Bill restored benefits lost because of school closures. Unfortunately, students exiting the closing for-profit schools were unable to transfer 94 percent of their academic credits.

ROA asserts that loophole-closing legislation would be unfair to the taxpayer. The estimated cost of restoring benefits lost because of school closures is $320 million. In a New York Times opinion piece, student veteran experts highlight for-profits' propensity to receive improper G.I. Bill payments. The VA internal audit they cite warns the VA will issue $2.3 billion in improper payments if their capacity to exercise oversight is not improved. How is this fair to the taxpayer?

ROA cites the low graduation rates of three schools (Ashford University, Oklahoma State

University-Oklahoma City, and University of Maryland-University College). Ashford University is a for-profit school and has been a subject in numerous lawsuits, so it seems counterproductive to include this school in their argument. Second, arbitrarily selecting three schools with low graduation rates is a confirmation bias that does not accurately capture the public sector's performance. The focus should be on educational outcomes, not graduation rates — so how do outcomes differ between the two?

In two words, plain lousy.

A study analyzing for-profit school outcomes found that students who graduated from for-profit schools were less employable, and earned 11 percent less than their not-for-profit counterparts. Outcomes and academic preparation were even worse for students attending exclusively online,

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for-profit institutions. The study underscored crippling for-profit tuition rates, which are five times higher than the average community college. Tuition for certificate programs at for-profit schools is 11 times higher. Unsurprisingly, high tuition costs have led to four times as much student debt, coupled with high student loan default rates for proprietary schools.

Closing the loophole is common sense and will affect only a small portion of schools. There are 2,829 for-profit schools eligible for federal aid; of those schools eligible, only 112 would be out of compliance. Many vocational training institutions (HVAC, culinary arts, etc.) would be unaffected, because, while still covered under the G.I. Bill, they are ineligible for federal aid. Studies have shown that for-profit institutions ineligible for aid "can survive, and even thrive, alongside their aid-eligible counterparts." Lastly, reports illustrate that repealing the 90/10 rule would cost taxpayers $2 billion in Pell Grants and increase loan default rates.

Closing the 90/10 loophole is about eliminating government waste and curtailing unethical behavior — not competition. The rule of law must be upheld, and the original legislation must function as intended. We are tired of for-profit schools lying to veterans about the education they are receiving and the types of jobs in which they will qualify. We are tired of veterans paying ridiculous tuition rates set by profit-maximizing schools — with taxpayers footing the bill. We are tired of veterans working hard for a degree, with nothing to show for it.

The G.I. Bill is one of the most successful social programs in American history. If we want to continue the success of the G.I. Bill, then it is time for lawmakers to step up.

Wesley Wilson served in the U.S. Army from 2012-2017 as a military police officer. He is an advocacy fellow with High Ground Veterans Advocacy, a research assistant at the Institute for Veterans and Military Families, and a graduate student at the Maxwell School of Citizenship and Public Affairs at Syracuse University. He is the former president of the Fordham Veterans Association.

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6.2 - WCPO (ABC-9, Video): Despite ban, Cincinnati VA Medical Center continues to support transgender troops (27 August, Craig McKee, 680k uvm; Cincinnati, OH)

Lesbian, gay, bisexual and transgender people have served in the United States military for as long as there's been one. Edicts from the White House — like the bygone "Don't Ask, Don't Tell" and President Donald Trump's current ban on transgender troops — can't change that.

And they don't change the responsibility of the United States Department of Veterans Affairs, according to Cincinnati VA psychologist Connie Boehner.

"People don't think about it until they hear it on the news, but there have always been transgender folk in the military, and we're going to take care of them if they ask us to," she said. "And that's the bottom line of this."

The VA doesn't pay for transgender troops to receive gender confirmation surgery, but it covers pre- and post-operative care as well as therapy and hormone prescriptions.

In 2018, a short time after Trump enacted his ban, social worker Cindy Horn helped the Cincinnati VA Medical Center establish its first-ever support group for transgender veterans. Its

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members range in age from 32 to 74, she said, and monthly meetings are a place where they can come for an all-too-rare experience: Feeling valued, recognized and safe.

“The biggest challenge is just being accepted in society and to truly authenticate to who they are,” said Horn, who spent 12 years counseling active-duty troops at Fort Knox.

Air Force veteran Laura Ann Weaver knows that better than almost anyone. She knew who she was early in her life, she said — at three years old, maybe even before — but had no idea how to bring that real self into the world.

“In my generation, there wasn’t even a language to describe being transgender,” she said. “You just knew you were different, but you couldn’t put your finger on it. It was something you couldn’t talk about and you would practice in secret.”

She joined the Air Force in 1972, serving for two years out of Osan Air Base in South Korea, and married her wife in 1980. It was a classically masculine life, she said. She was good at living it, even if it made her feel incomplete. Even if she knew her wife didn’t approve of her secret.

(That’s a common experience for LGBTQ veterans born with a Y chromosome, according to Horn: joining the military in an attempt to feel or look more traditionally masculine.)

Weaver continued to live as a man for 30 years. In that time, she lost her wife and her parents, forcing her to begin seriously considering who she would be outside that web of obligation and expectation. Who did she want to be, now that she got to decide?

“I had very much during my marriage surrendered who I was as an individual and was very much part of a couple,” she said. “I had to relearn who I was, and that took me 10 years.”

At the end of it, she knew she had to bring Laura Ann into the real world despite her fears of being rejected. Some of those fears would be realized, she said. She lost her relationships with her brother and sister after coming out.

“When I went to the Cincinnati VA hospital, I was very concerned about being transgender and refused treatment,” she said.

She wasn’t. Weaver pays $50 for each clinical appointment and $27 every month for her three medications through the VA, where she said she’s been accepted and treated with respect.

“The Cincinnati VA is one of the best hospitals I’ve been to,” she said. “They do provide mental health care, they do provide hormone support, they do provide everything up to but not including surgery, and that is a tremendous benefit for veterans.”

Boehner and Horn said they’re proud of being able to provide those services, and the need is growing.

Many of the people who participate in the Cincinnati VA’s support group aren’t out to their families, making it one of just a few places they can be themselves without fear of judgment.

“It’s always there are going to be people uncomfortable with things they don’t understand,” Boehner said. “One of our big roles is educating people what this means and that this isn’t a

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threat to you. You're going to get your care, they're going to get their care, and you're all veterans."

"Transgender people are no different than anybody else," Weaver added. "Quite frankly, you have to resent that we're being treated differently."

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6.3 - WKYC (NBC-3): Local son, fiancee hold special wedding ceremony to include ailing father (25 August, 611k uvm; Cleveland, OH)

Most people dream of their parents being a part of their wedding day. But as many people come to understand due to health risks and deaths, it's not always possible.

In an effort to avoid that scenario, a local man held a special wedding service at Cleveland's VA Medical Center Sunday.

Zeke, 28, and his fiancee, 23, couldn't image their big day without Zeke's father, Fred Miller.

So when they found out Miller was having complications after having a heart transplant nearly 30 years ago, the two sprung into action.

The pair held the ceremony inside VA's chapel and held a short reception after, that even featured Fred's favorite snack--brownies.

The two will officially wed in October 2021.

Miller served in the U.S. Marine Corps from 1968 to 1970 before returning home to Northeast Ohio and working for U.S. Steel.

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6.4 - Villages-News.com: Rollout for $10 million monument plan at Florida National Cemetery taking place in The Villages (26 August, 195k uvd; Lady Lake, FL)

The rollout for a $10 million venture to bring a series of monuments to Florida National Cemetery will be announced this week in The Villages.

The Joint Veterans Support Committee (JVSC) is working to bring the Freedom Memorial Plaza to the national cemetery. It will be located near the entrance to the Bushnell facility, will encompass two-plus acres and will be inner-connected by sidewalks.

The JVSC will be responsible for the project, including fundraising, design, and submission of details to the Department of Veterans Affairs for final approval. Those wishing to learn more about the project are welcome to attend a gathering Wednesday, Aug. 28 at 3 p.m. at the Eisenhower Recreation Center.

The initial focus will be on two of the 16 monuments. A "Military Honors Funeral" will include two life-sized bronzed military figures folding a red, white and blue powder-coated American flag

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over a bronze casket. It will be surrounded by 7-feet-tall granite columns depicting other facets of a military honors funeral.

The columns will include porcelain pictures and emblems representing all branches of service, as well as scenes of a bugler playing taps, a chaplain, presentation of a folded flag to next of kin, an honor guard, a 21-gun salute, a missing-man flyover and a caisson.

A 470-foot-long "Defenders of Freedom Wall" will consist of etched black granite plates depicting scenes beginning with the Revolutionary War and progressing through today's defenses for freedom. The etchings on the 6-foot panels will be generated from photographs submitted by volunteers and organizations wishing to sponsor a section. Those wishing to do so will be asked to donate funds for that portion of the wall and submit photos to be used, which will then be sent to the Department of Veterans Affairs for final approval.

The themes for the remaining 14 monuments haven't yet been determined. A "Gold Star Families" Monument is expected to gain interest. And others being considered are Vietnam War, Native American, POW-MIA, Purple Heart, Medal of Honor, Women Veterans, Special Forces, World War II, Korean War and Iraq/Afghanistan. Those with ideas for other monuments are encouraged to share ideas the JVSC.

These monuments will be the first to be erected at the Florida National Cemetery, which is located just off Interstate 75 at the edge of the Withlacoochee Forest in Bushnell. It is the largest national cemetery in Florida with 169,000 interred and the second most active in the United States with 7,000 interments per year.

Those who want to volunteer to be a member of the JVSC Monument Committee, make donations or have further questions are encouraged to visit JVSC.US.

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7. Other

7.1 - FOX News: Presidential administrations from both sides like to spend, but then again, so do most Americans (26 August, Chad Pergram, 73.9M uvm; New York, NY)

Eat your veggies. Take your vitamins. Hit the gym. Eliminate alcohol and caffeine.

Everyone knows how to stay healthy.

Yet we don't like carrots and kale. We forget our Centrum. We go to happy hour with friends after work and skip the cardio class.

This is human nature. Who wouldn't rather eat goodies then pound away a few hours at the gym?

So, is it any surprise the federal debt and deficit is exploding?

The psychology is really the same.

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The public doesn't like to hear about burgeoning debt. People certainly lecture Washington about profligate spending. There's renewed worry about the federal deficit amid signals of a potential economic slowdown. The non-partisan Congressional Budget Office says the new fiscal blueprint lawmakers okayed earlier this summer could spike the deficit by $800 billion over the next decade. Few on either end of Pennsylvania Avenue have the will to make meaningful spending cuts.

Let's face it: the deficit is up because Congress and Presidents of both parties like to spend. But frankly, most Americans like spending too.

The Congressional Budget Office revised its economic outlook after Congress voted to terminate old spending limitations. Those strictures kept some federal expenditures in check. President Trump went along with the plan.

"The nation's fiscal outlook is challenging," said Congressional Budget Office Director Philip Swagel.

There's now a chasm between what the government takes in and what it spends. Swagel said the difference is now at "the highest level just after World War II."

[…]

Then, throw in money for the Department of Veterans Affairs and a spending line called "Military Construction." Nobody wants to cut the VA. So, if you couple the appropriations bill known on Capitol Hill as "MilCon/VA" with the annual Pentagon spending bill, 88 cents of each federal dollar is untouchable. That leaves only the remaining 12 cents as a potential place to cut. That final 12 cents funds everything from the State Department to the Department of Interior. It funds Congress. Homeland Security.

[…]

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7.2 - U.S. News & World Report (HealthDay): Staying Optimistic Might Lengthen Your Life, Study Shows (26 August, Alan Mozes, 23.3M uvm; Washington, DC)

An upbeat view of life may increase your odds for living to a ripe old age, new research suggests.

The finding stems from a look at optimism and longevity among nearly 70,000 women and 1,400 men. It builds on earlier research linking higher levels of optimism to lower risks of chronic illness and premature death.

"This study took us further by suggesting that optimistic people are more likely to achieve 'exceptional longevity,' which we defined as living to age 85 or older," said study lead author Lewina Lee, a clinical research psychologist with the U.S. National Center for Posttraumatic Stress Disorder at the Veterans Affairs Boston Healthcare System.

Compared to their least optimistic counterparts, the most optimistic men and women studied were 50% to 70% more likely to reach that advanced milestone, Lee said.

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They were also 11% to 15% more likely to live longer overall, the study found.

The findings held up even after accounting for other influences, such as educational background, marital status, friendships, chronic health problems, and depression, Lee said.

Optimism was also powerful predictor of longevity regardless of a person's habits when it came to tobacco and alcohol use, exercise, eating well or getting routine medical care.

"Most studies have focused on deficits or problems that increase the risk of dying," Lee noted. "Our study is novel is that we considered the benefits of a psychological asset -- optimism -- in promoting longevity."

The study team suggested that the findings could point the way towards new interventions that might foster optimism and thereby extend life, such as meditation and certain psychotherapy programs.

Lee and her colleagues discuss their findings in the Aug. 26 issue of Proceedings of the National Academy of Sciences.

They concluded that optimism matters after analyzing data from the Nurses' Health Study, which focused on women, and the Veterans Affairs Normative Aging Study, which focused on men.

The women were 58 to 86 years old (average age: 70) when their health habits, overall health and optimistic outlook were first assessed. They were followed for 10 years.

The men were 41 to 90 years old (average age: 62) when they had a similar assessment and a physical exam in 1986. They were followed for 30 years.

At the end of the tracking periods, researchers found that results for women and men were roughly the same: The more optimistic the individual, the greater the chances for living longer -- and the greater the chances for reaching an "exceptional" age.

But that doesn't necessarily mean that Debbie Downers are doomed to shorter lives, Lee said. Her team only found an association and not a cause-and-effect link.

"The association between optimism and exceptional longevity was independent of depression," Lee said. "This suggests that the presence of optimism is more than just the absence of depression," so that even among those who struggle with depression a little optimism might still work longevity wonders.

Kit Yarrow, a consumer psychologist at Golden Gate University in San Francisco, said there are many reasons why optimism breeds longevity.

"Optimists experience less stress, because they don't tend to dwell on negatives and feel more empowered to overcome hurdles," said Yarrow, who wasn't involved with the study. "They are less likely to give up, and they bounce back more quickly from problems and setbacks. Stress is a killer and wreaks havoc on our bodies."

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Optimists also are less likely to experience depression, feelings of hopelessness and negativity -- factors often linked to poorer health and higher rates of disease, she added.

On top of that, Yarrow said, optimists tend to take better care of themselves and have an easier time making and keeping friends, "a well-documented source of health and longevity."

She acknowledged that access to money, good food and education and, of course, genetics can also have a big impact on longevity.

But unlike good genes, Yarrow said, "optimism and her powerful sister, gratitude, can be learned."

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7.3 - U.S. News & World Report (AP): Former Trump Official to Helm Florida Republican Party (26 August, 23.3M uvm; Washington, DC)

TALLAHASSEE, FLA. (AP) — Florida's Republican Party has named Peter O'Rourke, a former acting secretary of the U.S. Department of Veterans Affairs under the Trump administration, as its new executive director.

O'Rourke is widely seen as a loyalist for President Donald Trump. In its announcement Monday, the party said O'Rourke would help the party deliver Florida for Trump's re-election.

O'Rourke was acting secretary for two months, from May 2018 until the confirmation of current VA Secretary Robert Wilkie.

Wilkie then asked for O'Rourke's resignation in December.

During his tenure, O'Rourke came under fire for his management style and for his clashes with lawmakers.

In December, the Washington Post noted that O'Rourke was being paid $160,000 a year while doing little work. He responded that "there were times I didn't have a lot to do."

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7.4 - Politico: Former VA official 'hand-picked' by Trump to lead Florida GOP (26 August, Matt Dixon, 14.4M uvm; Arlington, VA)

TALLAHASSEE — In a surprise move, Peter O'Rourke, a former top official at the U.S. Department of Veterans Affairs and an ally of President Donald Trump, will take over leadership of the Republican Party of Florida, the latest development in a party power struggle going into the 2020 presidential election.

O'Rourke, who was introduced to the party executive committee as Trump's "hand-picked" choice for the job, will replace Jennifer Locetta as executive director of one of the biggest state Republican operations in the country. Locetta was hired in January, shortly after Gov. Ron DeSantis, a Republican, took office.

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Trump's team put O'Rourke's name forward last week after DeSantis and his chief of staff, Shane Strum, talked to Trump campaign manager Brad Parscale about replacing Locetta.

Trump "personally endorsed" O'Rourke for the appointment, DeSantis said in a written statement Monday.

"We are a unified and united team as we head into 2020," state Republican Party Chairman Joe Gruters told POLITICO.

On a conference call with the party's executive committee Monday, Gruters introduced O'Rourke as "basically a cabinet secretary," a reference to his tenure as acting VA secretary.

Gruters had revealed O'Rourke's hiring in a press release Monday morning, an announcement that came as a surprise to party insiders, including some on the executive committee.

"No one in the state executive committee had a clue about the new executive director until the press release hit," said a Republican consultant. "People are confused and concerned."

GOP staff in Florida working with Trump's Victory Team will remain largely in place, but additional staff shakeups could be coming, Gruters said.

"There will probably continue to be some changes, but you can expect a broader expanded team," Gruters said on the call.

The appointment is O'Rourke's first job since leaving the VA in December.

When he cut ties with the department, he faced criticism for not showing up to the $161,000-a-year job. As VA chief of staff, he also came under fire for allowing members of Mar-a-Lago, Trump's Palm Beach County club, to influence department decision-making.

One of those members was Ike Perlmutter, chairman of Marvel Entertainment and one of DeSantis' top donors. POLITICO reported last year that Perlmutter objected to a $16 billion VA contract being awarded to a vendor he did not like.

"Peter O'Rourke has the political expertise and management skill necessary to support Governor DeSantis within the state and keep our party unified as we work to deliver Florida for President Trump in 2020," Perlmutter said in a written statement distributed as part of Gruters' press release.

The press release projected a message of unity after months of internal power struggles over the direction of the party and who should have influence over decision-making.

Prominent state Republicans led by Strum and first lady Casey DeSantis have sought to replace party staff allied with Susie Wiles, a political strategist who helped guide DeSantis' campaign to victory and led his transition. Wiles and Gruters co-chaired Trump's 2016 Florida campaign.

O'Rourke's hire is "the continuation of putting some of [DeSantis'] people versus 'Susie' people," said one party official.

Locetta, the outgoing executive director, was considered a Wiles ally.

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The rift with Wiles had prompted DeSantis to distance himself from his own party apparatus as it gears up for 2020. DeSantis said he would raise money for two Republican Party of Florida events, then focus on raising money for his own political committees.

DeSantis does not have a political spokesperson. Strum did not return a call seeking comment.

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1. Top Stories

1.1 - KIVI (ABC-6, Video): #FINDINGHOPE: US Secretary of VA works to open mental health dialogue in the armed forces (26 August, Madeline White, 111k uvm; Nampa, ID)
The national tragedy of veteran suicide has been a main concern for US Secretary of Veterans Affairs Robert Wilkie since his appointment to the job. During his recent visit to Boise, he sat down for an exclusive TV interview with 6 On Your Side's Madeline White.

Hyperlink to Above

1.2 - CBS News (Video): Inside a suicide prevention call center for veterans responding to 1,700 calls each day (26 August, Dean Reynolds, 30.2M uvm; New York, NY)
The Departments of Defense and Veterans Affairs are holding a conference in Nashville this week aimed at preventing suicides. A hotline launched in 2007 has answered more than 3.5 million calls, sending emergency help to nearly 100,000 people. At the Veterans Crisis Line in Canandaigua, New York, the calls come in all day and night. Every day, 1,700 calls come in from veterans on the brink. CBS News was given rare access to the Veterans Affairs responders and their life-saving conversations.

Hyperlink to Above

1.3 - ABC News (Video): Could a new drug treat veterans with severe depression? President Trump thinks so (27 August, Dr. Lauren Kelly and Elizabeth Mclaughlin, 22.2M uvm; New York, NY)
At a veterans event in Kentucky last week, President Donald Trump touted what he called an "incredible" new drug he says could help American veterans struggling with depression. The drug, called esketamine and marketed as Spravato, was produced by Johnson & Johnson subsidiary Janssen Pharmaceuticals and billed as a breakthrough treatment for patients who have not responded to other antidepressants.

Hyperlink to Above

1.4 - Military.com: The VA Removed a Vet's High-Risk Label. The Patient Died by Suicide. What Went Wrong? (26 August, Richard Sisk, 4.3M uvm; San Francisco, CA)
Again and again, teams at the Department of Veterans Affairs' San Diego Health Care System reached out to and helped a troubled veteran battling suicidal thoughts and substance abuse who frequently missed appointments or broke off contact. The efforts were not enough. The veteran was found dead in July 2018; the San Diego Medical Examiner's Office ruled the death a suicide by asphyxiation.

Hyperlink to Above

1.5 - The Daily Signal: VA Lifts Ban on Bibles in Move to Support Religious Freedom (26 August, Fred Lucas, 1.1M uvm; Washington, DC)
As a kid, Veterans Affairs Secretary Robert Wilkie recalls, he visited a VA hospital at Christmastime. “One of my fondest memories growing up, we used to sing Christmas carols at the VA hospital in Fayetteville, North Carolina,” Wilkie told The Daily Signal, sitting in a 10th-floor office at VA headquarters on Vermont Avenue Northwest, overlooking the White House.

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1.6 - Nextgov: **Veterans Affairs Launches Digital National Cemetery** (26 August, Brandi Vincent, 339k uvm; Washington, DC)
The Veterans Affairs Department's National Cemetery Administration developed and launched an online memorial platform—Veterans Legacy Memorial—to honor millions of veterans interred in national cemeteries across America. Deemed a "digital national cemetery," the new resource leverages technology and prioritizes security to boost community engagement and preserve the memories of those who served.

Hyperlink to Above

1.7 - Las Vegas Sun: **At VA, we protect those who protected us** (26 August, Sec. Robert Wilkie, 180k uvm; Henderson, NV)
Cpl. Orlando Camacho, Lt. Kenneth Frazier and officer Miguel Calderon didn't know they would save lives when they woke up Aug. 12 and reported to the Jesse Brown VA Medical Center in Chicago. The three members of the Veterans Affairs Police were on duty when shots were fired just outside the VA's doors. As alarms blared and people flooded 911 with calls, Camacho, Frazier and Calderon waded past panicked people toward a man with a rifle in his hand who entered the building.

Hyperlink to Above

1.8 - The Exponent Telegram: **Sen. Manchin: VA officials assure 'person of interest' in homicide no longer in contact with veterans in VA hospital** (26 August, Matt Harvey, 133k uvm; Clarksburg, WV)
A person of interest in 11 suspicious deaths at the Louis A. Johnson VA Medical Center — one of those deaths a confirmed homicide — "is no longer in any contact with veterans at the facility," U.S. Sen. Joe Manchin said Monday in a news release.

Hyperlink to Above

1.9 - Healthcare IT News: **OIG audit: Massive backlog in digitizing VHA medical records** (26 August, Nathan Eddy, 64k uvm; Chicago, IL)
Veterans Health Administration medical facilities are facing an enormous challenge as they scan and enter medical documentation into patients' electronic health records, according to an audit from the Office of the Inspector General for the Department of Veterans Affairs.

Hyperlink to Above

1.10 - WDTV (CBS-5, Video): **Update: Veteran speaks out about his time at the Louis A. Johnson VA Medical Center** (26 August, 32k uvm; Bridgeport, WV)
5 News spoke with local veteran, Ken Warman about his experience at the Clarksburg VA Medical Center. "That facility, I hate to tell you. Worst facility I have ever been to. Hands down, of all the states I have been to. Hands down the worst. I have been treated the worst," said Warman.

Hyperlink to Above

2. Improving Customer Service

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2.1 - Military Times: **Unable to sue the Army for medical malpractice, this retired soldier is now fighting the VA for benefits** (26 August, Meghann Myers, 1.7M uvm; Vienna, VA)
Retired Sgt. 1st Class Barbara Ospina is partially paralyzed, in debilitating pain and confined to a wheelchair for almost all of her day. Her condition is the result of malpractice at the hands of hands of military medicine, according to claims she made to the Department of Veterans Affairs, but she is paying out of pocket for a caregiver to help her bathe, dress and prepare meals, because the VA has denied her request for caregiver assistance.

Hyperlink to Above

2.2 - Military Times: **Did VA hospital leaders ignore recalls on faulty medical equipment?** (26 August, Leo Shane III, 1.7M uvm; Vienna, VA)
Staffers at a Florida-based Veterans Affairs hospital say leadership ignored a medical equipment recall for weeks — even after a patient's life was endangered — despite repeated warnings their inaction violated health and safety norms.

Hyperlink to Above

2.3 - KDKA (CBS-2, Video): **Family Of Westmoreland County Veteran Files Federal Tort Claims Act Following Stay At West Virginia VA Hospital** (25 August, Pam Surano, 1.3M uvm; Pittsburgh, PA)
A federal tort claims act has been initiated by the family of a Vietnam veteran whose death at a VA hospital promoted a homicide investigation. Retired Sergeant Felix McDermott died April 8, 2018, at the Loius A. Johnson VA Medical Center in Clarksburg, West Virginia after he was injected with a fatal dose of insulin while at the center, a lawsuit says.

Hyperlink to Above

2.4 - WREG (CBS-3): **Longtime Memphis pain doctor reprimanded for prescription issues** (26 July, Stacy Jacobson, 605k uvm; Memphis, TN)
The Tennessee Department of Health has reprimanded a Memphis pain management and addiction doctor for his prescribing practices. The state put Dr. Douglas Jones' license to practice on probation and banned him from owning or operating pain management clinics.

Hyperlink to Above

2.5 - Becker's Hospital Review: **Staff members claim VA hospital ignored medical equipment recall** (26 August, 593k uvm; Chicago, IL)
Staff members claim leadership ignored a medical equipment recall for weeks at the James A. Haley Veterans' Hospital in Tampa, Fla., according to the Military Times. Becton Dickinson, an IV tubing manufacturer, recalled its tubing equipment on May 6. The VA hospital failed to recall the tubing for weeks, even after the equipment endangered a patient on July 31, staff members said. The patient received too much medication due to what nurses claim was malfunctioning IV equipment.

Hyperlink to Above

2.6 - WINK (CBS-11, Video): **Veteran patients missing appointments, Cape VA clinic lacking resources** (26 August, Jack Lowenstein, 348k uvm; Fort Myers, FL)

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The U.S. Department of Veteran Affairs in Cape Coral says it is unable to provide transportation services to doctor appointments from its clinic due to lack of volunteers and donations that help provide necessary resources. Vietnam Bubba Schneider is someone who depends on these services for his health. He reflected on his time in the war overseas when we spoke to him.

Hyperlink to Above

2.7 - WBIR (NBC-10, Video): Veteran hopes toolbox gift will help other veterans transition back to life after deployment (25 August, Sean Franklin, 464k uvm; Knoxville, TN)
A wounded combat veteran from East Tennessee received a way to find his purpose in life after serving. A simple gift of a toolbox has helped him and others transition from the Army. More than a hundred soldiers filled the Knoxville Convention Center this weekend, learning how to make a transition from deployment to life back home.

Hyperlink to Above

2.8 - Idaho Statesman: Letters to the editor (26 August, Richard L. Barrett, 392k uvm; Boise, ID)
VA THANKS. Kudos to Boise VA Medical Center Director's superb staff and many thanks to Secretary of Veterans Affairs Director Robert Wilkie for giving those folks the recognition they so richly deserve.

Hyperlink to Above

2.9 - WMAZ (CBS-13, Video): Dublin VA going smoke free October 1st (26 August, Wanya Reese, 281k uvm; Macon, GA)
The Carl Vinson VA Medical Center plans to go smoke free starting in the fall, but some veterans have mixed opinions about the ban. Some say it will help, while others think it won't, but regardless of what they think the smoking ban will go into effect at the center starting in October. "I started smoking in the Navy, because that was really the only time I had the opportunity to take a break," Christopher Anderson said.

Hyperlink to Above

2.10 - MetroNews: Clarksburg VA death ruled homicide; VA investigating more possible victims (27 August, Hoppy Kercheval, 242k uvm; Charleston, WV)
On the morning of April 9, 2018, Felix McDermott died at the Louis A. Johnson VA Medical Center in Clarksburg. The retired Army Sergeant and Vietnam Veteran was 82 years old and had several health issues, including aspiration pneumonia. However, his condition was improving, and his death shocked his family.

Hyperlink to Above

2.11 - MetroNews: Autopsy: Vietnam veteran was not diabetic but died of insulin injection (26 August, Brad McElhinny, 242k uvm; Charleston, WV)
An autopsy report for a Vietnam veteran who died suspiciously at the Veterans Affairs Medical Center concludes that the man — who was not diabetic — was injected with a fatal amount of insulin. The autopsy uses clinical language to describe horror. "This case represents the administration of unprescribed insulin to a non-hyperglycemic, non-diabetic patient in a hospital setting," the report states.

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2.12 - WJET (ABC-24, Video): Erie VA Medical Center goes tobacco free (26 August, 73k uvm; Erie, PA)
Erie VA Medical Center will soon be tobacco free. According to the Medical Center Director, the new rule will also apply to all of their community based outpatient clinics. The director said the reasoning for this is to create a healthier environment for anyone who comes in contact with the center.

Hyperlink to Above

2.13 - Citizen Tribune: Group buys van to transport patients to VA clinic (26 August, Shawn Singleton, 64k uvm; Morristown, TN)
Veterans who receive care at the Morristown VA Clinic now have a new way to make their specialized appointments on time. The Jerry Alvis Disabled American Veterans Chapter 59 recently purchased a new van to transport disabled veterans to James H. Quillen Mountain Home VA Medical Center in Johnson City. Veterans from Hamblen, Hawkins, Grainger and Jefferson counties will be eligible for the transportation service.

Hyperlink to Above

2.14 - The Journal Gazette: Five questions for Brett P. Reistad. National commander, American Legion (26 August, 56k uvm; Fort Wayne, IN)
Are people surprised to learn your organization has been around for 100 years? How and when did the American Legion come to be headquartered in Indianapolis? Some people are surprised, but I think most people are aware that we've been around for quite some time. Depending on their age, some may recall how we were such strong advocates for those returning from World War II (just as our founders were for the WWI vets).

Hyperlink to Above

2.15 - Federal Computer Week: Congratulations to the 2019 Rising Stars (26 August, Troy K. Schneider, 46k uvm; Vienna, VA)
Each year, the Rising Star Awards recognize individuals who are early in their federal IT careers yet already are having an outsized impact. The women and men listed below have been selected both for their accomplishments over the past year and for their leadership potential in this community.

Hyperlink to Above

2.16 - Colorado Politics: VA appoints new director of Eastern Colorado Health Care System (26 August, Caitlin Curley, 57k uvm; Denver, CO)
The U.S. Department of Veterans Affairs is bringing on a new director for its Aurora-based Eastern Colorado Health Care System. Michael Kilmer, formerly the medical center director for the Western Colorado system in Grand Junction, will replace Sallie Houser-Hanfelder, who retired in May.

Hyperlink to Above

2.17 - Manistee News Advocate: Volunteers needed for veteran transportation service (26 August, Jane Bond, 1k uvm; Manistee, MI)

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A new vehicle is taking local veterans to their medical appointments, but Eric Sullivan of the local Disabled American Veterans (DAV) chapter is looking for more volunteers to drive it. As the ride coordinator for the DAV Manistee chapter, Sullivan spends most of his time organizing free transportation for retired soldiers to Veterans Affairs (VA) medical centers in locations like Traverse City, Cadillac, Wyoming and Saginaw.

Hyperlink to Above

3. Business Transformation

3.1 - The Virginian-Pilot: **Editorial: Veterans clinic a welcome addition to region** (27 August, 1.1M uvm; Norfolk, VA)
Sens. Mark Warner and Tim Kaine have been working for years to accelerate the painfully slow process of getting a new VA outpatient clinic open in Hampton Roads. Faced with reports of veterans having long, frustrating waits for care at VA facilities, Congress has approved leases for 28 new medical facilities around the country, including one in Hampton Roads and one in Fredericksburg.

Hyperlink to Above

3.2 - KCRG (ABC-9, Video): **Dubuque VA clinic open to patients starting Monday** (26 August, 505k uvm; Cedar Rapids, IA)
Veterans in Dubuque will now have access to the city's new VA clinic. The new clinic opened earlier this month inside a portion of the former K-Mart building off Highway 20. t's more than four times the space of the current clinic, offering new services like radiology, physical therapy, and expanded mental health services.

Hyperlink to Above

4. DOD Cooperation / Electronic Health Records / MISSION Act Implementation

4.1 - FedScoop: **Backlog of VA medical records awaiting digitization is 5 miles tall** (26 August, Billy Mitchell, 48k uvm; Washington, DC)
Across the country at Department of Veterans Affairs medical facilities, there's a massive backlog of documents waiting to be scanned and digitized that, if stacked, would stand more than 5 miles tall. For reference, that's taller than 18 Empire State Buildings. It's just 2,000 feet short of the peak of Mount Everest.

Hyperlink to Above

4.2 - Health Data Management: **OIG: VHA's document scanning backlog puts patients at risk** (27 August, Greg Slabodkin, 41k uvm; Chicago, IL)
Veterans Health Administration facilities are woefully behind when it comes to scanning and entering medical documentation into patients' electronic health records. According to an audit by the VA's Office of Inspector General, the agency found significant backlogs across the VHA, potentially putting patient care at risk because of a lack of timely and accurate EHR documentation.

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4.3 - Delaware Public Media (Audio): **Delaware VA officials discuss new patient health care access rules** (26 August, Sarah Mueller, 11k uvm; Dover, DE)
State Veterans Affairs officials discussed what's working and what's not with the newly-implemented VA Mission Act Monday. Congresswoman Lisa Blunt Rochester hosted a roundtable at the Wilmington VA Medical Center to hear about June's roll out of new patient rules. The VA Mission Act expands access to outside medical providers for veterans who have long drives or face long waits at VA facilities.

Hyperlink to Above

4.4 - HIT Infrastructure: **VHA's Lax Health Information Management Created 5-Mile-High Backlog** (26 August, Fred Donovan, 7k uvm; Danvers, MA)
The Veterans Health Administration's (VHA) poor health information management of medical record scanning has produced a paper record backlog of 600,000 documents, or a stack of paper more than five miles high, concluded a recent audit by the Department of Veterans Affairs' (VA) Office of Inspector General (OIG).

Hyperlink to Above

5. Suicide Prevention

5.1 - Becker's Hospital Review: **House chairman calls for national stand-down at VA hospitals for suicide prevention training** (26 August, Anne-Marie Kommers, 593k uvm; Chicago, IL)
The chairman of the House Veterans' Affairs Committee called for a one-day halt to all nonessential work at VA medical centers to allow staff to focus on suicide prevention policies, according to The Marine Corps Times. The call comes after an Aug. 22 inspector general report found numerous safety issues related to staffing, employee training and risk mitigation at West Palm Beach (Fla.) VA Medical Center, where a patient died by suicide in early 2019.

Hyperlink to Above

5.2 - Federal News Network (Audio): **House VA Committee chair calls for agencywide stand-down to address veteran suicide** (26 August, Eric White, 238k uvm; Washington, DC)
The head of the House Veterans Affairs Committee wants all hands on deck to address veteran suicide. Rep. Mark Takano (D-Calif.) is calling for The Department of Veterans Affairs to hold a nationwide suicide stand-down within the next 15 days, so every leadership executive, administrator, nurse, doctor, and employee across the agency understands how to identify veterans in crisis and get them the help they need.

Hyperlink to Above

5.3 - The Augusta Chronicle: **Family of veteran treated at Augusta VA who killed self files negligence suit** (26 August, Sandy Hodson, 133k uvm; Augusta, GA)
The family of a Gulf War veteran who killed himself after suffering for years with post traumatic stress disorder has filed suit against the federal government, alleging his VA doctors were negligent. Raymond Georgia Green died from a self-inflicted gunshot Jan. 10, 2017. His widow, Michele Green, and children Na'Kesha Green, Raven Simon Green-Harris, Raymond George Green Jr., and Dontair Wilson filed the federal lawsuit seeking $4 million in damages Aug. 8.

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5.4 - St. Cloud Times: **Suicide rates among women veterans continue to rise** (26 August, Patricia Wilson, 125k uvm; Saint Cloud, MN)
The Department of Veterans Affairs April 2019 press release that suicide rates among women veterans are going up and the suicide rate for women veterans was nearly twice the rate of non-veteran women should come as no surprise.

Hyperlink to Above

6. Women Veterans / Homelessness / Benefits / Cemeteries

6.1 - The Hill: **Here's why Congress must close the '90/10 loophole' in veterans' education** (26 August, Wesley Wilson, 18.4M uvm; Washington, DC)
For years, veteran advocates and lawmakers have worked to close the widely-known 90/10 loophole that for-profit schools use to target veterans unethically. This year, 37 veteran service organizations and lawmakers have banded together to make closing the loophole a real possibility. Unfortunately, organizations such as the Reserve Officers Association (ROA) are getting in the way of progress by defending for-profit schools and incorrectly promulgating veteran advocates' arguments.

Hyperlink to Above

6.2 - WCPO (ABC-9, Video): **Despite ban, Cincinnati VA Medical Center continues to support transgender troops** (27 August, Craig McKee, 680k uvm; Cincinnati, OH)
Lesbian, gay, bisexual and transgender people have served in the United States military for as long as there's been one. Edicts from the White House — like the bygone "Don't Ask, Don't Tell" and President Donald Trump's current ban on transgender troops — can't change that. And they don't change the responsibility of the United States Department of Veterans Affairs, according to Cincinnati VA psychologist Connie Boehner.

Hyperlink to Above

6.3 - WKYC (NBC-3): **Local son, fiancee hold special wedding ceremony to include ailing father** (25 August, 611k uvm; Cleveland, OH)
Most people dream of their parents being a part of their wedding day. But as many people come to understand due to health risks and deaths, it's not always possible. In an effort to avoid that scenario, a local man held a special wedding service at Cleveland's VA Medical Center Sunday.

Hyperlink to Above

6.4 - Villages-News.com: **Rollout for $10 million monument plan at Florida National Cemetery taking place in The Villages** (26 August, 195k uvm; Lady Lake, FL)
The rollout for a $10 million venture to bring a series of monuments to Florida National Cemetery will be announced this week in The Villages. The Joint Veterans Support Committee (JVSC) is working to bring the Freedom Memorial Plaza to the national cemetery. It will be located near the entrance to the Bushnell facility, will encompass two-plus acres and will be inner-connected by sidewalks.

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Hyperlink to Above

7. Other

7.1 - FOX News: **Presidential administrations from both sides like to spend, but then again, so do most Americans** (26 August, Chad Pergram, 73.9M uvm; New York, NY)
Eat your veggies. Take your vitamins. Hit the gym. Eliminate alcohol and caffeine. Everyone knows how to stay healthy. Yet we don't like carrots and kale. We forget our Centrum. We go to happy hour with friends after work and skip the cardio class. This is human nature. Who wouldn't rather eat goodies then pound away a few hours at the gym?

Hyperlink to Above

7.2 - U.S. News & World Report (HealthDay): **Staying Optimistic Might Lengthen Your Life, Study Shows** (26 August, Alan Mozes, 23.3M uvm; Washington, DC)
An upbeat view of life may increase your odds for living to a ripe old age, new research suggests. The finding stems from a look at optimism and longevity among nearly 70,000 women and 1,400 men. It builds on earlier research linking higher levels of optimism to lower risks of chronic illness and premature death.

Hyperlink to Above

7.3 - U.S. News & World Report (AP): **Former Trump Official to Helm Florida Republican Party** (26 August, 23.3M uvm; Washington, DC)
Florida's Republican Party has named Peter O'Rourke, a former acting secretary of the U.S. Department of Veterans Affairs under the Trump administration, as its new executive director. O'Rourke is widely seen as a loyalist for President Donald Trump. In its announcement Monday, the party said O'Rourke would help the party deliver Florida for Trump's re-election.

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7.4 - Politico: **Former VA official 'hand-picked' by Trump to lead Florida GOP** (26 August, Matt Dixon, 14.4M uvm; Arlington, VA)
In a surprise move, Peter O'Rourke, a former top official at the U.S. Department of Veterans Affairs and an ally of President Donald Trump, will take over leadership of the Republican Party of Florida, the latest development in a party power struggle going into the 2020 presidential election.

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1. Top Stories

1.1 - KIVI (ABC-6, Video): #FINDINGHOPE: US Secretary of VA works to open mental health dialogue in the armed forces (26 August, Madeline White, 111k uvm; Nampa, ID)

BOISE, Idaho — FULL STORY ON 6 ON YOUR SIDE MONDAY AT 10 P.M.:

The national tragedy of veteran suicide has been a main concern for US Secretary of Veterans Affairs Robert Wilkie since his appointment to the job. During his recent visit to Boise, he sat down for an exclusive TV interview with 6 On Your Side's Madeline White.

Since October of last year, every veteran who has come into the VA has received a mental health screening, according to Wilkie. He said they have now screened almost 1 million veterans— but their oversight continues in some who are struggling.

“We follow closely 3,000 of them because we believe that they could be a danger to themselves or to others," said Wilkie.

When it comes to preventing mental crises and suicide in veterans, Wilkie says stigmas need to be broken earlier on.

“It’s a cultural phenomenon that needs to be addressed when that young American first enters the military," said Wilkie.

He said, in the military, mental health issues weren’t always taken seriously.

“In my father’s day, the notion that anyone would express concern or anxiety while in uniform, would have been treated as a one-way ticket out of the service. Well that was fine in a draftee force-- its’ not fine in an all-volunteer force, nor is it helpful for the combat effectiveness of the armed forces.”

He said he’s working to create changes that he hopes will have impacts on generations to come.

“When I was under Secretary of Defense, working for General [James] Mattis, we started the program when people are in boot camp, they start being told about the signs of mental health problems— even something simple like anxiety," said Wilkie.

Through actions of this nature, he hopes to spread awareness on how to identify warning signs.

“They can see it in their comrades, they can see it in themselves, and they keep telling themselves throughout their career, 'It’s alright to go see the chaplain.' It’s alright to tell us, and that attitude then becomes part of the mindset once that individual comes into VA"

And those mental health screenings at the VA are one way Wilkie says his intention to open dialogue on mental health is taking form.

“So, it’s a cultural change that’s been slow and coming— but it is coming," said Wilkie.

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If you or someone you know is exhibiting warning signs or having thoughts of suicide, text or call the Idaho Suicide Prevention Hotline at (208) 398-4357 to get 24/7 confidential help from professionals.

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1.2 - CBS News (Video): Inside a suicide prevention call center for veterans responding to 1,700 calls each day (26 August, Dean Reynolds, 30.2M uvm; New York, NY)

For immediate help if you are in a crisis, call the toll-free National Suicide Prevention Lifeline at 1-800-273-TALK (8255), available 24 hours a day, seven days a week. All calls are confidential.

Canandaigua, New York — The Departments of Defense and Veterans Affairs are holding a conference in Nashville this week aimed at preventing suicides. A hotline launched in 2007 has answered more than 3.5 million calls, sending emergency help to nearly 100,000 people.

At the Veterans Crisis Line in Canandaigua, New York, the calls come in all day and night. Every day, 1,700 calls come in from veterans on the brink. CBS News was given rare access to the Veterans Affairs responders and their life-saving conversations.

Twenty veterans take their lives every day in America, or 6,000 a year. Personal finances, broken relationships and loneliness are all factors.

Responder Terrence Davis, a Navy veteran himself, said he always tries to answer by the second ring.

"It's highly stressful. Just knowing that you have someone else's life in your hands," Davis said.

Former Sergeant Danny O'Neel knows that feeling. Santa Cruz, California, may be a long way from the battlefield, but for him and his men, Sadr City, Iraq, is close by.

"It was hell on Earth. It was the most dangerous place at the time," O'Neel said.

In 2006, his unit lost nine men in the fighting. But back home, 14 have died at their own hands.

"The guys started isolating and drinking and doing things that they thought were helping them cope. And it, and it led to depression and suicide," he said.

O'Neel, who attempted suicide in 2012, today describes it as the new enemy with isolation as its accomplice. It's why he now arranges surfing reunions for his fellow warriors.

"When we're together, we feel that sense of family, that sense of a team that we miss," O'Neel said. "I've heard that the Pacific has no memory. For me, that's powerful because I can take Iraq out there and I can give it to the ocean. And I don't have to carry it around anymore."

Back in New York, the VA's responders are also trying to lift that burden — one call at a time.

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1.3 - ABC News (Video): Could a new drug treat veterans with severe depression? President Trump thinks so (27 August, Dr. Lauren Kelly and Elizabeth Mclaughlin, 22.2M uvm; New York, NY)

At a veterans event in Kentucky last week, President Donald Trump touted what he called an "incredible" new drug he says could help American veterans struggling with depression.

The drug, called esketamine and marketed as Spravato, was produced by Johnson & Johnson subsidiary Janssen Pharmaceuticals and billed as a breakthrough treatment for patients who have not responded to other antidepressants.

The Food and Drug Administration approved Spravato in March, although some uncertainties remain about its effectiveness, risks and long term effects, according to experts.

However, those concerns were absent when the president ordered the Department of Veterans Affairs last week to purchase it and "get as much as it as you can from Johnson & Johnson."

"It really has an incredible effect for a lot of people," Trump told an audience at the AMVETS National Convention in Louisville, Kentucky, on Wednesday.

In light of the burden of severe depression among veterans and the alarming rate of suicide -- with 20 veterans dying each day by suicide -- Trump is not the only one who feels the imperative of a timely solution.

What is Spravato?
Spravato is a nasal spray based on the drug ketamine, which has been used as an anesthetic for over half a century since its introduction in the 1960s and has played an emerging role in the treatment of chronic pain and treatment-resistant depression by doctors.

Typically given in IV form, ketamine was reformulated as Spravato for people with treatment-resistant depression, and it boasts quicker and easier delivery with fewer side effects.

A series of clinical trials have shown that the drug, when given in conjunction with a typical antidepressant, such as a selective serotonin reuptake inhibitor, can improve people's depressive symptoms.

Results in one out of three randomized controlled trials used by the FDA to fast-track the drug showed positive efficacy, but the size of the drug's impact on depressive symptoms has been critiqued. In the study used by the FDA, there was just a 4-point improvement in depression symptoms on a 60-point scale used by some clinicians to measure depression.

"The clinical trials of esketamine were completely underwhelming," said Dr. Wesley Boyd, psychiatrist at Cambridge Health Alliance and an assistant professor of psychiatry at Harvard Medical School who was not involved in the studies.

"I'm open to giving esketamine consideration, but given the data we have and its high cost, there are other drugs and therapies we can maximize first," he added.

Boyd cautioned about trials supported by the pharmaceutical industry, like the one used for Spravato, though it is not uncommon for pharmaceutical companies to sponsor trials. Two trials

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that had positive results used by the FDA in their approval of Spravato were funded and conducted by Janssen.

Another refrain among experts is that there is too little data to assess the medication's long term effects, including potential harms, and it has not shown to be efficacious in treating individuals over the age of 65 -- a population of particular relevance to the veteran community. It was also mainly tested in white people.

Long-term studies and reporting of adverse events associated with the use of the drug are ongoing.

A treatment for America's veterans?
Despite the limited research on esketamine, the FDA green-lighted Spravato because there's been a long-standing need for more effective treatments for treatment-resistance depression, which is considered a life-threatening condition, according to the FDA.

Used in conjunction with oral antidepressants, Spravato is administered by medical professionals who are required to monitor a patient for two hours after receiving treatment. Possible side effects of the drug include sedation, nausea and increased blood pressure.

Additionally, black box warnings include the risk of drug abuse and suicide in pediatric and young adult patients. While suicide warnings are seen with other antidepressants, Boyd notes that box warnings are not generic, saying, "A box warning would have to be a result of people during clinical trials who experienced suicidal thinking while taking the drug."

Although, severely depressed people may already have suicidal thoughts before starting treatment, he added.

"I applaud VA efforts to get good treatments into the hands of veterans -- not just the hottest treatment, but the whole menu of options" said Dr. Jonathan Avery, director of Addiction Psychiatry at Weill Cornell Medical College who completed his training at the VA but was not involved in the clinical trials for Spravato. "There's a lot of hope for esketamine, but we should be sure the VA is equipped with all the well-studied medications and psycho-social treatments that we have, including cognitive behavioral therapy."

In response to mounting rates of suicide among veterans, the VA has reformed its guidelines to reflect new data on best practices for screening, evaluating and treating veterans with increased suicide risks.

New recommendations suggest a combination of medication and cognitive behavioral therapy with routine medical visits, frequent outreach, and a "safety" or "crisis response" plan for those at greatest risk. The recommendations also address "lethal means" safety, including restricting people’s access to firearms, poisons, medications and installing barriers to prevent jumping from lethal heights.

Getting Spravato to veterans
A VA advisory panel in June decided the use of Spravato would require justification prior to use -- an authorization not unusual for an expensive and powerful new drug.

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Still, Spravato is now available to veterans enrolled in VA care "based on an individualized treatment plan developed by their provider in collaboration with the veteran," a VA spokesperson said.

The department has developed guidelines for Spravato's use "to promote thoughtful patient selection and safe administration practices."

VA Secretary Robert Wilkie, who described Spravato as in its "opening stages" during a Fox News interview on Thursday, said the drug is being used by veterans under the supervision of anesthesiologists at the VA who can monitor any side effects patients experience after taking the drug.

The VA spokesperson told ABC News that the department will continue to monitor the drug's use "to more fully understand its relative safety and effectiveness as compared to other available treatments. Based on this information, the VA may revise its clinical guidance and formulary status if warranted."

Trump pushes Spravato
While there is excitement in the medical community about the promise of Spravato, the president's public promotion of the drug's prescription for veterans has raised eyebrows.

The Center for Public Integrity, a nonprofit investigative news organization, reported in June that Trump was pushing VA officials for quicker adoption of Spravato, and, according to Bloomberg News, the president personally offered to help the VA negotiate purchases of the drug from Janssen.

Trump's ambassador to the United Kingdom Robert Wood "Woody" Johnson IV is the great-grandson of the co-founder of Johnson & Johnson and heir to the "consumer products fortune," owning over 1.5 million shares in the company, according to Bloomberg.

Johnson donated $1 million to Trump's inaugural campaign and was nominated to the ambassadorship in 2017.

Prior to departing for Louisville on Wednesday, the president said the VA would get Spravato "at a very good cost." But hours later at the AMVETS event, he suggested Johnson & Johnson should give the drug to the department for "free" because they "have done so well in this country and they have made so much money."

Janssen spokesperson Kaitlin Meiser told ABC News, "We have not had any conversations with President Trump regarding Spravato."

"Information regarding contracts with payers, including the VA, is proprietary," Meiser said, but "the VA is offered the lowest price in the country."

The VA also declined to say how much the purchase of Spravato would cost the department.

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1.4 - Military.com: **The VA Removed a Vet's High-Risk Label. The Patient Died by Suicide. What Went Wrong?** (26 August, Richard Sisk, 4.3M uvm; San Francisco, CA)

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Again and again, teams at the Department of Veterans Affairs' San Diego Health Care System reached out to and helped a troubled veteran battling suicidal thoughts and substance abuse who frequently missed appointments or broke off contact.

The efforts were not enough. The veteran was found dead in July 2018; the San Diego Medical Examiner's Office ruled the death a suicide by asphyxiation.

Prompted by charges from an anonymous caller, the VA's Office of Inspector General (OIG) investigated the circumstances of the death and issued a report earlier this month titled: "Alleged Deficiencies in Mental Health Care Prior to a Death by Suicide at the VA San Diego Healthcare System, California."

The anonymous caller who claimed that the veteran was "turned away" by the VA could not be reached by the IG's office to back up the accusations.

"The OIG inspection team attempted to contact the complainant by telephone, certified mail, and electronic mail; however, the complainant did not respond," the report states.

The 27-page IG report found procedural "deficits" in how the San Diego VA dealt with the veteran, but stopped short of leveling blame.

The IG's detailed report offered penetrating insight into a case that is emblematic of the challenges faced by the VA health care system. As VA staff serve nine million veterans each year, they must contend with what officials have described as an "epidemic" of suicides among veterans.

The challenges become even more acute, the IG report shows, when the veteran misses appointments, rejects treatment plans or sporadically ignores attempts at outreach.

The investigation was conducted to assess whether the VA failed to provide mental health care to a patient who subsequently died by suicide. Ultimately, investigators did not substantiate claims that the VA failed to provide mental health care when the patient sought help, according to the report.

"The OIG found that the suicide risk assessment of the patient was adequate" and complied with the standards of the Veterans Health Administration and the San Diego system's requirements, the report states.

Still, there were serious shortcomings. Investigators identified the move to deactivate the patient’s flag in medical records noting a high risk for suicide as a concern. The suicide prevention coordinator at the hospital removed the veteran from the high-risk list "without contacting the patient" or "consulting the patient's treatment team," the report states.

The veteran remained off the list even after failing to show up for mental health services for more than two months.

Patients are supposed to be added to the high-risk list so VA staff members can track those veterans closely, making efforts to reach them when they miss or cancel appointments, agency guidelines state.

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The IG made two recommendations for improving procedures and documentation at the San Diego VA based on a case that could serve as a valuable example for systemic improvements.

Investigations of such deaths often center on what the VA did, or didn't do, to assist the veteran, although statistics show that about 14 of the 20 veterans who die daily by suicide never have any contact with the department.

"It seems like the VA did a lot of things correctly" based on the IG report, said Navy Reserve Cmdr. Jeremy Butler, CEO of Iraq and Afghanistan Veterans of America. "But it's not a totally clean bill of health."

Butler called the issue of veteran suicide "a national emergency."

"We realize the VA can't do everything," he said, but he questioned the removal of the veteran in the San Diego case from the high-risk list.

Butler said the San Diego suicide case underlined the need for the VA to engage in more outreach to veterans, either by the department itself or through local and state partners when veterans become difficult to contact.

VA Secretary Robert Wilkie has repeatedly cited curbing the veteran suicide rate as the "top clinical priority" for the system's 170 hospitals and more than 1,100 clinics nationwide.

In March, President Donald Trump signed an executive order creating a cabinet-level task force that he pledged would "mobilize every level of American society" to address the crisis of suicides among veterans.

The death of the veteran in San Diego, and the report of the IG on the circumstances, illustrate how difficult the task will be.

Early Warning Signs

The veteran in this case, who was identified only as the "patient" due to privacy rules, was younger than 30 at the time of death.

The veteran's gender and military branch were not disclosed, but investigators found the individual "first experienced depressive symptoms including insomnia and thoughts of suicide during high school but did not seek treatment at that time."

Just a month after joining the military in 2013, the patient met with a counselor and was "feeling really depressed," the report states, but chose not to start medication until the summer of 2014 for fear that it might interfere with training.

The patient was then prescribed two antidepressant medications and a sleep aid. The patient's first contact with the VA came in the spring of 2017, after leaving the military.

"During that visit, the patient complained of periodic thoughts of self-harm," the report adds. "The patient asked to restart psychiatric medications, and the primary-care provider prescribed an antidepressant."

The investigation goes on to detail several contacts and visits to the VA by the patient, though it notes the veteran's follow-up on advice or treatment suggestions was sporadic.

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In the initial visit to the VA, the patient described "chronic passive suicidal ideation" and recounted an attempt while in the military. The patient ultimately stopped the attempt and called a suicide hotline, the report states.

A VA social worker drew up a risk assessment in which the patient reported researching methods of suicide on the internet. The social worker estimated the patient's risk of suicide to be "moderate/ambivalent," but the patient did not think a safety plan would be useful and declined to complete one.

Then followed meetings with a VA psychiatrist and psychologist in which the patient would ask for changes in medication and admit to substance abuse while refusing treatment for it. The patient also met with a private psychologist under the VA's "Choice" program for private-care options.

Rescheduled Appointments
In the summer of 2017, after the patient rescheduled appointments multiple times, the VA psychiatrist called the patient.

"The patient reported intrusive thoughts of suicide" and spoke of planning to discuss them with the VA Choice provider, but also "denied active suicidal ideation, intent, or plans," the report states.

The psychiatrist called the patient's Choice provider less than a week later. They agreed that, although the patient did not meet criteria for inpatient psychiatric admission, the patient was at long-term elevated risk for self-harm, according to the report.

"During a follow-up psychiatric visit four days later, the patient admitted to a suicide attempt in mid-summer of 2017," the report continues.

This attempt was also stopped by the patient after about a minute, the report states.

There was more back and forth between the VA and the patient on recommendations for treatment and medication, many of which the patient ignored, according to the report.

In early 2018, the VA psychiatrist reached out to the patient following a missed appointment. The patient said that two weeks prior while at an airport, they sent a photo to a friend showing an apparent self-strangulation attempt, and then turned the phone off, the report states.

The friend contacted the patient's family, who called airport security.

"The patient said that the police spoke with the patient upon landing but did not detain the patient," according to the report.

Three days after the phone call, it adds, the patient agreed to an intensive outpatient program referral, but declined the psychiatrist's offers for substance abuse treatment or restarting psychiatric medication.

"After the patient missed the next appointment, the psychiatrist contacted the system emergency department social worker, who called police and requested a health and welfare check," it continues.

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"During the health and welfare check, the patient expressed passive thoughts of death but did not meet criteria for inpatient admission," the report states. "The patient agreed to follow up with the outpatient providers the following week but did not."

After multiple calls to the patient without a response, the VA psychiatrist called the patient's mother and left a voice message. The patient's mother called back and said that she was speaking with the patient twice a week and was appreciative of staff concern, the report states.

Suicide Risk Flag Deactivated

In late winter 2017, a VA suicide prevention coordinator, or SPC, contacted the patient, who reported "decreased depression, and decreased frequency and intensity of suicidal thoughts."

"The SPC changed the patient's suicide risk assessment to moderate/ambivalent," and after additional calls, the patient's suicide risk flag was deactivated in late spring of 2018, the report states.

However, in the summer of 2018, the patient went to the VA emergency room with thoughts of suicide, according to the report.

The patient was evaluated by a second-year psychiatry resident, who "described the patient as 'pleasant, engaging, and jovial at times,' despite the patient's self-report of feeling suicidal for the prior two days after a fight with a friend," the report states.

The patient denied symptoms consistent with major depressive disorder, investigators found, including changes in appetite, energy or concentration, but admitted having fleeting thoughts of suicide most days of the week.

"The resident offered the patient voluntary psychiatric admission for stabilization, but the patient declined," the report states. "The patient stated that the conversation with the resident had improved the patient's mood and the patient now felt safe to return home with a roommate."

The resident decided that the patient did not meet the criteria for involuntary admission or "warrant psychiatric inpatient admission at that time," according to the report.

"The resident assessed the patient's short-term risk of suicide as low," but "acknowledged that the patient's long-term risk of suicide was elevated given the patient's history of chronic suicidality and other mental health conditions," the report adds.

The staff psychiatrist at the hospital co-signed the resident's consultation note about four hours after the patient left, the report states, and the resident added the outpatient psychiatrist, outpatient psychologist and lead suicide prevention coordinator to the note.

Several days later, the outpatient psychiatrist attempted to contact the patient by phone and left a voice message asking the patient to return to care. A psychiatry medical support assistant later attempted to phone the patient but was unsuccessful, according to the report.

The medical support assistant then sent a letter to the patient "that encouraged the patient to call to schedule an appointment and noted that there would be no further attempts to schedule an appointment," the report adds.

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"The patient expired two days after the medical support assistant sent the letter," the report states. "The Deputy Medical Examiner reported the patient's cause of death as asphyxia [suffocation] and manner of death as suicide."

In response to questions from Military.com, the IG office said that the detailed analysis of an individual case could point the way to improvements in suicide prevention.

"It is hoped that the identification of failures in a specific case will lead to lessons learned across the VA system of care," the office said in a statement.

In its response, the VA's San Diego Health Care System thanked the IG for the "thorough review of the circumstances involving this tragic veteran suicide which occurred in July 2018," but did not refer to any "failures."

"We appreciate their confirmation that there were no deficiencies in the care of the veteran provided by our mental health providers or our emergency department, or in the supervision of the resident physician staff who also participated in the veteran's care," Cynthia Butler, public affairs director for the San Diego VA, said in a statement.

On the subject of red flags for high-risk patients, Butler said, "We are also working with the VA Office of Mental Health and Suicide Prevention to assure that consistent processes are developed and implemented for the management of flags alerting staff to the presence of veterans who may be at higher risk for suicide."

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1.5 - The Daily Signal: **VA Lifts Ban on Bibles in Move to Support Religious Freedom** (26 August, Fred Lucas, 1.1M uvm; Washington, DC)

As a kid, Veterans Affairs Secretary Robert Wilkie recalls, he visited a VA hospital at Christmastime.

“One of my fondest memories growing up, we used to sing Christmas carols at the VA hospital in Fayetteville, North Carolina,” Wilkie told The Daily Signal, sitting in a 10th-floor office at VA headquarters on Vermont Avenue Northwest, overlooking the White House.

“Something as simple and as decent as that was being stopped,” he said. “With the support of the president, we just said enough is enough.”

Wilkie grew up at Fort Bragg, the son of an Army artillery commander. He himself served in both the Navy and Air Force reserves, and as a Pentagon official.

Since becoming VA secretary a little more than a year ago, he has returned to North Carolina.

“I was in my hometown. We have a beautiful chapel in the old VA hospital. And I walked in and there were no Bibles,” the secretary said. “It had been stripped of the symbols of religion.”

The VA revised directives to permit religious literature, symbols, and displays at agency facilities following a string of incidents in recent years in which individual medical centers banned

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Christmas carols and a Christmas tree, chapels removed Bibles, and chaplains faced restraints on religious expression.

Generally, the VA had inconsistent policies across the country.

Officials designed the changes to protect the religious freedom of veterans and their families.

The new guidelines, which went into effect last month, referred to the recent Supreme Court ruling allowing a cross-shaped memorial to World War I dead to continue standing on public land in Bladensburg, Maryland.

The high court's decision highlighted the important role that religious symbols plays in the lives of Americans and their consistency with constitutional principles.

"The military culture has been part of my being, an important part of what I believe," Wilkie told The Daily Signal. "I've seen the effects of combat, both in uniform and out of uniform."

That military culture in which he grew up, Wilkie said, also prioritizes the "ability of our troops to worship, their right to worship, their right to have access to chaplains, and to be free to celebrate their faith." He added:

Now, moving over to VA, I consider the spiritual well-being of our veterans, their spiritual health, to be just as important as the medical competence and technical competence of our doctors and nurses. They should have that fundamental right available to them to access chaplains, to access their Bibles.

The new guidelines call for "inclusion in appropriate circumstances of religious content in publicly accessible displays at VA facilities," and allow "patients and their guests to request and be provided religious literature, symbols and sacred texts during visits to VA chapels and during their treatment at VA."

The guidelines also allow the VA to accept donations of religious literature, cards, and symbols at its facilities, and to distribute them to VA patrons "under appropriate circumstances."

"Under the old regime, you couldn't have those outward symbols," Wilkie said. "You could not have religious texts in the chapels unless you brought them. The chaplains could not walk the halls seeking people to talk with. There had to be a specific request."

The allowed literature may include the Bible, the Quran, the Talmud, or any other religious text, VA officials noted.

Still, the policy faces opposition.

"The VA's actions undermine our Constitution, which intentionally establishes a secular government in order to preserve religious freedom, a right enjoyed by individuals," Sam Grover, associate counsel for the Freedom From Religion Foundation, wrote in a letter to Wilkie objecting to the standards.

"Were the VA truly concerned about protecting the religious freedom of veterans, it could simply do what the Constitution prescribes and keep its facilities free from government-endorsed religion," Grover wrote.

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Wilkie said he doesn't anticipate litigation over the policy because it is based on the recent Supreme Court ruling.

"What Justice [Neil] Gorsuch said in the Maryland cross case was absolutely on target," Wilkie said. "Because you might be offended doesn't give you standing to stop other people from worshiping. For me, this is not only a military issue. It's a religious liberty issue, and one that is vitally important to those we serve."

The high court's ruling should reaffirm the VA's policy, said Emilie Kao, director of the DeVos Center for Religion and Civil Society at The Heritage Foundation.

"On the heels of the Supreme Court's 7-2 decision that reaffirmed the Constitution's protection of the tradition of public displays of religious monuments, symbols, and practices, the U.S. Department of Veterans Affairs took a much-needed step to clarify that religious symbols as well as spiritual and pastoral care are welcome at VA facilities," Kao told The Daily Signal.

"Millions of soldiers from different religious backgrounds have relied upon their faith and gained encouragement from religious literature, symbols, and displays," Kao continued. "No member of the military should have to hide their faith when they put on a uniform. Nor should our public square be devoid of religious symbols."

In January, the Manchester Veterans Affairs Medical Center in New Hampshire removed a Bible on display at a "Missing Man" table after a secular group, the Military Religious Freedom Foundation, objected.

The Bible had been carried by a prisoner of war from World War II, but the group said some veterans had complained about its display.

After receiving new complaints about its removal, hospital officials restored the Bible the following month. In May, however, a Vietnam veteran sued to have the Bible removed.

"A Bible that was owned by a survivor in the Battle of the Bulge had to be put under lock and key because several people unknown had complained that this was an affront to them," Wilkie said, adding:

It's incongruous to me [because] we send our young people to some pretty rough places. The notion that someone who would have been in those situations is so offended by the sight of a Bible that he wants to sue and deprive his comrades of that comfort is just beyond the pale.

In late 2015, a VA clinic in Salem, Virginia, initially blocked a Christmas tree from the premises, stating in a letter to employees that "trees have been deemed to promote the Christian religion and will not be permitted in any public areas this year."

The clinic reversed course in late November after public pushback, and allowed the Christmas tree.

In January 2014, then-House Veterans Affairs Chairman Jeff Miller, R-Fla., wrote then-VA Secretary Eric Shinseki, citing a VA medical center in Augusta, Georgia, that banned high school Christmas carolers.

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Miller also wrote that VA officials in Iowa City, Iowa, had told the American Legion not to hand out gifts if the wrapping paper said “Merry Christmas” and a VA hospital in Dallas had refused a delivery of handwritten Christmas cards from schoolchildren because they included the words “Merry Christmas” and “God Bless You.”

Such matters are important beyond individuals’ freedom of religion, affecting the health of veterans in the VA’s care, Wilkie said.

“The issue of Christmas carols is about simple courtesy, the ability to make people smile at a time in their lives when they are in a hospital for whatever reason, for groups to come in and spread comfort,” he said. “Emotional sustenance is absolutely something that we should be allowing, not standing in the way of.”

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1.6 - Nextgov: **Veterans Affairs Launches Digital National Cemetery** (26 August, Brandi Vincent, 339k uvm; Washington, DC)

The Veterans Affairs Department’s National Cemetery Administration developed and launched an online memorial platform—Veterans Legacy Memorial—to honor millions of veterans interred in national cemeteries across America. Deemed a “digital national cemetery,” the new resource leverages technology and prioritizes security to boost community engagement and preserve the memories of those who served.

“It is first and foremost a memorialization tool to enhance and extend the national cemetery experience beyond the physical boundaries of the national cemetery and create something so that veterans, family members, friends, students, history buffs—whoever—can then connect with that veteran tradition, keep community and share memories whenever the moment strikes them,” Veterans Legacy Program Manager Bryce Carpenter told Nextgov Monday.

To Carpenter, an Army veteran who also has experience working in academia, the development of the tool was “personally and professionally powerful.” As an academic leading students in various research, Carpenter frequently searched for better resources to inspire the sorts of questions he encouraged them to ask, often to no avail.

In 2017, Carpenter was working for VA’s legacy program at Florida National Cemetery where he was engaging with students and professors from the University of Central Florida. He had a panoramic view of many of the agency’s stakeholders—students, professors, teachers, veterans, family members, civil war actors and others—and was inspired to create one digital product that could serve all of NCA’s customers, and ultimately, its mission.

“Our agency has a statutory mission to memorialize all veterans in perpetuity,” he said. “So through VLM, we can use this as a way to make sure that people can access the stories of all 3.7 million veterans in our national cemeteries, which go back through the Civil War, and even to the Revolution, to make sure that the story of every single veteran is not forgotten.”

The public can use the interactive site to search for any veterans who are buried in the 136 cemeteries that NCA manages. Every veteran interred has their own memorial page on the site. Individuals can access it for information about grave whereabouts, as well as basic details about the veterans’ lives and service. Carpenter said the agency’s goal is for people to use it to find

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new information about veterans they know about as well as study veterans that they don't know. He also hopes it will motivate teachers to engage their students and incorporate veteran history into their lesson plans in new and exciting ways.

"So many different perspectives in American history can be accessed through the veteran experience," he said.

For insights on how to build a site that customers would use, Carpenter and the development team met with veterans across many generations and a variety of other stakeholders for feedback and inspiration during the development process. They engaged directly with the Defense Department's survivors forum, educators in academia and organizations like the Tragedy Assistance Program For Survivors to learn what they'd want most from an online memorial site. He expects to incorporate those interactions and further feedback going forward.

"Just through that process alone we know that with more feedback we are going to get better information with which we can further refine the product so that we can serve our public with greater intentionality," he said.

The site will see a variety of future enhancements, as well. Carpenter said it eventually likely will offer users the ability to interact with others over comments, upload photos and access historical documents via VLM. He also emphasized how security and privacy were a major priority throughout the site's creation.

"The security and privacy standards right now are the highest for any public-facing government website," he said. "What we want to provide under the security and the neutrality of the VA brand is 100% assurance that our veterans and all of our customers know that their data is safe, it's being used for nothing other than memorialization and there's actually no way to access any personally identifiable information."

Ultimately, Carpenter said he hopes the platform helps unite diverse groups of veterans and allows them to connect and share memories about "battle buddies" they may have lost. He also hopes to inspire people across the country to learn more about America's history through streamlined information about those who fought on the frontlines.

"One of the things we often talk about in the Veterans Legacy Program is that we are striving to make sure that all veterans are honored for their service—not just high ranking officers or war heroes that have been decorated with medals of honor and things like that—but everybody who played a part and everybody who wore a uniform," he said. "And so hopefully this is a way for people to really access some of those stories of service."

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1.7 - Las Vegas Sun: **At VA, we protect those who protected us** (26 August, Sec. Robert Wilkie, 180k uvm; Henderson, NV)

Cpl. Orlando Camacho, Lt. Kenneth Frazier and officer Miguel Calderon didn't know they would save lives when they woke up Aug. 12 and reported to the Jesse Brown VA Medical Center in Chicago.

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The three members of the Veterans Affairs Police were on duty when shots were fired just outside the VA's doors. As alarms blared and people flooded 911 with calls, Camacho, Frazier and Calderon waded past panicked people toward a man with a rifle in his hand who entered the building.

All three drew their firearms and ordered him to drop the rifle. The suspect complied and was quickly handcuffed.

Less than a minute after the call went out, it was all over. VA Police had their man without firing a shot, and no one was hurt.

It's an incredible success story at a time when we continue to wake up to news of violence across the nation. Our hearts break when these tragedies occur, but when our first responders run toward danger and prevent tragedies as these three VA Police officers did that day, our hearts swell with pride.

On behalf of the entire VA family, I thank Camacho, Frazier and Calderon for their prompt, measured and heroic response.

The incident is just the latest point of pride for the VA Police, a family of 4,700 that works around the clock to ensure the safety and security of our medical centers and national cemeteries.

The origins of this police force date back to President Abraham Lincoln's time — they have been working alongside veterans for more than 150 years now, although their role has changed over the years.

The VA Police do more than just protect veterans, families and visitors from outsiders, they are also specially trained to ensure veterans are not a harm to themselves. Suicide prevention is our top clinical priority, and the decision to put our police through rigorous training on how to de-escalate potentially violent situations is a testament to our all-hands-on-deck approach to this issue.

Just months ago, a veteran on a VA campus in Atlanta threatened to take his life. VA Police officer Alonzo Pitmon found the veteran in a car in the parking lot, and repeated to the veteran, "I am here to help you and not hurt you."

This potential victim was taken into custody unharmed, thanks to Pitmon and others.

These officers undergo specialized training at the VA Law Enforcement Training Center in Arkansas, where they are taught "veteran-centered policing," which focuses on resolving incidents in a respectful manner that's designed to ensure the maximum level of safety for anyone in one of our medical centers. They learn to de-escalate situations through apprehension techniques that minimize the amount of force officers use to gain control over these situations.

Our officers also have another edge — many are veterans themselves, and have deeper insight into the sorts of challenges that our veteran patients and their families are facing.

This nation has a duty to understand and treat mental health disorders that lead to violence against others and the tragedy of suicide. As a start, we need discussions at all levels about the

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value of life, and we must have a plan beyond hoping we can save people by making the equivalent of a last-second diving catch.

We are making important strides in that direction, particularly when it comes to addressing the issue of veteran suicide. Meantime, those VA officers in Chicago, Atlanta and elsewhere have our eternal thanks for engaging in situations in which there is only time to act, not plan, and for fearlessly serving as our last line of defense against the unthinkable.

Robert Wilkie is the secretary of Veterans Affairs. He wrote this for InsideSources.com.

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1.8 - The Exponent Telegram: Sen. Manchin: VA officials assure 'person of interest' in homicide no longer in contact with veterans in VA hospital (26 August, Matt Harvey, 133k uvm; Clarksburg, WV)

CLARKSBURG — A person of interest in 11 suspicious deaths at the Louis A. Johnson VA Medical Center — one of those deaths a confirmed homicide — "is no longer in any contact with veterans at the facility," U.S. Sen. Joe Manchin said Monday in a news release.

Later in the day, Wesley Walls, chief of public affairs and community relations service at the Medical Center, issued a statement, saying the "allegations of potential misconduct you may have heard about in media reports do not involve any current Louis A. Johnson VA Medical Center employees."

Manchin spoke with Department of Veterans Affairs Secretary Robert Wilkie and the VA hospital's director, Dr. Glenn Snider, according to the release.

"I was ... assured by both Secretary Wilkie and Dr. Snider that the person of interest is no longer in any contact with veterans at the VA facility," Manchin said in the statement. "These crimes shock the conscience, and I'm still appalled they were not only committed, but that our veterans, who have sacrificed so much for our country, were the victims.

"As a member of the Senate Veterans Affairs Committee, I will do everything in my power to investigate these accusations and get to the bottom of what happened. These families and loved ones deserve answers as soon as possible, and I will make sure they get them," said Manchin, D-W.Va.

Manchin also said he "made sure to talk to Secretary Wilkie and Dr. Snider to make sure that their investigation into these deaths is accurate and thorough."

According to the statement from the Medical Center's Walls, "immediately upon discovering these serious allegations, Louis A. Johnson VA Medical Center leadership brought them to the attention of VA's inspector general while putting safeguards in place to ensure the safety of each and every one of our patients."

"The department informed the staffs of Senators Capito and Manchin and Rep. McKinley of these allegations August 7, 2018, and they are aware of the ongoing investigation," Walls wrote in an email. "VA is cooperating fully with the inspector general's ongoing investigation, and for additional questions, we refer you to them."

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Meanwhile, a Veterans Affairs Office of Inspector General report from 2018 found staff at the Louis A. Johnson VA Medical Center hasn't consistently applied criteria that would identify sentinel events.

Sentinel events are incidents or conditions that result "in patient death, permanent harm, severe temporary harm, or intervention required to sustain life," according to the report.

The review covered the period of Sept. 21, 2015, through May 7, 2018. On that date, an unannounced week-long site visit started. During that review period, inspectors discovered what they believed to be six "sentinel" events that were unreported.

The report was released last October, the same time that the body of retired Army Sgt. Felix Kirk McDermott, a patient who died at the VA hospital, was exhumed. A subsequent autopsy ruled McDermott's death a homicide, saying he was given insulin even though he wasn't a diabetic, and none was prescribed for him.

Up to 10 other deaths are suspicious and are believed to have occurred in the same manner," according to a notice of claim filed on behalf of McDermott's estate by Charleston attorney Tony O'Dell.

The report last October by the VA Office of Inspector General also found that hospital "managers did not follow local policy for single identified sentinel events and disclose relevant information to the patient or the patient's representative. The OIG noted that the Facility has opportunities to improve identification of events that require disclosure and sentinel event identification, tracking and reporting."

According to the claim filed by O'Dell on behalf of Melanie Proctor, McDermott's daughter from Ellenboro and the administrator of his estate, the VA Office of the Inspector General ordered McDermott's remains exhumed Oct. 23, 2018, and they were sent to Dover Air Force Base for an autopsy "because of the suspicious manner of Mr. McDermott's death."

"During its investigation, VA investigators advised Melanie Proctor ... that there was evidence that nine or ten other patients of the Louis A. Johnson VA Medical Center had been wrongfully injected with insulin in their abdomen, thereby causing their deaths," O'Dell wrote. "Ms. Proctor was further advised that her father was one of the last known victims."

The autopsy "confirmed investigators' suspicions that Ret. Army Sgt. McDermott had received an exogenous insulin shot in the left side of his abdomen," the claim states. "That finding was consistent with the clinical history of profound hypoglycemic event that occurred the morning of April 9, 2018.

"The autopsy report confirmed that Ret. Army Sgt. McDermott was not a diabetic and had no history of oral hypoglycemic use or previous insulin administration," O'Dell wrote. "The autopsy report also confirmed there were no hospital orders for the administration of insulin. The autopsy report noted that despite Ret. Army Sgt. McDermott's pre-existing health issues, he was showing clear improvement in his medical condition when he was negligently, wrongfully, or intentionally injected with insulin."

The claim contends that employees at the medical center "were aware of each of the unexpected and suspicious deaths."

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The claim, which serves as an official six-month notice of a coming lawsuit, seeks monetary damages of $1 million for personal injury and $5 million for wrongful death, as well as funeral expenses and other costs.

O'Dell said his law office is currently seeking out the families of the other patients who may have died the same way.

McDermott, who also had lived in Ruffs Dale, Pennsylvania, retired as a sergeant after a 20-year career in the Army, during which he was deployed to Vietnam, then served in the Pennsylvania National Guard and also worked as a truck driver.

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1.9 - Healthcare IT News: OIG audit: Massive backlog in digitizing VHA medical records
(26 August, Nathan Eddy, 64k uvm; Chicago, IL)

Veterans Health Administration medical facilities are facing an enormous challenge as they scan and enter medical documentation into patients' electronic health records, according to an audit from the Office of the Inspector General for the Department of Veterans Affairs.

WHY IT MATTERS
Based on provided data, the audit team calculated that VHA medical facilities have a cumulative medical document backlog equivalent to more than five miles of stacked paper, with nearly 600,000 individual electronic document files dating back to October 2016.

The backlog has built up in part because VHA staff had not been scanning and entering documents into the electronic medical record system in a timely manner, though the report also noted staffing shortages have contributed to the challenge.

Further complicating the situation, the audit found, was the fact that when medical facility staff scan medical documentation, they are not always performing the appropriate reviews and monitoring to assess the overall quality and legibility of the scanned documents.

This means the VHA must work to improve the management of scanning activities, including importing, indexing and legibility checks, and should also establish and implement a training program for those in charge of the scanning and indexing in medical facilities.

The audit also recognized the scale of the problem, noting specific backlog details such as descriptions of the documents, the size of the backlog and age of unscanned records are not consistently addressed as part of the OIG's inventory.

Another major challenge described in the report was the discovery that the eight medical facilities visited did not consistently follow training policy, and training by the health information management staff varied from site to site.

The audit recommended the VHA implement standardized quality assurance monitoring procedures and ensure original medical records are retained until it has been verified that those quality assurance standards have been met.

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THE LARGER TREND
The OIG audit comes as the VA is undergoing a massive push toward digitalization. In June, the Department of Defense and the VA announced the creation of a special office to help centralize decision making as the VA makes its multibillion-dollar electronic health records upgrade.

But just this past week, Politico reported that the VA's modernization effort is already encountering roadblocks that could delay the project for six months or more.

ON THE RECORD
“The VHA needs to improve its supervision and medical facilities’ management to ensure medical documents are accurately scanned and indexed,” the OIG report noted.

“During audit team site visits, neither the chiefs of HIM nor their designees responsible for supervising scanning activities always had direct knowledge of the scanning processes and backlog information within their facilities,” auditors said.

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1.10 - WDTV (CBS-5, Video): Update: Veteran speaks out about his time at the Louis A. Johnson VA Medical Center (26 August, 32k uvm; Bridgeport, WV)

CLARKSBURG, W.Va. (WDTV) -- 5 News spoke with local veteran, Ken Warman about his experience at the Clarksburg VA Medical Center.

"That facility, I hate to tell you. Worst facility I have ever been to. Hands down, of all the states I have been to. Hands down the worst. I have been treated the worst," said Warman.

According to a 2018 report by the Department of Veteran's Affairs Office of the Inspector General, officials found one sentinel event at the medical center. A sentinel event is defined by the report as a "incident or condition that results in patient death, permanent harm, severe temporary harm, or intervention required to sustain life."

Originally, inspectors found six cases that appeared to meet the criteria for sentinel events, however, after discussing with facility managers, those cases were re-evaluated.

Inspectors also found a presence of "organizational risk factors - [noted as] lack of identification, tracking, and reporting of sentinel events and disclosure of adverse events."

The report notes that these risk factors could contribute to "future issues of noncompliance and/or lapses in patient safety."

UPDATE 08/26/19 @ 1:03 p.m.
U.S. Senator Joe Manchin's office say he spoke with the Department of Veterans Affairs Secretary Robert Wilkie and Louis A. Johnson VA Medical Center Director Dr. Glenn Snider Monday about the ongoing investigation into the suspicious deaths being investigated at VAMC. One of the up to 11 deaths was ruled a homicide.

“Today I made sure to talk to Secretary Wilkie and Dr. Snider to make sure that their investigation into these deaths is accurate and thorough. I was also assured by both Secretary Wilkie and Dr. Snider that the person of interest is no longer in any contact with Veterans at the

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VA facility," said Manchin. "These crimes shock the conscience and I'm still appalled they were not only committed but that our Veterans, who have sacrificed so much for our country, were the victims."

Manchin says he will do everything in his power to investigate and get to the bottom of what happened.

"These families and loved ones deserve answers as soon as possible and I will make sure they get them," said Manchin.

The claim filed by Tiano O'Dell says that retired Army Sergeant Felix McDermott died of low blood sugar after he received a fatal dose of insulin in April.

The claim says McDermott's death was ruled a homicide after an autopsy was completed.

UPDATE 08/23/19
A claim filed by Tiano O'Dell law firm says that retired Army Sergeant Felix McDermott received a fatal dose of insulin while a patient at the Louis A. Johnson VA Medical Center.

According to the claim obtained by 5 News, first reported by the Clarksburg Exponent-Telegram, McDermott was admitted to the VAMC on April 6, 2018. He died of hypoglycemia, or severe low blood sugar, on April 9, 2018. He was 82.

The claim states that employees never told McDermott's family how he died. He was buried 4 days later.

On Oct. 23, 2018, McDermott's remains were exhumed and sent to the Dover Air Force Base for an autopsy and investigation.

The autopsy completed February 2019 confirmed that McDermott was not a diabetic and that he was showing improvement in his medical condition when was injected with insulin.

The autopsy ruled McDermott's death a homicide.

The claim also states that nine or 10 other patients died of severe low blood sugar before McDermott's death.

Tony O'Dell is the family's lawyer.

"It's all very disturbing that people who served our country were being killed either extremely negligently, grossly negligently, or intentionally, and nobody has done anything about it," O'Dell said.

The claim says the VAMC breached its duty and was negligent in several ways.

The claim says their client, the estate of McDermott, is seeking damages of up to $5 million for wrongful death, $1 million for personal injuries and expenses for the funeral and other costs.

"Each time one of these deaths happened, they have an obligation to run at the ground to find out what happened, why it happened, how it could be prevented," O'Dell said.

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McDermott was a Vietnam Veteran who served for 20 years before retiring.

U.S. Senators Joe Manchin and Shelley Moore-Capito released statements about the claim.

“This news is sickening and troubling," Capito said. My office has reached out to the VA to learn more details, and I will do everything I can to make sure this is fully investigated.”

5 news reached out to Congressman David McKinely's office for a statement.

“Congressman McKinley is aware of an ongoing investigation at Clarksburg by the Veterans Administration Office of the Inspector General," said McKinely's Communications Director Amanda Hyman "We hope to get more answers about this situation as that investigation progresses.”

The full claim is attached to the right of this article.

ORIGINAL STORY
U.S. Senator Joe Manchin release a statement on a claim filed by Tiano O'Dell law firm that one of the up to 11 suspicious deaths being investigated at the Louis A Johnson VA Medical Center has been ruled a homicide.

“This report is shocking and if accurate, I am appalled that these crimes were not only committed but that our Veterans, who have sacrificed so much for our country, were the victims. As a member of the Senate Veterans Affairs Committee I will do everything in my power to investigate these accusations and get to the bottom of what happened. These families and loved ones deserve answers as soon as possible and I will make sure they get them,” Senator Manchin said.

The claim states that the other nine or ten suspicious deaths are also expected to be a homicide.

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2. Improving Customer Service

2.1 - Military Times: **Unable to sue the Army for medical malpractice, this retired soldier is now fighting the VA for benefits** (26 August, Meghann Myers, 1.7M uvm; Vienna, VA)

Retired Sgt. 1st Class Barbara Ospina is partially paralyzed, in debilitating pain and confined to a wheelchair for almost all of her day. Her condition is the result of malpractice at the hands of hands of military medicine, according to claims she made to the Department of Veterans Affairs, but she is paying out of pocket for a caregiver to help her bathe, dress and prepare meals, because the VA has denied her request for caregiver assistance.

What began as a treatable birth defect turned into a dislocated neck and a stroke that went undetected for days, according to records provided to Military Times. Had that initial surgery taken place at a civilian hospital, Ospina, 29, would be able to seek damages. But the Feres Doctrine, a 1950 Supreme Court decision, prevents her from suing the Defense Department for service-connected illness or injury.

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“Her story represents the egregious conduct, consistent lack of care and malpractice at the hands of Wright-Patterson Air Force Base,” her attorney, Natalie Khawam of the Tampa, Florida- and D.C.-based Whistleblower Law Firm, told Military Times on Tuesday.

For now, the hope is that a bill in Congress will allow Ospina, a mother of a young son, and veterans like her to seek compensation for alleged medical mistakes that they claim have altered their lives forever.

“This case is an example of how flawed the system is, and why it’s time for change,” Khawam said.

Ospina was a public affairs noncommissioned officer for 5th Special Forces Group at Fort Campbell, Kentucky, when she started experiencing headaches, tingling and numbness in her limbs and occasional blurred vision, according to an appeal letter her husband wrote to the VA in 2017, after she was denied access to their caregiver program.

She thought perhaps she’d been injured during combatives training with her unit in early 2013, Khawam said. After making repeated requests for an MRI, the scan showed a deformity known as a “type I Chiari malformation” — essentially, her skull was putting pressure on her cerebellum, forcing it down into her spinal column.

On April 16, 2013, Ospina and her family traveled to Wright Patterson Air Force Base, Ohio, for a surgery to repair the malformation. The risks included hemorrhage, stroke or infection.

According to her husband’s statement in her VA claim appeal, her treatment there nearly killed her.

“The VA is claiming Barb’s condition is the result of ‘an Illness or Medical Condition,’ specifically Arnold Chiari 1 Malformation, and not from an ‘injury,’ "her husband wrote in her VA appeal, which was also denied. “Her current condition is due to INJURIES sustained from medical malpractice that occurred by a military Neurosurgeon, military nurses, and the overall horrible care she received at Wright-Patterson Air Force Base.”

Johnny Van Winkle, a spokesman for the base. declined to comment on the allegations, citing the Health Insurance Portability and Accountability Act of 1996, which prevents medical providers from disclosing a patient’s medical records.

As she began recovery, Fitzsimmon’s left eye was swollen shut and her head was leaning toward her left shoulder, Khawam said.

Her VA disability rating documents confirms that she suffers from a paralyzed cranial nerve and blindness on her left side.

“The lack of care continues when Barb is admitted for an MRI of her head and is ordered to lay flat without oxygen for an hour,” she said. “This is despite Barb crying and stating she cannot breathe without her oxygen.”

Following the MRI, she was intubated — put on a ventilator to help her breathe, preventing her from eating on her own or speaking — for a month.

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In the VA claims appeal, her husband wrote that on April 21, medical staff informed the family Ospina had suffered a stroke.

Further, he wrote wrote to the VA, the stroke went undetected for more than a day, “even though Barbara was supposed to be receiving hourly neuro checks.”

“This led to extensive brain damage and almost to her death,” he added.

She was transferred to Miami Valley Hospital in nearby Dayton, Ohio, where she had surgery to remove part of her skull, to relieve the pressure on her brain the following day.

“It is not until June 2014 that the family learned her neck had been dislocated during the Chiari surgery,” Khawam said, when they visited Northwestern Memorial Hospital in Chicago for a consult on her continuing pain and paralysis.

There, a neurosurgeon told Ospina that her dislocated neck would be “extremely rare” if it wasn’t done negligently.

Further, Ospina’s husband wrote, the Northwestern surgeon told them he believed the stroke was the result of the dislocation, which had created a tear in the inner lining of her vertebral artery, where a clot formed and blocked blood flow to her brain.

Jenny Nowatzke, a spokeswoman for the hospital, confirmed that Ospina had been a patient of Dr. Nader Dahdelah.

“This is not from Arnold Chiari: this is from the neurosurgeon dislocating Barbara’s neck at C1-C2 during surgery,” her husband wrote. “Not only did he injure Barbara’s neck, but he did not tell anyone."

In August of 2014, she had the removed skull portions replaced by a ceramic device, and in November, another surgery to fuse her neck.

A line-of-duty investigation found that Ospina had been permanently disabled by her medical condition, allowing her to retire in July 2016.

A month later, the VA denied her access to its caregiver program, which would provide a up to $30,000 a year so that a family member could take care of her full-time. Ospina continues to suffer from paralysis and chronic pain, her husband wrote, and spends most of her time of her time in a wheelchair.

Serious injury, according to the VA, includes “traumatic brain injury, psychological trauma, or other mental disorder, incurred or aggravated in the line of duty in the active military, naval, or air service on or after September 11, 2001, that renders the veteran or servicemember in need of personal care services,” spokeswoman Susan Carter told Military Times.

“Barb is left to pay for her own caregiver out of her VA disability paycheck,” Khawam said.

If Ospina had been originally operated on in a civilian hospital, she would have been able to sue her medical providers for the alleged negligence that led to her dislocated neck, and the pain, paralysis and loss of quality of life that followed.

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“This is another example of why the Feres Doctrine needs to be changed,” Khawam said. “Our troops and veterans deserve much better, especially after they proudly served our country.”

Feres, originally designed to protect DoD from lawsuits due to battlefield injuries, also applies to what goes on at home. Since its inception, numerous service members have suffered illness, injury and death without being able to hold care providers accountable.

The issue has circulated throughout the military community for years, but on April 30, Rep. Jackie Speier, D-California, introduced a law into the most recent National Defense Authorization bill, exempting medical malpractice from Feres.

Dubbed the SFC Richard Stayskal Military Medical Accountability Act of 2019, it would allow service members of their families to sue the United States damages following the personal injury or death of a service member because of “negligent or wrongful act or omission” stemming from health care, as well as investigations or clinical trials.

It’s named for a Green Beret facing terminal lung cancer that went unreported by Army doctors. He and others testified before the House Armed Services Committee in April about the breadth and depth of malpractice service members have faced.

“When doctors fail to perform or woefully misread tests, when nurses botch routine procedures, when clinicians ignore and disregard pain, service members deserve their day in court,” Speier, the chairwoman of the House Armed Services Committee’s personnel subcommittee, said in April.

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2.2 - Military Times: **Did VA hospital leaders ignore recalls on faulty medical equipment?**
(26 August, Leo Shane III, 1.7M uvm; Vienna, VA)

Staffers at a Florida-based Veterans Affairs hospital say leadership ignored a medical equipment recall for weeks — even after a patient’s life was endangered — despite repeated warnings their inaction violated health and safety norms.

But officials at the James A. Haley Veterans' Hospital in Tampa said their week they have removed all of the faulty items without any harm to patients, dismissing concerns that proper procedures were not followed.

It’s unclear whether the dispute is isolated to the single VA medical center or indicative of larger problems with recall alerts throughout the nation’s veterans hospital system. Department of Veterans Affairs officials in Washington, D.C. referred all questions to local hospital officials.

At issue is a July 31 incident where a patient at the Tampa medical center received too much prescribed medication because of what nurses described as malfunctioning IV equipment. Tubing designed to slowly drip out fluids into the patient’s bloodstream instead allowed a rush of medication all at once. In a grievance filed with facility leadership, staff said a medical disaster was avoided only because nurses on duty quickly diagnosed and responded to the problem.

But in a statement to Military Times, hospital leadership said that “no patient harm” occurred and praised medical personnel on staff for quickly identifying the problem. They also said an

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internal review found no specific equipment malfunctions but did uncover some system parts that were on recall lists.

Dennis McLain, head of the facility's National Nurses United chapter, said the manufacturer of the IV tubing (BD, headquartered in New Jersey) issued an urgent recall of the equipment two weeks earlier, instructing hospitals to "destroy all products" found in their inventory.

"Since this issue may lead to flow inaccuracies through the pumping cycle process, this may result in an over-infusion and the potential for serious patient injury or death, depending on the type of medication that is being delivered," the July 18 recall notice states.

In the grievance, McClain said the Tampa site continued not only overlooked that notice but also continued to use the faulty tubing for weeks after the July 31 incident, even after the union filed its formal complaints in early August.

Leadership issued a response this week (after Military Times inquiries on the matter) stating that "after speaking with the manufacturer today to ensure compliance with the recall, staff received additional clarification on tubing products affected" and that now "all affected IV tubing found at the facility is being replaced immediately."

Identifying the parts is difficult once it is in use, hospital officials said in their response to the union grievance, because they lack clear model numbers and identification markers once taken out of packaging.

Identifying the parts is difficult once it is in use, hospital officials said in their response to the union grievance, because they lack clear model numbers and identification markers once taken out of packaging.

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2.3 - KDKA (CBS-2, Video): Family Of Westmoreland County Veteran Files Federal Tort Claims Act Following Stay At West Virginia VA Hospital (25 August, Pam Surano, 1.3M uvm; Pittsburgh, PA)

CHARLESTON, W. Va. (KDKA) — A federal tort claims act has been initiated by the family of a Vietnam veteran whose death at a VA hospital promoted a homicide investigation.

Retired Sergeant Felix McDermott died April 8, 2018, at the Loius A. Johnson VA Medical Center in Clarksburg, West Virginia after he was injected with a fatal dose of insulin while at the center, a lawsuit says.

He was admitted three days before his death because he developed aspiration pneumonia.

McDermott, a Westmoreland County native, received an insulin shot in the left side of his abdomen, was not diabetic and had no history of insulin use, an autopsy revealed.

His death was ruled a homicide, and the VA investigators have a person of interest in the death.

McDermott's remains were exhumed and flown to the Dover Air Force Base for the autopsy in October 2018.

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The family's attorney, Tony O'Dell, said the McDermotts entrusted their father — a 20-year army veteran — in the care of the center.

O'Dell provided KDKA with a legal document sent to the hospital, claiming the 82-year-old may not have been the only victim.

"Our understanding is that there have been several patients, nine or 10, who had died under similar circumstances," O'Dell said.

O'Dell said the findings from the autopsy were negligent and preventable.

The suit is seeking damages of up to $5 million for wrongful death, $1 million for personal injuries and expenses for funeral costs.

The claim states that employees at the hospital never told McDermott's family how he died.

O'Dell explained the federal tort claims process involves putting the government on notice for six months before a lawsuit can be filed.

He fully expects the families of the other potential victims to retain attorneys as well.

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2.4 - WREG (CBS-3): Longtime Memphis pain doctor reprimanded for prescription issues
(26 July, Stacy Jacobson, 605k uvm; Memphis, TN)

The Tennessee Department of Health has reprimanded a Memphis pain management and addiction doctor for his prescribing practices.

The state put Dr. Douglas Jones' license to practice on probation and banned him from owning or operating pain management clinics.

Jones has been licensed in Tennessee since 1987.

In 2012, the Tennessee Medical Association posted this photo of Jones meeting with other doctors and state lawmakers. He's wearing a white coat with red writing that lists his specialties: "addiction medicine" and "pain management."

That's exactly the type of work that got him in trouble with the state starting around the same time.

In the order from the Tennessee Department of Health, officials said Dr. Jones treated patients for pain management between 2008 and 2016. He ran his own clinic in this Park Avenue office building during much of that time.

But, according to the board that regulates doctors, Jones did not meet standards of care for most of his patients.

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The allegations read like a list of what not to do as a doctor: prescribing controlled substances “without conducting a physical exam” or “formulating a treatment plan" and giving prescriptions to patients with a history of addiction and suicide attempts without any kind of mental health screening.

WREG analyzed federal statistics for opioid prescriptions in 2015, when records show he was the director of the Park Avenue clinic. Jones ranked in the top 15 percent of opioid prescribers in Tennessee, with more than 35 percent of his prescriptions being for an opioid.

WREG went to Jones’ East Memphis home. When a woman answered the door, we told her who we were and why we were looking for Dr. Doug Jones.

"We’re covering how his license was put on probation," reporter Stacy Jacobson said.

She promptly shut the door.

But neighbors confirmed Dr. Doug Jones lived at the home.

WREG also confirmed Jones lived at the home by spotting his white lab coat in the backseat of an Acura sedan parked outside. It was the same lab coat from the TMA photo on Facebook.

The back of the car also had piles of documents: research and even patient reports left out for anyone to see.

Neighbors said Dr. Jones’ messy car may be an indicator of his work.

But one of the names on those records was Felicia Price with a home address less than four miles away on Southern Avenue.

We found Felicia Price and told her how we knew about her.

“You’re kidding," Price said. "I don’t like that because I don’t know what it’s doing back there. Why would he have it open in the backseat of his car?”

In fact, WREG spoke with Parke Morris, an attorney who handles a lot of patient rights issues. Morris said Jones could be in big trouble.

"Extremely unprofessional. Violation of federal law and outrageous," he said, referencing the Health Insurance Portability and Accountability Act. "The records indicate you’re supposed to protect not only the treatment given, but their name, identifying information, date of birth and their social. This is no different than him leaving these records out in a waiting room for anyone to see."

Price, the patient, was also concerned because she didn't remember Dr. Jones, though she did know another doctor listed on paperwork in his backseat.

“I remember the last name. He did see me at Baptist,” Price said.

She was alarmed to hear about Jones’s license probation and other issues.

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"It's a good thing, so it should be done," she said. "People get operated on, they prescribe stuff, then they get addicted to it. Sometimes it gets to be so bad."

"There's a growing emphasis to discipline these doctors who are writing scripts for anything, for pain medication without an examination," Morris said.

A spokesperson for the Memphis Veterans Affairs Medical Center said Jones worked at the hospital from 1998 until 2008.

Methodist and VA officials said he does not have privileges anymore at their hospital.

Representatives for Baptist Hospital confirmed he still has privileges at their hospital.

Jones' practitioner profile with the Tennessee Department of Health states he has privileges at Saint Francis Hospital. Representatives did not respond to our repeated requests to confirm.

Jones faces fines up to $90,000 in the case.

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2.5 - Becker's Hospital Review: **Staff members claim VA hospital ignored medical equipment recall** (26 August, 593k uvm; Chicago, IL)

Staff members claim leadership ignored a medical equipment recall for weeks at the James A. Haley Veterans' Hospital in Tampa, Fla., according to the Military Times.

Becton Dickinson, an IV tubing manufacturer, recalled its tubing equipment on May 6. The VA hospital failed to recall the tubing for weeks, even after the equipment endangered a patient on July 31, staff members said. The patient received too much medication due to what nurses claim was malfunctioning IV equipment.

Officials at the hospital said they have removed all the faulty equipment and no patients were harmed. An internal review revealed some recalled equipment was involved in the July 31 incident, but hospital leadership said there were no equipment malfunctions. All recalled equipment has now been replaced, they said.

Staff members affiliated with National Nurses United have asked the Department of Veterans Affairs' inspector general to investigate whether the hospital followed proper procedures in complying with the recall. The VA has promised to inspect all equipment at the facility.

The VA did not respond to Becker's request for comment.

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2.6 - WINK (CBS-11, Video): **Veteran patients missing appointments, Cape VA clinic lacking resources** (26 August, Jack Lowenstein, 348k uvm; Fort Myers, FL)

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The U.S. Department of Veteran Affairs in Cape Coral says it is unable to provide transportation services to doctor appointments from its clinic due to lack of volunteers and donations that help provide necessary resources.

Vietnam Bubba Schneider is someone who depends on these services for his health. He reflected on his time in the war overseas when we spoke to him.

“We did what had to do,” Schneider said.

Schneider was on the front lines as a machine gun operator when he was 19 years old. Now, he suffers from several medical conditions, stemming from his experience on active duty. He worries he won’t make it to his appointments without help from the local VA clinic.

“I have problems getting dizzy, blacking out and falling,” Schneider said. “So now I have the chance to go to someone that can help me, but I can’t get there.”

The clinic said it only has one van that goes to Labelle, where Schneider lives, which picks up about half a dozen vets. Meanwhile, veterans like Schneider have waited months to see a doctor. He has an appointment Wednesday, but he doesn’t know if he will make it there.

“It has several of us in a turmoil that don’t drive trying to figure out how are we going to get to our appointments,” Schneider said.

Because of its lack of resources, the VA clinic said it can’t take veteran patients to appointments the clinic itself scheduled for them, something the clinic said it has always worked with veterans on.

To volunteer or donate to the local clinic, visit U.S. Department of Veteran Affairs.

“It would be an extremely sad thing for us not being cared for after what we did for our country,” Schneider said. “And we get pushed on the side of the road.”

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2.7 - WBIR (NBC-10, Video): Veteran hopes toolbox gift will help other veterans transition back to life after deployment (25 August, Sean Franklin, 464k uvm; Knoxville, TN)

A wounded combat veteran from East Tennessee received a way to find his purpose in life after serving.

A simple gift of a toolbox has helped him and others transition from the Army.

More than a hundred soldiers filled the Knoxville Convention Center this weekend, learning how to make a transition from deployment to life back home.

And retired Army Sergeant Lyle Allen knows exactly how that process works.

He has dedicated his life to serving others.

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"I'm a medically retired Army veteran, Purple Heart recipient," Allen said. "I got injured in Iraq in 2004."

Now, he has something that serves him.

"Yeah, somebody gave back to me, that's for sure," he said, looking down at his toolbox.

Allen laid out all $400 worth of tools in his new toolbox.

It was a way the Knoxville Vet Center employee helped welcome back members of the 278th Armored Cavalry Regiment at their Post-Deployment event Sunday.

"When a veteran gets back, they have to find a purpose," Allen said.

It's that purpose that drives the non-profit organization called Resources Exchange Association, based out of North Carolina.

Allen just sent them his information.

"I was impressed when I got the box," Allen said. "I went on their website and three weeks later there was a box at my doorstep."

A toolbox--a simple gift the program sends to veterans.

And Allen has the perfect way to put it to use.

It's his 1969 Red Ford Mustang--sitting in his garage and waiting to hit the road.

"This is actually giving us a purpose to get back out there, trying to keep busy," Allen said. "Because everyone has their own niche in life that keeps them going. So working with my hands and stuff is definitely one of them."

He said it's hard for veterans to get used to being home.

"The transition can be difficult," Allen said.

That's why he hopes the toolbox will help him serve those who have served this country.

"Just having different resources out there that people really don't know about, and just finding those resources for other veterans, to make their transition a lot better than mine," Allen said.

For more information about the Knoxville Vet Center, head to its website.

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2.8 - Idaho Statesman: **Letters to the editor** (26 August, Richard L. Barrett, 392k uvm; Boise, ID)

[…]

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VA THANKS
Kudos to Boise VA Medical Center Director's superb staff and many thanks to Secretary of Veterans Affairs Director Robert Wilkie for giving those folks the recognition they so richly deserve.

Richard L. Barrett, Boise

[…]

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2.9 - WMAZ (CBS-13, Video): Dublin VA going smoke free October 1st (26 August, Wanya Reese, 281k uvm; Macon, GA)

DUBLIN, Ga. — The Carl Vinson VA Medical Center plans to go smoke free starting in the fall, but some veterans have mixed opinions about the ban.

Some say it will help, while others think it won't, but regardless of what they think the smoking ban will go into effect at the center starting in October.

"I started smoking in the Navy, because that was really the only time I had the opportunity to take a break," Christopher Anderson said.

Anderson says spending days at sea helped him pick up a habit.

"They say it calms you down, it gives you an immediate rush of Nicotine," Anderson said.

He says it's the rush that kept him going.

"Two men talking with cigarettes in their hand," he said.

But starting October 1, the Carl Vinson VA Medical Center is going smoke free campus wide.

"If we can limit, reduce, or eliminate smoking, I think employees and veterans are going to be a lot healthier," Associate Director for the center Jay DeWorth said.

DeWorth says the VA will host free classes to help vets quit.

"What is new is we are going to be offering employees some of these same resources, classes to stop smoking if they choose to stop smoking, and also some medications," Deworth said.

He says these resources will be available to make sure all six area clinics are ready to go smoke free by October 1.

"And it is going to be a journey to get them not to smoke on our campus, but also to stop smoking all together," Deworth said.

Anderson says even with the new rule, he realizes it is going to be tough to quit.

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"I just think I'm going to have, to have the willpower and the proper mindset to throw the packs away, you know?" Anderson said.

You can find class details below.

Tobacco Cessation Classes: Classes usually meet one hour a week for five weeks. You can contact the following locations to confirm dates and times.

- Dublin Campus: Every Wednesday at 2 p.m. on 15A, and every Thursday at 2 p.m. on 10B for DOM in-patients only
- Tele-Health at all CBOC locations (Albany, Tifton, Brunswick, Macon, Milledgeville, and Perry): Every Friday at 1:15 p.m.

For more information, call Health Promotion Disease Prevention Program Manager Jennifer Johnson, BSN RN at 1-800-595-5229. Dial #1, then the extension 304.

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2.10 - MetroNews: **Clarksburg VA death ruled homicide; VA investigating more possible victims** (27 August, Hoppy Kercheval, 242k uvm; Charleston, WV)

On the morning of April 9, 2018, Felix McDermott died at the Louis A. Johnson VA Medical Center in Clarksburg. The retired Army Sergeant and Vietnam Veteran was 82 years old and had several health issues, including aspiration pneumonia.

However, his condition was improving, and his death shocked his family.

“No answers were given to the family at all,” said attorney Tony O’Dell, who represents McDermott’s relatives. “They really were left in the dark. He (McDermott) took a sudden turn. They didn’t know what to think. They were surprised.”

Another shock came later when the Veterans Administration contacted McDermott’s family for permission to exhume his body to conduct an autopsy after reports of other suspicious deaths at the Clarksburg VA.

The autopsy revealed the most stunning news of all; McDermott, who was not diabetic, had been given an insulin injection in the abdomen the morning of his death. He died of severe hypoglycemia. Deputy Medical Examiner Dr. Paul Uribe concluded, “Based on the investigative and autopsy findings, the manner of death is a homicide.”

O’Dell said the family wants answers. “We don’t know whether this is just an unbelievably incompetent person, which is hard to believe, or if someone is doing this willfully to people who have served our country,” O’Dell told me on Talkline Monday.

McDermott may not have been the only victim. O’Dell claims in his filing that prior to April, 2018, nine or ten patients at the Clarksburg VA “had died unexpectedly as a result of unexplained severe hypoglycemia” due to wrongful injections of insulin.

West Virginia Senator Joe Manchin, who is a member of the Senate Committee on Veterans’ Affairs, said on Talkline Monday that he has spoken with Veterans Affairs Secretary Robert

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Wilkie and Clarksburg VA Medical Center Director Dr. Glenn Snider to try to find out what happened.

Manchin said the investigation by the VA's Office of Inspector General has focused on an individual, who has not been identified. Manchin said he was assured by both Wilkie and Snyder that "the person of interest is no longer in any contact with veterans at the VA facility." There's no word of any criminal charges against anyone yet.

The investigation has gone on for months, and Manchin said despite his position on the Veterans' committee, he didn't find out about it until the story was first reported in the Clarksburg Exponent newspaper last week.

"It's very upsetting that it has taken this long for us to have gotten any kind of news," he said.

Wesley Walls, a spokesman for the hospital, said in a prepared statement that the hospital responded promptly when the allegations were discovered and put safeguards in place "to ensure the safety of each and every one of our patients."

Walls added that the hospital is cooperating with the investigation and the allegations of misconduct "do not involve any current Louis A. Johnson Medical Center employees."

Assurances that an unidentified "person of interest" no longer has access to patients at the Clarksburg VA is the bare minimum of information that patients, families and the public are entitled to. The fact that an autopsy, which was completed six months ago, determined McDermott was the victim of a homicide is alarming, and it is horrific to think there may have been nine or ten additional victims.

VA investigators have already acknowledged to McDermott's daughter, Melanie Proctor, that her father was the last known victim of these suspicious deaths as a result of wrongful insulin injections. There's been plenty of time for an investigation. A full accounting of exactly what happened to those veterans is long overdue.

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2.11 - MetroNews: **Autopsy: Vietnam veteran was not diabetic but died of insulin injection**
(26 August, Brad McElhinny, 242k uvm; Charleston, WV)

An autopsy report for a Vietnam veteran who died suspiciously at the Veterans Affairs Medical Center concludes that the man — who was not diabetic — was injected with a fatal amount of insulin.

The autopsy uses clinical language to describe horror.

"This case represents the administration of unprescribed insulin to a non-hyperglycemic, non-diabetic patient in a hospital setting," the report states.

"Based on the investigative and autopsy findings, the manner of death is homicide."

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The death of 82-year-old retired U.S. Army Sgt. Felix McDermott is drawing attention from the public, as well as West Virginia's congressional delegation, including senators Shelley Moore Capito and Joe Manchin.

Manchin said he spoke today with leaders with the U.S. Department of Veterans Affairs, as well as leadership at the VA hospital in Clarksburg.

A statement put out by Manchin's office made reference to a total of 11 suspicious deaths at the VA hospital.

"These crimes shock the conscience and I'm still appalled they were not only committed but that our veterans, who have sacrificed so much for our country, were the victims," Manchin stated.

McDermott's family has filed a claim over his death with the U.S. Department of Veterans Affairs.

McDermott's family was told by VA investigators that nine or ten additional patients of the Louis A. Johnson VA Medical Center had been given fatal injections of insulin, according to the claim.

"We don't know whether this is just an unbelievably incompetent person, which is hard to believe, or if someone is doing this willfully to people who have served our country," said Tony O'Dell, a Charleston lawyer who is representing McDermott's family.

McDermott was a Vietnam veteran who retired after 20 years of U.S. Army Service. He later served as a member of the Pennsylvania National Guard.

He was admitted for treatment at the VA Medical Center in Clarksburg on April 9, 2018 because he had choked on some food and developed aspiration pneumonia.

At first, his health improved.

Then, on April 9, 2018, his condition plummeted. He couldn't catch his breath. A fingerstick blood glucose test showed that he had critically low blood sugar.

The situation was so critical that his family was called in.

"All of a sudden they're called in the early morning hours. He's taken this sudden turn for the worse," O'Dell said on MetroNews' "Talkline.

By 9 a.m., McDermott was dead.

"Really, no answers were given to the family at all. They really were just left in the dark. He took a sudden turn. They didn't know what to think. They were surprised."

McDermott was buried on April 13, 2018.

The family grieved as time passed. After a few months, the family was asked for permission to exhume McDermott's body.

The exhumation occurred Oct. 23, 2018, and McDermott's remains were sent to the Dover Air Force Base for autopsy.

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The resulting autopsy report confirmed that McDermott was not diabetic and had no history of oral hypoglycemic use or previous insulin administration. The autopsy report also confirmed there were no hospital orders for the administration of insulin.

Yet, the autopsy identified a subcutaneous insulin injection site on the left side of his abdomen.

The report concluded that McDermott "died of exogenous insulin administration."

"If the medical examiner's conclusion is correct," the family's claim against the VA states, "Felix Kirk McDermott was murdered while he was in the care and custody of the Louis A. Johnson VA Medical Center despite the VAMC being on notice of previous wrongful injections."

Wesley Walls, who leads public affairs and community relations services at the medical facility, told MetroNews on Monday the allegations do not involve any current employees.

"Immediately upon discovering these serious allegations, Louis A. Johnson VA Medical Center leadership brought them to the attention of VA's inspector general while putting safeguards in place to ensure the safety of each and every one of our patients," he said.

Walls added Manchin's office was made aware of the allegations on Aug. 7, 2018, as were Capito's office and the staff of Rep. David McKinley, R-W.Va.

"VA is cooperating fully with the inspector general's ongoing investigation, and for additional questions we refer you to them," he concluded.

Manchin, who had spoken today with officials, said the investigation has identified a suspect. Manchin said that person was "removed immediately from any patient care."

"I did find out – the hospital did everything they could do when they found the person of suspicion," Manchin said on MetroNews' "Talkline." "They have secured and feel confident everything in the world is done for their patients."

He added, "There has been concern that they're looking into all the patients that person might have been in contact with."

Manchin expressed disappointment that the public just learned of the situation even though McDermott's death was a year ago.

"It's very upsetting that it has taken this long for us to have gotten any kind of news," Manchin said.

The claim by McDermott's family does not conclude whether the insulin injection was negligence or intentional.

O'Dell, the attorney, says the family is experiencing "total betrayal."

"Put yourself in that position where it's your father and someone may have purposefully killed that person," he said.

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2.12 - WJET (ABC-24, Video): **Erie VA Medical Center goes tobacco free** (26 August, 73k uvm; Erie, PA)

Erie VA Medical Center will soon be tobacco free.

According to the Medical Center Director, the new rule will also apply to all of their community based outpatient clinics.

The director said the reasoning for this is to create a healthier environment for anyone who comes in contact with the center.

In order to make this an easier transition, they are offering different outlets to help veterans and employees quit smoking.

“We know that this is not an easy thing to kick a habit, so we want to make sure that they feel fully supported. Overall we know the dangerous affects of smoke,” said John Gennaro, Medical Center Director.

The tobacco free policy will go into effect on October 1.

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2.13 - Citizen Tribune: **Group buys van to transport patients to VA clinic** (26 August, Shawn Singleton, 64k uvm; Morristown, TN)

Veterans who receive care at the Morristown VA Clinic now have a new way to make their specialized appointments on time.

The Jerry Alvis Disabled American Veterans Chapter 59 recently purchased a new van to transport disabled veterans to James H. Quillen Mountain Home VA Medical Center in Johnson City. Veterans from Hamblen, Hawkins, Grainger and Jefferson counties will be eligible for the transportation service.

“There are vets who are disabled and can’t drive to Johnson City (for their appointments),” said Steve Totino, a volunteer driver and Marine Corps veteran. “That’s the idea behind the new van.”

“(The van) looks nice,” said Phillip Armstrong, a volunteer driver from Bean Station. “Rides nicer (than the old van) too.”

The 2019 Ford van replaced an older van that reached the mileage threshold. The new van was purchased through the national chapter with funds raised through local donations stemming from the DAV’s annual “Forget Me Not” drive for Mother’s Day. The VA and DAV will share maintenance duties on the vehicle.

“The old van is in service now,” said Raymond Shockley, commander of Chapter 59, which was named for former commander Alvis, who lost his battle with cancer last year. “Once our vans

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exceed 250,000 miles, we replace them. We leave the van (at the Morristown clinic) and our volunteers give rides to Mountain Home."

"We are very grateful for this donation. This van replaces an older one that had reached nearly 150,000 miles," said Mike Kromoff, chief of voluntary services at James H. Quillen VA Medical Center. "The new one has been on the road for nearly two weeks now, and has already helped numerous veterans come to their appointments here at the medical center. We appreciate our partners at the DAV as we continue taking care of our veterans."

Jerry Barnard, an Army veteran who serves as a volunteer driver, and the scheduling coordinator for the DAV, said veterans should schedule rides to their appointments in Johnson City as early as possible, but the process is very simple.

"It's not too bad. It's pretty simple. You just have to keep the paperwork right," he said. "(Veterans) call us and tell us what time and day their appointments are scheduled. Then I call the drivers."

In addition to the Mother's Day fundraiser, DAV members also reached out to nonprofits from all four of the counties representative – as well as private citizens – for donations. Jerry Lane, an Air Force veteran from Morristown, said while his role is important, the organization received a great deal of assistance from people in their service area.

"I helped collect the money and kept it in order," said Lane, who is the treasurer for Chapter 59. "A great deal of credit goes to the community. We were able to raise $35,000 in donations to buy the van outright."

The DAV is still collecting donations for a new van for the Rogersville VA clinic. Members meet on the second Tuesday of each month at the Golden Corral on West Andrew Johnson Highway in Morristown. Interested donors can contact 312-6549.

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2.14 - The Journal Gazette: Five questions for Brett P. Reistad. National commander, American Legion (26 August, 56k uvm; Fort Wayne, IN)

1 - Are people surprised to learn your organization has been around for 100 years? How and when did the American Legion come to be headquartered in Indianapolis?

Some people are surprised, but I think most people are aware that we've been around for quite some time. Depending on their age, some may recall how we were such strong advocates for those returning from World War II (just as our founders were for the WWI vets). After World War II, people wondered if America would return to another Great Depression since so many of the returning service members would be searching for jobs. Yet, it was the American Legion that drafted in 1944 what would become the greatest social legislation ever passed by the U.S. Congress – the original GI Bill. It not only made higher education possible for millions of veterans, it made home ownership possible through low-cost guaranteed mortgages. It is responsible for the building of many middle-class communities throughout the country.

There is a funny story about Indianapolis winning the bid to become the home of the American Legion National Headquarters. Minneapolis was the site of the American Legion's first national

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convention and a strong contender to be the home of our headquarters. However, during the convention, which was held in November, temperatures dipped to 11 degrees and a snowstorm arrived. ... Indianapolis was chosen instead, and Washington, D.C., finished second in the voting.On June 4, 1924, ground was broken at777 N. Meridian St. in Indianapolis for our first permanent national headquarters. ...

2 - The challenges facing veterans returning from the conflicts of the 21st century must be quite different from those facing those who served in the world wars. Are young veterans today drawn to the American Legion the way earlier generations of servicemen and servicewomen were?

I think as people learn more about how the American Legion is making a difference in the lives of veterans and their families, the draw becomes greater. Many people serving in the military don't even think of themselves as veterans until they get out of the service and start reflecting on their past. But we consider those serving on active duty as veterans from the first day they enter basic training or boot camp. Also, younger veterans have many priorities ... . But as they learn about our many programs and see that we are here to assist them, they often decide to become members of our American Legion Family. We hope they join us, but even if they don't, we will vigorously advocate for their quality-of-life benefits.

... Due to medical advances and better evacuation methods, many veterans are surviving battlefield wounds that would have killed them if they had served in previous wars. But as a result, we have to find better and more comprehensive treatments ... . But even though technology and cultures change, veterans have a bond that transcends generations. ... They all understand service and sacrifice.

3 - Is America doing enough today for those who served?

We could always do more. Many veterans suffered disabilities from environmental exposures and contaminations that are still not covered today. I think about the service members who cleaned radioactive waste from Enewetak Atoll in the 1970s. Others served in places where they were sickened because of contaminated water. But many good things are happening. Vietnam veterans who were exposed to Agent Orange while serving on ships off that country's coast are finally getting benefits to compensate for their illnesses. VA health care is excellent, overall, but ... there have been enormous backlogs for those trying to access it. Today, we are seeing greater accountability and veterans who can't get into VA for various reasons can more easily opt for private-sector care. In short, America can never fully “do enough” for people who put their lives on the line, but VA is getting much better both in quality of care and responsiveness.

4 - Your 101st convention began in Indianapolis Friday and runs through Thursday. What event or aspect of this year's celebration are you most excited about?

... I'm excited about the job fair we are conducting to help veterans obtain employment and start businesses. I'm excited about our American Legion Family gathering and having the opportunity to ... bond as we discuss ways to improve the lives of veterans and their families. I'm excited about all of our speakers. The fact that the vice president of the United States, secretary of State, secretary of Veterans Affairs and members of Congress are taking the time from their busy schedules to be with us shows us the respect that America's leaders and the American public has not just for veterans but for the American Legion.

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5 - It's easy for us to acknowledge the immense debt we owe those who have served – but harder, perhaps, to repay it. What's the best way for Americans to honor our veterans?

... If you're an employer, hire veterans. You could volunteer at a VA Medical Center or place flags at veterans graves during Memorial Day, Veterans Day or frankly any day. If you are a son, grandson, wife, daughter or mother of a veteran, you could help support veterans by joining our American Legion Family. For more information, visit legion.org

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2.15 - Federal Computer Week: Congratulations to the 2019 Rising Stars (26 August, Troy K. Schneider, 46k uvm; Vienna, VA)

Each year, the Rising Star Awards recognize individuals who are early in their federal IT careers yet already are having an outsized impact. The women and men listed below have been selected both for their accomplishments over the past year and for their leadership potential in this community.

These awards are part of our larger Government Innovation Awards program. A joint effort of FCW, GCN, Washington Technology and Defense Systems, these awards also recognize the companies supporting the government's transformation and the most innovative technology initiatives across the public sector.

The Public Sector Innovation winners were announced today as well; the 2019 Industry Innovators will be revealed in the coming days. You can learn more about the overall Government Innovation Awards here.

We'll be running full profiles of the 2019 Rising Stars this fall, and the winners will be honored in person at the Nov. 7 Government Innovation Awards dinner. Until then, here's a quick salute this year's winners — 21 individuals we're confident you'll be hearing about for years to come:

Brecken W. Auchterlonie
Business Development Manager
SAIC

Kevin E. Brisley
Manpower Analyst / Senior Human Resources Manager
Command, Control, Communications and Cyber Systems Directorate, U.S. Transportation Command

Kaitlin I. Bulavinetz
Managing Director
Washington Cyber Roundtable

Will Cahoe
Projects Coordinator, 10x
General Services Administration

Gilberto Castro
Global Networking Manager

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Georgetown University

David Catanoso
Director, Enterprise Cloud Solutions Office, Dept of Veterans Affairs
Department of Veteran Affairs

Taylor K. Chott
Data Scientist
CACI

Anna Cordrey
Deputy Program Manager
NASA

Mahtab Emdadi
Regional Sales Director
Dell Technologies

Omid Ghaffari-Tabrizi
Acquisitions Lead
Centers of Excellence, General Services Administration

Ryan V. Hendricks
USA Performance Product Development Supervisor
Office of Personnel Management
Dr. Leonie Heyworth
Director of Synchronous Telehealth, VHA Office of Connected Care/ Telehealth Services,
Department of Veterans Affairs
Veterans Health Administration, Department of Veterans Affairs

Michelle Johnson
Communications Manager, Senior Research Analyst
Section 809 Panel, Defense Acquisition University

Samer Madarani
Partner Account Director - Partnership Development
Dovel Technologies

Ellen Nadeau
Deputy Manager, Privacy Framework
National Institute of Standards and Technology

Lt. Jason A. Pawlak
Cyber Battle Captain
U.S. Transportation Command

Jonathan Riksen
Associate Partner & Client Leader
IBM

Christopher Rorvig

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Senior Consultant, Consulting Services
CGI Federal

Blake M. Scates
Digital Program Manager
Department of Veterans Affairs

Robert G. Sheldon
Head of Technology Strategy, Public Sector
CrowdStrike

Travis Sorensen
CEO
Oddball, Inc.

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2.16 - Colorado Politics: **VA appoints new director of Eastern Colorado Health Care System** (26 August, Caitlin Curley, 57k uvm; Denver, CO)

The U.S. Department of Veterans Affairs is bringing on a new director for its Aurora-based Eastern Colorado Health Care System.

Michael Kilmer, formerly the medical center director for the Western Colorado system in Grand Junction, will replace Sallie Houser-Hanfelder, who retired in May.

The Eastern Colorado system covers more than 44,000 square miles through Colorado and Western Kansas, with a main hospital adjacent to the University of Colorado Anschutz Medical Campus in Aurora, according to a VA release Monday.

“We are excited to bring Mr. Kilmer on board as the new Director of VA Eastern Colorado Health Care System,” said Ralph Gigliotti, Veterans Integrated Service Network (VISN) 19 Director.

“Mr. Kilmer’s sound leadership qualities and proven experience will be valuable assets for the facility, the employees and volunteers, and most importantly, for the Veterans we are honored to serve.”

2. - Manistee News Advocate: **Volunteers needed for veteran transportation service** (26 August, Jane Bond, 1k uvm; Manistee, MI)

MANISTEE COUNTY — A new vehicle is taking local veterans to their medical appointments, but Eric Sullivan of the local Disabled American Veterans (DAV) chapter is looking for more volunteers to drive it.

As the ride coordinator for the DAV Manistee chapter, Sullivan spends most of his time organizing free transportation for retired soldiers to Veterans Affairs (VA) medical centers in locations like Traverse City, Cadillac, Wyoming and Saginaw.

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“This is a dire need service because we have a lot of elderly and disabled veterans that can’t drive themselves,” said Sullivan. “It’s a way for people to serve their country so-to-speak and provide a service to our veterans.”

The new Ford Flex van replaces an older model which has accumulated over 200,000 miles of wear and tear.

Sullivan said the Ford Flex was chosen for this program because they are all-wheel drive vehicles which seat seven.

“Because of our service range and location, we need all wheel drive vehicles or else we won’t be able to drive in the winter safely,” he said.

Two other vehicles in the DAV fleet are also nearing the 200,000 mile mark. Sullivan expects that they will be replaced in time for next summer.

Although the need for this service has remained constant, the number of volunteers has declined drastically. Since April, the shuttle service has lost three volunteers: two with health issues and one that moved away from the area.

“That’s our biggest hurdle, the critical need is for drivers,” said Sullivan.

The Manistee DAV relies on just four volunteers attending to veterans spread across five counties: Lake, Manistee, Mason, Osceola and Wexford.

Between March and July, DAV volunteers made 120 trips accounting for 23,704 miles traveled.

“The VA has valued DAV hours of volunteer service at nearly $34.7 million annually — making it an indispensable resource for veterans and a cost-effective solution for the VA,” said Brett Robbins, an Army veteran serving as a communications specialist detailed to the Department of Veterans Affairs.

According to Sullivan, the decline in volunteers has resulted in cutbacks within their program.

“Because there are very few volunteer drivers we have had to cut the number of counties served from Manistee,” he said. “We are no longer able to take veterans to the Detroit VA Hospital because of the shortage of drivers.”

Pat Vuksanovic is the local DAV’s longest serving volunteer, having driven with the organization since 2015. She volunteers on a regular basis, often making multiple stops every week.

Vuksanovic values the time she spends with the veterans she drives.

“Some days are early because of morning appointments — you go to their home, pick them up and take them where they need to go,” she said. “You get to know them. I have a lot that I’ve taken multiple times and you become friends with them. We don’t always talk war stories, but you get to talk personally.”

Vuksanovic hopes that veterans and other civic-minded community members will volunteer their time.

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“We want to get people who just want to do a little something when they can,” she said. “It’s very educational and it’s out of the goodness of your heart to be able to take someone to an appointment that they need to be physically better.”

Requirements for volunteering

• Pass a physical and background check;

• Possess a valid state driver’s license and clean driving record; and

• Possess personal auto liability insurance.

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3. Business Transformation

3.1 - The Virginian-Pilot: **Editorial: Veterans clinic a welcome addition to region** (27 August, 1.1M uvm; Norfolk, VA)

THE NEW STEVEN A. Cohen Military Family Clinic at The Up Center in Virginia Beach is a welcome and necessary addition to the services offered to veterans and military families in Hampton Roads.

Virginia’s first facility in the national Cohen Veterans Network, the clinic is expected to help more than 500 people in its first year and will offer a comprehensive range of services, including treatment for stress, anxiety, depression and post-traumatic stress disorder.

It will help veterans and their families with the often-difficult transition to civilian life, including couple’s therapy. People in crisis will be able to get help immediately — the clinic offers transportation and remote treatment through high-tech options — and will provide care at little or no cost as needed.

The demand for health and mental health services among veterans is substantial. Much remains to be done in the effort to provide adequate facilities, so that those who serve can get the help they need when they need it.

That is especially true in Hampton Roads, with its heavy concentration of military bases, service members, retired veterans and so many military families.

The military actions that began nearly 20 years ago in response to the 9/11 attacks have never ended. Nearly 3 million troops have served in combat zones, facing dangers, injuries and traumatic experiences. Families have endured the strains of long separation.

All that takes its toll. Estimates are that as many as 40 percent of those who serve in these conditions have some sort of mental health problem when they return home. And, despite years of efforts to change the culture, many of them still feel some hesitant to talk about their problems and seek help.

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If veterans don't have easy access to a facility that works with veterans, they are even less likely to seek help. And if they face a long wait before they can see a physician or therapist, things only get worse.

Suicide is a serious problem among veterans, and it's on the rise among younger veterans. Department of Veterans Affairs statistics say the suicide rate for veterans is 1.5 times greater than among those who have not served in the military. In 2016, 14 percent of all adults who died by suicide in the United States were veterans, even though fewer than 8 percent of Americans have served. By some estimates, about 20 veterans across the country kill themselves on any given day.

Family members generally learn to watch out for the warning signs of depression or other mental distress. Here in Hampton Roads, we all would do well to be aware and offer a sympathetic ear or a helping hand when we can.

The Cohen clinic will be an invaluable help in those situations as well, providing crisis services and other care as needed regardless of one's ability to pay.

Additionally, it's good that Virginia's lawmakers continue to champion veterans' causes in Congress. That includes Rep. Elaine Luria, a Navy veteran who represents Virginia Beach and other parts of Hampton Roads, who is building on the work of her predecessor, former Navy SEAL Scott Taylor.

Sens. Mark Warner and Tim Kaine have been working for years to accelerate the painfully slow process of getting a new VA outpatient clinic open in Hampton Roads. Faced with reports of veterans having long, frustrating waits for care at VA facilities, Congress has approved leases for 28 new medical facilities around the country, including one in Hampton Roads and one in Fredericksburg.

When it becomes reality, the new one in Hampton Roads should help veterans here have easier, prompter access to primary care, mental health and other services. The leases were approved in 2017, but the current timeline projects the two facilities in Virginia won't open until 2023.

Those who serve in the nation's military do what their country asks of them, when it asks. That service takes its toll on them and their families. The nation should make every effort to give veterans support and help when they need it.

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3.2 - KCRG (ABC-9, Video): Dubuque VA clinic open to patients starting Monday (26 August, 505k uvm; Cedar Rapids, IA)

DUBUQUE, Iowa (KCRG) - Veterans in Dubuque will now have access to the city's new VA clinic.

The new clinic opened earlier this month inside a portion of the former K-Mart building off Highway 20.

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It's more than four times the space of the current clinic, offering new services like radiology, physical therapy, and expanded mental health services.

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4. DOD Cooperation / Electronic Health Records / MISSION Act Implementation

4.1 - FedScoop: **Backlog of VA medical records awaiting digitization is 5 miles tall** (26 August, Billy Mitchell, 48k uvm; Washington, DC)

Across the country at Department of Veterans Affairs medical facilities, there's a massive backlog of documents waiting to be scanned and digitized that, if stacked, would stand more than 5 miles tall.

For reference, that's taller than 18 Empire State Buildings. It's just 2,000 feet short of the peak of Mount Everest.

Since 2014, the VA has allowed veterans to seek care outside of its facilities under the Veterans Access, Choice and Accountability Act. When that happens, those non-VA facilities generate records and send them, often as paper copies, to the VA to be integrated digitally with a veteran's electronic health record.

Veterans have visited community providers — as the non-VA facilities are called — for more than 70 million appointments and counting, each time creating at least one new medical document to send to the VA and integrate into an EHR.

According to a new inspector general's report, "[s]ignificant medical documentation backlogs have occurred VHA-wide in part because VA medical facility staff did not scan documentation and enter electronic medical records into patients' EHRs in a timely manner." The result is a "backlog of paper documentation that measured approximately 5.15 miles high and contained at least 597,000 individual electronic document files dating back to October 2016."

To make things worse, this could just be the tip of the digitization iceberg. As of June, the MISSION Act allows veterans to see a more expanded network of community providers. With that, there's "the potential to significantly increase the volume of documentation VA medical facilities will receive from outside providers for scanning, as well as any related backlog," the IG says.

The IG based its calculation on self-reported "data provided by the eight facilities visited and the 78 facilities interviewed." And there's probably quite a bit more than that, as the "totals do not include facilities that lacked quantifiable measures for their backlogs (i.e., those without paper document or electronic file calculations, such as facilities that only noted the age of the oldest document without calculating quantity)."

The paper pileup stems from the lack of "adequate oversight or resources to support the mission of medical document scanning and indexing for quality patient care," the IG said.

"Inaccurate EHRs put patients at risk and compromise continuity of care because accurate medical diagnoses and treatment depend on complete and current documentation," the report

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concludes. “VHA needs to improve supervision and management of scanning activities to ensure medical documents are indexed to patients’ EHRs in a timely manner. This will help ensure veterans receive appropriate, thorough, and timely care.”

The backlog provides yet another layer of challenges the VA faces in developing an effective modernized electronic health records system. The department has struggled for decades to provide a system that will interoperate with the Department of Defense’s, so transitioning service members can access their files when they become veterans.

However, the VA has made progress in recent years, signing a contract with Cerner estimated to be worth $16 billion to develop a modernized system that should work seamlessly with DOD’s Cerner-based system. The VA also touted a “major milestone” this summer, saying it migrated 78 billion health records, including vital signs, lab tests and others from its legacy systems to the new EHR.

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4.2 - Health Data Management: **OIG: VHA’s document scanning backlog puts patients at risk** (27 August, Greg Slabodkin, 41k uvm; Chicago, IL)

Veterans Health Administration facilities are woefully behind when it comes to scanning and entering medical documentation into patients’ electronic health records.

According to an audit by the VA’s Office of Inspector General, the agency found significant backlogs across the VHA, potentially putting patient care at risk because of a lack of timely and accurate EHR documentation.

“Based on data provided by the eight facilities visited and the 78 facilities interviewed, the audit team calculated that as of July 19, 2018, VA medical facilities had a cumulative medical documentation backlog of paper documentation that measured approximately 5.15 miles high and contained at least 597,000 individual electronic document files dating back to October 2016,” states OIG’s report.

In addition, auditors revealed that “when medical facility staff scan medical documentation, they are not always performing the appropriate reviews and monitoring to assess the overall quality and legibility of the scanned documents.”

While VHA facility directors are responsible for establishing policies and processes to ensure all duties associated with health record scanning are conducted in a timely manner, OIG concluded that staffing shortages were a factor in medical documentation backlogs.

“Staffing levels should be proportional to the volume of scanning to be completed; however, staffing levels and productivity standards varied significantly among the facilities reviewed, even between facilities with comparable veteran populations, demonstrating that VHA facility directors are not consistently assessing staffing needs based on scanning demand,” according to auditors.

OIG warned that what could make an already bad situation worse is last year’s enactment of the VA Maintaining Internal Systems and Strengthening Integrated Outside Networks (MISSION)

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Act, which is meant to consolidate the VA's community care programs into a new, streamlined and more efficient Veterans Community Care Program.

"The MISSION Act has the potential to significantly increase the volume of documentation VA medical facilities will receive from outside providers for scanning, as well as any related backlog," added auditors.

To address these shortcomings, OIG made nine recommendations to the VHA in three areas—define and promptly reduce backlogs; assess staffing resources to account for scanning demand; and develop monitoring roles, controls and procedures.

VHA concurred with all of OIG's recommendations and submitted what auditors described as "acceptable" corrective action plans.

"The OIG will monitor implementation of planned actions and will close the recommendations when VA provides sufficient evidence demonstrating progress in addressing the issues identified," concluded auditors.

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4.3 - Delaware Public Media (Audio): Delaware VA officials discuss new patient health care access rules (26 August, Sarah Mueller, 11k uvm; Dover, DE)

State Veterans Affairs officials discussed what's working and what's not with the newly-implemented VA Mission Act Monday.

Congresswoman Lisa Blunt Rochester hosted a roundtable at the Wilmington VA Medical Center to hear about June's roll out of new patient rules.

The VA Mission Act expands access to outside medical providers for veterans who have long drives or face long waits at VA facilities. It also gives vets a new ability to go to community urgent care facilities instead of VA clinics.Vince Kane said he believes the VA gives veterans better primary care and mental health care than private medical care providers.

Terry Baker, with Vietnam Veterans of America, said he likes the urgent care provision because vets can get minor issues addressed locally.

But Baker said more veterans need access to dental care coverage.

"A guy that's here and he's 90 percent disabled, but he's not "100 percent," he doesn't get dental care," Baker said. "I'm service-connected, I don't get dental care. I have to go to the outside, deal with a doctor out there."

He takes issue with state lawmakers expanding dental services to people on Medicaid - although he acknowledges Congress would have to approve changes to dental coverage for veterans.

Blunt Rochester said her takeaway is the act is working, but challenges remain.

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“Another thing that I think we heard about was the whole issue of medical shortages," she said. "Here we are expanding options for veterans, but if there are no people to actually provide the services, it’s a moot point.”

Delaware’s shortages of some medical providers are leading to lengthy wait times for some veterans.

Staff from the VA Community Based Outpatient Clinic in Georgetown say vets in Sussex County can wait up to eight months for an outside dermatology appointment. A veteran in Southern Delaware may wait up to a year to see a gastrointestinal specialist.

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4.4 - HIT Infrastructure: VHA’s Lax Health Information Management Created 5-Mile-High Backlog (26 August, Fred Donovan, 7k uvm; Danvers, MA)

The Veterans Health Administration’s (VHA) poor health information management of medical record scanning has produced a paper record backlog of 600,000 documents, or a stack of paper more than five miles high, concluded a recent audit by the Department of Veterans Affairs’ (VA) Office of Inspector General (OIG).

To address the backlog, OIG recommended that VHA improve the management of document scanning activities and ensure related resources and staffing are adequate. In addition, VHA should train personnel who are scanning and indexing the document on the proper procedures to improve quality assurance monitoring.

“These actions are necessary to help ensure veterans receive appropriately informed quality care in a timely manner,” the audit stressed.

Several recent laws have made it easier for veterans to be treated by third-party providers, who send paper medical records to the VA to add to the electronic health records. Since 2014, more than 70 million appointments with non-VA providers have been conducted.

“Incorporating these non-VA medical documents into the patients’ EHRs is critical to supporting patient care because it contributes to more complete, accurate, and readily accessible health records that guide clinicians’ decisions,” the audit stressed.

For the audit, OIG visited eight VA medical facilities and interviewed personnel from 78 other medical facilities.

The OIG related that VHA’s health information management staff conducts an annual inventory on the status of information management operations to decide on future training needs and to identify facilities that need technical assistance.

This annual inventory does not examine specific document backlog information, such as description of documents, size of the backlog at each facility, and/or the age of unscanned medical records, the audit related.

In addition, the VA health information management leaders and the VA medical facility staff do not use the annual inventory to advise facility on how to prevent document backlogs.

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While health information management personnel have authority in creating policy, it is the VHA facility directors who are tasked with enforcing that policy.

This divided authority, along with staffing shortages and poor training, has contributed to the document backlog, the audit concluded.

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5. Suicide Prevention

5.1 - Becker's Hospital Review: House chairman calls for national stand-down at VA hospitals for suicide prevention training (26 August, Anne-Marie Kommers, 593k uvm; Chicago, IL)

The chairman of the House Veterans' Affairs Committee called for a one-day halt to all nonessential work at VA medical centers to allow staff to focus on suicide prevention policies, according to The Marine Corps Times.

The call comes after an Aug. 22 inspector general report found numerous safety issues related to staffing, employee training and risk mitigation at West Palm Beach (Fla.) VA Medical Center, where a patient died by suicide in early 2019.

"We appreciate the Office of Inspector General's oversight, which focuses on an event that occurred in March 2019," the VA told Becker's following the report's release. "We continue to reinforce education to all staff and maintain suicide prevention as a priority."

Nearly 30 veterans have died from suicide at VA medical centers since 2017.

The VA did not respond to Becker's request for comment on the chairman's call for a national stand-down.

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5.2 - Federal News Network (Audio): House VA Committee chair calls for agencywide stand-down to address veteran suicide (26 August, Eric White, 238k uvm; Washington, DC)

The head of the House Veterans Affairs Committee wants all hands on deck to address veteran suicide. Rep. Mark Takano (D-Calif.) is calling for The Department of Veterans Affairs to hold a nationwide suicide stand-down within the next 15 days, so every leadership executive, administrator, nurse, doctor, and employee across the agency understands how to identify veterans in crisis and get them the help they need. There were three veteran suicides in five days on VA property back in April, and a recent VA inspector general report found there was a series of leadership failures at the West Palm Beach VA Medical Center which lead to a patient committing suicide in a secure psychiatric ward back in March. (House Veterans Affairs Committee)

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Veterans Affairs has a backlog of paper medical records that measures over five miles high. The VA inspector general said medical facility staff have struggled to quickly and accurately scan and enter patient documents into electronic health records. The department hasn't ensured the information in the documents is legible and accurate. The IG said VA should first address staffing shortages to help the department manage and improve its medical records backlog. (Department of Veterans Affairs Office of Inspector General)

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5.3 - The Augusta Chronicle: Family of veteran treated at Augusta VA who killed self files negligence suit (26 August, Sandy Hodson, 133k uvm; Augusta, GA)

The family of a Gulf War veteran who killed himself after suffering for years with post traumatic stress disorder has filed suit against the federal government, alleging his VA doctors were negligent.

Raymond Georgia Green died from a self-inflicted gunshot Jan. 10, 2017. His widow, Michele Green, and children Na'Kesha Green, Raven Simon Green-Harris, Raymond George Green Jr., and Dontair Wilson filed the federal lawsuit seeking $4 million in damages Aug. 8.

According to the lawsuit, Green was stationed at the National Training Center in Fort Irwin between 1994 and 1995. The fort is in the Mojave Desert in California. Green, a tank mechanic, witnessed a tank explosion that killed several servicemen. For years he suffered nightmares and flashbacks, according to the lawsuit. Green retired in 2006.

From 2011 Green was treated for depression at Charlie Norwood VA Medical Center. In April 2016 his primary care psychiatric care provider changed his medication to treat insomnia, anxiety, nightmares and flashbacks, according to the lawsuit.

On Nov. 14, 2016, Green's wife and daughter contacted social workers at the VA Center because he was having auditory and visual hallucinations, according to the lawsuit. He was exhibiting delusional behavior and extreme paranoia and refused to leave his bedroom, stopped attending classes and cancelled a major medical appointment, which had had never done before, the lawsuit contends.

In response to the Green family's concern, his treating physicians responded they couldn't have Green involuntarily admitted to an emergency room or mental health facility, the lawsuit alleges. Two months later, Green was dead. A review of his medical records at the VA revealed that between July and November 2016 Green didn't fill most of his prescriptions and had not visited a psychiatrist since April.

The Green family contends the medical staff was negligent and deviated from the standard of care in not ensuring Green received adequate follow-up psychiatric examination and treatments with careful monitoring of his prescription intake. The lawsuit includes an affidavit by Dr. Moustafa Shafey, chairman of the psychiatry department at CentraState Medical Center in Freehold, N.J., who considered Green's care negligent.

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There are 20 million veterans in the U.S. , and only about 30 percent seeks medical treatment at VA centers, according to the Department of Veterans Affairs. Since 2005, about 20 veterans commit suicide every day.

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5.4 - St. Cloud Times: **Suicide rates among women veterans continue to rise** (26 August, Patricia Wilson, 125k uvm; Saint Cloud, MN)

The Department of Veterans Affairs April 2019 press release that suicide rates among women veterans are going up and the suicide rate for women veterans was nearly twice the rate of non-veteran women should come as no surprise.

Women are becoming the fastest-growing veteran group and will probably rise to 15% by 2035. The VA further indicates that it is devising a national strategy to prevent veteran suicide.

“Sexual trauma is a significant risk factor for suicide,” according to former RAND researcher Rajeev Ramchand, now senior vice president of Cohen Veterans Network. Ramchand’s three years of intensive research and study concluded that women veterans “who screen positive for military sexual trauma have a higher risk of dying by suicide than those who don’t.”

The VA states that one in four women who have served or who are still serving in the military have experienced sexual trauma. Ramchand said that number is likely low because of “the stigma and possible consequences associated with reporting military sexual trauma.”

Ramchand has it right. Many women I have worked with in the military and those who are now my sister veterans have spent years in a secret, private hell because they know their families, friends and other veterans will tend to blame them for what happened. Women on active duty are very cautious to not report sexual assault to their commanders, as they do not want to jeopardize their careers.

The RAND Corporation conducted an intensive survey in 2014 of every military installation in the United States, including all Navy vessels to determine the extent of MST (Military Sexual Trauma), and released a comprehensive list of the “most dangerous” ones where a military woman can expect to be assaulted.

To cite just one example, the following Army bases were listed as leaders in MST involving women: Fort Huachuca, Arizona; Osan Base, Korea; Fort Drum, New York; Okinawa, Japan; and Fort Riley, Kansas.

It is stunning to read this list and realize that the VA is still behind the curve on reaching the “hidden and invisible women veterans” who struggle daily to deal with what has happened to them.

The recent St. Cloud VA Women’s Expo on Aug. 17 was a perfect example of lack of innovation and use of updated material.

What I and other women I spoke with who attended this expo were hoping for was to hear perhaps how money might have been approved to completely update the Women’s Clinic and

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bring more female providers. We were told not to expect much happening in that regard for at least two years.

Instead of having speakers who were excited about new ways to improve the situation for women veterans, we were treated to an afternoon of “art therapy,” painting clay fish and teapots while VA employees read 10-year-old statistics from their slide presentations. And they wonder why turnout at their events are so low?

In fairness, the VA employees are not completely to blame. After all, there is no solid, settled leadership at the top of the St. Cloud VA Medical Center.

For the past two years the St. Cloud VA has had a succession of acting directors, but cannot seem to find a candidate to elevate to the position of director. There are 11 other VA Medical Centers in the U.S. dealing with the same problem.

United States Secretary of Veterans Affairs Robert Wilkie is so busy patting himself on the back that I fear he may dislocate his shoulder and is not exactly the epitome of leadership.

Wilkie has again turned down the American Legion’s request to go ahead and start early processing of Blue Water Navy Claims, stating the VA has until January 1, 2020 to BEGIN the process. Heaven forbid you might take the initiative and forge ahead, Mr. Secretary!

Meanwhile my sister veterans continue to try to stay invisible and find their way through the maze of MST. These women have served with honor and distinction and need to have confidence that if they come forward that they will receive the help they have earned.

Self-destruction is terrible option, but we are losing these women because they are deciding that the shame and fear that MST has brought to their lives will never end. They make the decision that the pain of dying is better than one more day of the pain of living with MST.

This is the opinion of Patricia Wilson, a veteran and a resident of St. Cloud. Her column appears on the fourth Tuesday of the month.

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6. Women Veterans / Homelessness / Benefits / Cemeteries

6.1 - The Hill: **Here's why Congress must close the '90/10 loophole' in veterans' education**
(26 August, Wesley Wilson, 18.4M uvm; Washington, DC)

For years, veteran advocates and lawmakers have worked to close the widely-known 90/10 loophole that for-profit schools use to target veterans unethically. This year, 37 veteran service organizations and lawmakers have banded together to make closing the loophole a real possibility. Unfortunately, organizations such as the Reserve Officers Association (ROA) are getting in the way of progress by defending for-profit schools and incorrectly promulgating veteran advocates' arguments.

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ROA claims advocates push to close the 90/10 loophole with interests of curtailing competition between the for-profit and not-for-profit sectors; this is not true. Here is why Congress should close the 90/10 loophole.

Created under the Higher Education Act Amendments of 1998, the 90/10 rule mandated that proprietary institutions must derive 10 percent of their revenue from non-federal sources. The legislative intent was to combat waste and fraud, not default rates. Despite originating from taxpayer pockets, G.I. Bill payments do not count as federal dollars under the rule. Because of this, for-profit schools are incentivized to target veterans and their benefits.

According to the American Economic Journal, for-profit institution tuition rates often mirror the amount of money they would receive in per-student federal aid subsidies. With tuition set at a profit-maximizing rate, for-profits can “strategically” recruit G.I. Bill-eligible students.

This strategy explains why for-profit schools received the largest amount of G.I. Bill dollars. Between 2009 and 2017, eight of the top 10 recipients of G.I. Bill dollars were for-profit institutions — collecting a whopping $34 billion. Six of those eight schools have come under fire in state and federal lawsuits (most of them multiple times) for predatory recruitment and fraud.

For example, in 2015, the University of Phoenix (the top recipient of G.I. Bill dollars) was sued by two university employees when they were asked to misrepresent information to recruit veterans. The recruiters claimed they “were trained to lie to students about their future employment prospects.” Unfortunately, similar stories are commonplace. The VA has received 2,000 complaints against for-profit institutions — more than any other type of school.

Accusations of fraud and recruitment malpractice caused proprietary giants such as ITT Tech and Corinthian College to close their doors permanently — leaving 7,000 student veterans without degrees and G.I. Bill benefits. Fortunately, provisions of the new Forever G.I. Bill restored benefits lost because of school closures. Unfortunately, students exiting the closing for-profit schools were unable to transfer 94 percent of their academic credits.

ROA asserts that loophole-closing legislation would be unfair to the taxpayer. The estimated cost of restoring benefits lost because of school closures is $320 million. In a New York Times opinion piece, student veteran experts highlight for-profits’ propensity to receive improper G.I. Bill payments. The VA internal audit they cite warns the VA will issue $2.3 billion in improper payments if their capacity to exercise oversight is not improved. How is this fair to the taxpayer?

ROA cites the low graduation rates of three schools (Ashford University, Oklahoma State

University-Oklahoma City, and University of Maryland-University College). Ashford University is a for-profit school and has been a subject in numerous lawsuits, so it seems counterproductive to include this school in their argument. Second, arbitrarily selecting three schools with low graduation rates is a confirmation bias that does not accurately capture the public sector’s performance. The focus should be on educational outcomes, not graduation rates — so how do outcomes differ between the two?

In two words, plain lousy.

A study analyzing for-profit school outcomes found that students who graduated from for-profit schools were less employable, and earned 11 percent less than their not-for-profit counterparts. Outcomes and academic preparation were even worse for students attending exclusively online,

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for-profit institutions. The study underscored crippling for-profit tuition rates, which are five times higher than the average community college. Tuition for certificate programs at for-profit schools is 11 times higher. Unsurprisingly, high tuition costs have led to four times as much student debt, coupled with high student loan default rates for proprietary schools.

Closing the loophole is common sense and will affect only a small portion of schools. There are 2,829 for-profit schools eligible for federal aid; of those schools eligible, only 112 would be out of compliance. Many vocational training institutions (HVAC, culinary arts, etc.) would be unaffected, because, while still covered under the G.I. Bill, they are ineligible for federal aid. Studies have shown that for-profit institutions ineligible for aid "can survive, and even thrive, alongside their aid-eligible counterparts." Lastly, reports illustrate that repealing the 90/10 rule would cost taxpayers $2 billion in Pell Grants and increase loan default rates.

Closing the 90/10 loophole is about eliminating government waste and curtailing unethical behavior — not competition. The rule of law must be upheld, and the original legislation must function as intended. We are tired of for-profit schools lying to veterans about the education they are receiving and the types of jobs in which they will qualify. We are tired of veterans paying ridiculous tuition rates set by profit-maximizing schools — with taxpayers footing the bill. We are tired of veterans working hard for a degree, with nothing to show for it.

The G.I. Bill is one of the most successful social programs in American history. If we want to continue the success of the G.I. Bill, then it is time for lawmakers to step up.

Wesley Wilson served in the U.S. Army from 2012-2017 as a military police officer. He is an advocacy fellow with High Ground Veterans Advocacy, a research assistant at the Institute for Veterans and Military Families, and a graduate student at the Maxwell School of Citizenship and Public Affairs at Syracuse University. He is the former president of the Fordham Veterans Association.

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6.2 - WCPO (ABC-9, Video): Despite ban, Cincinnati VA Medical Center continues to support transgender troops (27 August, Craig McKee, 680k uvm; Cincinnati, OH)

Lesbian, gay, bisexual and transgender people have served in the United States military for as long as there's been one. Edicts from the White House — like the bygone "Don't Ask, Don't Tell" and President Donald Trump's current ban on transgender troops — can't change that.

And they don't change the responsibility of the United States Department of Veterans Affairs, according to Cincinnati VA psychologist Connie Boehner.

"People don't think about it until they hear it on the news, but there have always been transgender folk in the military, and we're going to take care of them if they ask us to," she said. "And that's the bottom line of this."

The VA doesn't pay for transgender troops to receive gender confirmation surgery, but it covers pre- and post-operative care as well as therapy and hormone prescriptions.

In 2018, a short time after Trump enacted his ban, social worker Cindy Horn helped the Cincinnati VA Medical Center establish its first-ever support group for transgender veterans. Its

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members range in age from 32 to 74, she said, and monthly meetings are a place where they can come for an all-too-rare experience: Feeling valued, recognized and safe.

“The biggest challenge is just being accepted in society and to truly authenticate to who they are,” said Horn, who spent 12 years counseling active-duty troops at Fort Knox.

Air Force veteran Laura Ann Weaver knows that better than almost anyone. She knew who she was early in her life, she said — at three years old, maybe even before — but had no idea how to bring that real self into the world.

“In my generation, there wasn’t even a language to describe being transgender,” she said. “You just knew you were different, but you couldn’t put your finger on it. It was something you couldn’t talk about and you would practice in secret.”

She joined the Air Force in 1972, serving for two years out of Osan Air Base in South Korea, and married her wife in 1980. It was a classically masculine life, she said. She was good at living it, even if it made her feel incomplete. Even if she knew her wife didn’t approve of her secret.

(That’s a common experience for LGBTQ veterans born with a Y chromosome, according to Horn: joining the military in an attempt to feel or look more traditionally masculine.)

Weaver continued to live as a man for 30 years. In that time, she lost her wife and her parents, forcing her to begin seriously considering who she would be outside that web of obligation and expectation. Who did she want to be, now that she got to decide?

“I had very much during my marriage surrendered who I was as an individual and was very much part of a couple,” she said. “I had to relearn who I was, and that took me 10 years.”

At the end of it, she knew she had to bring Laura Ann into the real world despite her fears of being rejected. Some of those fears would be realized, she said. She lost her relationships with her brother and sister after coming out.

“When I went to the Cincinnati VA hospital, I was very concerned about being transgender and refused treatment,” she said.

She wasn’t. Weaver pays $50 for each clinical appointment and $27 every month for her three medications through the VA, where she said she’s been accepted and treated with respect.

“The Cincinnati VA is one of the best hospitals I’ve been to,” she said. “They do provide mental health care, they do provide hormone support, they do provide everything up to but not including surgery, and that is a tremendous benefit for veterans.”

Boehner and Horn said they’re proud of being able to provide those services, and the need is growing.

Many of the people who participate in the Cincinnati VA’s support group aren’t out to their families, making it one of just a few places they can be themselves without fear of judgment.

“It’s always there are going to be people uncomfortable with things they don’t understand,” Boehner said. “One of our big roles is educating people what this means and that this isn’t a

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threat to you. You're going to get your care, they're going to get their care, and you're all veterans."

"Transgender people are no different than anybody else," Weaver added. "Quite frankly, you have to resent that we're being treated differently."

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6.3 - WKYC (NBC-3): Local son, fiancee hold special wedding ceremony to include ailing father (25 August, 611k uvm; Cleveland, OH)

Most people dream of their parents being a part of their wedding day. But as many people come to understand due to health risks and deaths, it's not always possible.

In an effort to avoid that scenario, a local man held a special wedding service at Cleveland's VA Medical Center Sunday.

Zeke, 28, and his fiancee, 23, couldn't image their big day without Zeke's father, Fred Miller.

So when they found out Miller was having complications after having a heart transplant nearly 30 years ago, the two sprung into action.

The pair held the ceremony inside VA's chapel and held a short reception after, that even featured Fred's favorite snack--brownies.

The two will officially wed in October 2021.

Miller served in the U.S. Marine Corps from 1968 to 1970 before returning home to Northeast Ohio and working for U.S. Steel.

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6.4 - Villages-News.com: Rollout for $10 million monument plan at Florida National Cemetery taking place in The Villages (26 August, 195k uvd; Lady Lake, FL)

The rollout for a $10 million venture to bring a series of monuments to Florida National Cemetery will be announced this week in The Villages.

The Joint Veterans Support Committee (JVSC) is working to bring the Freedom Memorial Plaza to the national cemetery. It will be located near the entrance to the Bushnell facility, will encompass two-plus acres and will be inner-connected by sidewalks.

The JVSC will be responsible for the project, including fundraising, design, and submission of details to the Department of Veterans Affairs for final approval. Those wishing to learn more about the project are welcome to attend a gathering Wednesday, Aug. 28 at 3 p.m. at the Eisenhower Recreation Center.

The initial focus will be on two of the 16 monuments. A "Military Honors Funeral" will include two life-sized bronzed military figures folding a red, white and blue powder-coated American flag

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over a bronze casket. It will be surrounded by 7-feet-tall granite columns depicting other facets of a military honors funeral.

The columns will include porcelain pictures and emblems representing all branches of service, as well as scenes of a bugler playing taps, a chaplain, presentation of a folded flag to next of kin, an honor guard, a 21-gun salute, a missing-man flyover and a caisson.

A 470-foot-long "Defenders of Freedom Wall" will consist of etched black granite plates depicting scenes beginning with the Revolutionary War and progressing through today's defenses for freedom. The etchings on the 6-foot panels will be generated from photographs submitted by volunteers and organizations wishing to sponsor a section. Those wishing to do so will be asked to donate funds for that portion of the wall and submit photos to be used, which will then be sent to the Department of Veterans Affairs for final approval.

The themes for the remaining 14 monuments haven't yet been determined. A "Gold Star Families" Monument is expected to gain interest. And others being considered are Vietnam War, Native American, POW-MIA, Purple Heart, Medal of Honor, Women Veterans, Special Forces, World War II, Korean War and Iraq/Afghanistan. Those with ideas for other monuments are encouraged to share ideas the JVSC.

These monuments will be the first to be erected at the Florida National Cemetery, which is located just off Interstate 75 at the edge of the Withlacoochee Forest in Bushnell. It is the largest national cemetery in Florida with 169,000 interred and the second most active in the United States with 7,000 interments per year.

Those who want to volunteer to be a member of the JVSC Monument Committee, make donations or have further questions are encouraged to visit JVSC.US.

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7. Other

7.1 - FOX News: Presidential administrations from both sides like to spend, but then again, so do most Americans (26 August, Chad Pergram, 73.9M uvm; New York, NY)

Eat your veggies. Take your vitamins. Hit the gym. Eliminate alcohol and caffeine.

Everyone knows how to stay healthy.

Yet we don't like carrots and kale. We forget our Centrum. We go to happy hour with friends after work and skip the cardio class.

This is human nature. Who wouldn't rather eat goodies then pound away a few hours at the gym?

So, is it any surprise the federal debt and deficit is exploding?

The psychology is really the same.

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The public doesn't like to hear about burgeoning debt. People certainly lecture Washington about profligate spending. There's renewed worry about the federal deficit amid signals of a potential economic slowdown. The non-partisan Congressional Budget Office says the new fiscal blueprint lawmakers okayed earlier this summer could spike the deficit by $800 billion over the next decade. Few on either end of Pennsylvania Avenue have the will to make meaningful spending cuts.

Let's face it: the deficit is up because Congress and Presidents of both parties like to spend. But frankly, most Americans like spending too.

The Congressional Budget Office revised its economic outlook after Congress voted to terminate old spending limitations. Those strictures kept some federal expenditures in check. President Trump went along with the plan.

"The nation's fiscal outlook is challenging," said Congressional Budget Office Director Philip Swagel.

There's now a chasm between what the government takes in and what it spends. Swagel said the difference is now at "the highest level just after World War II."

[…]

Then, throw in money for the Department of Veterans Affairs and a spending line called "Military Construction." Nobody wants to cut the VA. So, if you couple the appropriations bill known on Capitol Hill as "MilCon/VA" with the annual Pentagon spending bill, 88 cents of each federal dollar is untouchable. That leaves only the remaining 12 cents as a potential place to cut. That final 12 cents funds everything from the State Department to the Department of Interior. It funds Congress. Homeland Security.

[…]

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7.2 - U.S. News & World Report (HealthDay): Staying Optimistic Might Lengthen Your Life, Study Shows (26 August, Alan Mozes, 23.3M uvm; Washington, DC)

An upbeat view of life may increase your odds for living to a ripe old age, new research suggests.

The finding stems from a look at optimism and longevity among nearly 70,000 women and 1,400 men. It builds on earlier research linking higher levels of optimism to lower risks of chronic illness and premature death.

"This study took us further by suggesting that optimistic people are more likely to achieve 'exceptional longevity,' which we defined as living to age 85 or older," said study lead author Lewina Lee, a clinical research psychologist with the U.S. National Center for Posttraumatic Stress Disorder at the Veterans Affairs Boston Healthcare System.

Compared to their least optimistic counterparts, the most optimistic men and women studied were 50% to 70% more likely to reach that advanced milestone, Lee said.

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They were also 11% to 15% more likely to live longer overall, the study found.

The findings held up even after accounting for other influences, such as educational background, marital status, friendships, chronic health problems, and depression, Lee said.

Optimism was also powerful predictor of longevity regardless of a person's habits when it came to tobacco and alcohol use, exercise, eating well or getting routine medical care.

"Most studies have focused on deficits or problems that increase the risk of dying," Lee noted. "Our study is novel is that we considered the benefits of a psychological asset -- optimism -- in promoting longevity."

The study team suggested that the findings could point the way towards new interventions that might foster optimism and thereby extend life, such as meditation and certain psychotherapy programs.

Lee and her colleagues discuss their findings in the Aug. 26 issue of Proceedings of the National Academy of Sciences.

They concluded that optimism matters after analyzing data from the Nurses' Health Study, which focused on women, and the Veterans Affairs Normative Aging Study, which focused on men.

The women were 58 to 86 years old (average age: 70) when their health habits, overall health and optimistic outlook were first assessed. They were followed for 10 years.

The men were 41 to 90 years old (average age: 62) when they had a similar assessment and a physical exam in 1986. They were followed for 30 years.

At the end of the tracking periods, researchers found that results for women and men were roughly the same: The more optimistic the individual, the greater the chances for living longer -- and the greater the chances for reaching an "exceptional" age.

But that doesn't necessarily mean that Debbie Downers are doomed to shorter lives, Lee said. Her team only found an association and not a cause-and-effect link.

"The association between optimism and exceptional longevity was independent of depression," Lee said. "This suggests that the presence of optimism is more than just the absence of depression," so that even among those who struggle with depression a little optimism might still work longevity wonders.

Kit Yarrow, a consumer psychologist at Golden Gate University in San Francisco, said there are many reasons why optimism breeds longevity.

"Optimists experience less stress, because they don't tend to dwell on negatives and feel more empowered to overcome hurdles," said Yarrow, who wasn't involved with the study. "They are less likely to give up, and they bounce back more quickly from problems and setbacks. Stress is a killer and wreaks havoc on our bodies."

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Optimists also are less likely to experience depression, feelings of hopelessness and negativity -- factors often linked to poorer health and higher rates of disease, she added.

On top of that, Yarrow said, optimists tend to take better care of themselves and have an easier time making and keeping friends, "a well-documented source of health and longevity."

She acknowledged that access to money, good food and education and, of course, genetics can also have a big impact on longevity.

But unlike good genes, Yarrow said, "optimism and her powerful sister, gratitude, can be learned."

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7.3 - U.S. News & World Report (AP): Former Trump Official to Helm Florida Republican Party (26 August, 23.3M uvm; Washington, DC)

TALLAHASSEE, FLA. (AP) — Florida's Republican Party has named Peter O'Rourke, a former acting secretary of the U.S. Department of Veterans Affairs under the Trump administration, as its new executive director.

O'Rourke is widely seen as a loyalist for President Donald Trump. In its announcement Monday, the party said O'Rourke would help the party deliver Florida for Trump's re-election.

O'Rourke was acting secretary for two months, from May 2018 until the confirmation of current VA Secretary Robert Wilkie.

Wilkie then asked for O'Rourke's resignation in December.

During his tenure, O'Rourke came under fire for his management style and for his clashes with lawmakers.

In December, the Washington Post noted that O'Rourke was being paid $160,000 a year while doing little work. He responded that "there were times I didn't have a lot to do."

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7.4 - Politico: Former VA official 'hand-picked' by Trump to lead Florida GOP (26 August, Matt Dixon, 14.4M uvm; Arlington, VA)

TALLAHASSEE — In a surprise move, Peter O'Rourke, a former top official at the U.S. Department of Veterans Affairs and an ally of President Donald Trump, will take over leadership of the Republican Party of Florida, the latest development in a party power struggle going into the 2020 presidential election.

O'Rourke, who was introduced to the party executive committee as Trump's "hand-picked" choice for the job, will replace Jennifer Locetta as executive director of one of the biggest state Republican operations in the country. Locetta was hired in January, shortly after Gov. Ron DeSantis, a Republican, took office.

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Trump's team put O'Rourke's name forward last week after DeSantis and his chief of staff, Shane Strum, talked to Trump campaign manager Brad Parscale about replacing Locetta.

Trump "personally endorsed" O'Rourke for the appointment, DeSantis said in a written statement Monday.

"We are a unified and united team as we head into 2020," state Republican Party Chairman Joe Gruters told POLITICO.

On a conference call with the party's executive committee Monday, Gruters introduced O'Rourke as "basically a cabinet secretary," a reference to his tenure as acting VA secretary.

Gruters had revealed O'Rourke's hiring in a press release Monday morning, an announcement that came as a surprise to party insiders, including some on the executive committee.

"No one in the state executive committee had a clue about the new executive director until the press release hit," said a Republican consultant. "People are confused and concerned."

GOP staff in Florida working with Trump's Victory Team will remain largely in place, but additional staff shakeups could be coming, Gruters said.

"There will probably continue to be some changes, but you can expect a broader expanded team," Gruters said on the call.

The appointment is O'Rourke's first job since leaving the VA in December.

When he cut ties with the department, he faced criticism for not showing up to the $161,000-a-year job. As VA chief of staff, he also came under fire for allowing members of Mar-a-Lago, Trump's Palm Beach County club, to influence department decision-making.

One of those members was Ike Perlmutter, chairman of Marvel Entertainment and one of DeSantis' top donors. POLITICO reported last year that Perlmutter objected to a $16 billion VA contract being awarded to a vendor he did not like.

"Peter O'Rourke has the political expertise and management skill necessary to support Governor DeSantis within the state and keep our party unified as we work to deliver Florida for President Trump in 2020," Perlmutter said in a written statement distributed as part of Gruters' press release.

The press release projected a message of unity after months of internal power struggles over the direction of the party and who should have influence over decision-making.

Prominent state Republicans led by Strum and first lady Casey DeSantis have sought to replace party staff allied with Susie Wiles, a political strategist who helped guide DeSantis' campaign to victory and led his transition. Wiles and Gruters co-chaired Trump's 2016 Florida campaign.

O'Rourke's hire is "the continuation of putting some of [DeSantis'] people versus 'Susie' people," said one party official.

Locetta, the outgoing executive director, was considered a Wiles ally.

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The rift with Wiles had prompted DeSantis to distance himself from his own party apparatus as it gears up for 2020. DeSantis said he would raise money for two Republican Party of Florida events, then focus on raising money for his own political committees.

DeSantis does not have a political spokesperson. Strum did not return a call seeking comment.

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Executive SummaryLocal and regional outlets sustained coverage of the claim that one Veteran, and perhaps 10 others, died of homicide at the Clarksburg VAMC. The backlog of VA medical records awaiting digitization trended in specialized outlets.

Storyline	Outlets	Analysis	Trend	Priority
Up to 11 deceased Veterans wrongfully injected with insulin	*Exponent Telegram*, *WDTV (CBS)*, *KDKA (CBS)*, *MetroNews 1*, *2*	Most outlets reported that Sen. Joe Manchin (D-W.Va.) has spoken with Sec. Wilkie and Clarksburg VAMC Dir. Dr. Glenn Snider, who assured him that the person of interest is no longer in contact with any Veterans at the facility. *Exponent Telegram* and *MetroNews* included messaging from public affairs and community relations employee Wesley Walls, whose statement reportedly said that leadership reported the allegations to the IG immediately while putting safeguards in place to ensure patient safety. *WDTV* quoted an individual who received treatment there as saying it was the, "Worst facility I have ever been to." *Exponent Telegram* and *WDTV* presented IG findings on sentinel events at the facility in 2018.	**Sustained**	Service
Tampa VA may have ignored recall of faulty medical equipment	*Military Times*	Leo Shane III covered claims by staff at the James A. Haley VAMC in Tampa that, "leadership ignored a medical equipment recall for weeks… despite repeated warnings their inaction violated health and safety norms." The article relayed the claim that a patient received too much of a prescribed medication due to faulty IV tubing, and that the hospital ignored a recall of the product for weeks before and after the situation occurred. It included responses by leadership, who reportedly denied the claims and said no patient harm had occurred.	**Emerged**	Service
Veteran died by Suicide after removal from high-risk list	*Military.com*	*Military.com* continued coverage of an IG report finding that, "the suicide risk assessment of the patient was adequate," in the case of a Veteran who died by Suicide after the San Diego VA removed him from the high-risk list. Though the article reported that VA was found to have acted properly, it said his removal from the high-risk list was questioned and the IG's office said his case could, "point the way to improvements in suicide prevention." San Diego VAMC Public Affairs Dir. Cynthia Butler was quoted as saying, "We appreciate their confirmation that there were no deficiencies in the care of the veteran…"	**Sustained**	Suicide

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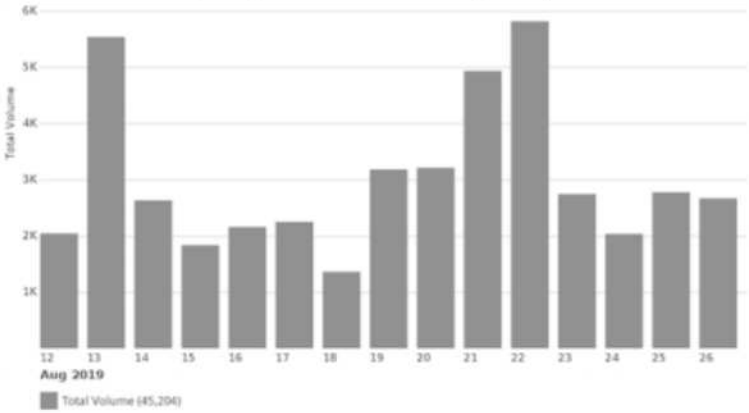
VA-19-1109-B-002641

VA Secretary's Stand-Up Brief27 August 2019

Social Media TakeawaySocial media volume sustained. Mar-a-Lago and Suicide continued to trend on Twitter.

Key Points@CREWcrew posted a new batch of tweets on Mar-a-Lago. The top post called the situation "ridiculous" and linked to the 25 Aug. CNN story (430+ retweets). The third post linked to the 23 Aug. Gov't Exec. article, saying VA employees were "exasperated and concerned about taking orders" from the members (210+ retweets). The fifth post linked to the 22 Aug. Rolling Stone story and said internal emails reveal how the President's "inexperienced… cronies" tried to influence care (170+ retweets). The CNN story was again embedded in the sixth post, which emphasized VA officials' "concern" about the members' "authority to influence policy" (150+ retweets). The eighth tweet linked to the Rolling Stones article and included a quote on the "president's paying customers" being given "deference and influence" (90+ retweets). @RepThomasMassie's 25 Aug. post saying that fmr. Pres. Obama implemented a red flag law at VA that results in Veterans being prohibited from owning firearms, "if they merely say someone else manages their finances," moved from first to second position (240+ additional retweets, 930+ total).@JuddLegum's 22 Aug. post on the President ordering VA to purchase Spravato, which Mr. Legum claims, "will benefit one of Trump's biggest donors," moved from fifth to fourth position (200+ additional retweets, 3.5k+ total).@SecWilkie's post promoting the #SuicidePrevention conference was the seventh top tweet (110+ retweets), and @DeptVetAffairs' 25 Aug. post moved to ninth position (70+ additional retweets, 250+ total).@Cocoa_Bean10 referenced Suicide in her post saying, "We run outta time waiting for @DeptVetAffairs to fix the VA system" (60+ retweets).

Twitter and Facebook Volume: 12 August – 26 August



Notable Social Media Items

Platform	Item	Relevance
Twitter	Topic: Mar-a-Lago	26% of Volume
Twitter	Topic: Suicide	18% of Volume
Facebook	VAantage Point: Recognizing the first female four-star general on Women's Equality Day	850+ Reactions, 910+ Shares, 120+ Comments

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The Daily Signal: VA Lifts Ban on Bibles in Move to Support Religious Freedom (26 August, Fred Lucas, 1.1M uvm; Washington, DC)As a kid, Veterans Affairs Secretary Robert Wilkie recalls, he visited a VA hospital at Christmastime. "One of my fondest memories growing up, we used to sing Christmas carols at the VA hospital in Fayetteville, North Carolina," Wilkie told The Daily Signal, sitting in a 10th-floor office at VA headquarters on Vermont Avenue Northwest, overlooking the White House. Hyperlink to Above WCPO (ABC-9, Video): Despite ban, Cincinnati VA Medical Center continues to support transgender troops (27 August, Craig McKee, 680k uvm; Cincinnati, OH)Lesbian, gay, bisexual and transgender people have served in the United States military for as long as there's been one. Edicts from the White House — like the bygone "Don't Ask, Don't Tell" and President Donald Trump's current ban on transgender troops — can't change that. And they don't change the responsibility of the United States Department of Veterans Affairs, according to Cincinnati VA psychologist Connie Boehner. Hyperlink to Above Idaho Statesman: Letters to the editor (26 August, Richard L. Barrett, 392k uvm; Boise, ID)VA THANKS. Kudos to Boise VA Medical Center Director's superb staff and many thanks to Secretary of Veterans Affairs Director Robert Wilkie for giving those folks the recognition they so richly deserve. Hyperlink to Above Nextgov: Veterans Affairs Launches Digital National Cemetery (26 August, Brandi Vincent, 339k uvm; Washington, DC)The Veterans Affairs Department's National Cemetery Administration developed and launched an online memorial platform—Veterans Legacy Memorial—to honor millions of veterans interred in national cemeteries across America. Deemed a "digital national cemetery," the new resource leverages technology and prioritizes security to boost community engagement and preserve the memories of those who served. Hyperlink to Above Federal Computer Week: Congratulations to the 2019 Rising Stars (26 August, Troy K. Schneider, 46k uvm; Vienna, VA)Each year, the Rising Star Awards recognize individuals who are early in their federal IT careers yet already are having an outsized impact. The women and men listed below have been selected both for their accomplishments over the past year and for their leadership potential in this community. Hyperlink to Above

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VA Secretary's Stand-Up Brief23 August 2019

Executive SummaryNational coverage remained strong yesterday with outlets covering several impactful storylines. Reporting increased on the President's directive concerning Spravato. Coverage of the President's executive action on Disabled Veterans' loans and the arrest of Dr. Levy declined, yet remained highly visible.

Storyline	Outlets	Analysis	Trend	Priority
Pres. Trump directed VA to purchase Spravato	*FOX News*, *MSNBC*, *WLEX (NBC)*, *Post and Courier*	In an interview with *FOX News,* Sec. Wilkie touched on multiple topics, including how Spravato will be administered at VA. In another interview covering several VA topics on *MSNBC,* Paul Rieckhoff spoke against what he characterized as the President promoting Spravto as a "crazy magic pill" to cure PTSD. While *WLEX* labelled it a "controversial drug," *Post and Courier* published a supportive and more detailed analysis of the President's decision.	**Sustained**	Suicide, Service
OIG: Suicide at West Palm Beach VA	*Military Times*, *Stars and Stripes*, *Connecting Vets*, *Palm Beach Post*	Military-oriented and local Palm Beach outlets reported heavily on OIG findings that hospital "leadership failures" led to a Suicide at the West Palm Beach VA.	**Emerged**	Suicide
CREW released Mar-a-Lago emails	*Politico*, *Rolling Stone*	Traditional outlets began covering the Mar-a-Lago emails published this week by CREW. *Politico* and *Rolling Stone* wrote from a similar perspective, forwarding that VA employees walked a "tightrope" in their dealings with the Mar-a-Lago members.	**Emerged**	Service

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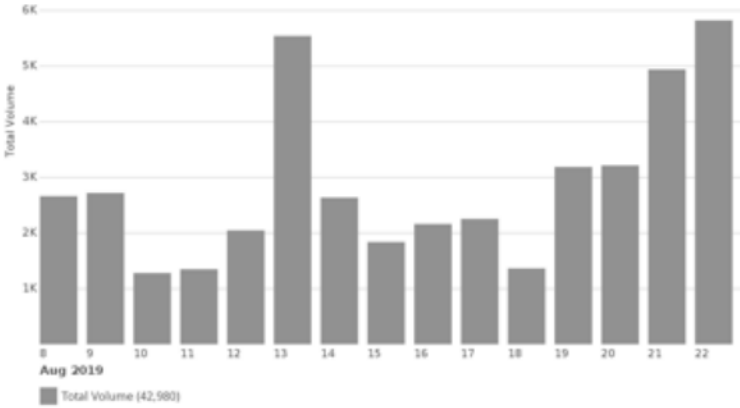
VA Secretary's Stand-Up Brief23 August 2019

Social Media TakeawayThe increase in volume yesterday came from user engagement with @JuddLegum's post on Spravato.

Key PointsPopular Information writer @JuddLegum authored a particularly popular post stating that "unproven and potentially dangerous" Spravato costs up to $885 per dose, and that, "The decision will benefit one of Trump's biggest donors" (3k+ retweets). The top post linked to the related article by Mr. Legum. In the fifth post, CNN's @abbydphillip linked to a related Politico summary (160+ retweets).In second position, @WhiteHouse promoted the Accountability and Whistleblower Act, saying it led to the firing of, "thousands of failing employees and instituted reforms to increase efficiency and decrease abuse" (630+ retweets). The post also linked to a White House release listing accomplishments made by the President concerning VA.White House @PressSec Stephanie Grisham's 21 Aug. post on Pres. Trump at @AMVETSHQ's 75th Nat'l Convention dropped from first to third position (400+ additional retweets, 2.1k+ total).The fourth post, by @CREWcrew, promoted yesterday's Rolling Stone article on the new Mar-a-Lago emails (300+ retweets). @CREWcrew highlighted one of the email exchanges in the sixth post (100+ retweets). The ninth post, by @weareoversight, linked to CREW's 20 Aug. report showing the emails (90+ retweets).@SecWilkie's

Twitter and Facebook Volume: 8 August – 22 August



Notable Social Media Items

Platform	Item	Relevance
Twitter	Topic: Pres. Trump	58% of Volume
Twitter	@JuddLegum	24% of Volume
Twitter	Topic: Mar-a-Lago	15% of Volume
Facebook	FOX News: Trump signs executive order cancelling student loan debt for disabled veterans	1.4k+ Reactions, 280+ Shares, 590+ Comments

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CBS News (Video): Wounded veterans find solace in wheelchair rugby: "It becomes the brotherhood" (22 August, Chip Reid, 30.2M uvm; New York, NY)In our series, A More Perfect Union, we aim to show that what unites us as Americans is far greater than what divides us. In this installment, CBS News national correspondent Chip Reid introduces us to the National Veterans Wheelchair Games in Louisville, Kentucky, where sports like wheelchair rugby are helping wounded warriors heal. Hyperlink to AboveThe Fayetteville Observer: "Stand Down" event at Festival Parks hooks homeless veterans up with services (22 August, John Henderson, 194k uvm; Fayetteville, NC)As a homeless veteran who has been living in his truck, Alfonso Jackson said he really appreciated Thursday's "Community Homeless Stand Down" event at Festival Park. "I think it's great," he said. The event was designed to link homeless people to agencies and services that can help them get assistance. Hyperlink to AboveWYOU (CBS-22, Video): Smoke-free initiative at the VA (22 August, Mark Hiller, 117k uvm; Wilkes Barre, PA)Smoking in the military dates back a century ago to World War I. But now the veteran population is bracing for a major no-smoking initiative. Eyewitness News Reporter Mark Hiller explains how a new national policy will impact men and women who've served. Hyperlink to AboveChico Enterprise-Record: Ceremony marks new Chico Veteran's Affairs clinic (22 August, Laura Urseny, 56k uvm; Chico, CA)Better health services for veterans and their families was the underlying theme for several speakers during Wednesday's opening ceremony for the Chico Veterans Affairs Outpatient Clinic at 1601 Concord Ave. The $30 million clinic will actually open to patients on Tuesday. Until then, services are still available at the current VA facilities at 280 Cohasset Road. Hyperlink to Above KAAL (ABC-6, Video): New VA clinic now open in Rochester (22 August, 19k uvm; Austin, MN)Community leaders and veterans gathered with health care professionals Thursday to celebrate the grand opening of the new Rochester VA Clinic dedication. The clinic moved from its previous location in Northwest Rochester to 3551 Commercial Drive South West. Hyperlink to Above

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VA Secretary's Stand-Up Brief22 August 2019

Executive SummaryCoverage surged yesterday with nearly all Tier 1 outlets covering President Trump's executive action on Disabled Veterans' loans as well as the arrest of Dr. Levy. Several other major storylines emerged, including on the smoking ban, Spravato, and emails by fmr. Sec. Shulkin.

Storyline	Outlets	Analysis	Trend	Priority
Pres. Trump signs executive action on loan forgiveness	*NYT*, *FOX News*, *NBC News*, *CNN*, *Washington Post*, *AP*	These articles represent a sample of Tier 1 coverage of the executive action that will reportedly make automatic student loan cancellation for permanently Disabled Veterans. *NYT, Washington Post, FOX News* and *NBC News* focused on supportive messaging concerning the action, usually mentioning the roles of VA and DoEd. *CNN* added commentary on Choice and Accountability. *AP* wrote more broadly about VA, mentioning Suicide and Spravato.	**Emerged**	Interests
Fmr. VA doctor charged with deaths of three Veterans	*CNN*, *FOX News*, *Ark. Democrat-Gazette*, *CBS News 1*, *2*	While the tone and details of the arrest remained generally steady, the visibility of this storyline further increased *(CNN, FOX News,* and others). *Arkansas Democrat-Gazette* provided the most comprehensive reporting. *CBS 1* was similar to other reporting, while *CBS 2* highlighted the experience of a widow whose husband's case had been reviewed by Dr. Levy.	**Sustained**	Service
Smoking ban will also apply to VA employees	*Military.com*, *Stars and Stripes*, *Government Executive*, *Military Times*, *Connecting Vets*	Many military-oriented publications wrote on this storyline. Some outlets relayed the VA announcement that the smoking ban will also apply to VA employees (*Military.com, Military Times, Connecting Vets),* while others focused on the AFGE filing a grievance on the matter (*Government Executive*, *Stars and Stripes*).	**Emerged**	Service
VA sued over fmr. Sec. Shulkin emails	*Stars and Stripes*, *Connecting Vets*	These articles reported that an activist organization, Democracy Forward, filed a lawsuit against VA, alleging that the Department "failed to preserve private emails" written by fmr. Sec. Shulkin to Mar-a-Lago members.	**Emerged**	Service
Pres. Trump directed VA to purchase Spravato	*Military Times*, *Stars and Stripes*, *McClatchy*	These outlets relayed Pres. Trump's support for Spravato, saying he directed VA officials to purchase large quantities of the drug. Coverage incorporated some questioning or criticism of the decision.	**Emerged**	Service

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VA-19-1109-B-002647

VA Secretary's Stand-Up Brief22 August 2019

Social Media TakeawaySocial media volume increased yesterday as users engaged with posts on recent comments made by the President and the Mar-a-Lago emails.

Key PointsIn the top post, White House @PressSec Stephanie Grisham quoted Pres. Trump at @AMVETSHQ's 75th Nat'l Convention, "After years of neglect, we are fixing the heartbreaking failures from the last Administration at the [VA]" (1.7k+ retweets).In response to the Military Times story of Pres. Trump encouraging VA to use Spravato to combat Suicide, @PaulRieckhoff wrote in the second post that the President is, "pushing unproven, corporate-sponsored magic pills for veterans suicide" (410+ retweets). In the eighth post, @RedTRaccoon indicated that Johnson & Johnson would benefit financially as a result of the President "pushing" a treatment "that may not work" on Veterans (160+ retweets). @kenvogel noted in the tenth post that a founder of Johnson & Johnson, "donated $1M to Trump's inaugural, & was tapped to be @USAmbUK." (150+ retweets).The third and sixth posts, by @DefenseBaron and CNN's @ddale8, criticized the President for supposedly saying Veterans struggling with the VA health system is "fake news" (350+ and 190+ retweets, respectively).In the fourth tweet, @votevets criticized Pres. Trump over Mar-a-Lago (200+ retweets). In the fifth post @CREWcrew said, "Despite misgivings, career VA employees were obligated to waste taxpayer time and resources," communicating with Mar-a-Lago members (200+ retweets). The ninth post said the emails @CREWcrew obtained show, "just how bad it was" (150+ retweets).@SenKamalaHarris' post saying the impact of the President's immigration policies on Veterans is "cruel and reprehensible" moved from fifth to seventh position (170+ additional retweets, 370+ total).

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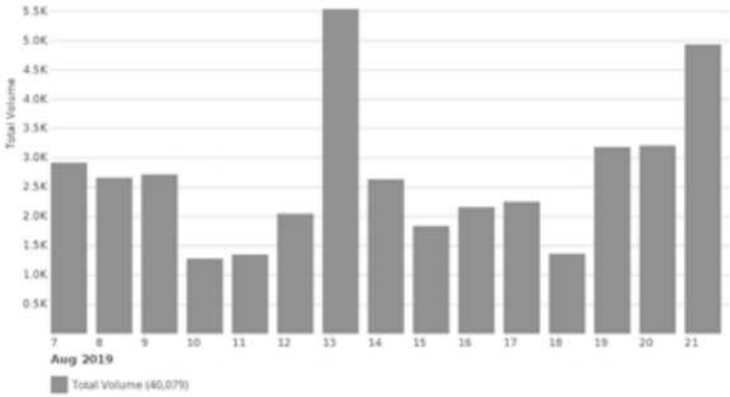
Twitter and Facebook Volume: 7 August – 21 August



Notable Social Media Items

Platform	Item	Relevance
Twitter	Topic: Pres. Trump	55% of Volume
Twitter	Topic: Mar-a-Lago	13% of Volume
Facebook	VAntage Point: LifeWaters provides adaptive scuba programs to disabled Veterans	250+ Reactions, 110+ Shares

VA Secretary's Stand-Up Brief22 August 2019

KFOX (FOX-14): El Paso VA Healthcare System to break ground on new facility for veterans (21 August, Mia Villanueva, 285k uvm; El Paso, TX)El Paso's VA Healthcare System is breaking ground on a new facility to support the growing number of veterans in the community. The new facility will be located in northwest El Paso, and will cover almost 15,000 square feet. Officials say the new facility will help veterans gain greater access to health care. Hyperlink to AboveWLUC (NBC-6, Video): Adaptive bike clinic in Kingsford helps veterans to ride again (21 August, Alyssa Jawor, 170k uvm; Negaunee, MI)The Oscar G. Johnson VA Medical Center partnered with the UP Superior Alliance for Independent Living (SAIL) to hold an adaptive bike clinic for Veterans Wednesday. Feeling the wind through their hair was just one of the many joys veterans experienced, thanks to the bikes. Hyperlink to AboveWYOU (CBS-22, Video): Turning the tide against veteran opioid abuse (21 August, Mark Hiller, 117k uvm; Wilkes Barre, PA)A disturbing development in the ongoing opioid crisis is the number of U.S. military veterans at risk for overdose. Like other segments of the population, the emphasis is to get more veterans off addictive medication and in favor of other treatments. Eyewitness News Healthbeat Reporter Mark Hiller explains how. Hyperlink to AboveInsideSources: Protecting Those Who Protected Us (21 August, Sec. Robert Wilkie, 48k uvm; Washington, DC)Cpl. Orlando Camacho, Lt. Kenneth Frazier and officer Miguel Calderon didn't know they would save lives when they woke up August 12 and reported to the Jesse Brown VA Medical Center in Chicago. The three members of the Veterans Affairs Police were on duty when shots were fired just outside VA's doors. As alarms blared and people flooded 911 with calls, Camacho, Frazier and Calderon waded past panicked people toward a man with a rifle in his hand who entered the building. Hyperlink to AboveKJCT (ABC-8, Video): Veterans Affairs committee meet to improve patient experience (21 August, Nikki Sheaks, 38k uvm; Grand Junction, CO)The Grand Junction Veterans Affairs hosted the VA national committee this week. VA leaders from across the country discussed how to improve patient experience. Their goal is to make care at VA centers nationwide easy, effective and they hope workers will make an emotional connection with their patients. Hyperlink to Above

AMERICAN OVERSIGHT

VA Secretary's Stand-Up Brief26 June 2019

Executive SummaryNational outlets shifted their attention to the testimony of whistleblowers at the HVAC hearing, which was the most prominent story of the period, as coverage of Beto O'Rourke's plan and the 75th anniversary of the GI Bill declined sharply.

Storyline	Outlets	Analysis	Trend	Priority
Whistleblowers testify at HVAC hearing	*USA Today*, *ABC News*, *Connecting Vets 1*, *2*, *Military Times*, *Washington Times*, *The Blaze*, *C-SPAN*, *Government Executive*	Major national outlets reported on the HVAC Whistleblower hearing on VA retaliation against Whistleblowers. *USA Today* included messaging from Randall Noller saying Asst. Sec. Tamara Bonzanto, has been "working on a number of key improvements." Most coverage, such as by *ABC News*, noted that Dr. Minu Aghevli received a "notice of proposed removal" the day before the hearing, suggesting retaliation for her coming-testimony. Some articles characterized the problem as "rampant" (*Government Executive, Connecting Vets 2*), and outlined details of the testimony given. *Connecting Vets 1* included Rep. Jack Bergman's (R-Mich.) statement that he doubts the notice of termination was connected to Dr. Aghevli's decision to testify because, "VA doesn't work that fast." *Connecting Vets 2* contrasted Sec. Wilkie's reported frustration that the Department was not included in the Whistleblower hearing with his alleged refusal to attend the last congressional oversight hearing.	**Emerged**	Interests
Investigation of DC VAMC	*WRC (NBC)*	*WRC* broadcast a highly critical nineteen-minute video featuring interviews with Veterans and employees reporting ongoing maintenance problems, supply shortages, postponed procedures, problems with sterilizing equipment, and lack of parking at the DC VAMC. The video included a brief clip of WRC's interview of Sec. Wilkie saying the facility has improved.	**Sustained**	Service
Pres. Trump's Mission Act phone call	*Military.com*	In the only observed coverage on the topic, *Military.com* reported that President Trump touted the Mission Act, Spravato, and Sec. Wilkie's work on a phone call with over 10k+ Veterans. The article reported that VA had to "open another line" due to the high volume of participants. Reporting emphasized that VA officials, "abruptly declared the conversation off the record and asked members of the press to leave" at the start of the call.	**Sustained**	Inter-operability
75th anniversary of the GI Bill	*Arizona Daily Star 1*, *2*, *3*	*Arizona Daily News* published dozens of supportive letters on how the GI Bill has affected individual Veterans' lives.	**Sustained**	Interests

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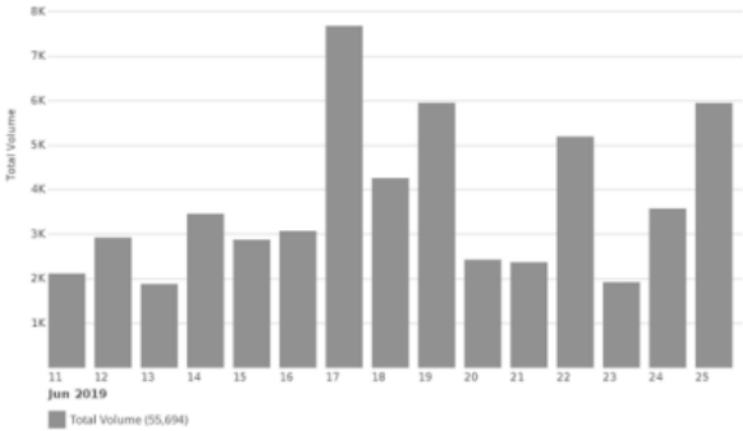
VA-19-1109-B-002650

VA Secretary's Stand-Up Brief26 June 2019

Social Media TakeawayActivity related to the HVAC hearing on Whistleblowers trended heavily on Twitter largely due to a single tweet. Facebook users engaged with a pair of posts on the #KoreanWar.

Key PointsThe top tweet, by MSNBC's @kylegriffin1, said a VA employee received a termination letter one day before she was scheduled to testify at the Whistleblower hearing (4.8k+ retweets). @RedTRaccoon (200+ retweets), @WomanRises (170+ retweets), and @ABC (120+ retweets) posted similar tweets. Each post linked to the ABC News story.OANN journalist @Liz_Wheeler's post against "free" healthcare, using in part the example of Veterans dying while waiting for VA care, sustained as the second top post (290+ additional retweets, 870+ total).YouTuber @jackieaina's post listing various benefits Veterans receive, including VA loans, to argue Veterans do not need a #pride month moved from first to third position (250+ additional retweets, 1.4k+ total).@RedTRaccoon wrote a pair of posts on Spravato, saying Pres. Trump is "pushing Special K on veterans" and wants to negotiate the purchase of the drug himself. The first post (240+ retweets) embedded the 12 June Bloomberg story, and the second post (200+ retweets) embedded the 18 June Guardian article.@BetoORourke's 24 June post touting his new four-part plan "to help veterans" moved from third to tenth position (120+ additional retweets, 500+ total). Another tweet by @BetoORourke promoting a round table held with "local veterans, medical professionals and advocates" garnered 250+ retweets.

Twitter and Facebook Volume: 11 June – 25 June



Notable Social Media Items

Platform	Item	Relevance
Twitter	Topic: Whistleblowers	52% of Volume
Twitter	@kylegriffin1	38% of Volume
Facebook	Remembering the Korean War on the 69th anniversary... invasion of South Korea	1.5k+ Reactions, 950+ Shares, 100+ Comments
Facebook	69-year anniversary of the #KoreanWar	1.2k+ Reactions, 1k+ Shares, 100+ Comments

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VA-19-1109-B-002651

VA Secretary's Stand-Up Brief26 June 2019

Arizona Daily Star: Success may not have happened without GI Bill (25 June, Jerry Petersen, 365k uvm; Tucson, AZ) I entered the Army immediately after high school in 1969, served in Vietnam from 1970-71, and was honorably discharged upon returning to the states. Almost immediately I started post-secondary education at a local community college under the GI bill. Hyperlink to Above WZTV (FOX-17): Country star Trace Adkins surprises veterans at VA Hospital (25 June, Kaylin Jorge, 135k uvm; Nashville, TN)Country star Trace Adkins surprised patients at a VA hospital in West Virginia over the weekend. Veterans at the Martinsburg VA Medical Center got to meet Adkins and take photos, a local news station reported. "I just love rubbing shoulders with heroes," Adkins tweeted. Hyperlink to Above WDTN (ABC-2, Video): 100-year-old Dayton DAV member honored by VA Medical Center (25 June, 78k uvm; Moraine, OH)The oldest member of the Disabled American Veterans (DAV) in Dayton was honored Tuesday. Edgar Moorman, 100, and a World War II veteran who was drafted in 1941, was honored by the Dayton VA Medical Center with a plaque and ceremony. Hyperlink to Above WMAZ (CBS-13, Video): Dublin VA honors 7 Korean War veterans (25 June, Sabrina Burse, 70k uvm; Macon, GA)Dublin paid a special tribute to veterans of the Korean War Tuesday. The Carl Vinson VA Medical Center honored seven veterans for their service from "the Forgotten War" more than 60 years ago. Sabrina Burse went to the ceremony and spoke with one prisoner of war to learn his story. Hyperlink to Above WGXA (ABC-24, Video): Korean War veterans honored with Ambassador of Peace Medal in Dublin (26 June, Claire Helm, 37k uvm; Macon, GA)Seven Korean War veterans were honored at the Carl Vinson VA Medical Center in Dublin Tuesday. The ceremony recognized residents of the VA's Community Living Center. Each veteran who served in the Korean War were honored with the Ambassador of Peace Medal, nearly 70 years later. Hyperlink to Above Muskogee Phoenix: Couple marries at hospital to include father (25 June, Kenton Brooks, 12k uvm; Muskogee, OK)All Cynthia Strader knew is that she wanted her father to be at her wedding. But when Charles Strader was diagnosed as terminal with Plasma Cell Leukemia, Cynthia and her husband-to-be Daniel Holder left their home in Clemson, S.C. and came to Muskogee to exchange their vows in her father's room at the Jack C. Montgomery VA Medical Center. Hyperlink to Above

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VA Secretary's Stand-Up Brief24 June 2019

Executive SummaryAlthough volume was only slightly above average during the weekend, Friday saw an unusually large number of impactful storylines. GI Bill stories saw high visibility in large and small outlets. A Saturday USA Today article on whistleblowers was broadly reprinted nationwide.

Storyline	Outlets	Analysis	Trend	Priority
Pres. Trump to hold Mission Act phone call	*Stars and Stripes*	*Stars and Stripes* was the only observed outlet to preview the President's call scheduled for Tuesday during which he will reportedly address 10k Veterans on the Mission Act and recently accomplished milestones.	**Emerged**	Inter-operability
75th anniversary of the GI Bill	*Today, Saturday Evening Post, Arizona Republic, Capital Journal, Military Times*	Stories on the GI Bill anniversary often mentioned, as in the video by *Today,* that the benefits did not apply equally to all Veterans following WWII. *Saturday Evening Post* further detailed the multigenerational benefits for those who received GI Bill funds. *Arizona Republic* provided a history of the bill, focusing on the role of fmr. AZ Sen. Ernest McFarland. *Topeka Capital-Journal* covered Kansas-based calls for honoring the role of Harry Colmery. *Military Times* printed an opinion by a IAVA manager on improvements that could be made to the Post 9/11 GI Bill.	**Sustained**	Interests
Medical Advisory Panel decision on Spravato	*Center for Public integrity, STAT, NYT 1, 2*	*The Center for Public Integrity* and *STAT* reported on the Medical Advisory Panel's vote to not include Spravato as a drug that would be available through prescription at VA pharmacies. *The New York Times (1)* centered around cost as being an impediment to prescribing the medication. *(2)* listed the drug's approval by VA for severe depression as one of the top 10 stories of the week.	**Emerged**	Service / Suicide
Upgrading adaptive housing grant	*Military Times, Connecting Vets*	These specialized outlets provided greater visibility on the lobbying effort by Veteran Ryan Kules and the Wounded Warrior Project to upgrade the Specially Adaptive Housing Grant by over 15%, and allow disabled Veterans to renew the payout every 10 years.	**Emerged**	Interests
GAO report on role of VA regional offices	*Government Executive*	According to this article, GAO auditors found that VA has never clearly defined the role of regional entities, and that the Department relies primarily on annual performance assessments from regional directors.	**Emerged**	Service

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VA-19-1109-B-002653

VA Secretary's Stand-Up Brief24 June 2019

Social Media TakeawayTwitter volume spiked on Saturday due to another tweet from @charliekirk11 on VA care and illegal immigrants.

Key PointsIn the top post, @charliekirk11 wrote that, "Bernie Sanders' healthcare plan would give coverage to '11-22 million illegal aliens'" and to retweet if no illegal aliens should receive care while Veterans are "waiting in line at the VA" (8.5k+ retweets). Veteran @TracyMFinch tagged #veteransfirst in the second post and stated she has waited since 2015 for @DeptVetAffairs, "to make decision on my case," while Democrat leaders are giving away billions to #illegalimmigrants (710+ retweets).The third post, by @RDVarley, stated that reparations were already paid to slaves through the grave stones at the Chattanooga National Cemetery, representing some of the 360k Union soldiers, "who gave their lives for freedom" (230+ retweets). @tariqnasheed's 20 June post on white descendants of Civil War veterans still receiving VA pensions dropped from first to fourth position (190+ additional retweets, 470+ total).In the fifth post, @PublicI (The Center for Public Integrity) promoted its 21 June article on the VA panel voting to not include Spravato in the list of drugs available through prescription at VA pharmacies (120+ retweets).@ShelbyKStewart connected Mar-a-Lago to the 22 June USA Today article on whistleblowers (100+ retweets). This was the sixth top post, and the only

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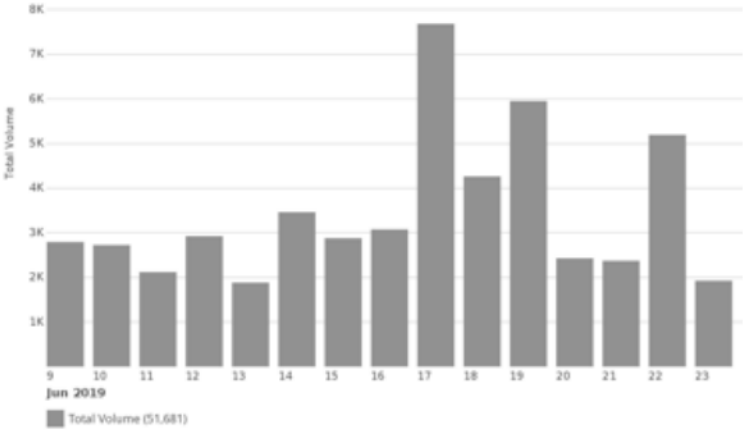
Twitter and Facebook Volume: 9 June – 23 June



Notable Social Media Items

Platform	Item	Relevance
Twitter	@charliekirk11	41% of Volume
Twitter	#veteransfirst	5% of Volume
Facebook	VAntage Point: VA releases Request for Information, seeks strategies for ways to end Veteran suicide	970+ Reactions, 660+ Shares, 390+ Comments

VA Secretary's Stand-Up Brief24 June 2019

Las Vegas Review-Journal: CEO sees new opportunities for North Las Vegas VA hospital (22 June, Briana Erickson, 662k uvm; Las Vegas, NV)For the new director and CEO of the VA Southern Nevada Healthcare System, a sense of duty and service goes back generations. William "Bill" Caron, who just finished his second week at the helm of the North Las Vegas VA facility, is an Air Force veteran who began his medical career as a physical therapist at Barksdale Air Force Base in Louisiana. Hyperlink to AboveWKRC (CBS-12, Video): Cincinnati VA Hospital looks to sign LGBTQ vets up for benefits during Pride Parade (23 June, Christian Hauser, 130k uvm; Cincinnati, OH)Thousands of people lined up to be part of the Cincinnati Pride Parade on Saturday. Thousands more lined the parade route to show their support and love for everyone in the parade. Many of Cincinnati's companies were represented with floats or groups of people. One of those was a group from the Cincinnati VA Hospital. Hyperlink to AboveWDVM (TV-25): Country singer Trace Adkins surprises patients at Martinsburg VA medical center (22 June, Thao Ta, 48k uvm; Hagerstown, MD)Veterans at the Martinsburg VA Medical Center had a surprise visit from country music star, Trace Adkins. Adkins showed up Saturday morning and greeted smiling veterans and staff; snapping photos along the way. Adkins is known for his patriotic songs and non-profit work with veterans organizations across the country, such as his role as a volunteer in the Wounded Warrior Project. This is Adkins' second appearance at the Martinsburg VA. Hyperlink to AboveWest Virginia Public Broadcasting (Audio): Q&A: VA Secretary on Veterans Affairs Mission Act (21 June, 32k uvm; Charleston, WV)On this West Virginia Morning, the 2019 Veterans Affairs Mission Act went into effect earlier this month. It makes emergency and specialized care available to more U.S. veterans. The act promises to provide less red tape and greater satisfaction and predictability for veterans. The legislation passed through Congress easily with broad bipartisan support and President Trump signed it into law. Hyperlink to AboveWTOV (NBC-9, Video): Wheeling Vets Center lauded for the support its given (21 June, Gage Goulding, 29k uvm; Mingo Junction, OH)Forty years ago today, Congress passed public law 9622, establishing vet centers within the Department of Veteran Affairs. Today in Wheeling, the Vet Center serves thousands of area veterans. "We're celebrating our 30th year being here in Wheeling. About 4,000 veterans have been served, veterans and their families," said John Looney, team leader Wheeling Vet Center. Hyperlink to Above

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Veterans Affairs Media Summary and News Clips

24 June 2019

1. Top Stories

1.1 - Today (Video): **The GI Bill turns 75: Are all veterans being helped equally?** (23 June, 4.3M uvm; New York, NY)
Four-minute video: There have been countless success stories since President Franklin D. Roosevelt signed the GI Bill in 1944, but some say the financial aid hasn't helped everyone equally. NBC's Rehema Ellis shares stories of three veterans in this week's Sunday Spotlight.

Hyperlink to Above

2. Improving Customer Service

2.1 - The New York Times: **Iran, 2020, World Cup: Your Weekend Briefing** (23 June, Remy Tumin and Lance Booth, 44.2M uvm; New York, NY)
Back on Earth, there were two drug advances this week. Spravato, a nasal spray derived from ketamine, was approved by the Department of Veterans Affairs for severe depression, and Vyleesi became the second drug approved to treat low libido in women.

Hyperlink to Above

2.2 - U.S. News & World Report (Wisconsin Watch, AP): **In Wisconsin, Cannabis and CBD Users Close as Main Street** (23 June, Olivia Herken, 12.3M uvm; Washington, DC)
In a tiny room inside a hair salon in Viroqua, Wisconsin, two women gaze over a glass case. They have driven 30-some miles down the Mississippi River from La Crosse just to check out Kickapoo Kind, a shop established last summer in the heart of the state's politically liberal Driftless region.

Hyperlink to Above

2.3 - Epoch Times: **6 GOP Senators Want to Make Firing Bad Bureaucrats Easier** (23 June, Mark Tapscott, 2.1M uvm; New York, NY)
Firing underperforming career civil servants should take no more than a year, according to six Republican senators who introduced legislation to make that time limit a reality. "Government employees should be held to the same standards as private sector employees, yet it is nearly impossible to fire bureaucrats for failing to do their jobs," said Sen. David Perdue (R-Ga.) in a June 19 statement.

Hyperlink to Above

2.4 - Hot Air: **Democrats At 24 For 2020 Presidential Election** (23 June, Taylor Millard, 578k uvm; New York, NY)
His key plank? Health care and his desire for a government-run system. Sestak is open and honest about his desire for a VA-style health system for the country.

Hyperlink to Above

2.5 - The Spokesman-Review: **A week of tragedies tested Fairchild Air Force Base and Spokane 25 years ago** (23 June, Jim Camden, 438k uvm; Spokane, WA)

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Knight transferred from Fairchild, was later stationed at Buckley Air Force Base in Colorado, and eventually retired from the Air Force. He left the ministry and went to work for the Veterans Administration, where he now works as a paralegal.

Hyperlink to Above

2.6 - Portland Press Herald: **Letter to the editor: Maine veteran thanks Togus for skilled, attentive care** (23 June, Patrick Eisenhart, 349k uvm; Portland, ME)
As a disabled retired veteran, I would like to thank and recognize the outstanding medical treatment I receive at the Togus VA Hospital. From janitor to surgeon, everyone there demonstrates genuine care for us from ensuring the facility is clean to providing top-notch surgical procedures.

Hyperlink to Above

2.7 - Times-News: **Twin Falls physician receives award** (23 June, Julie A. Ferraro, 46k uvm; Twin Falls, ID)
Dr. Brian Fortuin of Twin Falls is one of two recipients of the 2019 Richard M. Tucker WWAMI Faculty Excellence in Teaching Award. He is affiliated with St. Luke's Magic Valley Medical Center and board certified in internal medicine and sleep medicine. The other award recipient is Dr. Andrea Christopher of Boise. She is the clerkship site director and general internal medicine physician at the Boise Veterans Affairs Medical Center.

Hyperlink to Above

2.8 - The St. Augustine Record: **A new leash on life: Congressman John Rutherford pushes for more service dogs for veterans** (23 June, Colleen Jones, 43k uvm; Saint Augustine, FL)
Jerome Jaques took one look at the service dog he'd been matched with and thought there must be some mistake. "Here's this giant dog — he's 90 pounds — with big, floppy ears like Goofy, and I'm thinking to myself, 'No way,'" Jaques said, laughing at the memory.

Hyperlink to Above

3. Business Transformation

4. DOD Cooperation / Electronic Health Records / MISSION Act Implementation

4.1 - Providence Journal: **Veterans Journal: VA launches expanded privatization program that may affect veterans' care** (23 June, George W. Reilly, 265k uvm; Providence, RI)
Last week's column reviewed the new Mission Act in which eligible veterans can use VA health-care services nationwide, including through mobile health clinics that serve rural areas and via telehealth care through a phone or computer. To receive care from the VA or a community provider, an eligible veteran must be enrolled in VA health care for which you can apply online, by mail, or in person

Hyperlink to Above

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4.2 - Daily News Journal (Video): Sen. Blackburn: Give veterans more local health care choices for VA benefits (23 June, Scott Broden, 25k uvm; Murfreesboro, TN)
The VA Mission Act should help rural health care providers serve veterans in their communities, Republican U.S. Sen. Marsha Blackburn said Friday. "This is a great opportunity for our veterans," Blackburn said during an interview at The Daily News Journal office in Murfreesboro.

Hyperlink to Above

5. Suicide Prevention

5.1 - WDTV (CBS-5, Video): Sen. Manchin introduces a bill for a veteran 3 digit crisis hotline similar to 911 (23 June, 32k uvm; Bridgeport, WV)
Senator Joe Manchin is introducing a bill that would create a 3-digit phone number similar to 9-1-1 for veterans in crisis. According to the Senator the VA crisis line's current phone number is 11 digits long and the caller has to listen to a menu and press an additional button to talk to someone.

Hyperlink to Above

5.2 - Bluefield Daily Telegraph: WWII Medal of Honor recipient speaks of community at Marine Corp. conference (23 June, Emily D. Coppola, 23k uvm; Bluefield, WV)
United States Marines gathered to fellowship and listen to the keynote speaker, World War II Medal of Honor recipient, Hershel “Woody” Williams, at the 2019 Marine Corps League Mideast Division Conference on Saturday.

Hyperlink to Above

5.3 - Mid Hudson News: Public health summit addresses “Moving Forward Together” (23 June, Middletown, NY)
Dozens of community leaders both in and out of the medical profession have joined forces by participating in the county’s ninth annual Putnam Health Summit. Organized by the Putnam Health Department and Putnam Hospital Center, the event stimulated discussion regarding “moving forward together” in an effort to prevent chronic and communicable disease as well as mental and substance abuse disorders while promoting well being and a healthy and safe environment.

Hyperlink to Above

6. Women Veterans / Homelessness / Benefits / Cemeteries

6.1 - WFXT (FOX-25, Video): Trace Adkins makes surprise visit to VA medical center, wishes veteran a happy 106th birthday (23 June, Michelle Ewing, 409k uvm; Dedham, MA)
A group of veterans got a special surprise Saturday when country music icon Trace Adkins stopped by a VA Medical Center in West Virginia. According to WDVM-TV, Adkins visited the Martinsburg VA Medical Center, where he spoke with veterans and even wished one a happy 106th birthday.

Hyperlink to Above

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6.2 - Macomb Daily: **Motorcycle ride raises funds for military veterans** (23 June, 41k uvm; Clinton Township, MI)
Hundreds of motorcycle enthusiasts hit the road in northern Macomb County on Sunday to raise money for a pair of facilities that service military veterans. The 17th annual Patrick Wisniewski Memorial Ride for Freedom departed the Wolverine Harley-Davidson dealership on North Gratiot Avenue in Clinton Township for a 60-mile ride. Organizers say the fundraiser has become one of Wolverine's key public service efforts.

Hyperlink to Above

6.3 - Salisbury Post: **Letter: Cemetery is the best place for 'Fame'** (23 June, Pete Prunkl, 25k uvm; Salisbury, NC)
When "Fame" was erected in 1905, it could have joined the 1875 Civil War monument honoring the unknown soldiers at the Historic Salisbury National Cemetery. Instead, it was sited in the median of our busiest street. At the time, city officials wanted a more prominent place to honor Confederate war dead than Union dead. In 1908 and 1910, the states of Maine and Pennsylvania erected memorials to their Civil War dead in the Historic Salisbury National Cemetery. That is where "Fame" belonged and belongs now.

Hyperlink to Above

7. Other

7.1 - Washington Examiner: **SEAL who killed bin Laden mocks 2020 Democrat for caring about 'immigrant families' instead of 'homeless veterans'** (23 June, Ellie Bufkin, 3.9M uvm; Washington, DC)
The former Navy SEAL who killed Osama bin Laden in 2011 criticized Rep. Eric Swalwell, D-Calif., for a Saturday tweet that expressed support for immigrant families separated at the border. Swalwell tweeted Saturday, "To Immigrant families: We see you, we are here for you and we will not stop fighting for you. Families belong together. Period." Former SEAL Robert J. O'Neill responded by correcting Swalwell, "You spelled 'Homeless Veterans' wrong."

Hyperlink to Above

7.2 - Florida Politics: **With help of a zombie campaign, Jeff Miller works harder than ever** (23 June, Noah Pransky, 73k uvm; Saint Petersburg, FL)
Former Congressman Jeff Miller is working harder than ever, talking regularly to the Donald Trump administration about Department of Veterans Affairs (VA) reform. However, he's no longer doing it on behalf of the constituents of Florida's 1st Congressional District; he's doing it now on behalf of his new lobbying clients, who stand to make billions of dollars through the privatization of veterans' care.

Hyperlink to Above

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1. Top Stories

1.1 - Today (Video): **The GI Bill turns 75: Are all veterans being helped equally?** (23 June, 4.3M uvm; New York, NY)

Four-minute video: There have been countless success stories since President Franklin D. Roosevelt signed the GI Bill in 1944, but some say the financial aid hasn't helped everyone equally. NBC's Rehema Ellis shares stories of three veterans in this week's Sunday Spotlight.

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2. Improving Customer Service

2.1 - The New York Times: **Iran, 2020, World Cup: Your Weekend Briefing** (23 June, Remy Tumin and Lance Booth, 44.2M uvm; New York, NY)

Here are the week's top stories, and a look ahead.

1. Facing an intensifying confrontation with Iran, President Trump has few appealing options.

His last-minute decision to pull back from a retaliatory strike on Iran underscored the larger, more complex showdown over containing its nuclear program, our national security correspondent writes. The administration is relying first on economic sanctions, but it has recently conducted cyberattacks and continues to weigh military options.

Our reporters broke down what happened leading up to the president's late reversal.

And after an unmanned U.S. drone was shot down, some in Iran's Revolutionary Guards saw the incident as a vindication, and resented that Americans had belittled their prowess.

[…]

7. Mars is belching a large amount of methane gas, a NASA rover discovered. It's a sign of possible life on the red planet.

Most of the time there's not much methane in the Martian air, less than 1 part per billion. On Wednesday, NASA's Curiosity rover measured 21 parts per billion. Scientists are seeking additional readings.

Back on Earth, there were two drug advances this week. Spravato, a nasal spray derived from ketamine, was approved by the Department of Veterans Affairs for severe depression, and Vyleesi became the second drug approved to treat low libido in women.

[…]

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2.2 - U.S. News & World Report (Wisconsin Watch, AP): In Wisconsin, Cannabis and CBD Users Close as Main Street (23 June, Olivia Herken, 12.3M uvm; Washington, DC)

VIROQUA, Wis. (AP) — In a tiny room inside a hair salon in Viroqua, Wisconsin, two women gaze over a glass case. They have driven 30-some miles down the Mississippi River from La Crosse just to check out Kickapoo Kind, a shop established last summer in the heart of the state's politically liberal Driftless region.

On a Saturday morning, customers flow in and out of the shop, where a neon CBD sign glows in the window and a fan spreads the smell of cannabis as soon as you walk in the door.

A limping man in a neon green hoodie and jogger pants enters and sits in the salon's waiting room. A girl in Star Wars lounge pants is greeted by her first name. A man in a camouflage jacket and a hat that reads "Craig's Towing" comes in with his high school-aged daughter, sees the line and leaves. They come back 20 minutes later.

A man with a long gray beard and round eyeglasses shops with his son, who wears a pair of Converse and a flannel shirt.

They are all here for one thing.

Recently, the state of Wisconsin legalized the sale and use of CBD, or cannabidiol, an active ingredient in cannabis. CBD contains just trace amounts or no THC, the psychoactive chemical found in the plant.

Marijuana remains illegal in Wisconsin, although Democratic Gov. Tony Evers has proposed legalizing its use for medical conditions and decriminalizing possession of small amounts. He has signaled he is open to legalization for recreational uses. However, top Republicans in the GOP-run Legislature have vowed to block Evers' proposals.

Kickapoo Kind owner Tim Murphy said he has seen the popularity of cannabis blossom, including among some unlikely people. Customers come from many miles away to check out Murphy's products. The shop recently moved to larger space on Main Street in Viroqua to handle the demand.

"I've had people come from Richland Center, Prairie du Chien, Elroy, all over," Murphy said. "All walks of life. I've had 90-year-old grandmas in here, and I've had little babies (with epilepsy) in here. Every single walk of life that you can think of has walked through that door."

In the United States, an estimated 40.9 million people used cannabis in 2017, and 22.2 million Americans 12 or over have used it in the past 30 days, according to the National Survey on Drug Abuse and Health.

In Wisconsin, an estimated 13 percent of all residents had used marijuana in 2013-14, according to a 2016 state Department of Health Services report. Cannabis was used in Wisconsin more often than any other illicit drug or painkiller. People of all races and ethnicities use cannabis, and over the past 30 years, U.S. residents have steadily become more accepting of it.

AMERICAN OVERSIGHT

Early use sparks career in cannabis

Sitting inside Kickapoo Kind, his dreadlocks tucked under a stocking cap, is Keegan Murray-King, who has been using cannabis since he was 14. He became a regular user, although he occasionally takes breaks. He is now 26.

"The interest was using it as a way to have fun with friends at first, and then slowly it evolved into more of something I did for myself," Murray-King said. He credits cannabis for helping him quit drinking alcohol, something he also says he started at a young age. "I quickly decided that I wanted to be involved with that plant, probably for the rest of my life."

He moved to California to work on a cannabis farm. He soon realized he was not happy with the cannabis industry in California, which he said was not regulated enough. So he decided to return to Wisconsin and wait for the tides to shift.

About 13 miles south of Viroqua, near Rising Sun, Wisconsin, Murray-King farms vegetables. This year, he plans to begin growing hemp, which produces CBD, under the state's new pilot program.

In 2013, Murray-King was arrested in Waushara County in central Wisconsin for possession of THC after being pulled over for an expired license plate. He was fined $400 and now has a misdemeanor drug offense on his record.

Another arrest would be a felony, and could eliminate Murray-King from participating in the hemp pilot program.

CBD aids rare skin disorder

Charlie Knuth was abandoned at birth. He was born with epidermolysis bullosa (EB), a genetic disease that leaves the skin covered in blisters and requires intensive, constant care.

Now 13, Charlie has had a home, a family and proper care since he was adopted at two weeks old. He is also one of Wisconsin's many cannabis users.

Every morning when Charlie wakes up, he is a bloody mess. The bandages that wrap his blistering skin shifts while he sleeps, and wounds are exposed and reopened; his joints are often stiff with arthritis. He usually takes his time getting out of bed because it is such a painful process.

Every other day Charlie goes to school. On those days, Charlie feels anxious, because the fear of being knocked over or somehow injured by another student is so pressing. CBD, which he takes three times daily, eases his discomfort.

On the days he is not attending school, Charlie goes through the nearly two-hour process of replacing the bandages that cover large portions of his body. The room and tools must be disinfected and bandages cut to size. An entire, $200 jar of donated CBD cream is smeared on the bandages.

"He is a new child after his new bandages go on," said his mother, Trisha Knuth. "The CBD cream helps his skin pain and joint pain tremendously."

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VA-19-1109-B-002662

Because of the complications with his disease, Charlie is not able to use other painkillers for his symptoms.

The Knuth family first heard about using cannabis to treat Charlie's condition on Facebook, when two different pro-cannabis groups offered her a free supply of "lab-tested, high quality products" for Charlie's condition A few weeks ago, however, Trisha Knuth said the supply ended, and the nonprofit that supplies the cream said it could no longer send CBD to families.

"We're just basically doing without it," she said.

The Knuth family lives near Appleton, Wisconsin, an area that often lights up red on voting maps. Despite that, the Appleton Common Council voted unanimously in 2018 to support a resolution to push state government to legalize medicinal cannabis.

"Attitudes have changed," Knuth said. "Minds have been opened."

Education changes view on cannabis

In La Crosse, Jessica Polacek has been busy re-enrolling in classes at the University of Wisconsin-La Crosse. The 52-year-old recently returned to school to earn her bachelor's degree, but took a semester off to undergo gender confirmation surgery.

Before her venture back to school, Polacek said, she served 23 years in the U.S. Army, eventually being medically discharged in 2012 in part because of questioning her gender identity. She said she returned from Iraq with a back injury and post-traumatic stress disorder, and her recent surgery has caused them to flare up.

Polacek's sister owns a shop in Illinois where she produces a CBD balm. Because of Illinois law, she refers to it as a "relief product." Polacek decided to try it out.

"It takes a lot for me to say that because I was raised in a home where smoking marijuana was an everyday occurrence," Polacek said. "It was also a place where I experienced much abuse."

Polacek was born in Milwaukee and "moved around quite a bit," graduating from high school in Merrill. At age 10, she started separating "weed from seed" for her dad and his friends. She attributed the abuse she endured to the cannabis, and became staunchly against it from then on out. "If drugs turned people into uncontrolled raging maniacs," she thought, "then it had no place in society."

After returning from Iraq, Polacek began researching the effects of medical cannabis on veterans and duty-related injuries and illnesses. Polacek began to use CBD in September.

What changed? For Polacek, it was learning more about the plant and its possibilities. She recently began work in the health care field. She had read about new research that the Veterans Administration was doing with veterans.

Education was the key to Polacek's decision to use cannabis. The results for her have been great.

"Until we honestly take time to get educated, we will remain biased and closed off," Polacek said. "Knowledge is the best tool for countering hatred, misunderstanding and prejudice."

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CBD acceptance grows in rural Wisconsin

Back at Kickapoo Kind, Murphy is sitting down after about an hour of back-to-back customers. He is wearing an army-green T-shirt with the "ARMY" logo printed on it, only the "Y" is crossed out and an "F" has been drawn in at the beginning of the word — spelling FARM. Murphy and his wife, Noelle Kehoe, started Kickapoo Kind, partly to help local farmers.

"I thought that (hemp) farmers needed an outlet in this area, that would be where I could actually work with the farmers and sell straight to the consumer from the farmer," Murphy said. Soon, Murphy will be teaming up with Murray-King to grow their own hemp for the shop.

Murphy has spent his entire life in the Driftless region of Wisconsin, and has been a cannabis user for around 30 years. He uses it medicinally for inflammation — he said it even helped him quit smoking cigarettes. And when it came time, he used it to treat his father, who had Parkinson's disease.

Murphy said his dad grew up in the "reefer madness" generation when cannabis was considered a bad drug with no redeeming qualities.

"Even 'til the day my dad died, he was semi-against it, even though I started treating him (with CBD)," Murphy said. "It was actually helping. But even then he was like, 'goddamn wacky-tobacky.' "

But perceptions are beginning to change, even if slowly. Murphy, who considers himself a part of the "alternative" crowd of Viroqua, said he has heard few criticisms since he began selling CBD and hemp from the hair salon.

"Really, I expected a little bit of pushback here and there, but I have not had any at all," he said.

The nonprofit news outlet Wisconsin Center for Investigative Journalism provided this article to The Associated Press through a collaboration with Institute for Nonprofit News.

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2.3 - Epoch Times: **6 GOP Senators Want to Make Firing Bad Bureaucrats Easier** (23 June, Mark Tapscott, 2.1M uvm; New York, NY)

WASHINGTON — Firing underperforming career civil servants should take no more than a year, according to six Republican senators who introduced legislation to make that time limit a reality.

“Government employees should be held to the same standards as private sector employees, yet it is nearly impossible to fire bureaucrats for failing to do their jobs,” said Sen. David Perdue (R-Ga.) in a June 19 statement.

“Right now, it can take more than a year to fire or replace a civil service employee, even for poor performance or misconduct. With a $22 trillion debt crisis, we cannot afford to hold onto bureaucrats who aren’t doing their jobs.”

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Perdue, along with Republican senators Marsha Blackburn of Tennessee, Tom Cotton of Arkansas, Mike Braun of Indiana, Charles Grassley of Iowa, and Roger Wicker of Mississippi, introduced the Modern Employment Reform, Improvement, and Transformation (MERIT) Act of 2019.

A companion version of the measure also has been introduced in the House of Representatives by Rep. Barry Loudermilk (R-Ga.).

Their bill would apply throughout the federal career civil service reforms approved by Congress and already implemented by President Donald Trump at the Department of Veterans Affairs (VA).

“Since President Trump took office, more than 4,300 bad actors have been fired, demoted, or suspended at the VA. It’s time to expand those efforts and address problems across the entire federal government,” Perdue said.

The VA personnel changes were approved by the 115th Congress, which included Republican majorities in both the Senate and House of Representatives.

The MERIT proposal, according to its backers, would

- streamline the process and shorten the amount of time required to remove underperforming employees.
- permit agencies to remove a senior executive for performance reasons, rather than merely demoting them.
- limit retirement benefits of employees who are removed from their position due to a felony conviction related to their official duties.
- authorize agencies to recoup bonuses and awards when performance or conduct issues are discovered.
- extend the probationary period for competitive appointments and promotions from one year to two years so that there is adequate time to evaluate a new employee.
- curb the ability to use intermediaries to overrule or undermine Merit Systems Protection Board (MSPB) precedent.
- uphold critical whistleblower protections.

“The American people deserve high-performing and effective federal employees,” Grassley said in the June 19 statement. “That’s not always what they get, unfortunately.”

Grassley added that “although most federal employees work hard to do their jobs well, some government employees chronically display poor performance or misconduct, and get away with it, due to the current byzantine process for removing an employee.”

Cotton said that “whether in the private sector or in government work, employees should succeed and fail based on merit.”

“Our bill will introduce a new level of accountability for civil service employees, one that ensures agencies can take appropriate measures against bad actors,” he said.

Although the MERIT proposal has solid prospects for passage in the Republican-led Senate, it’s doubtful the House Democratic majority will allow Loudermilk’s bill to reach the floor for a vote.

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Public sector employee unions, including the American Federation of Government Employees (AFGE), the National Treasury Employees Union (NTEU) and the National Federation of Federal Employees (NFFE), adamantly oppose shortening the firing process, and such labor groups contributed more than $16 million to Democrats last year, including many members of the current House majority, according to OpenSecrets.org.

In addition, Speaker of the House Nancy Pelosi (D-Calif.) and House Majority Leader Steny Hoyer (D-Md.) represent congressional districts with a large number of federal workers.

Conservative activist groups quickly lined up to support the MERIT proposal.

Americans for Limited Government President Richard Manning, for example, said on June 21 in a news release issued by Perdue's office that "you can't drain the swamp unless you can fire the swamp. The MERIT Act allows a faster pathway for firing incompetent, lazy, or recalcitrant federal employees and is a necessary first step toward ending the politicization of the federal civil service workforce."

The National Taxpayers Union (NTU) Director of Policy and Government Affairs Thomas Aiello said in the release that the MERIT bill is needed because "due to the arduous termination process, it is often easier for federal agencies to simply retain workers that would otherwise be let go if they were in the private sector."

"Holding federal employees to similar standards as those in the private sector would help curb wasteful spending, increase productivity, and boost morale … it can make an immediate difference within the federal bureaucracy," he said.

Kevin Kosar, vice president of the R Street Institute, said in the release: "Today's civil service protocols make it very costly and very difficult for an agency to fire an underperforming federal employee. No private company could succeed with such restrictions."

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2.4 - Hot Air: **Democrats At 24 For 2020 Presidential Election** (23 June, Taylor Millard, 578k uvm; New York, NY)

The Democrats are almost halfway towards a full deck of cards in the race for the 2020 presidential nomination.

Former Pennsylvania Congressman Joe Sestak announced his plan to run for the nomination this weekend, for…reasons? Via Adm Joe's (this is what he's calling himself) campaign website:

What Americans most want today is someone who is accountable to them, above self, above party, above any special interest … a President who has the depth of global experience to restore America's leadership in the world to protect our American Dream at home … and one who is trusted to restructure policies where too many see only the growth of inequity not of the economy.

I want to be that President who serves the American people the way they deserve to be served…

Now, the hour has become late to restore U.S. global leadership that convenes the world for two primary objectives that serve our collective well-being here at home: putting a brake on climate change and putting an end to an illiberal world order's injustices, from China's control of the 5G network to Russian interference in democratic elections.

However, we cannot meet the defining challenges of our time without a united America. This is our Hobson's Choice: not just to win this Presidential election, but to heal our nation's soul by regaining the trust of Americans – all Americans – by a President who the people know will remain accountable to them alone, no matter the cost to him.

Sestak said his campaign announcement is later than all the others because his daughter was fighting – and beating – brain cancer (congrats to her on her victory!). It just seems quite odd for Sestak to come into the nomination unless he's seeking a position within some administration.

His key plank? Health care and his desire for a government-run system. Sestak is open and honest about his desire for a VA-style health system for the country.

I believe that the public option is one part of a transition of choice to a national healthcare system. Creating such a system will not be easy, but I believe our country can rise to the challenge. I know from my experiences visiting our wounded warriors at Veterans Health Administration (VHA) facilities across the country that a national healthcare system can work — indeed, it already exists for veterans. The VHA directly provides high-quality medical services to over 9 million people at some 1,250 facilities, employing over 300,000 healthcare professionals. It is the country's largest integrated healthcare system, providing comprehensive care to its patients whether they walk in to a Vet Center in Fairbanks, Alaska, or a VA hospital in San Juan, Puerto Rico. And it provides medical education and training to over 100,000 people every year, including more than 37,000 medical residents, or 30% of all residents trained across the country each year.

The 300K or so veterans who may have died while waiting for medical help from the VA were unavailable for comment.

It should also be pointed out the infusion of cash into the VA system still hasn't solved the problem with wait times. The GAO reported last year there were still plenty of issues despite the new Veterans Choice Program.

[W]hen GAO analyzed 55 routine care authorizations that were created between January and April of 2016, it found that the process took at least 64 calendar days, on average. When VHA analyzed about 5,000 authorizations created between July and September of 2016, it took an average of 51 calendar days for veterans to receive care.

The issue wasn't necessarily private health providers scheduling with veterans but the fact vets had to go through the VA to get a Third Party Administrator – the government only uses two contractors as TPA to find a private doctor.

GAO found that numerous factors adversely affected veterans' access to care through the Choice Program. These factors include: (1) administrative burden caused by complexities of referral and appointment scheduling processes, (2) poor communication between VHA and its VAMCs, and (3) inadequacies in the networks of community providers established by the TPAs, including an insufficient number, mix, or geographic distribution of community providers. VA and

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VHA have taken numerous actions throughout the Choice Program's operation that were intended to help address these factors, though not all access factors have been fully resolved. For example, to help address administrative burden and improve the process of coordinating veterans' Choice Program care, VA established a secure e-mail system and a mechanism for TPAs and community providers to remotely access veterans' VA electronic health records. However, these mechanisms only facilitate a one-way transfer of necessary information. They do not provide a means by which VAMCs or veterans can view the TPAs' step-by-step progress in scheduling appointments or electronically receive medical documentation associated with Choice Program appointments.

Bureaucracy kills or at least makes it harder for people to get care, apparently.

This doesn't appear to be an issue for Sestak who heaped an inordinate amount of praise on the work doctors did to help his daughter. A cynic would suggest his family got amazing treatment because he happens to be a retired Navy Admiral and a former congressman.

It really isn't known what Adm Joe brings to the table in the race for the Democratic nomination except another body and a whole host of government-strengthening policy choices. He's not really different than any other candidate who has already announced a run for the nomination.

At least he's a retired Admiral, right?

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2.5 - The Spokesman-Review: A week of tragedies tested Fairchild Air Force Base and Spokane 25 years ago (23 June, Jim Camden, 438k uvm; Spokane, WA)

Fairchild Air Force Base and the city to the west went into mourning twice on the third week of June 1994.

The week began warm and sunny, with the base preparing for an open house the following Sunday. It ended with the base hospital closed, walls scarred from bullets and floors stained with blood. The burnt wreckage of the base's last B-52 was scattered near the runway.

"It seems like someone is trying to test us," a Fairchild spokesman said shortly after the giant warplane went down.

Between Monday, when a mentally unstable former airman would go on a rampage through the base medical complex, and Friday, when the huge bomber would crash while practicing unsafe maneuvers for an upcoming air show, 10 would die and some 22 would be wounded. The Spokane community's medical and emergency services would be stretched to its limits.

Bad news from Spokane would bump the O.J. Simpson trial as the lead story on some network newscasts.

Investigations of the two separate incidents would call into question decisions made by Air Force officials at Fairchild and elsewhere.

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Epilogue
Knight transferred from Fairchild, was later stationed at Buckley Air Force Base in Colorado, and eventually retired from the Air Force. He left the ministry and went to work for the Veterans Administration, where he now works as a paralegal.

In Denver in 1999 when the Columbine High School massacre happened, he recalls thinking "you people don't realize this isn't unique. This is modern America."

What he saw and experienced that June week 25 years ago left him with post traumatic stress disorder, although until recently he didn't know that's what it was. He recently completed a 49-day treatment program for PTSD with the VA.

Joneil Del Rosario joined the Air Force when he turned 19, and became a security officer, in part, he said recently, because of what he witnessed in and around the Fairchild hospital that day. He left the military after a few years and now works as a business manager for Boeing.

"I think about it every day," he said recently. "I see it vividly."

Andy Brown, the security policeman who downed Mellberg, was assigned to Hawaii after the shooting. He eventually left the Air Force and returned to Spokane. He wrote a book "Warnings Unheeded," about the shootings and the crash.

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2.6 - Portland Press Herald: **Letter to the editor: Maine veteran thanks Togus for skilled, attentive care** (23 June, Patrick Eisenhart, 349k uvm; Portland, ME)

As a disabled retired veteran, I would like to thank and recognize the outstanding medical treatment I receive at the Togus VA Hospital. From janitor to surgeon, everyone there demonstrates genuine care for us from ensuring the facility is clean to providing top-notch surgical procedures.

One is always greeted with a smile and a "how can I help," can-do attitude. There are written and verbal appointment reminders and less than a 15-minute wait to see the doctor.

On behalf of myself and all the other veterans, I thank all of the Veterans Affairs service providers there for providing a level of care that far surpasses anything I have seen in the private sector.

I pray the Trump administration's efforts to cut and privatize veterans' health care will fail.

Patrick Eisenhart

Augusta

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2.7 - Times-News: **Twin Falls physician receives award** (23 June, Julie A. Ferraro, 46k uvm; Twin Falls, ID)

A physician who teaches medical students has received an award for his excellence in the field.

Dr. Brian Fortuin of Twin Falls is one of two recipients of the 2019 Richard M. Tucker WWAMI Faculty Excellence in Teaching Award. He is affiliated with St. Luke's Magic Valley Medical Center and board certified in internal medicine and sleep medicine.

The other award recipient is Dr. Andrea Christopher of Boise. She is the clerkship site director and general internal medicine physician at the Boise Veterans Affairs Medical Center.

WWAMI is Idaho's oldest medical school and stands for the states Washington, Wyoming, Alaska, Montana and Idaho. The program was created in 1972 through a partnership with the University of Washington's School of Medicine.

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2.8 - The St. Augustine Record: **A new leash on life: Congressman John Rutherford pushes for more service dogs for veterans** (23 June, Colleen Jones, 43k uvm; Saint Augustine, FL)

Jerome Jaques took one look at the service dog he'd been matched with and thought there must be some mistake.

"Here's this giant dog — he's 90 pounds — with big, floppy ears like Goofy, and I'm thinking to myself, 'No way,'" Jaques said, laughing at the memory.

It was at that moment, though, that Jaques turned his trust over to the process, and to Roger, the big Labrador retriever he'd begin to bond with over the next few days at the training facility for K9s For Warriors in Ponte Vedra Beach. The organization is the largest service dog provider for disabled post-9/11 veterans in the U.S.

Some of the 150 soldiers the center places with dogs each year have lost limbs, and others have less tangible wounds but ones that resonate just as deeply as they struggle with the effects of Post Traumatic Stress Disorder in civilian life.

When a veteran is accepted into the K9s For Warriors program, he or she is paired with a dog that staff have carefully chosen for that individual. Over the next three weeks, animals are tethered to their new owners, eating, sleeping and training with them in a variety of immersive situations as the two learn each other's cues.

For Jaques, 48, of Nocatee, that has meant recognizing when Roger is anxious, which forces him to focus on soothing the dog's nerves, in turn helping alleviate his own anxiety.

If U.S. Congressman John Rutherford (R-4th district) has his way, every former military servicemember will be given the option of receiving a companion dog to help deal with PTSD.

Rutherford, a former sheriff with the Jacksonville Sheriff's Office, recently introduced a bill to Congress toward this end. Called the PAWs (Puppies Assisting Wounded Servicemembers)

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Act, the legislation would direct the Veterans Administration to grant a voucher to each qualifying veteran for any service dog organization of their choosing.

The VA estimates that 11 to 12% of all Iraq and Afghanistan veterans have PTSD, according to the U.S. Dept. of VA National Center for PTSD. Approximately, 22 veterans take their own lives each day.

Service dog programs aren't cheap, with the cost of training each dog at about $25,000. K9s For Warriors, for example, takes rescue dogs from high-kill shelters and trains them for six months on the Ponte Vedra Beach campus before they are matched with veterans.

The bill Rutherford is sponsoring would be funded at $10 million for a national pilot program over the next three years.

K9s For Warriors CEO Rory Diamond is hopeful the measure will be adopted and that other organizations can be launched on the same model.

"We're hoping smaller agencies will be able to follow in K9s For Warriors' footsteps and become sustainable to keep up with the demand," Diamond said.

The legislation has the support of other local lawmakers, such as Congressman Michael Waltz (R-6th district) who said in a news release issued by Rutherford: "There's no denying the emotional and psychological benefits dogs have on humans, but for our veterans, that connection is even more impactful."

After returning from tours in Iraq and Afghanistan, among other deployments, Jaques, a former chief warrant officer two, realized he needed help after a failed marriage, substance abuse issues, major anxiety and delusional behavior.

That was in 2013. He'd been enlisted for 20 years in the Army and the after effects had become too much to take.

"I was pretty messed up," Jaques said matter-of-factly.

After hearing about the K9s For Warriors program that was practically in his backyard, Jaques was doubtful at first. "I thought it [the dog] would be just one more thing I'd have to take care of," he said.

But after sitting on a waiting list for a year and having time to research the program, Jaques said, "It was sounding like people's lives were changing because of these dogs."

Less than two months after graduating from training with Roger, Jaques said he can't imagine life without that big, floppy-eared pup by his side, even taking him along on rides at Disney World and in the back of his golf cart on the trails of Nocatee.

"He is just another tool I have that, when things are not perfect, reminds me I have to work through my problems," Jaques said.

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3. Business Transformation

4. DOD Cooperation / Electronic Health Records / MISSION Act Implementation

4.1 - Providence Journal: **Veterans Journal: VA launches expanded privatization program that may affect veterans' care** (23 June, George W. Reilly, 265k uvm; Providence, RI)

Last week's column reviewed the new Mission Act in which eligible veterans can use VA health-care services nationwide, including through mobile health clinics that serve rural areas and via telehealth care through a phone or computer. To receive care from the VA or a community provider, an eligible veteran must be enrolled in VA health care for which you can apply online, by mail, or in person. Learn more about eligibility criteria and required enrollment documents online at https://bit.ly/2IdxYOY.

This week, opinions are presented from those who are skeptical about the Mission Act and believe that the Department of Veterans Affairs is rushing to begin an expanded privatization program that they believe will harm veterans' care.

The union representing 260,000 employees at the Department of Veterans Affairs is warning that veterans' health care will suffer as the current administration rushes to push millions of veterans outside the VA without any accountability to veterans or taxpayers.

"The VA will be sending veterans out to the private sector without any way of measuring the timeliness and quality of the care they receive," American Federation of Government Employees national president J. David Cox, Sr. said. "This is a clear double standard that is designed to push veterans out of the VA, no matter the consequences, and to starve the VA of the resources it needs to continue providing the high-quality care veterans expect and deserve."

Cox believes there is no guarantee that a veteran who is referred to the private sector will be seen any faster than staying with the VA. There is no system in place to track how long it takes veterans to receive care in the private sector or measure the quality of care received, even though the VA's own clinicians are held to strict timelines and exacting quality standards.

"The health and safety of veterans is at stake, yet VA Secretary Robert Wilkie thinks it's more important to meet an artificial deadline (set by the Trump administration) rather than do what's best for their care," AFGE National VA Council president Alma Lee said. "This is yet another unfortunate example of how the VA under this administration is silencing our voices and doing everything it can to dismantle the VA from the inside out."

Despite assurances from VA Secretary Wilkie that they are ready to put the Mission Act in place, there is widespread concern from groups representing veterans, employees, and private-sector physicians about this rushed rollout. "Expanding the number of veterans who can go outside the VA for their care is a major change, and the VA's attempts to prepare employees and veterans for this drastic adjustment has been woefully inadequate," Cox said.

"The VA did not seek the input of employee unions or veterans' organizations and has ignored our collective warnings that rushing this rollout will imperil veterans' care. The only so-called training VA clinicians have received has come from a series of prepared videos they have been

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made to watch. The VA is clearly rushing to implement this program despite our very real concerns that veterans will suffer as a result."

Under a provision of the Mission Act that took effect June 6, the percentage of veterans eligible to receive private sector care will expand from 8 percent under the previous Choice Program to more than 39 percent under the new Community Care Program (Mission Act). The standards stipulating when veterans must be referred to care outside the VA were not even made final until just before the program's launch, says the American Federation of Government Employees union.

The push to privatize more of the VA comes as the department quietly released data showing a marked increase in the number of vacancies inside the agency. There were 50,201 vacancies as of March 31, up from 49,000 at the end of 2018 and 35,000 at the end of 2017. In addition to doctors and nurses, there are significant shortages of mental-health clinicians and VHA police officers, critical positions that the VA needs to fill to help combat a rise in veteran suicides and to protect both patients and employees at VA facilities.

"The vast majority of veterans want to get their care at the VA, where the medical staff is trained to address their unique and specialized needs, and where one-third of employees are veterans themselves," Lee said. "Yet by allowing vacancies inside the VA to steadily rise, and rushing through reforms that will push more veterans to the private sector, it's clear that this administration is ignoring the will of veterans in a blind pursuit to privatize the VA."

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4.2 - Daily News Journal (Video): Sen. Blackburn: Give veterans more local health care choices for VA benefits (23 June, Scott Broden, 25k uvm; Murfreesboro, TN)

The VA Mission Act should help rural health care providers serve veterans in their communities, Republican U.S. Sen. Marsha Blackburn said Friday.

"This is a great opportunity for our veterans," Blackburn said during an interview at The Daily News Journal office in Murfreesboro.

Blackburn was running for her seat as a former U.S. representative from Brentwood when Republican President Donald Trump signed the VA Mission Act June 2018 to replace the Veterans Choice law.

The newer law's goal will mean VA officials will be entering into arrangements with local health care clinics, so veterans will have shorter commutes and faster access to treatment, Blackburn said.

Rules established under the law and published recently in the Federal Register say the VA will pay for veterans to see non-VA doctors if they have to wait more than 20 days or drive more than 30 minutes for primary or mental health care at a VA hospital or clinic.

For specialty care, they can see private doctors at VA expense if they have to wait longer than 28 days or drive more than an hour to see a VA provider.

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Advocate: VA needs more doctors
Veterans advocate Hooper Penuel of Rutherford County's Lascassas community said the Mission Act is a "Band-Aid fix" to the problems at VA hospitals.

"I think that's another excuse for not fixing the problem," said Penuel, who retired as a lieutenant colonel from the Air Force after a 28-year military career. He also served on a board to raise funds to build a Fisher House that provides free lodging to veterans getting treatment and their families on the York VA Medical Campus in Murfreesboro.

Rather than sending veterans to struggling rural hospitals and clinics that could end up closing, policy makers should be providing the needed funds to improve VA health care, said Penuel, who also served for two years as the first public affairs officer for the Tennessee Department of Veterans Affairs.

"I would suggest that they continue to improve the Veterans Affairs hospitals by hiring more doctors and nurses, more technicians and more people to handle the veterans who are coming in for service to collect their benefit that the United States offered them to begin with," Penuel said.

Penuel also is a former Rutherford County election administrator who accepted appointment from an Election Commission with a Democrat majority.

Veterans need access to VA records
Sen. Blackburn contends the VA Mission Act will benefit veterans and their family members by reducing the amount of time and traveling needed for health care check ups.

"I don't see this taking away resources from the VA," Blackburn said.

Case workers also are involved to determine if deadlines are missed in providing care for veterans, she said.

The senator also wants more VA accountability in establishing electronic records that veterans can access from their phones. This should prevent veterans from having to wait on treatment while health care providers "chase down these records," Blackburn said.

Help veterans exposed to burn pits
Blackburn also backs legislation that recognizes when combat veterans were exposed to toxic burn pits used to eliminate waste, such as in Iraq and Afghanistan.

"That needs to be in their health records," Blackburn said.

The senator also said she wants the military commanders involved in establishing stronger sexual harassment policies.

"We want to make sure all men and women in uniform feel safe," Blackburn said.

The senator also backs legislation to proclaim June 12 to be a day to celebrate and recognize the contributions of female veterans.

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President signs VA Mission Act: Veterans to get expanded access to private doctors at VA expense starting Thursday

VA health-care choices: VA unveils proposed rules extending more private care to veterans

Senate race comes to Rutherford County: Blackburn campaigns with NRA leaders at Outpost Armory

What should be done to improve VA care for veterans? Reach Scott Broden at sbroden@dnj.com or 615-278-5158, and follow him on Twitter @ScottBroden.

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5. Suicide Prevention

5.1 - WDTV (CBS-5, Video): Sen. Manchin introduces a bill for a veteran 3 digit crisis hotline similar to 911 (23 June, 32k uvm; Bridgeport, WV)

CHARLESTON, W.Va. (WDTV) -- Senator Joe Manchin is introducing a bill that would create a 3-digit phone number similar to 9-1-1 for veterans in crisis.

According to the Senator the VA crisis line's current phone number is 11 digits long and the caller has to listen to a menu and press an additional button to talk to someone.

The rate of veteran suicide is nearly twice that of the normal civilian population and an estimated 20 veterans die by suicide each day in the United States. Senator Manchin hopes an easy to remember crisis hotline number could help prevent some of those deaths.

"One of the first lines of defense that we have all of us know, in times of emergency especially preventing a veteran suicide is the crisis line we have. The number is 1-800-273-8255.. How many of us can remember that?" said Senator Manchin.

As of right now if a veteran is in need they should call the current hotline number at 1-800-273-8225.

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5.2 - Bluefield Daily Telegraph: WWII Medal of Honor recipient speaks of community at Marine Corp. conference (23 June, Emily D. Coppola, 23k uvm; Bluefield, WV)

PRINCETON — United States Marines gathered to fellowship and listen to the keynote speaker, World War II Medal of Honor recipient, Hershel “Woody” Williams, at the 2019 Marine Corps League Mideast Division Conference on Saturday.

The MCL Mideast Division consists of Marines from Delaware, the District of Columbia, Maryland, North Carolina, Virginia, and West Virginia, according to Scott Kirby of the MCL. Since these Marines don’t get to see each other often, events such as this conference give them time to reconnect.

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At the conference, the Marines passed a resolution to establish a 311 call line for veterans in need in this division, according to Williams.

“The resolution is to ask for a 311 number to be set up so those veterans who have a crisis such as suicidal thoughts can dial 311 and get help,” Williams said, “The VA, the Department of Veterans Affairs, establishes this number so veterans that might be having problems can call 311 and won’t have to wait on anyone.”

Of the importance of the MCL engaging in communities, such as Princeton, Williams said, “The more we can become involved the more we draw closer together. We have more division in our country now than we have been in since probably the Civil War.”

Along with being one of a few WWII Medal of Honor recipients still living, Williams also received a Purple Heart for his heroic and outstanding service during the Battle of Iwo Jima. After landing on the beaches of Iwo Jima Williams fought for four hours straight under immense enemy fire, armed with a flame thrower, clearing out the pillboxes, or concrete structures along the beach filled with enemy soldiers.

On the same day, Williams witnessed the raising of the American flag on Mount Suribachi. During his service, Williams was wounded by shrapnel, this being the reason for him receiving a Purple Heart.

“This is time for the Marines to get together and show success and ways to help the veterans in the states,” Kirby said, “At the conference, we do training, meetings, it’s an opportunity for each department commandant to brag on his marines.”

Kirby also said that he and his fellow Marines were looking forward to listening to Williams speak and hear his tales. During his speech, Williams spoke on topics such as leadership and the importance of strengthening a community.

Not only is Williams a prime example of the United State Marine Corps’ true grit, but he is also an exemplary West Virginian. Born in Quiet Dell in 1923, Williams has always advocated for the civilians and Marines of West Virginia. Above all, Williams has made it his mission to honor the men and women who have sacrificed for the United States of America.

To prove of Williams’ life long dedication to the men and women of the United States military, he currently leads his own foundation entitled the Hershel Woody Williams Medal of Honor Foundation. This organization honors Gold Star Families or families who have lost a loved one in the line of duty, by placing beautiful monuments in the family’s community. For more information on this organization, visit http://www.hwwmohf.org/monument-overview.html.

If you are or know of a veteran in crisis, call 1-800-273-8255, text 838255, or chat online at https://www.veteranscrisisline.net/get-help/chat.

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5.3 - Mid Hudson News: **Public health summit addresses “Moving Forward Together”** (23 June, Middletown, NY)

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CARMEL – Dozens of community leaders both in and out of the medical profession have joined forces by participating in the county's ninth annual Putnam Health Summit.

Organized by the Putnam Health Department and Putnam Hospital Center, the event stimulated discussion regarding "moving forward together" in an effort to prevent chronic and communicable disease as well as mental and substance abuse disorders while promoting well being and a healthy and safe environment.

Commissioner of Health Dr. Michael Nesheiwat explained the seminar last Wednesday highlighted the CHA (Community Health Assessment) and the CHIP (Community Health Improvement Plan) that "involves the partnering of all agencies within the county to do what's best for the healthcare of Putnam's 99,000 residents."

One of the workshops that attracted wide attention centered on the New York Warrior Promise Wall, established last December, that honors members of the military from New York State who have taken their own lives.

County Director of Veterans Services Karl Rohde, John Bourges, chairman of the Dwyer Vet2Vet program and Meghan Castellano, executive director of the Mental Health Association of Putnam were all extremely passionate with the program.

Rohde described veteran suicide as an epidemic. "Twenty-two veterans per day take their own lives throughout the United States."

Bourges described the number as "outrageous. We must change the concept of people believing the high rate is a result of failure of the Veterans Administration. It's not the V.A.'s issue. It's a community issue that must be addressed allowing communities near and far to become proactive and address the concern by finding individuals in need."

Castellano noted no one is alone. "A person must reach out for help. Peer-to-peer support affords individuals someone who has walked in those shoes and underwent similar experiences."

Rohde noted the 22 veteran suicides each day consists of seven percent of the population: "In New York State, the numbers are even higher since 29 suicides occur daily."

Of those taking their own lives, many are senior citizens.

Rohde said "veterans always have a mission and are mission-oriented men and women. When they retire, a spouse passes away or family moves on, the mission is no more."

Bourges added that Putnam has had its share of suicides including those of veterans. "All we want a person to do is reach out for help."

Last Wednesday evening, the Putnam Suicide Prevention Task Force conducted a special Veteran Suicide Awareness event where the public was requested to "become part of the solution."

Tee shirts with the logo "In Your Darkest Hour when the Demons Come, Call on Me Brother and We will Fight Them Together," were available.

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Castellano said help is only a phone call away. “Vet2Vet, Cove Care, Mental Health Association, Veteran’s Affairs Office or the V.A. itself is always available. Better yet, have that person contact you. You are the one who will provide support while figuring out where they can connect and get the assistance needed.”

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6. Women Veterans / Homelessness / Benefits / Cemeteries

6.1 - WFXT (FOX-25, Video): Trace Adkins makes surprise visit to VA medical center, wishes veteran a happy 106th birthday (23 June, Michelle Ewing, 409k uvm; Dedham, MA)

MARTINSBURG, W. Va. - A group of veterans got a special surprise Saturday when country music icon Trace Adkins stopped by a VA Medical Center in West Virginia.

According to WDVM-TV, Adkins visited the Martinsburg VA Medical Center, where he spoke with veterans and even wished one a happy 106th birthday.

"Known for his patriotic songs and non-profit work with Veterans organizations, Mr. Adkins spent time with our Veterans in the Domiciliary and Community Living Center and signed a birthday card for Mr. Clark, who just turned 106," the center captioned a now-viral Facebook post that featured several photos from the event. "Thank you to Trace Adkins and his team for coordinating this amazing visit. We appreciate you taking the time to visit Veterans at the Martinsburg VA Medical Center!"

Adkins, who was in town for a concert later that evening, told WDVM that working with veterans is "the most rewarding thing" he's done.

"I just love rubbing shoulders with heroes," he said.

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6.2 - Macomb Daily: Motorcycle ride raises funds for military veterans (23 June, 41k uvm; Clinton Township, MI)

Hundreds of motorcycle enthusiasts hit the road in northern Macomb County on Sunday to raise money for a pair of facilities that service military veterans.

The 17th annual Patrick Wisniewski Memorial Ride for Freedom departed the Wolverine Harley-Davidson dealership on North Gratiot Avenue in Clinton Township for a 60-mile ride. Organizers say the fundraiser has become one of Wolverine's key public service efforts.

The ride is dedicated to Patrick Wisniewski, a 33-year-old married father of five who was killed in 2013 when his motorcycle was struck by another vehicle near Selfridge Air National Guard Base, where he worked as a security officer. He also was a a reserve officer for the New Baltimore Police Department.

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After Sunday's ride, participants enjoyed a lunch prepared by Texas Roadhouse of Chesterfield Township, along with music, raffles and more.

Through registration fees, merchandise sales and donations, organizers hoped to raise several thousand dollars for the Detroit Veterans Administration Medical Center and the Fisher House of Michigan.

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6.3 - Salisbury Post: **Letter: Cemetery is the best place for 'Fame'** (23 June, Pete Prunkl, 25k uvm; Salisbury, NC)

When "Fame" was erected in 1905, it could have joined the 1875 Civil War monument honoring the unknown soldiers at the Historic Salisbury National Cemetery.

Instead, it was sited in the median of our busiest street. At the time, city officials wanted a more prominent place to honor Confederate war dead than Union dead. In 1908 and 1910, the states of Maine and Pennsylvania erected memorials to their Civil War dead in the Historic Salisbury National Cemetery. That is where "Fame" belonged and belongs now.

City officials today should finally integrate the Salisbury National Cemetery or the annex at the Salisbury VA Medical Center and move "Fame" there. Salisbury's National Cemetery is the best place to honor all the Americans who died in the Civil War. It is hallowed, emotional and educational ground.

— Pete Prunkl

Salisbury

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7. Other

7.1 - Washington Examiner: **SEAL who killed bin Laden mocks 2020 Democrat for caring about 'immigrant families' instead of 'homeless veterans'** (23 June, Ellie Bufkin, 3.9M uvm; Washington, DC)

The former Navy SEAL who killed Osama bin Laden in 2011 criticized Rep. Eric Swalwell, D-Calif., for a Saturday tweet that expressed support for immigrant families separated at the border.

Swalwell tweeted Saturday, "To Immigrant families: We see you, we are here for you and we will not stop fighting for you. Families belong together. Period." Former SEAL Robert J. O'Neill responded by correcting Swalwell, "You spelled 'Homeless Veterans' wrong."

O'Neill has been outspoken on veteran-related issues, and has been critical of Democrats seeming unwillingness to improve the notoriously malfunctioning Department of Veteran Affairs.

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He specifically criticized Rep. Alexandria Ocasio-Cortez, D-N.Y., for her comment defending the VA, in which she said, "If it ain't broke, don't fix it."

O'Neill tweeted in response to her comment, "Ever take your kid to work, let ‘em color and tell ‘em they’re helping? New York did."

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7.2 - Florida Politics: With help of a zombie campaign, Jeff Miller works harder than ever
(23 June, Noah Pransky, 73k uvm; Saint Petersburg, FL)

Editor’s note: This is the sixth in a series of stories looking at what former Florida politicians are doing with campaign accounts they never shut down.

Former Congressman Jeff Miller is working harder than ever, talking regularly to the Donald Trump administration about Department of Veterans Affairs (VA) reform. However, he’s no longer doing it on behalf of the constituents of Florida’s 1st Congressional District; he’s doing it now on behalf of his new lobbying clients, who stand to make billions of dollars through the privatization of veterans’ care.

To help subsidize his new lobbying career, Miller has tapped his old campaign war chest — about $180,000 in leftover funds from when he left the House in January 2017 — to cut checks to powerful members of Congress, including at least ten checks to members of the Senate Committee on Veterans’ Affairs, according to federal campaign disclosures.

Miller also reported spending thousands of campaign dollars on meals, hotels, and undisclosed self-reimbursements in the months after he left Congress, as he was picking up new clients and starting to lobby the Trump administration.

Federal Election Commission (FEC) rules prohibit any personal gain from campaign donations. The agency suggests campaigns take no more than six months to wind down once a member leaves public office and the campaigning is done.

But Miller’s campaign — like so many others exposed by the Tampa Bay Times/WTSP-TV “Zombie Campaigns” investigation — remains open and active, with no apparent legitimate campaigning purpose. That investigation prompted the FEC to review former lawmakers’ campaign filings for the first time, but the agency has been slow to take any action against politicians using campaign donations to lobby their former colleagues.

Washington watchdogs say the FEC and Congress need to protect the American people and put an end to the abuse of lawmakers-turned-lobbyists.

“Miller’s use of campaign funds to influence policy for the benefit of his clients is not only illegal but egregiously misuses the donations voters entrusted to him,” said Jordan Libowitz, Communications Director for Citizens for Responsibility and Ethics in Washington (CREW).

The influence Miller has exerted on DC politics since leaving the House two-and-a-half years ago has been well-documented inside the Washington Beltway. However, his impact will be felt far beyond the capital, through changes to the care of millions of U.S. veterans.

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POLITICO detailed how Miller helped turn the VA's $180 billion budget into a "massive feeding trough for the lobbying industry," while the Center for Investigative Reporting reported the former Congressman "facilitated a gravy train of government largesse to his clients — a list that includes a disgraced hedge fund magnate pushing unproven treatments for post-traumatic stress disorder and a trade group for proton beam therapy, an expensive radiation application. Miller also lobbied on behalf of a troubled disability evaluation company as it secured a $205 million contract to evaluate veterans' benefits claims."

At one point last year, Miller was rumored to be the leading candidate for President Trump's next VA Secretary, but the job went to Robert Wilkie instead.

Had Miller gotten the job, he would have joined a handful of other former Congressmembers in the Cabinet who were keeping old campaign accounts open — and active — longer than the FEC suggests is allowable.

"Leftover campaign money is not supposed to be used to advance a former Congressman's lobbying career," said Brendan Fischer, Director of Federal Reform for Washington watchdog group Campaign Legal Center. "Miller is not an isolated case. There are numerous instances of former officeholders using their old campaign accounts as slush funds. This is another example of why the FEC needs to write new rules defining the permissible uses of leftover campaign funds — and perhaps require that former members shut down their old campaign accounts."

Other former Florida politicians using leftover campaign funds to lobby their former colleagues include George LeMieux and Mike Haridopolos.

Miller's campaign treasurer did not respond to a request for comment.

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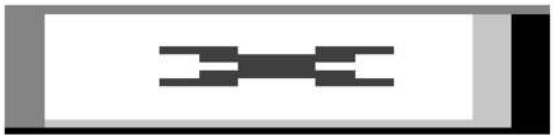
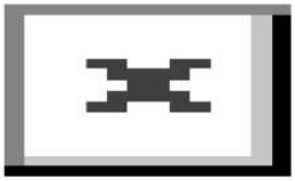


News From Patient Care Services Header

August 23 2019



In The Spotlight



Join the VA Sports4Vets social buzz

National Veterans Sports Programs &Special Events (Sports4Vets) team is leveraging the power of social media to better tell stories of our Veterans and build trust with our communities throughout the nation. There are thousands of great, untold stories about your Veterans, their courage and success in

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the face of indomitable odds. We're also proud of the care and opportunities our employees provide that can't be found anywhere else.

These are awe-inspiring stories of Veterans who are succeeding and thriving as they recover physically and psychologically from disabilities, post-traumatic stress or even substance abuse. Many of our Veterans find that healing through our six national events – Winter Sports Clinic, Golden Age Games, Wheelchair Games, TEE Tournament, Summer Sports Clinic and Creative Arts Festival -- not to mention adaptive programs and art therapy in the communities.

We tell these stories on the VAntage Point blog, in photos, videos and more and share them on our social media pages at **Sports4Vets on Facebook, Twitter, Instagram and YouTube**. If you haven't checked us out lately, follow our pages and invite your family and friends. It helps tell one of VA's best success stories to hundreds of thousands around the globe.

Just click, like and share our icons below to obtain your daily dose of inspiration!

Sports4Vets

Michael Valentino, the New Acting Assistant Deputy Under Secretary for Health for Patient Care Services

PCS is happy to announce that Michael A. Valentino, R.Ph., M.H.A is now serving in the role as, Acting Assistant Deputy Under Secretary for Health (ADUSH) for Patient Care Services (PCS) through September 2019!

SAVE THE DATE NOTIFICATION!

Update: Diagnosis of Chronic Multisymptom Illness and Gulf War Illness

Program Description:

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The purpose of this virtual knowledge-based webinar will educate attendees about what makes a good case definition, remind them of the currently accepted case definitions of Gulf War Illness (GWI), discuss strengths and limitations of the current case definitions, and provide new information about efforts to improve the case definition of GWI. This program is for healthcare teams.

Date / Time: August 27, 2019 / 12:00 pm ET to 1:00 pm ET

Modality: Adobe Connect

Credit/hours: ***1.0 CEUs***

Accreditations: ACCME, ACCME-NP, ANCC, APA, ASWB, JA IPCE, NYSED SW

For more information contact Urbano Delgado at (b)(6) @va.gov



Women's Equality Day August 26!



VA proudly joins the Nation in celebrating Women's Equality Day each year on August 26. Congress designated this date in 1971 to honor women's continuing efforts toward full equality. Join VA in celebrating!

For more information on VA's National Federal Women's Program, contact the program manager.



In The News

Trump orders VA to by controversial antidepressant in an effort to stem Veterans suicide

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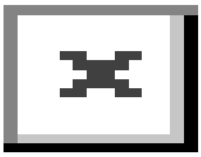
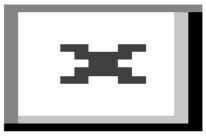


Ahead of his remarks at the AMVETS national convention on Wednesday, President Donald Trump announced he has instructed Veterans Affairs officials to make a massive purchase of the antidepressant Spravato in an effort to stem veterans suicide.

The president said the drug — developed by a subsidiary of the pharmaceutical firm Johnson &Johnson — has shown a "tremendously positive" effect in early testing and he is optimistic it can help with mental health problems in the Veterans community. VA research shows that nationwide, about 20 veterans a day die by suicide.

For more on this story go to: https://www.militarytimes.com



https://media.graytvinc.com/images/690*386/VETBIKES.JPG

Adaptive bike clinic in Kingsford helps Veterans to ride again

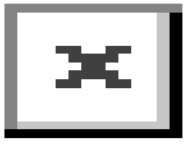
Feeling the wind through their hair was just one of the many joys veterans experienced, thanks to the bikes.

"We have a fleet of adaptive bikes and we wanted to be able to get those out and have veterans try them out, so we're very excited to have them here," said SAIL Executive Director Sarah Peuraokski.

Adaptive bikes come in many shapes and sizes. Some allow the rider to pedal with their hands, some with feet and many allow the rider to choose what works best. There was also a two person bike where riders can pedal together.

For more on this story go to: https://www.uppermichiganssource.com

Meridian Naval Air Station to train clergy on suicide



The Naval Air Station in Meridian will host one of several training sessions hosted by Mississippi

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Veterans Affairs to train clergy throughout the state in veteran oriented suicide awareness and prevention.

Veterans Affairs spokesperson Caroline Kennard said earlier this month that these training sessions are in response to high rates of suicide among veterans that experts have called an “epidemic.”

According to the U.S. Department of Veteran Affairs, over 20 veterans in the United States will commit suicide each day.

For more on this story go to: http://kempercountymessenger.com



Press Releases & Blogs

- • Advisory Committee assesses VA homeless Veteran programs- VAntage Point

- • VA modifies smoke-free policies at health care facilities to include workers aimed at increasing the quality of care for Veterans - Press Release

- • VA releases Launchpad app to streamline health care access for Veterans and caregivers - Press Release

Connect.

PCS Intranet - check out the banner promos, In the Spotlight story and the PCS Communications Toolkit.
VA Pulse - view past issues of PCS Weekly Report and more…
Share - VHA 10P4 Communications Group (email us with ideas, submissions)



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Department of Veterans Affairs

Consent for Clinical Treatment/Procedure

A. IDENTIFICATION

1. Patient name, Social Security Number and Date of Birth:

Name: Last, First, Middle	Social Security Number	Date of Birth

2. Decision-making capacity:

☐ The patient HAS decision-making capacity (skip to item 3).

☐ The patient DOES NOT HAVE decision-making capacity. Enter surrogate name and relationship to the patient. (If the patient's surrogate is not established or available, refer to Handbook 1004.1 for guidance.)

Name: Last, First, Middle	Relationship

3. Name of the treatment(s)/procedure(s):

patient-administered intranasal esketamine

4. Part of the body on which the treatment/procedure will be performed: (Correct site includes the correct side [i.e., left or right] and the precise anatomical part, such as a specific finger. DO NOT ABBREVIATE.)

nostrils

5. Practitioner obtaining consent:

Name: Last, First, Middle

6. Supervising practitioner: (if applicable)

Name: Last, First, Middle

7. Additional practitioner(s) performing or supervising the treatment/procedure: (if not listed above)

B. INFORMATION ABOUT THE TREATMENT/PROCEDURE

8. Reason for the treatment/procedure (diagnosis, condition, or indication):

treatment-resistant major depressive disorder

9. Brief description of the treatment/procedure:

You will take esketamine nasal spray yourself, under the supervision of a healthcare provider in a healthcare setting. Your healthcare provider will give you full instructions on use of the device. You will place the device in a nostril and press the plunger while breathing in through the nose. You will rest in a semi-reclined position for 5 minutes, then repeat based on dose. You will remain in the healthcare setting for at least 2 hours of monitoring clinical status.

10. Potential benefits of the treatment/procedure:

Possible benefits of esketamine may include: •Improved symptoms of depression •Less anxiety •Better quality of sleep •Reduced negative thoughts •Reduction or elimination of suicidal thoughts and urges

11. Known risks and side effects of the treatment/procedure: (Include potential problems related to recuperation.)

•Sleepiness(sedation)•fainting•feeling disconnected from yourself, your thoughts, feelings, space & time(dissociation)•dizziness•nausea/vomiting•spinning sensation•anxiety•blood pressure increase•feeling drunk•lack of energy•numbness•risk for abuse and physical and psychological dependence or addiction•bladder problems•problems thinking clearly•increased risk of suicidal thoughts or actions•full list available (see SPRAVATO Prescribing Information)

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12. Alternatives to the treatment/procedure:

•Continued treatment with other antidepressants or combinations of medications •Electroconvulsive Therapy •Transcranial Magnetic Stimulation •Admission to the hospital for psychiatric treatment •Psychotherapy alone or in combination (These alternatives are not direct substitutes for esketamine treatment and require additional criteria to be utilized)

13. Anesthesia / Moderate Sedation (CHECK ONE):

☒ Neither anesthesia nor moderate sedation will be used in this treatment/procedure.

☐ **Moderate sedation will be used**. Medications will be administered to decrease anxiety and discomfort during the treatment/procedure. These medications will be administered by a qualified practitioner. Patient response to some of these medications varies. Patients are expected to remain aware and responsive during the treatment or procedure. Minor risks of moderate sedation include temporary amnesia or forgetfulness and drowsiness. Moderate sedation can interfere with your ability to drive, operate machinery, or make important decisions for up to 24 hours. Medications used for moderate sedation can cause allergic reactions, respiratory depression (this is when your breathing slows down and may stop), low blood pressure, and a slow or irregular heart beat. In rare instances these complications can cause death. Tell your health care team if you do not want to receive moderate sedation.

☐ **Anesthesia will be administered.** A member of the anesthesia care team will visit you before your treatment to discuss the type(s) of anesthesia you may need and to give you more information about anesthesia. It may become necessary to alter your anesthesia care plan after this discussion. Devices may be applied to your body and placed in your veins and arteries to monitor you during your anesthesia. All forms of anesthesia involve some risk. Minor (not life-threatening) risks include: nausea, vomiting, and pain where an injection is given. Although rare, severe complications include: injury to blood vessels, drug reactions, bleeding, blood clots, loss of sensation or limb function, infection, paralysis, stroke, brain damage, heart attack, and death.

Here is a basic description of the major types of anesthesia including their risks in addition to those described above:

General anesthesia involves drugs that are injected into the bloodstream or breathed into the lungs. A tube or other device may be inserted into your airway to help you breathe. The expected benefit is that you will be totally unconscious and you will not feel pain during the procedure. Additional risks include: injury to the teeth, throat, eyes, or lung. In less than one case in a thousand, patients may be aware of activities during their surgery.

Spinal or epidural analgesia/anesthesia involves a drug being injected through a needle or catheter placed into the spinal canal. The expected benefit is a temporary decreased feeling in the area of surgical incision, allowing surgery to proceed without pain. Additional risks include: headache, backache, convulsions, persistent weakness and or numbness, abnormal heart rhythms, and incomplete pain relief during the operation that may require general anesthesia.

Major/minor nerve block involves a drug being injected near nerves providing loss or reduction of sensation and movement to the area. The expected benefit is a temporary loss of feeling and/or movement of a specific limb or area of your body. Additional risks include: convulsions, persistent weakness and or numbness, and incomplete pain relief during the operation that may require general anesthesia.

Monitored anesthesia care involves monitoring of the heart and lungs to make sure that they are functioning adequately during your procedure. A local anesthetic will be injected to prevent pain, and the anesthesia care provider may use drugs to help you relax, and lessen any pain. You may remain conscious throughout your procedure, or you may be given medications that will make you unconscious. The expected benefit is that you will be comfortable during your operation with a minimum amount of anesthesia. This may result in a shorter stay in the hospital. Additional risks include: incomplete pain relief during the operation that may require additional anesthesia. Convulsions from the injected drug are a rare but serious complication.

14. Blood products (CHECK ONE)

☒ It is not expected that blood products will be used in this treatment/procedure.

It is anticipated that blood products may be needed in this treatment/procedure and:

☐ I CONSENT to the use of blood products during this treatment/procedure if they are needed to improve my overall condition or save my life. I understand that my consent for use of blood products is valid during the treatment/procedure and during the recovery period after the treatment/procedure. My provider will determine when this recovery period ends. I will be asked again for my consent for use of blood products if this consent form expires, my treatment plan changes, or if blood products are needed for a reason that is unrelated to this treatment/procedure. I understand that common risks of using blood products include (but are not limited to) infection or irritation where the needle is placed, fever, chills, and skin rashes. Other rare but more serious complications may occur such as allergic reactions, heart failure due to fluid overload, acute pulmonary edema (fluid leaking into the lungs), shock, or death. I also understand that transfusions of blood or blood products involve a small risk of transmission of diseases such as Hepatitis B (1 in 137,000), Hepatitis C (1 in 1,000,000), and HIV/AIDS (1 in 1,900,000). There is also a small risk of bacterial infection when blood products are transfused. Alternatives to blood or blood products may be available if my health, time, and procedure permit. These alternatives may include auto-donation (using my own previously donated blood) and intra-operative salvage (my own blood collected during surgery). In addition, medications may be used to reduce the need for blood products. (Please note exceptions to consent in the “Comments” section of the consent form.)

☐ I DO NOT CONSENT to the use of blood products and I do not wish them to be used even if it is determined that they are needed to improve my overall condition or save my life. Alternatives to blood or blood products may be available if my health, time, and procedure permit. These alternatives may include auto-donation (using my own previously donated blood) and intra-operative salvage (my own blood collected during surgery). In addition, medications may be used to reduce the need for blood products.

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15. Additional information

VA hospitals are teaching facilities, and trainees may participate in or observe this treatment/procedure. In certain circumstances, the presence of a vendor representative (company representative) is important to the success of the procedure. Prior to the procedure the representative will sign an agreement to strictly adhere to VA's privacy rules. The representative may provide technical advice but will not physically participate in the procedure. The representative will be closely monitored by the VA treatment team.

16. Comments

I understand: 1)I should make arrangements to safely leave the healthcare setting and get home 2) I should not drive or use heavy machinery for the rest of the day on which I receive SPRAVATO 3) I should contact my doctor if I believe I have a side effect or reaction

C. SIGNATURES

Practitioner obtaining consent:

- All relevant aspects of the treatment/procedure and its alternatives (including no treatment) have been discussed with the patient **(or surrogate) in language that s/he could understand. This discussion included the nature, indications, benefits, risks, side effects, and likelihood of success of each alternative.**
- The patient (or surrogate) demonstrated comprehension of the discussion.
- I have given the patient (or surrogate) an opportunity to ask questions.
- I did not use threats, inducements, misleading information, or make any attempt to coerce the patient/surrogate to consent to this **treatment/procedure.**
- I have offered the patient (or surrogate) the opportunity to review a printed copy of the consent form.

Signature _____ Date and Time _____

Patient or surrogate:

- Someone has explained this treatment/procedure and what it is for.
- Someone has explained how this treatment could help me and things that could go wrong.
- Someone has told me about other treatments/procedures that might be done instead, and what would happen if I have no **treatment.**
- Someone has answered all my questions.
- I know that I may refuse or change my mind about having this treatment/procedure. If I do refuse or change my mind, I will not **lose my health care or any other VA benefits.**
- I have been offered the opportunity to read the consent form.
- I choose to have this treatment/procedure.

Signature _____ Date and Time _____

Witnesses: No witness is required if the patient or surrogate signs their name. Two witnesses are required only when the patient's signature is indicated with an "X" or some other identifying mark.

Witness name (please print) _____

Signature _____ Date and Time _____

Witness name (please print) _____

Signature _____ Date and Time _____

AMERICAN OVERSIGHT

Department of Veterans Affairs

Consent for Clinical Treatment/Procedure

A. IDENTIFICATION

1. Patient name, Social Security Number and Date of Birth:

Name: Last, First, Middle	Social Security Number	Date of Birth

2. Decision-making capacity:

☐ The patient HAS decision-making capacity (skip to item 3).

☐ The patient DOES NOT HAVE decision-making capacity. Enter surrogate name and relationship to the patient. (If the patient's surrogate is not established or available, refer to Handbook 1004.1 for guidance.)

Name: Last, First, Middle	Relationship

3. Name of the treatment(s)/procedure(s):

patient-administered intranasal SPRAVATO™

4. Part of the body on which the treatment/procedure will be performed: (Correct site includes the correct side [i.e., left or right] and the precise anatomical part, such as a specific finger. DO NOT ABBREVIATE.)

nose

5. Practitioner obtaining consent:

Name: Last, First, Middle

6. Supervising practitioner: (if applicable)

Name: Last, First, Middle

7. Additional practitioner(s) performing or supervising the treatment/procedure: (if not listed above)

B. INFORMATION ABOUT THE TREATMENT/PROCEDURE

8. Reason for the treatment/procedure (diagnosis, condition, or indication):

treatment-resistant major depressive disorder

9. Brief description of the treatment/procedure:

You will take SPRAVATO nasal spray yourself, under the supervision of a healthcare provider in a healthcare setting. You will be in semi-reclined position, place device in your nose, press plunger while breathing in through nose. You will rest in a semi-reclined position for 5 minutes, then repeat based on dose. You remain in the healthcare setting for 2 hours.

10. Potential benefits of the treatment/procedure:

Possible benefits of esketamine may include:

- Improved symptoms of depression
- Less anxiety
- Better quality of sleep
- Reduced negative thoughts

11. Known risks and side effects of the treatment/procedure: (Include potential problems related to recuperation.)

•Sleepiness(sedation)•fainting•feeling disconnected from yourself, your thoughts, feelings, space & time(dissociation)•dizziness•nausea/vomiting•spinning sensation•anxiety•blood pressure increased•feeling drunk•lack of energy•reduced sense of touch and sensation•risk for abuse and physical and psychological dependence•bladder problems•problems thinking clearly•increased risk of suicidal thoughts or actions•full list available SPRAVATO Prescribing Information

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12. Alternatives to the treatment/procedure:

- Continued treatment with other antidepressants or combinations of medications
- Electroconvulsive Therapy
- Transcranial Magnetic Stimulation
- Admission to the hospital for psychiatric treatment

13. Anesthesia / Moderate Sedation (CHECK ONE):

☒ Neither anesthesia nor moderate sedation will be used in this treatment/procedure.

☐ **Moderate sedation will be used**. Medications will be administered to decrease anxiety and discomfort during the treatment/procedure. These medications will be administered by a qualified practitioner. Patient response to some of these medications varies. Patients are expected to remain aware and responsive during the treatment or procedure. Minor risks of moderate sedation include temporary amnesia or forgetfulness and drowsiness. Moderate sedation can interfere with your ability to drive, operate machinery, or make important decisions for up to 24 hours. Medications used for moderate sedation can cause allergic reactions, respiratory depression (this is when your breathing slows down and may stop), low blood pressure, and a slow or irregular heart beat. In rare instances these complications can cause death. Tell your health care team if you do not want to receive moderate sedation.

☐ **Anesthesia will be administered.** A member of the anesthesia care team will visit you before your treatment to discuss the type(s) of anesthesia you may need and to give you more information about anesthesia. It may become necessary to alter your anesthesia care plan after this discussion. Devices may be applied to your body and placed in your veins and arteries to monitor you during your anesthesia. All forms of anesthesia involve some risk. Minor (not life-threatening) risks include: nausea, vomiting, and pain where an injection is given. Although rare, severe complications include: injury to blood vessels, drug reactions, bleeding, blood clots, loss of sensation or limb function, infection, paralysis, stroke, brain damage, heart attack, and death.

Here is a basic description of the major types of anesthesia including their risks in addition to those described above:

General anesthesia involves drugs that are injected into the bloodstream or breathed into the lungs. A tube or other device may be inserted into your airway to help you breathe. The expected benefit is that you will be totally unconscious and you will not feel pain during the procedure. Additional risks include: injury to the teeth, throat, eyes, or lung. In less than one case in a thousand, patients may be aware of activities during their surgery.

Spinal or epidural analgesia/anesthesia involves a drug being injected through a needle or catheter placed into the spinal canal. The expected benefit is a temporary decreased feeling in the area of surgical incision, allowing surgery to proceed without pain. Additional risks include: headache, backache, convulsions, persistent weakness and or numbness, abnormal heart rhythms, and incomplete pain relief during the operation that may require general anesthesia.

Major/minor nerve block involves a drug being injected near nerves providing loss or reduction of sensation and movement to the area. The expected benefit is a temporary loss of feeling and/or movement of a specific limb or area of your body. Additional risks include: convulsions, persistent weakness and or numbness, and incomplete pain relief during the operation that may require general anesthesia.

Monitored anesthesia care involves monitoring of the heart and lungs to make sure that they are functioning adequately during your procedure. A local anesthetic will be injected to prevent pain, and the anesthesia care provider may use drugs to help you relax, and lessen any pain. You may remain conscious throughout your procedure, or you may be given medications that will make you unconscious. The expected benefit is that you will be comfortable during your operation with a minimum amount of anesthesia. This may result in a shorter stay in the hospital. Additional risks include: incomplete pain relief during the operation that may require additional anesthesia. Convulsions from the injected drug are a rare but serious complication.

14. Blood products (CHECK ONE)

☒ It is not expected that blood products will be used in this treatment/procedure.

It is anticipated that blood products may be needed in this treatment/procedure and:

☐ I CONSENT to the use of blood products during this treatment/procedure if they are needed to improve my overall condition or save my life. I understand that my consent for use of blood products is valid during the treatment/procedure and during the recovery period after the treatment/procedure. My provider will determine when this recovery period ends. I will be asked again for my consent for use of blood products if this consent form expires, my treatment plan changes, or if blood products are needed for a reason that is unrelated to this treatment/procedure. I understand that common risks of using blood products include (but are not limited to) infection or irritation where the needle is placed, fever, chills, and skin rashes. Other rare but more serious complications may occur such as allergic reactions, heart failure due to fluid overload, acute pulmonary edema (fluid leaking into the lungs), shock, or death. I also understand that transfusions of blood or blood products involve a small risk of transmission of diseases such as Hepatitis B (1 in 137,000), Hepatitis C (1 in 1,000,000), and HIV/AIDS (1 in 1,900,000). There is also a small risk of bacterial infection when blood products are transfused. Alternatives to blood or blood products may be available if my health, time, and procedure permit. These alternatives may include auto-donation (using my own previously donated blood) and intra-operative salvage (my own blood collected during surgery). In addition, medications may be used to reduce the need for blood products. (Please note exceptions to consent in the “Comments” section of the consent form.)

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16. Comments

I understand: 1)I should make arrangements to safely leave the healthcare setting and get home 2) I should not drive or use heavy machinery for the rest of the day on which I receive SPRAVATO 3) I should contact my doctor if I believe I have a side effect or reaction

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- Someone has told me about other treatments/procedures that might be done instead, and what would happen if I have no **treatment.**
- Someone has answered all my questions.
- I know that I may refuse or change my mind about having this treatment/procedure. If I do refuse or change my mind, I will not **lose my health care or any other VA benefits.**
- I have been offered the opportunity to read the consent form.
- I choose to have this treatment/procedure.

Signature _____ Date and Time _____

Witnesses: No witness is required if the patient or surrogate signs their name. Two witnesses are required only when the patient's signature is indicated with an "X" or some other identifying mark.

Witness name (please print) _____

Signature _____ Date and Time _____

Witness name (please print) _____

Signature _____ Date and Time _____

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Janssen Scientific Affairs, LLC

1125 Trenton-Harbourton Road
PO Box 200
Titusville, NJ 08560
800.526.7736 tel
609.730.3138 fax

June 13, 2019

Robert Connell, PharmD
1 Jefferson Barracks Drive
Saint Louis, MO 63125
USA

Dear Dr. Connell,

Thank you for your interest in SPRAVATO™(esketamine) marketed by Janssen Pharmaceuticals, Inc. Jasleen Kaur has forwarded your specific request to the Medical Information Center.

Response(s):

- Esketamine - Concomitant Use with Opioids

The enclosed information has been supplied to you in response to your unsolicited request and is not intended as an endorsement of any usage not contained in the prescribing information. For complete information, please refer to the full Prescribing Information below, including the following sections: BOXED WARNING(S), INDICATIONS AND USAGE, DOSAGE AND ADMINISTRATION, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS.

If you have any additional questions, please contact us via:

- Phone: 1-800-JANSSEN (1-800-526-7736)
- Web Site: www.janssenmd.com
- Fax: 609-730-3138

To report a possible adverse event or product quality complaint, please call the Medical Information Center immediately, at 1-800-JANSSEN (1-800-526-7736).

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Sincerely,



Akintunde Zubair,

Inquiry #:01426730

Enclosure(s)/Electronic Link(s):

- SPRAVATO™(esketamine) Prescribing Information at https://imedicalknowledge.veevavault.com/ui/approved_viewer?token=7994-21c864d4-b928-49c5-b101-4d34e95f2be3

Need Help? If you have any additional questions, please contact us via:

1-800-JANSSEN Monday - Friday, 9 am - 8 pm EST	**24x7 Access to Medical Information** www.janssenmd.com
Email Medical Information	**Locate Medical Science Liaison** www.janssenmsl.com

To report a possible adverse event or product quality complaint, please call the Medical Information Center immediately, at 1-800-JANSSEN (1-800-526-7736).

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Esketamine
Concomitant Use with Opioids

SUMMARY

- The concomitant use of opioid medications with esketamine nasal spray has not been studied. Across the phase 3 program in treatment resistant depression, the use of opioids was prohibited.[1]

LITERATURE SEARCH

A literature search of MEDLINE®, EMBASE®, BIOSIS Previews®, and DERWENT® (and/or other resources, including internal/external databases) pertaining to this topic was conducted on 04 March 2019.

REFERENCES

1. Janssen Research and Development, LLC; Esketamine Clinical Protocol; DoF.

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From:	APA Psych News Update <PNUpdate@psych.org>
To:	Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M (b)(6) @va.gov>
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Priority:	Normal
Type:	Note

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ht to you by Janssen Pharmaceuticals and was not peer-
ican Psychiatric Association or Psychiatric News.

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sional,

portunity to attend the promotional non-CME Product Theater on Sunday, May 19, with Dr. Vladimir Maletic, "The First NMDA Receptor Antagonist Approv
Adults With Treatment-Resistant Depression." Dr. Maletic is a paid speaker for Janssen Pharmaceuticals, Inc.

booth and learning more about SPRAVATO™.

tohcp.com for resources, including full clinical information, dosing and administration guide, and a locator tool of certified treatment centers where SPRAVA

onal activity was brought to you by Janssen Pharmaceuticals, Inc., and was not certified for continuing medical education. The consultant was a paid spea

ting on behalf of Janssen Pharmaceuticals, Inc., and presented information in compliance with the FDA requirements applicable to Janssen Pharmaceutica

ne) CIII Nasal Spray is indicated, in conjunction with an oral antidepressant (AD), for the treatment of treatment-resistant depression (TRD) in adults.

roved as an anesthetic agent. The safety and effectiveness of SPRAVATO™ as an anesthetic agent have not been established.

NFORMATION

WARNING: SEDATION, DISSOCIATION; ABUSE AND MISUSE;
and SUICIDAL THOUGHTS AND BEHAVIORS
See full prescribing information for complete boxed warning

edation and dissociation after administration. Monitor patients for at least two hours after administration (5.1, 5.2).

or abuse and misuse. Consider the risks and benefits of using SPRAVATO™ prior to use in patients at higher risk of abuse. Monitor for signs ar misuse (5.3).

O™ is only available through a restricted program called the SPRAVATO™ REMS (5.4).

risk of suicidal thoughts and behaviors in pediatric and young adult patients taking antidepressants. Closely monitor all antidepressant-treated orsening and emergence of suicidal thoughts and behaviors. SPRAVATO™ is not approved for use in pediatric patients (5.5).

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dicated in patients with:

al vascular disease (including thoracic and abdominal aorta, intracranial and peripheral arterial vessels) or arteriovenous malformation

ntracerebral hemorrhage

itivity to esketamine, ketamine, or any of the excipients

AUTIONS

s, 49% to 61% of SPRAVATO™-treated patients developed sedation and 0.3% of SPRAVATO™-treated patients experienced loss of consciousness.

y of delayed or prolonged sedation, patients must be monitored by a healthcare provider for at least 2 hours at each treatment session, followed by an asse
dered clinically stable and ready to leave the healthcare setting.

tion with concomitant use of SPRAVATO™ with CNS depressants *[see Drug Interaction (7.1)]*.

e only through a restricted program under a REMS.

common psychological effects of SPRAVATO™ were dissociative or perceptual changes (including distortion of time, space and illusions), derealization an
treated patients developed dissociative or perceptual changes). Given its potential to induce dissociative effects, carefully assess patients with psychosis b
should be initiated only if the benefit outweighs the risk.

issociation, patients must be monitored by a healthcare provider for at least 2 hours at each treatment session, followed by an assessment to determine w
le and ready to leave the healthcare setting.

e only through a restricted program under a REMS.

RAVATO™ contains esketamine, a Schedule III controlled substance (CIII), and may be subject to abuse and diversion. Assess each patient's risk for abus
all patients for the development of these behaviors or conditions, including drug-seeking behavior, while on therapy. Individuals with a history of drug abuse
se careful consideration prior to treatment of individuals with a history of substance use disorder and monitor for signs of abuse or dependence.

e only through a restricted program under a REMS.

uation and Mitigation Strategy (REMS): SPRAVATO™ is available only through a restricted program called the SPRAVATO™ REMS because of the risk
dissociation, and abuse and misuse.

f the SPRAVATO™ REMS include the following:

e settings must be certified in the program and ensure that SPRAVATO™ is:

- Only dispensed in healthcare settings and administered to patients who are enrolled in the program.
- Administered by patients under the direct observation of a healthcare provider and that patients are monitored by a healthcare provider for at least 2 ho
  SPRAVATO™.

s must be certified in the REMS and must only dispense SPRAVATO™ to healthcare settings that are certified in the program.

ding a list of certified pharmacies, is available at www.SPRAVATOrems.com or 1-855-382-6022.

Behaviors in Adolescents and Young Adults: In pooled analyses of placebo-controlled trials of antidepressant drugs (SSRIs and other antidepressant d
e incidence of suicidal thoughts and behaviors in patients age 24 years and younger was greater than in placebo-treated patients. SPRAVATO™ is not app

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variation in risk of suicidal thoughts and behaviors among drugs, but there was an increased risk identified in young patients for most drugs studied.

t-treated patients for clinical worsening and emergence of suicidal thoughts and behaviors, especially during the initial few months of drug therapy and at t
or caregivers of patients to monitor for changes in behavior and to alert the healthcare provider. Consider changing the therapeutic regimen, including pos
concomitant oral antidepressant, in patients whose depression is persistently worse, or who are experiencing emergent suicidal thoughts or behaviors.

sure: SPRAVATO™ causes increases in systolic and/or diastolic blood pressure (BP) at all recommended dosages. Increases in BP peak approximately 4
tion and last approximately 4 hours.

% of SPRAVATO™-treated patients experienced an increase of more than 40 mmHg in systolic BP and/or 25 mmHg in diastolic BP in the first 1.5 hours aft
eeks of treatment. A substantial increase in blood pressure could occur after any dose administered even if smaller blood pressure effects were observed w
ATO™ is contraindicated in patients for whom an increase in BP or intracranial pressure poses a serious risk (e.g., aneurysmal vascular disease, arteriover
age). Before prescribing, patients with other cardiovascular and cerebrovascular conditions should be carefully assessed to determine whether the potentia

nistration of SPRAVATO™. In patients whose BP is elevated prior to SPRAVATO™ administration (as a general guide: >140/90 mmHg), a decision to delay
ount to balance the benefit and risk in individual patients.

for at least 2 hours after SPRAVATO™ administration. Measure blood pressure around 40 minutes post-dose and subsequently as clinically warranted unti
eek assistance from practitioners experienced in BP management. Refer patients experiencing symptoms of a hypertensive crisis (e.g., chest pain, shortne
athy (e.g., sudden severe headache, visual disturbances, seizures, diminished consciousness or focal neurological deficits) immediately for emergency ca

essure with concomitant use of SPRAVATO™ with psychostimulants or monoamine oxidase inhibitors (MAOIs) *[see Drug Interactions (7.2, 7.3)]*.

f hypertensive encephalopathy, more intensive monitoring, including more frequent blood pressure and symptom assessment, is warranted because these
halopathy with even small increases in blood pressure.

pairment: In a study in healthy volunteers, a single dose of SPRAVATO™ caused cognitive performance decline 40 minutes post-dose. SPRAVATO™-treat
e the cognitive tests at 40 minutes post-dose. Cognitive performance and mental effort were comparable between SPRAVATO™ and placebo at 2 hours po
s post-dose.

pairment: Long-term cognitive and memory impairment have been reported with repeated ketamine misuse or abuse. No adverse effects of SPRAVATO™
d in a one-year open-label safety study; however, the long-term cognitive effects of SPRAVATO™ have not been evaluated beyond one year.

e and Operate Machinery: Before SPRAVATO™ administration, instruct patients not to engage in potentially hazardous activities requiring complete men
ving a motor vehicle or operating machinery, until the next day following a restful sleep. Patients will need to arrange transportation home following treatme

l Cystitis: Cases of ulcerative or interstitial cystitis have been reported in individuals with long-term off-label use or misuse/abuse of ketamine. In clinical st
higher rate of lower urinary tract symptoms (pollakiuria, dysuria, micturition urgency, nocturia, and cystitis) in SPRAVATO™-treated patients than in placeb
ted interstitial cystitis were observed in any of the studies, which involved treatment for up to a year.

nd bladder symptoms during the course of treatment with SPRAVATO™ and refer to an appropriate healthcare provider as clinically warranted.

SPRAVATO™ may cause fetal harm when administered to pregnant women. Advise pregnant women of the potential risk to an infant exposed to SPRAVA
otential to consider pregnancy planning and prevention.

benzodiazepines, opioids, alcohol): Concomitant use may increase sedation. Closely monitor for sedation with concomitant use of CNS depressants.

, amphetamines, methylphenidate, modafinil, armodafinil): Concomitant use may increase blood pressure. Closely monitor blood pressure with concor

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hibitors (MAOIs): Concomitant use may increase blood pressure. Closely monitor blood pressure with concomitant use of MAOIs.

ULATIONS

™ is not recommended during pregnancy. SPRAVATO™ may cause fetal harm when administered to pregnant women. Advise pregnant women of the pot
™ *in utero*. There are risks to the mother associated with untreated depression in pregnancy. If a woman becomes pregnant while being treated with SPRA
discontinued and the patient should be counseled about the potential risk to the fetus.

gistry: There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to antidepressants, including SPRAVATO™, during p
d to register patients by contacting the National Pregnancy Registry for Antidepressants at 1-844-405-6185 or online at *https://womensmentalhealth.org/cli*
stry/antidepressants/.

™ is present in human milk. Because of the potential for neurotoxicity, advise patients that breastfeeding is not recommended during treatment with SPRAV

Reproductive Potential: SPRAVATO™ may cause embryo-fetal harm when administered to a pregnant woman. Consider pregnancy planning and preven
ring treatment with SPRAVATO™.

ty and effectiveness of SPRAVATO™ in pediatric patients have not been established.

al number of patients in Phase 3 clinical studies exposed to SPRAVATO™, 12% were 65 years of age and older, and 2% were 75 years of age and older.
bserved between patients 65 years of age and older and patients younger than 65 years of age.

$_{max}$ and AUC values were higher in elderly patients compared with younger adult patients.

geriatric patients was evaluated in a 4-week, randomized, double-blind study comparing flexibly-dosed intranasal SPRAVATO™ plus a newly initiated oral
s a newly initiated oral antidepressant in patients ≥65 years of age. At the end of four weeks, there was no statistically significant difference between group
baseline to Week 4 on the Montgomery-Åsberg Depression Rating Scale (MADRS).

PRAVATO™-treated patients with moderate hepatic impairment may need to be monitored for adverse reactions for a longer period of time.

een studied in patients with severe hepatic impairment (Child-Pugh class C). Use in this population is not recommended.

PENDENCE

SPRAVATO™ contains esketamine hydrochloride, the (S)-enantiomer of ketamine and a Schedule III controlled substance under the Controlled Substance

a history of drug abuse or dependence may be at greater risk for abuse and misuse of SPRAVATO™. Abuse is the intentional, non-therapeutic use of a dru
gical effects. Misuse is the intentional use, for therapeutic purposes, of a drug by an individual in a way other than prescribed by a healthcare provider or f
deration is advised prior to use of individuals with a history of substance use disorder, including alcohol.

uce a variety of symptoms including anxiety, dysphoria, disorientation, insomnia, flashback, hallucinations, and feelings of floating, detachment and to be "s
se is recommended.

rse reactions with SPRAVATO™ plus oral AD (incidence ≥5% and at least twice that of placebo nasal spray plus oral AD) were dissociation, dizziness, naus
thargy, blood pressure increased, vomiting, and feeling drunk.

bing Information, including Boxed WARNINGS, and Medication Guide

nt Advertisement

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Spray
(esketar
nasal spray

AMERICAN PSYCHIATRIC ASSOCIATION

750 First St. NE, Washington, DC 20002-4242

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Recipient:	Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M (b)(6) @va.gov>
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Subject:	[MARKETING] [EXTERNAL] Gottlieb Quits; Esketamine OK'd; $$ for Gun Research
Date:	2019/03/09 10:02:54
Priority:	Normal
Type:	Note

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Having trouble funding your rural health center? Lawmakers are asking what they can do to help you. Email us at editorial@medpagetoday.com.



D.C. Week: Gottlieb Quits; Esketamine OK'd; $$ for Gun Research

Also, a Republican senator stands up for vaccine mandates

FDA Chief's Resignation Greeted Mostly by Surprise, Praise

'It seemed like he was still kind of mid-stride'

House Panel Debates Gun Violence Research Funding

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Dems press for dollars for CDC, and to reauthorize NIH funding

Physician-Senators Square Off on Vaccine Mandates

If one person's choices on vaccines threaten other people's health, whose liberty is infringed?

Trump Administration Keeps Up Assault on 'Medicare for All'

Proposal 'goes in exactly the wrong direction,' White House official says

Esketamine Approved for Treatment-Resistant Depression

Fast-acting drug called a 'groundbreaking advance' in depression treatment

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Recipient:	Good, Chester B /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b07f74af87334f688429e3ac310ba6d0-Good, Chest *(b)(6)* @va.gov>
Sent Date:	2019/03/09 10:00:58
Delivered Date:	2019/03/09 10:02:54

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Message Flags:	Unread

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From:	Pain Medicine News | Doximity <support@doximity.com>
To:	Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M (b)(6) @va.gov>
Subject:	[EXTERNAL] Why the New Ketamine-like Nasal Spray Is Worrying Some Physicians
Date:	2019/06/22 21:00:19
Priority:	Normal
Type:	Note

This Week in Pain Medicine Ne

Curated for Maria Llorente, MD

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Ffncsmxdl7zz6dyjdr5a

Healthline Networks

Why the New Ketamine-like Nasal Spray Is Worrying Some Physicians

American Journal of Obstetrics &Gynecology

Multimodal Opioid Sparing Postoperative Pain Regimen vs. Standard Regimen in Vagina

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The Atlantic

The Worst Patients in the World

American Journal of Preventive Medicine

Binge Drinking and Prescription Opioid Misuse in the U.S., 2012–2014

CME CME eligible

Colorado Public Radio

Prescriptions Fall 14% as Colorado Doctors Cut Back on Opioids

BMJ

Associations Between Gabapentinoids and Suicidal Behaviour, Unintentional Overdoses
Crime: Population Based Cohort Study in Sweden

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British Journal of Sports Medicine

Physiotherapist-Delivered Training Integrated with Exercise Versus Physiotherapy Exerc
Disorder: A RCT

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VA-19-1109-B-002708



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Recipient:	Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M *(b)(6)* @va.gov>
Sent Date:	2019/06/22 21:00:00
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From:	U.S. Department of Veterans Affairs <veteransaffairs@public.govdelivery.com>
To:	Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da (b)(6) @va.gov>
Subject:	[EXTERNAL] VA to make new nasal spray drug available for treatment-resistant depression
Date:	2019/03/19 15:07:57
Priority:	Normal
Type:	Note

VETERANS AFFAIRS

VA News Release

VA News Releases

VA to make new nasal spray drug available for treatment-resistant depression

03/19/2019 03:02 PM EDT

WASHINGTON - Today the U.S. Department of Veterans Affairs (VA) announced its health care providers will now be able to offer the newly approved Spravato nasal spray for treatment-resistant depression.

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Explore VA benefits at explore.va.gov

[redacted]

Sent to david.carroll@va.gov on behalf of US Department of Veterans Affairs
810 Vermont Avenue, NW · Washington, DC 20420

Sender:	U.S. Department of Veterans Affairs <veteransaffairs@public.govdelivery.com>
Recipient:	Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da (b)(6) @va.gov>
Sent Date:	2019/03/19 15:03:31
Delivered Date:	2019/03/19 15:07:57

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From:	SPRAVATO REMS <SPRAVATOrems@ubc.com>
To:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) va.gov>
Subject:	[EXTERNAL] SPRAVATO (esketamine hydrochloride) CIII REMS - Authorized Representative Registration Initiated – Password
Date:	2019/03/12 12:04:18
Sensitivity:	Company Confidential
Priority:	Normal
Type:	Note

Dear Thomas Emmendorfer,

Welcome to the SPRAVATO REMS. This notification provides you with a temporary Password for registration. To access the program's secure website, log in to https://www.spravatoremsenroll.com using the username provided to you in a separate e-mail and the temporary password below.

Temporary Password: (b) (6)

Upon your initial log in, you will be prompted to immediately change your temporary password for security reasons.

You must complete the Healthcare Setting Enrollment Form, before your Healthcare Setting is certified in the SPRAVATO REMS. Thank you for your participation in the program. If you have any questions please contact the SPRAVATO REMS Monday through Friday, 8:00 AM to 8:00 PM ET at 1-855-382-6022 to speak with a SPRAVATO REMS team member.

Please see full Prescribing Information, including Boxed WARNING, and Medication Guide for SPRAVATO

Sincerely,

The SPRAVATO REMS
Phone: 1-855-382-6022

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Fax: 1-877-778-0091
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Sent Date:	2019/03/12 12:02:14
Delivered Date:	2019/03/12 12:04:18

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To:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b)(6) @va.gov>
Subject:	[EXTERNAL] SPRAVATO (esketamine hydrochloride) CIII REMS - Authorized Representative Registration Initiated
Date:	2019/03/12 12:02:58
Sensitivity:	Company Confidential
Priority:	Normal
Type:	Note

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Sincerely,

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The SPRAVATO REMS
Phone: 1-855-382-6022
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To:	Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd.DIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b)(6) @va.gov>
Subject:	[EXTERNAL] Re: naval spray
Date:	2019/03/21 18:14:30
Priority:	Normal
Type:	Note

Excellent

Sent from my iPhone

On Mar 21, 2019, at 4:42 PM, Valentino, Michael (VACO) ·(b)(6) @va.gov>wrote:

https://vaww.insider.va.gov/va-to-make-new-nasal-spray-drug-available-for-treatment-resistant-depression/

Michael A. Valentino, R.Ph., MHSA
Chief Consultant, Pharmacy Benefits Management Services
Department of Veterans Affairs
810 Vermont Avenue, NW
Washington, DC 20420

(b)(6)

Sender:	(b) (6))(6)
Recipient:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, ·(b)(6) @va.gov>
Sent Date:	2019/03/21 18:13:39
Delivered Date:	2019/03/21 18:14:30

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From:	(b) (6) *(b)(6)*
To:	Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd.23SPDLT)/cn=Recipients/cn=29e9d648c29f4885828c10446fdd7379-McGuire, Ma *(b)(6)* @va.gov>
CC:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I *(b)(6)* @va.gov>; VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>; Mohamed, Somaia /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=37831d1786914522b90bb85b2a8e1441-Mohamed, So *(b)(6)* @va.gov>
Subject:	[EXTERNAL] Re: esketamine briefing slides for clearance to present at ORD meeting
Date:	2019/08/23 13:36:10
Priority:	Normal
Type:	Note

Thank you Ilse and 10NCS. We look forward to successful collaboration.
Somaia

On Aug 23, 2019, at 1:31 PM, McGuire, Marsden H. *(b)(6)* @va.gov>wrote:

Cleared for 10NC5.

From: Wiechers, Ilse
Sent: Friday, August 23, 2019 12:52 PM
To: VHA 10NC5 Action <VHA10NC5Action@va.gov>
Cc: Mohamed, Somaia *(b)(6)* @va.gov>; 'Mohamed, Somaia' *(b)(6)*
Subject: esketamine briefing slides for clearance to present at ORD meeting

Hi 10NC5 Action

I need assistance getting clearance of the attached slide deck on the Esketamine Clinical Implementation for presentation at the upcoming VA ORD Esketamine Study Planning Meeting. We are making efforts to coordinate and collaborate between clinical implementation and research implementation of esketamine. There will likely be some participants present who are not VA employees.

The presentation is on Monday, September 9th.

Please let me know if you have any questions, and thanks for your help.

Ilse

From: Mohamed, Somaia *(b)(6)*
Sent: Friday, August 23, 2019 9:35 AM

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To: Wiechers, Ilse ·(b)(6) @va.gov>
Subject: [EXTERNAL] Re: Esketamine Study Planning Meeting (9/9/19)

Thank you Ilse! I think there is at least one person who is not a VA employee. Does it take longer to get it approved?

Somaia

Sent from my iPhone

On Aug 23, 2019, at 12:22 PM, Wiechers, Ilse (b)(6) @va.gov>wrote:

Hi Somaia –

I think the best thing for me to do would be to walk people through the recent briefing slides I used for updating leadership last week. I've attached them here. Am I correct in assuming this is an all internal to VA group in the meeting? I ask because these slides are not cleared for use with external stakeholders, and I would need to get that approved first before you disseminate, if needed.

I'll let Fran walk people through the MUE tool in detail (I will simply mention it as part of the broader implementation plan). I believe she has slides she can use for that as well.

Best,
Ilse

From: Mohamed, Somaia
Sent: Friday, August 23, 2019 7:31 AM
To: Wiechers, Ilse ·(b)(6) @va.gov>; Cunningham, Fran (b)(6) @va.gov>; Beed, Alexander (b)(6) @va.gov>
Cc: (b)(6)
Subject: Esketamine Study Planning Meeting (9/9/19)

Hi Fran and Ilse,

It is good to hear you will be joining our planning meeting for the TRD esketamine study. Our meeting on 9/9/19 starts at 8:00 am and we would like to suggest that you join us at 9:00 am for one hour to introduce the clinical implementation to the group and let us know how the group could be of any help and perhaps ask any questions about the measures we plan to use. If you will be using any slides or would like to share any material, please send them to me as soon as you can so we can review and distribute in advance. We are setting up a live meeting and will provide you the information prior to the meeting. Thank you both.

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Somaia

Somaia Mohamed, M.D, Ph.D.
Associate Director, VA Northeast Program Evaluation Center,
Office of Mental Health and Suicide Prevention, VACO
Faculty VISN 1 MIRECC
Associate Clinical Professor of Psychiatry Yale University School of Medicine
Ph (b)(6)

<2019_08-14 Esketamine Clinical Implementation Update (1).pptx>

Sender:	Mohamed, Somaia (b)(6)
Recipient:	McGuire, Marsden H. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29e9d648c29f4885828c10446fdd7379-McGuire, Ma (b)(6) @va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b)(6) @va.gov>; VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>; Mohamed, Somaia /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=37831d1786914522b90bb85b2a8e1441-Mohamed, So (b)(6) @va.gov>
Sent Date:	2019/08/23 13:34:02
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Subject:	[EXTERNAL] RE: a request for our collaboration with the VA
Date:	2019/06/25 15:18:43
Priority:	Normal
Type:	Note

Thanks! I also have it on my schedule for tomorrow- thought that I screwed up as I have conflicts with today.
Looking forward to speaking tomorrow.

From: (b) (6))(6)
Sent: Tuesday, June 25, 2019 2:55 PM
To: Valentino, Michael (VACO) (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) (b)(6) @va.gov>; Glassman, Peter A. (b)(6) @va.gov>; (b) (6)
(b)(6) @upmc.edu>
Subject: Re: a request for our collaboration with the VA

Apologies, you're right! Talk with you all tomorrow, thanks.

(b) (6)
Institute for Clinical and Economic Review
Two Liberty Square, 9th floor
Boston, MA 02109
(b)(6)
www.icer-review.org

Executive Assistant: (b) (6)
(b)(6) @icer-review.org
(b)(6)

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From: Valentino, Michael (VACO) <(b)(6) @va.gov>
Sent: Tuesday, June 25, 2019 2:26 PM
To: (b) (6) Zacher, Jennifer L. (PBM); Glassman, Peter A.; (b) (6)
Subject: RE: a request for our collaboration with the VA

Hi (b) (6)

I have the call on my calendar for tomorrow.....do I have that wrong?

From: (b) (6) (6)
Sent: Tuesday, June 25, 2019 2:07 PM
To: Valentino, Michael (VACO) (b)(6) @va.gov>; Zacher, Jennifer L. (PBM) (b)(6) @va.gov>; Glassman, Peter A. (b)(6) @va.gov>; (b) (6) (b)(6)
Subject: [EXTERNAL] Fw: a request for our collaboration with the VA

FYI to discuss as part of our call later today.

Steve

(b) (6)
Institute for Clinical and Economic Review
Two Liberty Square, 9th floor
Boston, MA 02109
(b)(6)
www.icer-review.org

Executive Assistant: (b) (6)
(b)(6)
(b)(6)

From (b) (6)
Sent: Wednesday, June 19, 2019 9:21 AM
To: (b) (6)
Subject: RE: a request for our collaboration with the VA

Hi (b) (6)
Attached is the updated VA data request document with changes made based on our discussion on this a few days ago. When we spoke, we had discussed using "price paid" instead of "cost",

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for anti-depressant use. I have stuck to using costs here since these are essentially costs to the VA that would come from reimbursed claims, and can be different therapies for different patients. Please let me know if you think otherwise.

The attached document now specifies a suggested time-duration for the VA to use to look up TRD patient population and associated health care resource use, and specifies resource use to be depression management-related. Mortality and utility-specific requests have now been removed since we believe the VA will not have any data on these estimates.

Thank You.

(b) (6)

From: (b) (6) *(b)(6)*
Sent: Thursday, May 30, 2019 11:41 AM
To (b) (6) *b)(6)*
Subject: Re: a request for our collaboration with the VA

Thanks, (b) (6) please bring a printed out copy of the template to our meeting on Friday so we can go over it together.

Thanks,

(b) (6)

(b) (6)
Institute for Clinical and Economic Review
Two Liberty Square, 9th floor
Boston, MA 02109
(b)(6)
www.icer-review.org

Executive Assistant: (b) (6)
(b)(6)
(b)(6)

From: (b) (6)
Sent: Wednesday, May 29, 2019 7:47 PM
To: (b) (6)

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Cc: (b) (6) (b) (6)
Subject: Re: a request for our collaboration with the VA

Hi (b) (6)
Sure, will work with (b) (6) to find some time in your calendar when you are here.
Thanks.

(b) (6)

On May 29, 2019, at 6:59 PM, Steve Pearson *(b)(6)* wrote:

(b) (6)

Thanks for sending this through. I was going to share with the VA today but realized that I don't understand some elements of this and need to talk with you to understand better what we are asking for and what role that data point plays in our model. I will need to talk with you about this later next week, perhaps when I'm up at ICER on June 6-7. Could you please work with (b) (6) to find a good time, and very glad if (b) (6) wants to join as well but not required.

Thanks,

(b) (6)

(b) (6)
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Two Liberty Square, 9th floor
Boston, MA 02109
(b) (6)
www.icer-review.org

Executive Assistant: (b) (6)
(b)(6)
(b)(6)

From: (b) (6)
Sent: Tuesday, May 21, 2019 3:48 PM
To: (b) (6)
Cc: (b) (6)
Subject: RE: a request for our collaboration with the VA

Hi (b) (6)

AMERICAN OVERSIGHT

Attached is the data request list for esketamine that was prepared in collaboration with (b) (6) from UIC.
Will check on Xarelto's data request and revert.

Please let me know if you have any questions.
Thanks.

(b) (6)

From: (b) (6))(6)
Sent: Tuesday, May 21, 2019 2:56 PM
To: (b) (6) (b)(6) ; (b) (6) (b)(6)
Subject: Fw: a request for our collaboration with the VA

Hi,

I'm hoping that now that Valuing a Cure analyses won't be as intensive that we can get back to the VA request below. Soon it will be two months since I told them we would be getting them information as per below so it's important we get back to them as soon as we can. If we need to talk again about the overall goal of this just let me know. Otherwise, when you get back from ISPOR please let me know a new timeline for this that fits in with other responsibilities.

Thanks,

(b) (6)

(b) (6)
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(b)(6)
www.icer-review.org

Executive Assistant: (b) (6)
(b)(6)
(b)(6)

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From: (b) (6)
Sent: Monday, April 1, 2019 7:49 PM
To:
Cc: (b) (6)
Subject: Re: a request for our collaboration with the VA

Perfect, thanks (b) (6)

(b) (6)
Institute for Clinical and Economic Review
Two Liberty Square, 9th floor
Boston, MA 02109
(b)(6)
www.icer-review.org

Executive Assistant: (b) (6)
(b)(6)
(b)(6)

From (b) (6)
Sent: Monday, April 1, 2019 7:00 PM
To:
Cc: (b) (6)
Subject: Re: a request for our collaboration with the VA

Hi (b) (6)
I believe this can be done. It is still early days for Xarelto, which can be a good thing actually since we can model this scenario alongside our main analysis. For esketamine, as you mentioned, population characteristics such as age and gender mix, comorbidities, and cost parameters would be the ones we can change to fit a VA setting. Will speak to the modeling group about this and revert by the end of this week.

(b) (6)

On Apr 1, 2019, at 6:06 PM, (b) (6) (b)(6) wrote:

Hi guys,

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In a recent conversation with the VA we decided to try a pilot effort in "customizing" one of our reports to their population and their costs. This pilot is intended to serve as a proof of concept, so it doesn't have to be perfect, but here's what we were thinking: for esketamine or Xarelto/Vascepa, which parameter inputs would we want the VA to provide in order to give them model results that reflected their system/population -- but they would have to be data points that they can find easily in their medical records/utilization records. What comes to my mind are things like level of comorbidities/severity; age; cost and mix of comparators; cost of events like hospitalization, ER visit, etc.

Can you let me know whether you think it would be possible to get an Excel chart or something similar with a list of these data elements so we could give it to the VA, have them fill it out, and then use it to run a "VA" scenario analysis? There is no specific timeline for this so it's not like we have to squeeze it in during a busy phase for the modelers or us, but let me know what you think about how big an ask this would be. Thanks!

(b) (6)
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Two Liberty Square, 9th floor
Boston, MA 02109
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Executive Assistant: (b) (6)
(b)(6)
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MARCH 18, 2019

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New guidelines advise against aspirin to prevent heart disease

Wall Street Journal (03/18/19) Loftus, Peter

The American College of Cardiology (ACC) and American Heart Association on Sunday said low-dose aspirin should not be given on a routine basis for the purpose of preventing heart attacks and other heart disease in people aged 70 years and older or adults of any age who are at increased risk of bleeding. These guidelines apply to people who have not been previously diagnosed with heart disease. Aspirin became increasingly used for the purpose of preventing a first heart... Read More

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New guidelines advise against aspirin to prevent heart disease
Wall Street Journal (03/18/19) Loftus, Peter

The American College of Cardiology (ACC) and American Heart Association on Sunday said low-dose aspirin should not l given on a routine basis for the purpose of preventing heart attacks and other heart disease in people aged 70 years an older or adults of any age who are at increased risk of bleeding. These guidelines apply to people who have not been previously diagnosed with heart disease. Aspirin became increasingly used for the purpose of preventing a first heart attack after studies in the 1980s and 1990s showed a benefit. Low-dose aspirin may be considered to prevent heart attacks in adults aged 40–70 years who are at higher risk for cardiovascular disease but not at increased risk of bleedin according to the new guidelines. People at higher risk for heart disease include those with a strong family history of it. The medical organizations made the revised aspirin recommendation as part of a new set of "primary prevention" guidelines for people who have not been diagnosed with heart disease. Doctors presented the guidelines at an ACC

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conference in New Orleans. The change follows newer studies that flagged a bleeding risk for aspirin, including gastrointestinal bleeding. The new studies "really have shown us the place for aspirin has diminished in terms of primar prevention," said Amit Khera, MD, director of the preventive cardiology program at UT Southwestern Medical Center in Dallas. "Fewer people should be taking aspirin" for this purpose, he added.

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Major U.S. study finds Apple Watch can detect heart issues
The Hill (03/16/19) Frazin, Rachel

Preliminary results from the Apple Heart Study indicate that the Apple Watch can detect irregular heart rhythms. In the study, reported by researchers with the Stanford University School of Medicine, 0.5% (about 2,000 people) of the more than 400,000 participants wearing Apple Watches in the 8-month study were sent irregular heart rhythm notifications. "The results of the Apple Heart Study highlight the potential role that innovative digital technology can play in creating more predictive and preventive health care," said Lloyd Minor, dean of the Stanford School of Medicine. The irregular rhythm notification periodically monitors heart rhythm in the background and alerts users if their heart rhythm is not regular. Participants who received the irregular heart rhythm notification also received a telemedicine consultation with physician and an electrocardiogram (ECG) patch to further monitor their heart. Approximately a third of the patients wh agreed to wear the ECG were diagnosed with atrial fibrillation. One researcher noted that AFib can come and go, so individuals whose ECGs did not show signs of the condition could also have it. "Atrial fibrillation is just the beginning, as this study opens the door to further research into wearable technologies and how they might be used to prevent diseas before it strikes—a key goal of precision health," Minor said.

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Surgery no better than medication at preventing serious complications of AF
NIH News Release (03/15/19)

Two new papers in the *Journal of the American Medical Association* discuss the effects of catheter ablation vs. drug therapy in the treatment of patients with atrial fibrillation. The articles report the outcomes of the Catheter Ablation versus Antiarrhythmic Drug Therapy for Atrial Fibrillation (CABANA) trial, funded in part by the National Heart, Lung, an Blood Institute. From November 2009 to April 2016, the trial enrolled more than 2,200 patients at sites across the Unite States, Canada, Europe, and Asia. Approximately one-half of the patients were randomized to the ablation procedure, while the others were assigned to drug therapy, though they could opt for ablation if their symptoms could not be controlled. Ultimately, about 27% of the drug therapy patients also ended up receiving ablation. After a median followu period of 48.5 months, the researchers concluded that catheter ablation appeared to be no more effective than drug therapies in preventing strokes, deaths, and other complications in patients with atrial fibrillation. They noted, however, that ablation patient had greater symptom relief and long-term improvements in the quality life, compared with the dru therapy-only recipients. Douglas L. Packer, MD, a cardiologist and professor of medicine at Mayo Clinic, in Rochester, M and the study's principal investigator, said: "When we examined the data according to the treatment actually received, the ablation group had significantly lower rates of death as well as the combination of death, disabling stroke, serious bleeding, or cardiac arrest compared with patients who only received drug therapy."

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Legacy announces voluntary recalls of losartan tablets
FDA Recalls, Market Withdrawals, &Safety Alerts (03/15/19)

Legacy Pharmaceutical Packaging said, in two separate announcements Friday, that it is recalling 43 repackaged lots of losartan tablets to the consumer levels. The nationwide recalls follow the detection of trace amounts of N-Nitroso N-Methyl 4-amino butyric acid (NMBA) in an active pharmaceutical ingredient manufactured by Hetero Labs Ltd. The first recall includes 3 repackaged lots of losartan tablets USP 50 mg, with the NDC number NDC 68645-494-54. The second recall includes 40 repackaged lots of losartan tablets USP 25 mg, 50 mg, and 100 mg. Legacy said it has not received a reports of adverse events related to the recalls.

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Older Americans are awash in antibiotics
New York Times (03/15/19) Span, Paula

Older adults take too many antibiotics, despite efforts by CDC and other groups to reduce the rates. A recent study in tl *Journal of the American Geriatrics Society* found that physicians wrote enough antibiotic prescriptions each year for eve individual aged 65 years and older to receive at least one. The study may underestimate the issue, as researchers used national pharmacy database that followed only outpatients. "The volume would be higher if you included hospitals and nursing homes and other long-term care settings," said Katherine Fleming-Dutra, deputy director of CDC's Office of Antibiotic Stewardship. While antibiotic prescriptions for older adults leveled off between 2011 and 2014, after rising 30 in the previous decade, public health advocates want to see a decline. "It's hard to feel heartened about a plateau wher overuse remains so prevalent," said Caleb Alexander, MD, co-director of the Johns Hopkins Center for Drug Safety and Effectiveness. Antibiotic overuse can lead to drug resistance, and antibiotics can also interact poorly with a number of tl drugs older adults take, such as statins, blood thinners, and kidney and heart medications. Additionally, some antibiotics—such as fluoroquinolones—can cause serious adverse effects.

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AAP: No influenza vaccine preference for 2019–20 season
AAP News (03/19) Jenco, Melissa

For the 2019–20 influenza season, the American Academy of Pediatrics (AAP) says it will no longer indicate a preferenc for the injection versus the nasal spray form of the vaccine for children. The recommendation comes after AAP evaluate current data on vaccination coverage and effectiveness and influenza season characteristics. The guidance is expected t be aligned with CDC recommendations. AAP recommends universal vaccination for everyone aged 6 months and older. Flor M. Munoz, MD, FAAP, a member of the AAP's Committee on Infectious Diseases, says: "Every effort should be mad to ensure that all children receive their influenza vaccine every year before influenza viruses begin circulating in the community. Any licensed influenza vaccine given as indicated for age and health status can be used to protect children against influenza in 2019–20." The formulation of the live attenuated influenza vaccine (LAIV) has been changed by its manufacturer, AstraZeneca, to include a new strain (A/Slovenia) that it suggested would produce better antibody responses than the previous H1N1 strain (A/Bolivia). AAP said it reviewed U.K. data showing that the reformulated LAI has been effective against influenza A/H1N1 for children this season. Interim effectiveness data released by CDC for all vaccinations showed 61% effectiveness against medically attended influenza for children and 48% for the overall population in the current influenza season.

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A trial of a shorter regimen for rifampin-resistant TB
New England Journal of Medicine (03/13/19) Nunn, Andrew J.; Phillips, Patrick P.J.; Meredith, Sarah K.; et al.

Researchers involved in the STREAM clinical study explored whether a shorter-than-recommended course of treatment multidrug-resistant tuberculosis (TB) would improve outcomes. They recruited adults with pulmonary TB and evidence resistance to rifampin, which is managed similarly to multi-drug resistant TB, for a Phase III noninferiority trial. A total 282 participants were randomized to 9–11 months of treatment that included high-dose moxifloxacin, while 142 were directed to continue the therapy for 20 months in accordance with World Health Organization recommendations. Favorable status, as indicated by cultures negative for *Mycobacterium tuberculosis* at 132 weeks, was observed in 78.8 of participants in the short-regimen group and 79.8% of participants in the long-regimen group. The difference of 1 percentage point fell well within the margin to establish noninferiority, which had been set at 10 percentage points or le The treatment approaches shared similar safety profiles, as well.

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FDA approves Pfizer's biosimilar to trastuzumab
Pfizer (03/11/19)

FDA has approved trastuzumab-qyyp (Trazimera—Pfizer), a biosimilar to trastuzumab (Herceptin—Genentech), for the treatment of human epidermal growth factor receptor-2 (HER-2) overexpressing breast cancer and HER2 overexpressin

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metastatic gastric or gastroesophageal junction adenocarcinoma. The approval was based on review of a comprehensiv data package that demonstrated a high degree of similarity between trastuzumab-qyyp and the originator product. "Wit the availability of biosimilars like Trazimera in the U.S., oncologists will have additional treatment options to choose fro which may help provide patients with greater access to the medicines they need," said Mark Pegram, MD, associate director for clinical research at the Stanford Comprehensive Cancer Institute, and director of the Breast Oncology Progr at the Stanford Women's Cancer Center.

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CVS Health's Moriarty: Pharmacy is 'front line' of health care strategy
Drug Store News (03/14/19) Levy, Sandra

Tom Moriarty, CVS Health's chief policy and external affairs officer and general counsel, recently said that pharmacists a at the front line of CVS Health's strategy with its newly combined company Aetna. So far, HealthHUB has been introduc at CVS Pharmacy stores in Houston. "With personalized pharmacy support programs and MinuteClinic services, the HealthHUB pilot is improving care for patients managing chronic conditions with a focus on recommending next best actions and driving medical costs savings," said Moriarty. He added that the number of Americans impacted by chronic conditions continues to grow, and HealthHub will help coordinate care across a patient's full care teams. "For a patient living with diabetes, we can be there more frequently to provide counsel on lifestyle and dietary needs," he said. "In the case of respiratory disease, a respiratory therapist will be on-site to help patients track their conditions and provide the with personalized counsel."

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Sens. Gillibrand and Gardner announce bipartisan legislation to limit prescriptions to 7 days
U.S. Sen. Kirsten Gillibrand News Release (03/15/19)

Sens. Kirsten Gillibrand (D-NY) and Cory Gardner (R-CO) on Friday announced bipartisan legislation to limit the supply initial opioid prescriptions for acute pain to 7 days. The bill would create a 7-day prescription limit for opioids so that no more than a 7-day supply may be prescribed to a patient at one time for acute pain. "The 7-day limit for initial acute-pa opioid prescriptions is consistent with pharmacists' recommendations from the front-lines of care, their collaboration wit law enforcement, and the needs of chronic pain sufferers," said National Association of Chain Drug Stores (NACDS) President and CEO Steven C. Anderson, IOM, CAE. "Six-in-10 Americans support this measure, with only two-in-10 indicating opposition, according to a January 2019 *Morning Consult* poll commissioned by NACDS. This bill will help prevent addiction and help prevent unused medications from falling into the wrong hands. Our support reflects pharmacies' longstanding commitment to serve as part of the solution." The legislation would require medical professionals, as a part of their DEA registration, to certify that they will not prescribe an opioid as an initial treatment f acute pain in an amount that exceeds a 7-day supply. Medical professionals would also have to certify that they would r provide a refill. This prescription limit would not apply to the treatment of chronic pain; pain being treated as part of cancer care, hospice care, or other end-of-life care; or pain treated as part of palliative care.

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Purdue Pharma's new overdose antidote fast-tracked by FDA
CNN.com (03/14/19) Kounang, Nadia

FDA has granted Purdue Pharma's experimental opioid overdose drug fast-track designation. The drug, nalmefene hydrochloride injection, reportedly has a longer effect than naloxone. FDA's fast-track designation facilitates the development and expedites the review of drugs that treat serious conditions and fill an unmet medical need. "If approve the duration of effect of nalmefene HCl injection has the potential to serve as an important alternative for the treatment

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of opioid overdose," Purdue said in a statement. Purdue, which is privately owned by the Sackler family, is named as a plaintiff in dozens of lawsuits across the country for its role in contributing to the opioid crisis. The Sacklers and Purdue have been accused of aggressively marketing oxycodone (OxyContin) using deceptive sales and marketing practices an downplaying its abusive and addictive properties.

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Virginia and the military sharing prescription details to prevent opioid abuse
Military.com (03/11/2019) Sauers, Elisha

In Virginia, a statewide drug monitoring program now enables physicians in the state to check if their patients have gotten prescriptions filled for opioids and other medications at military hospitals and clinics. This is possible because the Defense Department recently unveiled its own system for monitoring controlled substances and how they are given to military patients. The program tracks quantities and strengths of medications. With the Virginia and military systems linked, officials says physicians and pharmacists have a more complete picture of patients' prescription histories. In addition, police and medical licensing boards can use the data to support investigations into doctor shopping and other criminal activity. Diane Powers, a spokeswoman for the Virginia Department of Health Professions, says Virginia was the first state or territory to go "live" with its connection to the military's electronic database. David Bobb, chief of the Defense Health Agency's pharmacy operations, notes: "We didn't want to share it in such a way that an enemy could ge tipped off that ... maybe there's going to be a movement of personnel or something like that. It took a while to come u with a solution and that's why I think ... we were a little bit behind times in making this operation." Virginia's database connects with 32 jurisdictions, including Washington, DC; it most recently began communicating with North Carolina's system.

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Queridos Amigos:

This could be an interesting development. Not new because the studies go back to the late 1990s but new in terms of marketing.
Luis

FDA Approves Esketamine Nasal Spray for Resistant Depression

Caroline Cassels

March 05, 2019

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The US Food and Drug Administration (FDA) has approved esketamine nasal spray *(Spravato,* Janssen Pharmaceuticals*)* for treatment-resistant depression.

"There has been a long-standing need for additional effective treatments for treatment-resistant depression, a serious and life-threatening condition," Tiffany Farchione, MD, acting director of the Division of Psychiatry Products in the FDA's Center for Drug Evaluation and Research, said in an FDA release announcing the drug's approval.

"Controlled clinical trials that studied the safety and efficacy of this drug, along with careful review through the FDA's drug approval process including a robust discussion with our external advisory

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committees, were important to our decision to approve this treatment. Because of safety concerns, the drug will only be available through a restricted distribution system and it must be administered in a certified medical office where the health care provider can monitor the patient," Farchione added.

The potential risk for serious adverse outcomes associated with the drug, including sedation and dissociation and the potential for abuse and misuse, means it is only available through a restricted distribution system, under a Risk Evaluation and Mitigation Strategy.

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Hi, Matthew.

Did you know that on March 4ththe FDA officially approved esketamine for treatment-resistant depression and suicidal ideations?

This is the most significant medicinal psychiatric innovation in the last 30 years, arriving at a crucial point in time for behavioral health in the United States. We are in the midst of a major crisis in our country, with congested emergency rooms, unacceptable wait times to see a mental healthcare provider, and skyrocketing suicide rates. Esketamine will become a solution for many patients who are treatment-resistant and searching for options.

In order for your patients to fully benefit from esketamine's approval, here are some facts you need to know:

- • It can only be administered in a clinic, not prescribed for home use
- • It may be self-administered by the patient with a trained provider supervising
- • The patient's vitals must be monitored for two hours after receiving the nasal spray, including EKG, blood pressure, pulse oximetry, and end title CO2 as indicated

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- • The drug may be dispensed only in certain healthcare settings
- • Insurance providers will be covering esketamine for treatment-resistant depression and suicidal ideations

With esketamine's breakthrough comes a momentous opportunity for innovation in behavioral health business models.

As a comprehensive psychiatric clinic, we have been successfully treating patients with ketamine for over a year and a half and have a lot of insight for both infusion therapy and nasal administration.

One key point is this: unless you have sufficient space and personnel in your practice to fully monitor each patient for two hours, you and your patients will not benefit from this breakthrough.

At Alleviant Health Centers, our business model is built ***for*** procedures like this. We can help you own your own spa-like, fully integrated, holistic mental healthcare practice.

Alleviant Health Centers is a network of full-service mental health clinics helping people heal mood disorders and certain pain conditions with a combination of traditional therapies and innovative, holistic modalities like ketamine infusion therapy and TMS. It is our goal to become a resource of education, inspiration, and empowerment to people suffering from mood disorders and chronic pain.

Our business model has become highly sought-out due to our unique and innovative approach.

We have remarkable data and client feedback to illustrate our success.

We opened our flagship clinic in Little Rock, AR, and have since then branched out into Honolulu, HI, and Naples FL. We are also on track to open clinics in Akron, OH, Nashville, TN, San Diego, CA , and Rogers, AR, over the next few months.

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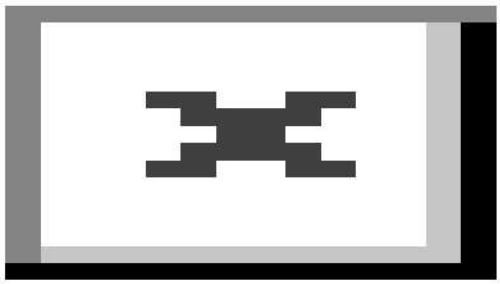

We are incredibly proud of the impact we have on the mental health field in the United States and it is our goal to replicate our integrated care model to be accessible throughout the country.

With this email, we invite you to become a part of this amazing growth. We can help you open your own private practice or offer you partnership or employment opportunities.

If you are interested in working with us, simply reply to this email. We look forward to continuing the conversation.

Click here to download more information about our business model and ways to get involved.

Click here to download FDA's guidelines for administration of esketamine nasal spray.

We are also excited to meet you at the upcoming APA meeting on May 18-22 in San Francisco. We will be in booth 1639 – stop by to find out how we are bringing integrated holistic psychiatry to the market, how you can do it with us, play fun games, participate in giveaways, and more.

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Sincerely,

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Chief Medical Officer of Alleviant Health Centers

Medical Director of Alleviant Health Centers of Naples

Board Certified General Adult Psychiatrist

Board Certified Child and Adolescent Psychiatrist

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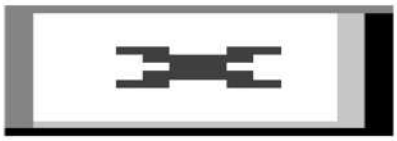

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FDA approves nasal spray for depression
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FDA approves first drug exclusively intended for female postpartum depression

Gail M. Herrine, MD, FACOG, IBCLC, FABM

Daily, high-potency cannabis use increases psychosis risk



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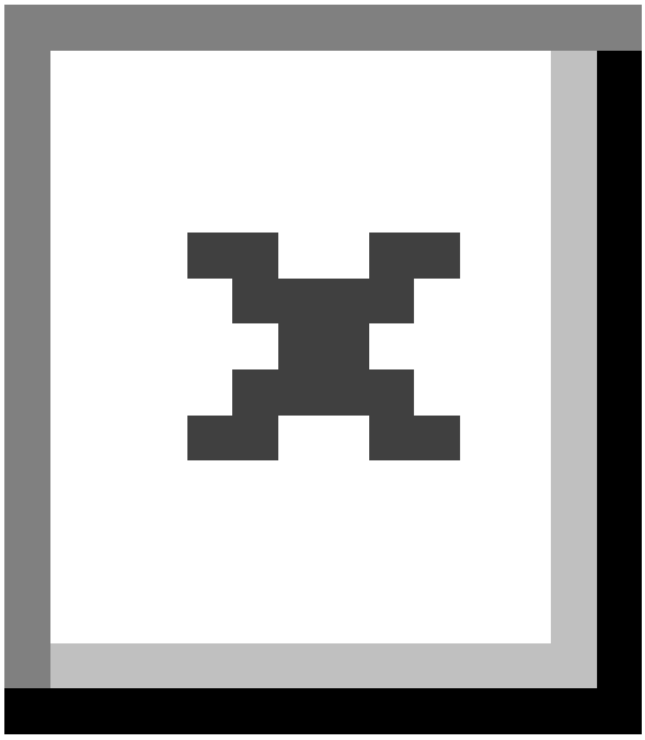

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PSYCHIATRIC NEWS | ALERT

ıe Voice of the American Psychiatric Association and the Psychiatric Community

FDA Approves Fast-Acting Esketamine for Treatme Depression

Yesterday the Food and Drug Administration (FDA) approved Spravato (esk to be used in conjunction with an oral antidepressant for treatment-resistar adults. Spravato is the first medication for depression with a new mechanis Prozac (fluoxetine hydrochloride) was approved in the late 1980s.

"There has been a long-standing need for additional effective treatments fo depression, a serious and life-threatening condition," said Tiffany Farchione of the Division of Psychiatry Products in the FDA's Center for Drug Evaluati the agency's press release. "Controlled clinical trials that studied the safety drug, along with careful review through the FDA's drug approval process in discussion with our external advisory committees, were important to our de

ıatment."

cause of the risks of sedation, dissociation, and misuse, Spravato is subject to a comprehensive Risk Eva ·ategy (REMS) program and carries a black-box warning. Patients can take Spravato only under the super ofessional in the office of a certified physician and must be monitored by a health care professional for at ı administration of the drug. The patient must remain on site until the health care professional determine tient to leave. In addition to the medication's serious side effects, the black-box warning notes the risk of

a Phase 3 clinical trial of adults with treatment-resistant depression, 223 patients were randomized to re ses of Spravato or placebo. All participants also took an oral antidepressant. Those who took the active n perienced greater improvement in their depression symptoms at four weeks compared with those who to

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See attached. It'll no doubt grow again before Thursday morning.

Be sure to see the Xanax advertisement toward the end of the document.

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Esketamine Notes

Note: comments in ALL CAPS represent notes to follow-up, points to check, or unresolved questions. Comments in *italics* provide perspective or comments on study results.

Last revision: 6/19/19

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A different study appears to counter the STANFORD STUDY PI result showing naltrexone inhibits ketamine's antidepressant effect. In this study, five subjects with major depression and alcohol use disorder received 380mg naltrexone depot was administered intramuscularly 2-6 days prior to the first of four weekly IV ketamine infusions. By the fourth weekly ketamine infusion, all five subjects met the response criteria of 50% decline in MADRS score.
(Yoon, Petrakis, Krystal. JAMA Psychiatry 2019;76:337-338)

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The Yoon et al patent filing discloses a list of compounds that antagonize the NMDA receptor, including ketamine, and comments on the misuse potential of these substances:

> However, the class of NMDA receptor antagonists is plagued with high abuse potential, and drug supplies are often misused as recreational drugs. Ketamine (known as K or Special K) is a widely abused substance, especially in southern Asia (for example, China, Taiwan, HongKong, Vietnam, and Cambodia). Some data suggest that ketamine is the third most commonly abused drug, after methamphetamine and MDMA. Ketamine abuse

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VA-19-1109-B-002751

is associated with damage to the mucosa of the urinary bladder and nasal passages, as well as with cognitive, behavioral and emotional abnormalities, including persisting psychosis in some heavy users. Nitrous oxide (known as "whippets"), dextromethorphan (known as "Robo-tripping" or "skittling") and amantadine also are abused. The most highly abused NMDA receptor antagonist is ethanol, which produces significant occupancy of NMDA receptor at ethanol doses associated with heavy social drinking (>4 alcohol drinks). [emphasis added]

(Yoon, Petrakis, and Krystal. WIPO PCT filing WO 2018/075481 A1, initial priority filing date 10/27/2016 as US 62/408,983).

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Ketamine shares pharmacologic actions with ethanol, including non-competitive antagonism at NMDA receptors, disinhibiting pyramidal cells to release excess glutamate, and amplifying glutamate non-NMDA signals mediated by mechanistic target of rapamycin complex 1 (mTORC1), and increased neurotrophins (including brain-derived neurotrophic factor [BDNF]). mTORC1 activity is believed involved because sirolimus-mediated decrease in mTORC1 activity in transplant patients is temporally linked to depression. Moderate alcohol intake can, like ketamine, decrease pro-inflammatory cytokines. Ethanol vapor induces increased dendritic spine density in pyramidal neurons, similar to synaptic changes noted with ketamine. Alcohol does not, however, induce hallucinations.

(Bonnet. Life Sci 2017;168:54-57)

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NMDA Receptor Antagonists

Substance

Substance	IC50 (nM)	Ki (nM)	
MK-801	4.1	2.5	
PCP	91	58	
Ketamine	509	324	
Memantine	594	378	

(Wallach, Kang, Colestock et al. PLoS One 2016;11:e0157021)

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Ketamine Demonstrates Monoamine Receptor Activity

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Dopamine, DOPAC, and HVA all increased 1.4x after KET-10. IMI increased dopamine 1.7x. Both fluoxetine and KET-10 increased serotonin 2.7x. KET-5 and KET-10 induced 42% and 59% increases in tyrosine hydroxylase immunoreactivity, and 24% and 88% decreases in dopamine transporter immunoreactivity. Serotonin transporter immunohistochemical assays were decreased in the KET-5 and -10 groups by 19-88% depending upon brain region.
(de Barros Viana, Xavier, do Vale et al. IBRO Reports 2018;4:7-13)

Ketamine inhibits the rat dopamine transporter. This study determined Ki values for S-ketamine, R-ketamine, and included results from previously published work to provide a concentration-dependent view of ketamine's activity. The Ki values (μM) are:

	R-ketamine	S-ketamine	R/S Ratio
NMDA	2.5	0.9	2.7
Opioid mu	84	29	2.9
DAT	390	47	8.3
Opioid kappa	60	24	2.5
NET	69	65	1.1
Opioid delta	286	205	1.4
Muscarinic ACh	91	125	0.7
SERT	148	156	0.9
Opioid sigma	19	131	0.15

DAT = rat dopamine transporter, NET = human norepinephrine transporter, SERT = rat serotonin transporter. NMDA, muscarinic, and opioid results cited by Nishimura and Sato from others.

These results may explain differential antidepressant and psychotomimetic effects.
(Nishimura, Sato. Neurosci Letters 1999;274:131-134)

USEFUL QUESTION TO ANSWER:

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Ketamine infusion at 0.1mg/kg over 5 minutes to 0.5mg/kg for 40 minutes leads to plasma concentrations of 75 – 185 ng/ml (0.32 – 0.78 uM). A single IV bolus of 0.15-0.25mg/kg ketamine prior to general anesthesia was associated with reductions in pro-inflammatory cytokines. Ketamine infusions of 0.5 mg/kg leading to 100-250ng/ml (0.42 – 1.1 uM) lead to feeling intoxicated, comparable to alcohol intoxication. Infusion at 0.1mg/kg (25-50ng/ml, 0.1 – 0.2 uM) cause mild euphoria. Reported dosage ranges for ketamine abuse are 1-2mg/kg IV, 50-150mg IM, 100-500mg oral, or 30-400mg nasal insufflation.

Hyperphosphorylated tau (microtubule associated protein) was reported after chronic daily ketamine infusion at 1mg/kg in prefrontal nad entorhinal cortices in mice and nonhuman primates.

SCALE THAT 1 MG/KG TO HUMAN USE WITH FORMULAS BELOW.

(Zanos et al, Pharmacol Rev 2018;70:621-660).

(b5)

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Duration of Ketamine's Antidepressant Effect

Ketamine duration of action in unipolar and bipolar depression typically runs 10-14 days. One long-term study found median time to relapse = 18 days. The longitudinal studies did not include an active control group for comparing ketamine to an active treatment. A meta-analysis did not find any difference in effect sizes by time point; 4h post-infusion was not significantly different from 14d post-infusion. Comparing the only available pre-post study at 12-14d post-infusion to the one available 12-14d results from a ketamine-placebo study shows a marked difference in effect size. The pre-post study effect size was -1.55 compared to the placebo-controlled study result of -0.21. Although the number of data points were limited, male sex was a predictor of larger effect size at 7d but not 4h or 24h, an apparent contradiction of rodent study results (Carrier and Kabaj, 2013).

Several of the reviewed ketamine trials (Salvadore 2012 included 4/14 subjects from Salvadore 2010, which in turn included 7/15 subjects from Salvadore 2009; aan het Rot retested all 10 subjecs from Mathew 2010). Unsurprisingly, the effect size for aan het Rot's open-label unblinded trial was about twice that reported by Mathew.

Coyle and Laws, Hum Psychopharmacol Clin Exp 2015;30:152-163)

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Ketamine's dysphoria may be similar to that observed with pentazocine. A previous study used different ketamine doses in the rat, smaller doses caused increased excitability without analgesia or anesthesia. Higher doses showed analgesia and anesthesia. Only the analgesic effect is known to be blocked by naloxone. Ketamine doses in this study were 40, 80, 120, or 160 mg/kg intraperitoneal ketamine. Only the highest dose caused a decline in systolic BP (mean 152 to 101mmHg); approximately 15% animals died at this dose without external cardiac compression. The overall results of opiate binding sites show racemic ketamine requiring micromolar concentrations to inhibit radioligand binding with values for morphine in the nanomolar range. These results are similar to prior results in peripheral tissue (e.g. guinea pig ileum). Racemic ketamine was statistically more likely to bind the delta opiate site over the mu, kappa, or sigma sites. Ketamine and morphine show similar relative binding preference for delta vs mu opiate sites. Ketamine, like pentazocine but not other opiates, does not induce analgesia when injected into periaqueductal gray region.

(Smith, Bouchal, et al. Neuropharmacol 1987;26:1253-1260).

Ketamine's oral bioavailability is 16-30% due to significant hepatic first-pass metabolism. Esketamine oral bioavailability is only 8-11%.

(Zanos et al, Pharmcol Rev 2018;70:621-660)

Medications delivered intraperitoneally are absorbed through the mesenteric circulation into the portal vein and are subject to hepatic first-pass metabolism.

(Turner, Brabb, Pekow, and Vasbinder. J Am Assoc Lab Anim Sci 2011;50:600-613)

(b5)

Scaling can be done based upon the ratio of mass to surface area, or by the cube root of mass. Allometric scaling for body surface area is (animal mass/BSA) / (human mass/BSA). Using assumptions for human mass and BSA of 60kg and 1.62 m^2, and rat mass and BSA 0.15kg, 0.025m^2, the BSA scaling from rat to human dosing is 6/37 = 0.1621. Alternative scaling utilizes the cube root of mass (animal mass / human mass) ^0.33. For the rat and human assumptions: (0.15/60)^0.33 = 0.1357

(Nair and Jacob. J Basic Clin Pharm. 2016;7:27-31).

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R- and S-ketamine binding to receptors was measured with results as:

Receptor	Kd (nM)	Ki R-ketamine (μM)	Ki S-ketamine (μM)	R/S Ratio
Mu	1.2	28	11	2.5
Sigma	1.3	130	130	1.0
Kappa	1.0	100	24	4.2
PCP	45	3.2	1.1	2.9
Sigma	40	19	131	0.15
Muscarinic	0.09	37	20	1.8

In guinea pig ileum, naloxone inhibited racemic ketamine's action in a dose-dependent manner. Naloxone doses of 1 nM showed no effect but greater doses inhibited racemic ketamine up to total blockade at naloxone 10 μM. The EC85 concentration for ketamine was estimated to correspond to EC50 for opioids from the researcher's prior data. At 1 nM naloxone, the greatest concentration of naloxone with no pharmacologic effect upon ketamine binding, the ketamine EC85 was approximately 110 μM.

S-ketamine was known to have approximately four times the analgesic potency of R-ketamine, suggesting the analgesic properties are caused by interactions at mu, kappa, and PCP

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receptors (note the R/S ratio for kappa receptors in the table above). Results from other animal studies combined with these results suggest ketamine is a kappa agonist and mu antagonist.
(Hustveit, Maurset, Oye. Pharmacol Toxicol 1995;77:355-359).

A comparison of ketamine and salvinorin A, a known kappa opioid receptor agonist, showed considerable similarity between the two compounds. A kappa opioid antagonist blocked the effect of either ketamine or salvinorin A. This study concluded ketamine is a full kappa opioid receptor agonist but its effects relative to salvinorin A are both less potent and less selective for the kappa opioid receptor.
(Nemeth, Paine, Rittiner et al. Psychopharmacol (Berl) 2010;210:264-74).

The analgesic effects of ketamine in mice are decreased in a dose-dependent manner by mu or delta opiate antagonists but not kappa opiate antagonists. Ketamine doses were 4ug injected intrathecally into 25-30g mice.
(da Fonseca Pacheco, Romero, Duarte; Brain Res 2014;1562:69-75).

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The kappa opioid agonist salvinorin A decreases phasic dopaminergic tone in the nucleus accumbens. The timing of this change in dopamine was correlated with decreased motivation.
(Ebner, Roitman, Potter et al. Psychopharmacol (Berl) 2010;210:241-252).

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The kappa opioid receptor is activated by dynorphin. Existing work has shown female rats are less sensitive than males to changes in motivation induced by kappa opioid agonists. This study examined the effects of gonadectomy in male and female rats exposed to a kappa opioid agonist. When administered a kappa opioid agonist, pre-gonadectomy male rats demonstrated greater decreases in motivation compared to pre-gonadectomy female rats. The anhedonic effect occurs in a dose-dependent fashion with higher doses of kappa opioid agonist creating significantly greater effects. Similar results were observed for castrated vs ovariectomized rats, removing the possibility that observed differences are attributable to sex hormones. Further investigation found elevated expression of tyrosine hydroxylase mRNA in the ventral tegmental area of female but not male rats. There were no differences in kappa opioid receptor mRNA except lower expression in female BNST. Dynorphin mRNA expression was similar except for greater expression in female PVN. Overall, dopamine release in rats decreased in response to a kappa opioid agonist but to a much lesser degree in female rats. The authors conclude females are more resistant to kappa opioid mediated declines in dopamine release but perhaps more vulnerable to reinforcing effects of substance use.

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VA-19-1109-B-002758

(Conway, Puttick, Russell et al. Neuropharmacology 2019:146:231-241).

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Female rats respond to ketamine IV at lower doses than male rats. This response is ablated by ovariectomy and restored by administering both estrogen and progesterone. Replacing only one of these sex hormones does not promote ketamine activity. Increased mTOR phosphorylation in the medial prefrontal cortex did not occur at the dose of ketamine that induced antidepressant effect in intact female rats, suggesting the ketamine effect is not mediated through mTOR, at least in females. mTOR activation did occur at higher ketamine doses. Another proposed mechanism for ketamine's antidepressant effect is NMDA-mediated decrease in kinase eEF2 activity with subsequent increased BDNF expression. However, this study did not find any change in eEF2 among female rats at any ketamine dose. Physiologic fluctuations in sex hormones previously were found to influence dendritic spine density in female rats.

(Carrier and Kabaj, Neuropharmcology 2013;70:27-34).

Estrogen is required for ketamine's antidepressant response in animal models as shown by ovarectomized rodents with or without replacement hormones. Subsequent rodent model testing showed adequate levels of estrogen appear to be necessary for ketamine's antidepressant effect. (2R,6R)-Hydroxynorketamine (HNK) exhibits antidepressant effects in animal models without as many adverse effects. HNK may accumulate in female brains to a greater extent than male brains.

(Williams and Trainor, Front Neuroendocrin 2018;50:107-117)

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Male and female rats can develop depressive symptoms after exposure to chronic stress. Treating those symptoms with repeated IV ketamine infusions leads to greater self-administration of ketamine. Ketamine was associated with increased dendritic thin spine

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formation in the nucleus accumbens. Chronically stressed female rats demonstrated a greater self-administration effect than male rats. The authors commented "Taken together, we have demonstrated a sex-specific responsivity to KET addiction-like behavior following exposure to chronic stress in females, an effect not observed in male counterparts." These clinical implications of these findings should be explored.

(Wright, Hagerty, Strong et al. Chronic Stress 2019;3:1-12).

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Defective fronto-cortical and hippocampal glutaminergic circuits and downregulation of mTOR are believed to contribute to depression. These changes can be reversed by ketamine, SSRI, or ECT. A common downstream effect is increased BDNF activity, leading to increased dendrite length or branching, and/or an increased number of dendritic spines and/or branching, However, this model doesn't address decreased mesolimbic dopaminergic activity. Bupropion, amphetamine, and pramipexole, a D3-specific agonist, all can decrease depressive symptoms. Ketamine is known to increase dopaminergic activity in rodents and primates. This study evaluated mesolimbic dopaminergic activitiy in neurons harvested from rodents and in human stem cells differentiated into dopaminergic neurons. Ketamine at a concentration of 1 uM increased dopaminergic neuron dendritic length, number, and surface area. Rapamycin inhibited this ketamine action. Blocking AMPA activity prevented this ketamine effect. A different NMDA antagonist showed similar effects to ketamine. Similiarly, ketamine's effect upon mesolimbic dopaminergic neuron dendrites was blocked by inhibiting BDNF activity through an anti-BDNF antibody, or pretreatment with a D3 antagonist but not a D1 antagonist.

In human neuronal culture, ketamine at 0.1 – 1 uM concentration promoted dopaminergic dendritic plasticity. This activity was blocked by AMPA antagonist, rapamycin, anti-BDNF antibody, inhibitors of TrkB/MEK, or a D3 antagonist.

(2R,6R)-HNK at 0.5 uM concentration induced similar effects to ketamine in both murine and human cell cultures.

(Cavalleri, Merlo Pich, et al. Mol Psychiatry 2018;23:812-823)

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Ketamine increases dopaminergic activity in rodent and non-human primate brains but to a lesser degree than amphetamine. Memantine did not change prefrontal cortex dopamine levels. Anesthetic level doses of ketamine do not appear to change dopamine levels.
(Kokkinou, Ashok, Howes. Mol Psychiatry 2018;23:59-69).

Chronic ketamine administration at 100mg/kg/day for 1, 2, or 3 months resulted in a time-dependent decrease in penile smooth muscle, cavernous nerve nitric oxide synthase, and increased penile fibrosis. Exogenous electrical stimulation of the cavernous nerve in the 3-month ketamine group showed a significantly lower increase in intracavernosal pressure. Smooth muscle apoptosis was clearly visible after only one month of ketamine administration.
(Shang, Wu, Liao, et al. Oncotarget 2017;8:73670-73683)

Crab-eating macaques (3 years old) were given ketamine IV 1mg/kg daily for 6 months and mice were given ketamine intraperitoneally 30mg/kg for 1, 3, or 6 months. Brains were examined for hyperphosphorylated tau. Starting at 3 months, hyperphosphorylated tau was observed in frontal but not entorhinal cortices in the mice. In monkeys, the density for hyperphosphorylated tau cells increased in both prefrontal and entorhinal cortices in experimental (15 and 27 cells per 1500 square micrometer) and control monkeys (0.6 and 0.2 cells per 1500 square micrometer). The number of monkey cells staining TUNEL positive, an apoptosis marker, in prefrontal cortex vs control was significantly elevated (7.2 vs 0.8 cells per square micrometer). The authors note their unpublished work showing hyperphosphorylated tau in deceased cocaine users.
Control animals did not show these increases in hyperphosphorylated tau.
(Yeung, Wai, Fan, et al. Toxicol Lett 2010;193:189-193).

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Chronic ketamine abuse (mean 350mg daily) will decrease serum oxytocin (5.9 vs 9.5 in control subjects). Abstinence from ketamine increased oxytocin levels over a 14d period but they remain lower than controls. Higher anxiety was associated with lower oxytocin levels. Total years of ketamine use and amount of ketamine used daily did not correlate with lower oxytocin levels.
(Huang, Chen, Chang, et al. Front Psychiatry 2018;9:633).

Adding IV ketamine 0.5 mg/kg to ECT in a placebo-controlled RCT does not change neurocognitive outcomes or the overall remission rate measured on MADRS.
(Anderson, Blamire, Branton et al; PMID: 28383867)

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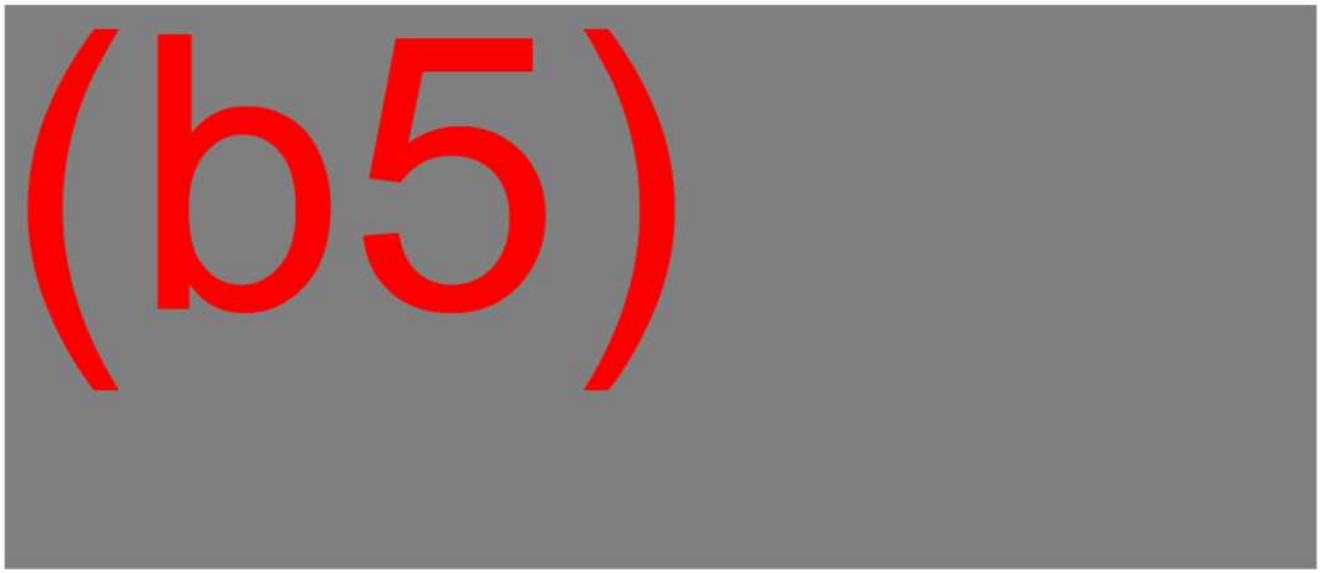
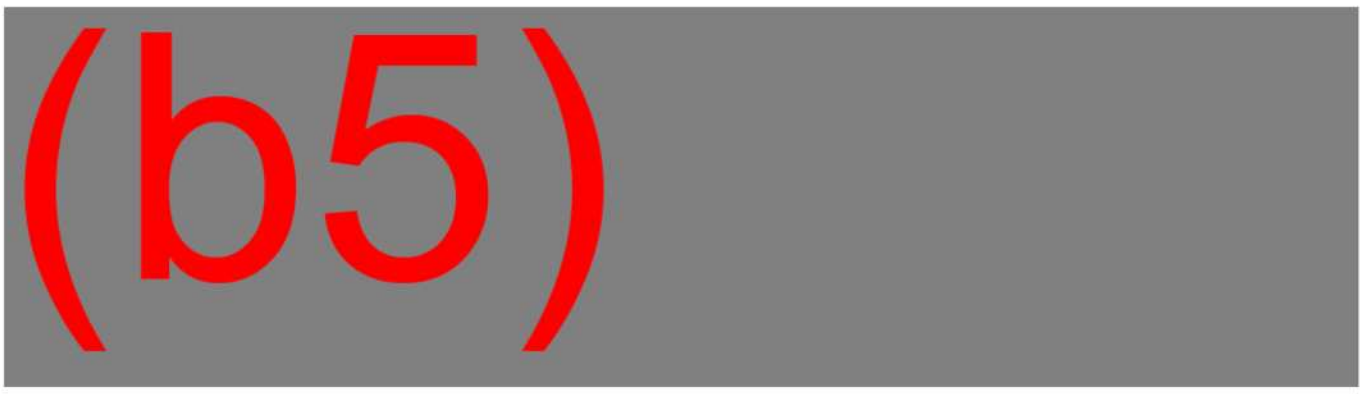
Ketamine treatment effect upon MDD is maintained up to four weeks in subjects with a family history of alcohol use disorder. Treatment with riluzole removes any effect of family history, resulting in a gradual increase in MADRS scores after ketamine infusion.
(Niciu, Luckenbaugh et al, Int J Neuropsychopharmacol 2015;18(1):pyu039).

In a RCT crossover trial with riluzole and placebo (R/R, pla/pla, or pla/R), riluzole failed to separate from placebo in subjects with a current MDD episode. All subjects were taking a SSRI, SNRI, or bupropion. Response rates across all three groups were 20-25% with remission rates of 8-13%.
(Mathew, Gueorguieva et al, Neuropsychopharmacology 2017;42:2567-2574).





Depressed subjects showing decreased urinary levels of 3-MHPG, a norepinephrine metabolite, were more likely to respond positively to either imipramine or alprazolam. This work showed analysis of urinary catecholamine metabolites also predicts response to alprazolam vs an antidepressant (imipramine, desipramine, nortriptyline, or maprotiline).
(Mooney, Schatzberg, Cole et al. J Clin Psychopharmacol 1991;11:339-343)

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A trial comparing depressed outpatients response to placebo, amitriptyline, alprazolam, or lorazepam found no significant differences after six weeks among the three active treatments; all were superior to placebo. Subjects were moderately depressed (HRSD = 19.7 baseline). One interesting element of this study was a gradual tapering of study drugs. Following this taper, all subjects received two weeks of placebo. About 20% of subjects in all groups reported worsening symptoms in this end of study placebo period, including subjects originally randomized to the placebo arm. The final mean amitriptyline dose was 100mg, noted as low by the investigators. The paper concluded with a cautionary recommendation on antidepressants vs benzodiazepines for major depression:



(Laakman, Faltermaier-Temizel, Bossert-Zaudig et al. Psychopharmacology 1995;120:109-115)



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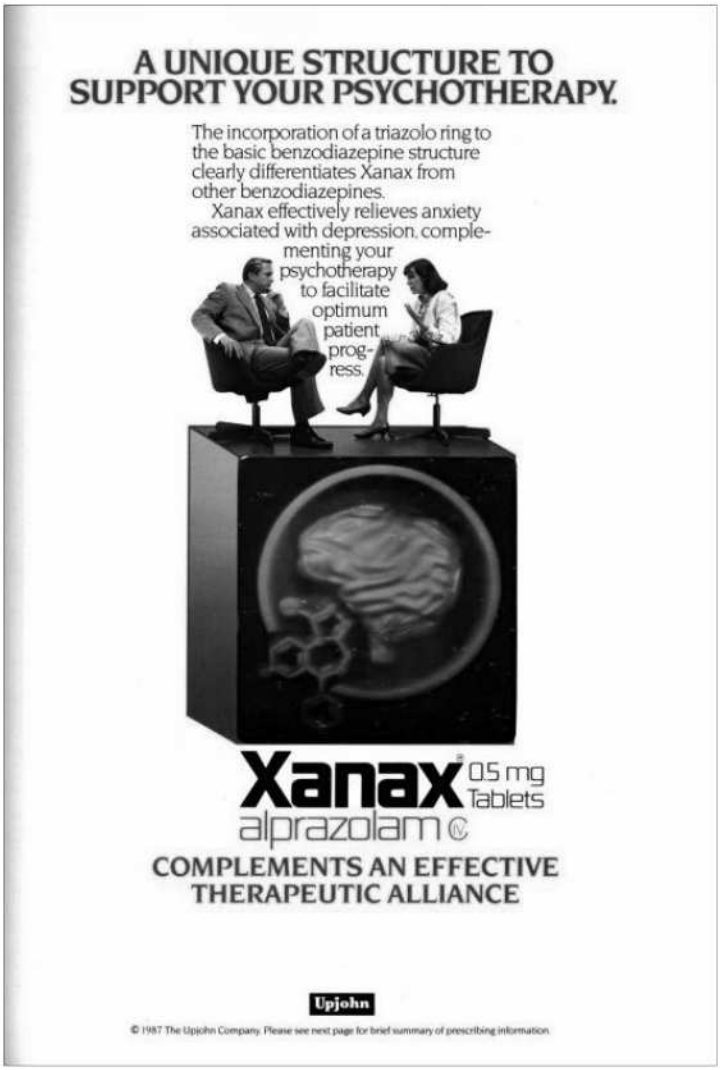
The ability of catecholamine metabolites to identify potential alprazolam responders was referenced in published studies and company marketing messages through reference to alprazolam's triazolo ring structure. A 1987 advertisement claimed "A unique structure to support your psychotherapy" and refers to "incorporation of a triazolo ring to the basic benzodiazepine structure clearly differentiates Xanax from other benzodiazepines." Graphically, the advertisement shows a two people seated in chairs on a box. Inside the box is a black background, the proverbial 'black box', containing a brain circled by a ring, with the chemical structure of alprazolam piercing the circle. The overall message suggests triazolo ring structure – a unique differentiator for alprazolam – helps the medication pierce the blood-brain barrier, and this change within the 'black box' facilitates psychotherapy.



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Studies Not Yet Incorporated into the Outline Above

A single dose of ketamine IV 0.5mg/kg resulted in improved depressive symptoms with an effect size of 1.17. Subjects with a current history of psychosis were excluded but a lifetime history of psychosis was permitted. Among subjects with a lifetime history of psychosis, ketamine's effect size upon depressive symptoms was 0.35. Lifetime psychosis patients were more likely to report dissociation but not psychosis at 40 minutes post-infusion (effect size 0.23). The increased dissociation resolved by 80 minutes post-infusion.

Pennybaker SJ et al. Biol Psychiatry 2017;82:e35-36.

Comparison of remote vs site-based assessments in nasal esketamine. As a check against potential bias from unblinding due to treatment-emergent side effects, investigators compared the MADRS ratings from site investigators and a separate rater who was blinded to any medication side effect. 21% of subjects were selected at random, 7 each placebo and esketamine, for review. Investigators reviewed audio recordings of the MADRS scale at baseline (pre-medication) and at 2h after the initial dose. Some of the initial and 2h post-treatment scores differed, but the baseline vs 2h score differentials did not show statistically significant differences between the original study and the repeat analysis. However, the repeat analysis investigators reported similar treatment emergent adverse effects unique to estketamine (dizziness, dissociation) at rates similar to the original study.

Targum SD et al. J Psychiatric Research 2019;111:68-73.

Case Series of Esketamine for MDD with Psychosis. Esketamine at 0.5mg/kg was infused over 40 minutes (1 subject) or given subcutaneously (3 subjects) to subjects with MDD with psychosis (N=2), bipolar depression with psychosis or schizoaffective disorder, depressive type (N=1 each). All 4 subjects were prescribed antipsychotic medication as risperidone (n=2), quetiapine or haloperidol (n=1 each). The MDD and Bipolar Depression subjects showed a good response to esketamine with MADRS score changes of 39, 34, and 35. Among subjects showing improved mood symptoms, psychosis improved as well. Dissociation was a transient side-effect in three subjects.

Ajub E. Biol Psychiatry 2018;83:e15-16.

RCT of IV Esketamine for TRD. Subjects with treatment resistant depression (TRD) were randomized 1:1:1 to esketamine 0.2mg/kg, 0.4mg/kg, or placebo on day #1. Exclusion criteria were anxiety disorder, PTSD, or an eating disorder. Subjects were 60% female. Around half had failed 4+ lifetime antidepressants. Responders (>50% reduction in MADRS) received the same dose on day #4. Non-responders who received placebo were randomized to either esketamine group, and non-responders who received either esketamine dose received esketamine 0.4mg/kg. 67% and 64% of the 0.2 and 0.4mg/kg groups were responders with a mean MADRS change of 16.3 and 13.4. Drug related treatment related side effects occurred among the three groups as 30%, 25%, and 67% for placebo, 0.2mg/kg, and 0.4mg/kg groups.

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Cognitive effects are observed among frequent users of illicit ketamine. Frequent use appears more related to cognitive effects than high dose intermittent use. The common cognitive adverse effect is impaired short- and long-term memory. However, in this study, no adverse effect upon memory were observed.

Singh JB et al. Biol Psychiatry 2016;80:424-431.

Open-label uncontrolled trial of ketamine infusion for depression and comorbid PTSD. Minneapolis VAMC. Exclusion criteria were lifetime history of psychotic or bipolar disorders, mod-severe TBI, or SUD in prior six months. Subjects were veterans aged 18-75 with moderate to severe TRD and chronic PTSD. Diagnoses were determined using SCID and CAPS. Subject received 0.5mg/kg iv ketamine MWF for two consecutive weeks. Primary outcomes were PCL5 and MADRS score changes. From baseline to after the 6th infusion, the mean changes in PCL5 and MADRS showed an effect size of 2.17 and 4.64. At four weeks, the PCL and MADRDS scores increased with an effect size of 0.24 and 1.42. 20% of subjects required beta blockers for elevated BP during infusion.

Ketamine effect size upon PCL subscales ranged from 1.5 – 2.1, suggesting the improvement was not limited to overlapping symptoms between PTSD and MDD.

Albott CS et al. J Clin Psychiatry 2018;79:3.

Rodent model for anxiety using Wistar – Kyoto rats, known for impaired hippocampal long term potentiation. Control was Sprague Dawley rats. Results show ketamine improved extinction among WKY rats but not SD rats. Not all WKY rats responded, however. Among the responding WKY rats, long-term potentiation improved to levels similar to SD rats. The results suggest ketamine may be an effective adjunctive treatment to psychotherapy for anxiety or PTSD.

Fortress AM et al. Neuropharmacology 2018;137:372-381.

Morphine = ketamine as 1:1 ratio for anesthesia. Reference is Elia, Nadia Pain 2005;113:61-70. See also DEA equivalencies for additional insights.

See also Anesthesiology 2005;102:211-20 and Br J Anesthesia 2000;84:739-42.

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Good morning Dr Maria D. Llorente Monday, August 26, 20

Leading The News

Depression, Marijuana Use, Alcohol Abuse Increasing Among Former Smokers, Research Indicates

MedPage Today (8/23, Boyles) reported, "The prevalence of depression, marijuana use, and alcohol abuse among former cigarette smokers in the U.S. have all increased since the mid-2000s, according to data through 2016 from the annual National Survey on Drug Use and Health (NSDUH)" analyzed by researchers at City University of New York. Data indicate that "prevalence of past-year major depressive episodes among former smokers rose from 4.88% to 6.04% from 2002 to 2016." The findings were published in the American Journal of Preventive Medicine.

PSYCHIATRIC NEWS ALERT

APA Speaks Out Against Administration Effort to Replace Flores Settlement

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Risk for Psychiatric Disorders, Suicide Higher in Children With IBD

Now Accepting Abstracts for the APA Annual Meeting, April 25-29, 2020

Submit your ideas for general sessions, media sessions, courses or posters for APA's 2020 Annual Meeting, April 25-29, 2020, in Philadelphia. The theme for the meeting is Advancing Quality: Challenges and Opportunities. All abstracts must be entered in APA's submissions site for consideration. View the Submissio Guidelines. **The deadline is Thursday, Sept. 5, at 11:59 p.m. ET.**

Learn more and submit an abstract.



Psychiatric Treatment/Disorders

Psychiatric Illness May Be Common In Patients With ESRD, Study Suggests

Medscape (8/23, Parry, Subscription Publication) reported a new study suggests that "psychiatric illnesses are common in children and adults with end-stage renal disease (ESRD) who are receiving dialysis." Specifically, while "only approximately 2% of all adults and 1% of children had been hospitalized with a primary psychiatric diagnosis, these amounted to a large number of patients (9058 elderly adults, 8570 middle-aged adults, and 122 children)." Also, researchers saw "that the rate of hospitalizations with psychiatric diagnoses increased over the course of the study period, predominantly attributed to secondary diagnoses." The findings were published online in the Clinical Journal of the American Society of Nephrology.

Healio (8/23) also reported.

Government and Psychiatry

Trump Asks VA To Order Esketamine Spray For Depressed Veterans

The Atlantic (8/23, Hamblin) reported President Trump last week said the VA will purchase "a lot" of esketamine, a nasal-spray ketamine derivative, for veterans with depression. However, only "one of three clinical trials" of the drug "showed any benefit" for treating depression, and VA spokeswoman Susan Carter clarified that the "agency has no immediate plans to change its policy." She explained that the "VA will closely monitor the use of esketamine in veterans to more fully understand its relative safety and effectiveness as compared to other available treatments. Based on this information, VA may revise its clinical guidance and formulary status if warranted."

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Psychiatry and Public Health

Pediatric Exposure To Cannabis Has Increased Since Medical Legalization In Massachusetts, Study Indicates

Pulmonology Advisor (8/23) reported a new study by researchers at University of Massachusetts Amherst indicates that "following medical marijuana legalization (MML) in Massachusetts in 2012, there was an increase in pediatric cannabis exposure." Study authors wrote, "The increase occurred despite the cannabis product packaging being designed to be difficult for young children to open, being unappealing to the youth, and requiring warning labels instructing that the product be kept away from children." The findings were published online in JAMA Network Open.

Restless Legs Syndrome May Increase Risk Of Suicide And Self-Harm, Study Suggests

HealthDay (8/23) reported a new study by researchers at Penn State suggests that "people with restless legs syndrome (RLS) have nearly three times the risk of suicide and self-harm, which indicates that there may be a link between the physical condition and mental health." Investigators "analyzed data on more than 24,000 people with RLS and about 145,000 people without the neurological condition. None had a history of suicide attempts or self-harm." Results indicate that "during the study period, people with RLS had a 2.7-fold higher risk of suicide or self-harm than people without the condition." The findings were published in JAMA Network Open.

Other News

Dementia Caregivers Sleep Less Per Week Than Other Age-Matched Adults, Analysis Suggests

Reuters (8/23, Carroll) reported a new analysis of 35 studies suggests that "dementia caregivers slept about 3 hours less per week than age-matched adults." The findings were published in JAMA Network Open.

Friday's Lead Stories

- **First-Degree Relatives Of Patients With Schizophrenia And Bipolar Disorder Appear To Have**

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Distinct Brain Patterns, Meta-Analysis Indicates

- **White House Considering Creating Agency To Examine Links Between Mental Health, Violent Behavior**
- **People Who Mix Marijuana With Opioids May Be More Vulnerable To Mental Health Issues, Research Suggests**
- **Buprenorphine Use May Be Associated With Higher Likelihood Of Adherence To All Chronic Medication Classes, Especially Antidepressants, Research Suggests**
- **Wearable Device Can Reportedly Predict Aggressive Behaviors In People With Autism**

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Date:	2019/06/24 15:15:19
Start Date:	2019/07/30 08:00:00
End Date:	2019/07/30 08:30:00
Priority:	Normal
Type:	Appointment

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