



November 16, 2021

Christine H. Monahan
American Oversight
1030 15th Street NW, B255
Washington, DC 20005

RE: FDA FOIA Request 2020-1977 & 2020-4765;
American Oversight v. HHS et al., Civil No. 20-cv-01063

Dear Ms. Monahan:

This is a partial response to the Freedom of Information Act (FOIA) request numbers 2020-1977 & 2020-4765 that is the subject of the Amended Complaint filed in *American Oversight v. HHS et al.*, Civil No. 20-cv-01063, now pending in the U.S. District Court for the District of Columbia.

FDA's Office of the Commissioner sent records to the Department of Health and Human Services and the White House for further review and return to us. That consultation has been completed and the records, FDA-OC-2020-1977/2020-4765-000993 to 001313, are enclosed. This production completes the number of pages that OC intends to process for FOIA request FDA-2020-1977 & 2020-4765.

We have withheld portions of these pages under the exemptions provided in 5 U.S.C. §§ 522(b)(4), (b)(5), and (b)(6) of FOIA, as delineated below:

Exemption (b)(4) permits the withholding of "trade secrets" (TS) and /or commercial or financial information that was obtained from a person outside the government and that is privileged or confidential.

Exemption (b)(5) permits the withholding of inter-agency or intra-agency communications records which are part of the deliberative process and pre-decisional (DPP). Disclosure of such material could inhibit the open and candid expression of opinions and diminish the quality of the decision-making process. The presidential communications privilege (PCP) protects documents solicited and received by the President or his immediate White House advisers who have broad and significant responsibility for investigating and formulating the advice to be given to the President.

Exemption (b)(6) permits the withholding of information which, if released, would constitute a clearly unwarranted invasion of personal privacy. The information that has been withheld under Exemption (b)(6) consists of personal information, such as direct contact information, and conference and passcode numbers. In this case, we have determined that there is no countervailing public interest qualifying under the standard set forth under exemption (b)(6) to release the personal identifying information of certain third parties.

Please direct any questions regarding this response to Amy Powell of the U.S. Department of Justice, at (919) 856-4013 or Amy.Powell@usdoj.gov.

Sincerely,

**Meredith J.
Schlaifer -S**

Meredith J. Schlaifer, M.S., J.D.

FOIA Officer, Office of the Commissioner

Division of Freedom of Information

U.S. Food and Drug Administration

Digitally signed by Meredith J.
Schlaifer -S

Date: 2021.11.16 16:06:19 -05'00'

From: O'Malley, Devin M. EOP/OVP [Devin.M.O'Malley@ovp.eop.gov]
Sent: 4/8/2020 4:49:35 PM
To: Caccamo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
Subject: RE: flag: WaPo on testing, CDC test manufacturing

ok

From: Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>
Sent: Wednesday, April 8, 2020 4:23 PM
To: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>
Subject: RE: flag: WaPo on testing, CDC test manufacturing

Hey—just pinging on this one, I really need to get to reporter. Ok to proceed?

Stephanie Caccamo
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: 301.348.1956
Cell: (b)(6)
stephanie.caccamo@fda.hhs.gov

From: Caccamo, Stephanie
Sent: Wednesday, April 8, 2020 2:15 PM
To: 'O'Malley, Devin M. EOP/OVP' <Devin.M.O'Malley@ovp.eop.gov>; DL OVP Comms COVID
<(b)(6)> <(b)(6)>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caligui, Laura <Laura.Caligui@fda.hhs.gov>; Block, Molly <Molly.Block@fda.hhs.gov>; Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>; McKeogh, Katherine (OS) <Katherine.McKeogh@hhs.gov>; Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>
Subject: RE: flag: WaPo on testing, CDC test manufacturing

(b) (5)

(b) (5)

Stephanie Caccamo
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: 301.348.1956
Cell: (b)(6)
stephanie.caccamo@fda.hhs.gov

From: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>
Sent: Wednesday, April 8, 2020 2:08 PM
To: Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; DL OVP Comms COVID
<(b)(6)> <(b)(6)>

FDA-OC-2020-1977/2020-4765-000993

MULTI-HHS-FDA-20-0400, 20-0415-C-000001

Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caligui, Laura <Laura.Caligui@fda.hhs.gov>; Block, Molly <Molly.Block@fda.hhs.gov>; Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>; McKeogh, Katherine (OS) <Katherine.McKeogh@hhs.gov>; Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>
Subject: RE: flag: WaPo on testing, CDC test manufacturing

(b) (5)

From: Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>

Sent: Wednesday, April 8, 2020 1:14 PM

To: DL OVP Comms COVID (b)(6)

Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caligui, Laura <Laura.Caligui@fda.hhs.gov>; Block, Molly <Molly.Block@fda.hhs.gov>; Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>; McKeogh, Katherine (OS) <Katherine.McKeogh@hhs.gov>; Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>

Subject: flag: WaPo on testing, CDC test manufacturing

Hi—

Flagging below Qs and responses from WaPo's David Willman, on the investigative team, about our waiver of manufacturing quality standards during an emergency and the application to the CDC test. Reporter is writing this afternoon, so sincerely appreciate fast feedback. Thank you!

(1) What standards related to Current Good Manufacturing Practices (CGMPs) does FDA encourage and/or require of manufacturers of diagnostic test kits for PCR use, such as those that are now circulating to detect covid-19?

(b) (5)

(2) Has FDA encouraged or enforced CGMPs at the CDC facility that manufactured the original test kits for detecting covid-19? Please describe any related guidance or actions taken.

(b) (5)

(3) Is FDA examining or assisting in examining the CDC's original design and/or manufacturing of the covid-19 test kits?

(b) (5)

(b) (5)

My article will refer, as have others, to FDA's role with ultimately approving the circulation of covid-19 kits made by entities other than CDC. Please provide FDA's general basis for granting the emergency authorizations along with any explanation of the breadth of time that the agency took in doing so. I am seeking FDA's general basis/rationale/criteria for the non-CDC EUAs. I'm asking about this because FDA, as you know, has come under criticism related to the length of time it took for non-CDC manufacturers to win authorization to circulate the covid-19 test kits.

(b) (5)

Stephanie Cacomo
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: 301.348.1956
Cell: (b)(6)
stephanie.cacomo@fda.hhs.gov

From: O'Malley, Devin M. EOP/OVP [Devin.M.O'Malley@ovp.eop.gov]
Sent: 4/7/2020 4:54:35 PM
To: Manchester, Brittney [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bd6ca86f5a3f43ffb295122f23a95770-Brittney.Ma]; Caccamo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Block, Molly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e32ca68078848889751e7ec26910142-Molly.Block]; DL OVP Comms COVID ((b)(6) Oakley, Caitlin B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8feed045e954557aa1e0052f925865f-HHS-Caitlin]; McKeogh, Katherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3facab3fd03480f8553892121fd2009-HHS-Katheri]
CC: Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]
Subject: RE: Flagging--WaPo on KN95s

Ok from my end

From: Manchester, Brittney <Brittney.Manchester@fda.hhs.gov>
Sent: Tuesday, April 7, 2020 3:14 PM
To: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>; Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; Block, Molly <Molly.Block@fda.hhs.gov>; DL OVP Comms COVID ((b)(6) Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>; McKeogh, Katherine (OS) <Katherine.McKeogh@hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: RE: Flagging--WaPo on KN95s

Hi Devin,

In the EUA for KN95 we've set up specific conditions and processes to verify the information we are requesting to determine authenticity, which we are not doing for the others. We are making that point via the red text below.

((b)(5)).

Thank you,
Brittney

Brittney Manchester
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: 301-796-1026 | Cell: 202-763-9073
brittney.manchester@fda.hhs.gov



From: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>
Sent: Tuesday, April 7, 2020 2:24 PM

AMERICAN
OVERSIGHT

FDA-OC-2020-1977/2020-4765-000996

MULTI-HHS-FDA-20-0400, 20-0415-C-000004

To: Cacco, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Block, Molly <Molly.Block@fda.hhs.gov>; Manchester, Brittney <Brittney.Manchester@fda.hhs.gov>; DL OVP Comms COVID <(b)(6)> Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>; McKeogh, Katherine (OS) <Katherine.McKeogh@hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: RE: Flagging--WaPo on KN95s

(b) (5)

From: Cacco, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Tuesday, April 7, 2020 2:08 PM
To: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>; Block, Molly <Molly.Block@fda.hhs.gov>; Manchester, Brittney <Brittney.Manchester@fda.hhs.gov>; DL OVP Comms COVID <(b)(6)> Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>; McKeogh, Katherine (OS) <Katherine.McKeogh@hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: RE: Flagging--WaPo on KN95s

How about this:

(b) (5)

(b) (5)

Stephanie Caccomo

Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: 301.348.1956
Cell: 240.762.8873
stephanie.caccomo@fda.hhs.gov

From: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>

Sent: Tuesday, April 7, 2020 12:46 PM

To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Block, Molly <Molly.Block@fda.hhs.gov>; Manchester, Brittney <Brittney.Manchester@fda.hhs.gov>; DL OVP Comms COVID (b)(6) <(b)(6)@ovp.eop.gov>; Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>; McKeogh, Katherine (OS) <Katherine.McKeogh@hhs.gov>

Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>

Subject: RE: Flagging--WaPo on KN95s

Ok thank you! I do think we should say that (b)(6) but I'll let y'all hash it out and send back a new draft.

Thanks!

Devin

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>

Sent: Tuesday, April 7, 2020 12:35 PM

To: Block, Molly <Molly.Block@fda.hhs.gov>; O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>; Manchester, Brittney <Brittney.Manchester@fda.hhs.gov>; DL OVP Comms COVID

(b)(5); Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>; McKeogh, Katherine (OS) <Katherine.McKeogh@hhs.gov>

Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>

Subject: RE: Flagging--WaPo on KN95s

Devin—

Just to clarify, the part you highlighted in green—(b)(5)

We can adjust line to say: (b)(5)

(b)(5) The FDA established a special email inbox, COVID19FDAIMPORTINQUIRIES@fda.hhs.gov, for industry representatives to quickly communicate with the agency and address questions or concerns.

Stephanie Caccomo

Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration

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FDA-OC-2020-1977/2020-4765-000998

MULTI-HHS-FDA-20-0400, 20-0415-C-000006

Desk: 301.348.1956
Cell: (b)(6)
stephanie.caccommo@fda.hhs.gov

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Tuesday, April 7, 2020 12:21 PM
To: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>; Manchester, Brittney <Brittney.Manchester@fda.hhs.gov>; Cacco, Stephanie <Stephanie.Caccommo@fda.hhs.gov>; DL OVP Comms COVID (b)(6) Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>; McKeogh, Katherine (OS) <Katherine.McKeogh@hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: RE: Flagging--WaPo on KN95s

Just my two cents:

DRAFT Response: (b)(5)

[REDACTED]

[REDACTED]

[REDACTED]

(b)(5)

From: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>
Sent: Tuesday, April 7, 2020 12:12 PM
To: Manchester, Brittney <Brittney.Manchester@fda.hhs.gov>; Cacco, Stephanie <Stephanie.Caccommo@fda.hhs.gov>; DL OVP Comms COVID (b)(6) Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>; McKeogh, Katherine (OS) <Katherine.McKeogh@hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Block, Molly <Molly.Block@fda.hhs.gov>
Subject: RE: Flagging--WaPo on KN95s

Adding Molly. (b) (5)

(b) (5)

From: Manchester, Brittney <Brittney.Manchester@fda.hhs.gov>

Sent: Tuesday, April 7, 2020 11:53 AM

To: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>; Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; DL OVP Comms COVID <(b)(6)@> Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>; McKeogh, Katherine (OS) <Katherine.McKeogh@hhs.gov>

Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>

Subject: RE: Flagging--WaPo on KN95s

Hi Devin,

(b) (5)

Can you please let me know if this better addresses your concerns? Wash Post has a 12PM deadline, so hoping to close the loop with them soon, pending your feedback.

Response:

(b) (5)

Thank you,
Brittney

Brittney Manchester
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: 301-796-1026 | Cell: 202-763-9073
brittney.manchester@fda.hhs.gov



From: Manchester, Brittney
Sent: Monday, April 6, 2020 5:18 PM
To: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>; Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; DL OVP Comms COVID (b)(6) @ [REDACTED] Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>; McKeogh, Katherine (OS) <Katherine.McKeogh@hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: RE: Flagging--WaPo on KN95s

Hi Devin,

Thanks for the feedback. I'll connect with our SMEs about updating this language and will circle back with you.

Thank you,
Brittney

Brittney Manchester
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: 301-796-1026 | Cell: 202-763-9073
brittney.manchester@fda.hhs.gov



From: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>
Sent: Monday, April 6, 2020 5:03 PM
To: Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; DL OVP Comms COVID (b)(6) [REDACTED] >; Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>; McKeogh, Katherine (OS) <Katherine.McKeogh@hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Manchester, Brittney <Brittney.Manchester@fda.hhs.gov>
Subject: RE: Flagging--WaPo on KN95s

MULTI-FHS-FDA-20-0400, 20-0415-C-000010

(b) (5)

For more information please see:

1. April 3, 2020, EUA: >>>><https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#coronavirusppe><<<<;
2. Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised): >>>><https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-face-masks-and-respirators-during-coronavirus-disease-covid-19-public-health><<<<;
3. Emergency Use Authorizations: >>>><https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization><<<<;

Stephanie Caccomo

Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: 301.348.1956
Cell: (b)(6)
stephanie.caccomo@fda.hhs.gov

From: Fetalvo, Ninio J. EOP/OVP [(b)(6)]
Sent: 4/2/2020 5:18:59 PM
To: Block, Molly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e32ca68078848889751e7ec26910142-Molly.Block]; Caccamo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
CC: Love, Kelly A. EOP/OVP [(b)(6)]
Subject: RE: Tucker tonight

Sorry for the confusion. We just realized that because Dr. Hahn is pre-taping with Watters World, he cannot also do Jeanine's show.

We'll try for another week. Thanks.

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Thursday, April 2, 2020 4:27 PM
To: Fetalvo, Ninio J. EOP/OVP [(b)(6)]; Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>
Cc: Love, Kelly A. EOP/OVP [(b)(6)]
Subject: RE: Tucker tonight

We are good for Justice on Saturday. Have you been talking with her producers? Can you loop us in?

Thanks!

From: Block, Molly
Sent: Thursday, April 2, 2020 2:58 PM
To: Fetalvo, Ninio J. EOP/OVP [(b)(6)]; Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>
Cc: Love, Kelly A. EOP/OVP [(b)(6)]
Subject: RE: Tucker tonight

Still waiting to hear back on the Judge Jeanine request. But wanted to flag something for you as well. Today, FDA released a PSA (see [link](#)) about food safety and supply. This is a good message that will help with the educational campaign that the U.S. food supply remains safe for both people and animals. There is no evidence of human or animal food or food packaging being associated with transmission of the coronavirus that causes COVID-19.

[(b)(5)]

Can you share some of the producers for those shows and I'd be happy to pitch this.

Molly

From: Fetalvo, Ninio J. EOP/OVP [(b)(6)] @ [(b)(6)]
Sent: Thursday, April 2, 2020 12:00 PM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>
Cc: Love, Kelly A. EOP/OVP [(b)(6)]
Subject: RE: Tucker tonight

Live

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Thursday, April 2, 2020 12:00 PM
To: Fetalvo, Ninio J. EOP/OVP <(b)(6)>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Cc: Love, Kelly A. EOP/OVP <(b)(6)>
Subject: RE: Tucker tonight

Live or pre-tape?

From: Fetalvo, Ninio J. EOP/OVP <(b)(6)>
Sent: Thursday, April 2, 2020 11:58 AM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Cc: Love, Kelly A. EOP/OVP <(b)(6)>
Subject: RE: Tucker tonight

Can he do Justice w/ Judge Jeanine on Saturday (9pm hour)? (b) (5)
(b) (5) Thanks.

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Thursday, April 2, 2020 10:19 AM
To: Fetalvo, Ninio J. EOP/OVP <(b)(6)>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Cc: Love, Kelly A. EOP/OVP <(b)(6)>
Subject: RE: Tucker tonight

Just connected with the team and tonight doesn't work. But he enjoyed America's Newsroom yesterday. Is there more morning television/radio we can work into his schedule next week?

Molly

From: Fetalvo, Ninio J. EOP/OVP <(b)(6)> @ (b)(6)
Sent: Thursday, April 2, 2020 10:15 AM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Cc: Love, Kelly A. EOP/OVP <(b)(6)>
Subject: RE: Tucker tonight

Let us know if he's available and we will connect.

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Thursday, April 2, 2020 10:07 AM
To: Fetalvo, Ninio J. EOP/OVP <(b)(6)>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Cc: Love, Kelly A. EOP/OVP <(b)(6)>
Subject: RE: Tucker tonight

Understood.

From: Fetalvo, Ninio J. EOP/OVP <(b)(6)>
Sent: Thursday, April 2, 2020 10:02 AM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Cc: Love, Kelly A. EOP/OVP <(b)(6)>
Subject: RE: Tucker tonight

(b) (5)

From: Block, Molly <Molly.Block@fda.hhs.gov>

Sent: Thursday, April 2, 2020 9:57 AM

To: Fetalvo, Ninio J. EOP/OVP <(b)(6)>; Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>

Cc: Love, Kelly A. EOP/OVP <(b)(6)>

Subject: RE: Tucker tonight

Checking. Are there particular topics they want to discuss with Dr. Hahn? Do you have any info on the segment?

From: Fetalvo, Ninio J. EOP/OVP <(b)(6)>

Sent: Thursday, April 2, 2020 9:52 AM

To: Block, Molly <Molly.Block@fda.hhs.gov>; Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>

Cc: Love, Kelly A. EOP/OVP <(b)(6)>

Subject: Tucker tonight

Molly and Stephanie,

Can Dr. Hahn do Tucker's show tonight in the 8pm hour?

Thanks,

Ninio

—

Ninio J.H. Fetalvo

Office of the Vice President

(b)(6)

From: Fetalvo, Ninio J. EOP/OVP (b)(6)
Sent: 4/3/2020 1:13:33 PM
To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Heck, Mia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=656b2fa5aca84a18851397d417a16672-HHS-Mia.Hec]; Oakley, Caitlin B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8feed045e954557aa1e0052f925865f-HHS-Caitlin]
CC: O'Malley, Devin M. EOP/OVP [Devin.M.O'Malley@ovp.eop.gov]; Deere, Judd P. EOP/WHO (b)(6) Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Hall, Bill (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e56218361cd4ffbaccdd06ac2d7b809d-HHS-bill.ha]; McKeogh, Katherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3facab3fd03480f8553892121fd2009-HHS-Katheri]; Block, Molly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e32ca68078848889751e7ec26910142-Molly.Block]; Broido, Tara (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b1ed7d3dee614eda879e4e5e8641601b-HHS-Tara.Br]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]
Subject: RE: Washington Post--FDA comment

Wasn't the interview on the record? Was this not addressed during the interview?

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Friday, April 3, 2020 10:18 AM
To: Heck, Mia (OS) <Mia.Heck@hhs.gov>; Fetalvo, Ninio J. EOP/OVP (b)(6)>; Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>
Cc: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>; Deere, Judd P. EOP/WHO (b)(6) Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>; Hall, Bill (OS) <bill.hall@hhs.gov>; McKeogh, Katherine (OS) <Katherine.McKeogh@hhs.gov>; Block, Molly <Molly.Block@fda.hhs.gov>; Broido, Tara (OS) <Tara.Broido@hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Subject: Washington Post--FDA comment

Hi folks—

Following up here, after connecting with WaPo last night, and hearing more about narrative, we'd like to provide below on the record. I'm also flagging some background info that is a bit crucial to what we understand is a big piece of the story—our interactions with one particular lab in Washington state. We need to send this AM, so appreciate quick ok.

(b)(5)

(b) (5)

Stephanie Caccomo

Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: 301.348.1956
Cell: (b)(6)
stephanie.caccomo@fda.hhs.gov

From: Heck, Mia (HHS/OASH) <Mia.Heck@hhs.gov>

Sent: Thursday, April 2, 2020 9:36 AM

To: Fetalvo, Ninio J. EOP/OVP <(b)(6)>; Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>

Cc: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; O'Malley, Devin M. EOP/OVP

<(b)(6)>; Deere, Judd P. EOP/WHO <(b)(6)>; Murphy, Ryan (OS)

<Ryan.Murphy1@hhs.gov>; Hall, Bill (OS) <bill.hall@hhs.gov>; McKeogh, Katherine (OS)

<Katherine.McKeogh@hhs.gov>; Block, Molly <Molly.Block@fda.hhs.gov>; Broido, Tara (OS) <Tara.Broido@hhs.gov>;

Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>

Subject: RE: Washington Post

copy

From: Fetalvo, Ninio J. EOP/OVP <(b)(6)>

Sent: Thursday, April 2, 2020 9:31 AM

To: Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>

Cc: Heck, Mia (HHS/OASH) <Mia.Heck@hhs.gov>; Caccomo, Stephanie (FDA/OC) <Stephanie.Caccomo@fda.hhs.gov>;

O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>; Deere, Judd P. EOP/WHO

<(b)(6)>; Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; Hall, Bill (HHS/ASPA)

<bill.hall@hhs.gov>; McKeogh, Katherine (OS/ASPA) <Katherine.McKeogh@hhs.gov>; Block, Molly (FDA/OC)

<Molly.Block@fda.hhs.gov>; Broido, Tara (HHS/OASH) <Tara.Broido@hhs.gov>; Caliguiri, Laura (FDA/OC)

<Laura.Caliguiri@fda.hhs.gov>

Subject: Re: Washington Post

Fine with that. I wouldn't give him more than 15 min though.

—

Ninio J.H. Fetalvo

Office of the Vice President

(b)(6)

On Apr 2, 2020, at 9:26 AM, Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@hhs.gov> wrote:

(b) (5)

Thanks everyone for your work on this.

Caitlin B. Oakley

Deputy Assistant Secretary, National Spokesperson

Office of the Assistant Secretary for Public Affairs

AMERICAN
OVERSIGHT

FDA-OC-2020-1977/2020-4765-001008

MULTI-HHS-FDA-20-0400, 20-0415-C-000016

U.S. Department of Health and Human Services
caitlin.oakley@hhs.gov

From: Heck, Mia (HHS/OASH) <Mia.Heck@hhs.gov>
Sent: Thursday, April 2, 2020 9:18 AM
To: Caccamo, Stephanie (FDA/OC) <Stephanie.Caccamo@fda.hhs.gov>; Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>
Cc: Fetalvo, Ninio J. EOP/OVP <(b)(6)>; O'Malley, Devin M. EOP/OVP <(b)(6)>; Deere, Judd P. EOP/WHO <Judson.P.Deere@who.eop.gov>; Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>; McKeogh, Katherine (OS/ASPA) <Katherine.McKeogh@hhs.gov>; Block, Molly (FDA/OC) <Molly.Block@fda.hhs.gov>; Broido, Tara (HHS/OASH) <Tara.Broido@hhs.gov>; Caliguiri, Laura (FDA/OC) <Laura.Caliguiri@fda.hhs.gov>
Subject: RE: Washington Post

(b) (6)

From: Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>
Sent: Thursday, April 2, 2020 8:52 AM
To: Heck, Mia (HHS/OASH) <Mia.Heck@hhs.gov>; Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>
Cc: Fetalvo, Ninio J. EOP/OVP <(b)(6)>; O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>; Deere, Judd P. EOP/WHO <(b)(6)>; Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>; McKeogh, Katherine (OS/ASPA) <Katherine.McKeogh@hhs.gov>; Block, Molly (FDA/OC) <Molly.Block@fda.hhs.gov>; Broido, Tara (HHS/OASH) <Tara.Broido@hhs.gov>; Caliguiri, Laura (FDA/OC) <Laura.Caliguiri@fda.hhs.gov>
Subject: RE: Washington Post

Hi Mia—

It will be a very negative story for FDA. A few themes came out of our 90 min convo:

(b) (5)

We are not sending separate on the record comments—our statement Monday covers everything we'd share anyway, although I will be highlighting a few lines from statement for reporters. We have a few minor things to follow-up on, like the names of the labs who first came to FDA under our new flexible policy.

(b) (5)

This could publish as early as tomorrow.

Happy to chat more, thanks Mia for considering!

Stephanie Caccomo

Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: 301.348.1956
Cell: (b)(6)
stephanie.caccomo@fda.hhs.gov

From: Heck, Mia (HHS/OASH) <Mia.Heck@hhs.gov>

Sent: Thursday, April 2, 2020 6:51 AM

To: Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>

Cc: Fetalvo, Ninio J. EOP/OVP <(b)(6)>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>;

O'Malley, Devin M. EOP/OVP <(b)(6)>; Deere, Judd P. EOP/WHO

<(b)(6)> Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>; Hall, Bill (OS) <bill.hall@hhs.gov>;

McKeogh, Katherine (OS) <Katherine.McKeogh@hhs.gov>; Block, Molly <Molly.Block@fda.hhs.gov>; Broido, Tara (OS)

<Tara.Broido@hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>

Subject: Re: Washington Post

Good morning,

(b) (5)

. ADM Giroir has one short block of time to do a call at 10:00AM so we need to decide rather quickly.

Mia

Sent from my iPhone

On Apr 1, 2020, at 1:50 PM, Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@hhs.gov> wrote:

(b) (5)

Thank you all.

From: Fetalvo, Ninio J. EOP/OVP <(b)(6)>

Sent: Wednesday, April 1, 2020 1:42 PM

To: Caccomo, Stephanie (FDA/OC) <Stephanie.Caccomo@fda.hhs.gov>; Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>; O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>; Deere, Judd P. EOP/WHO

<(b)(6)>

Cc: Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>; McKeogh, Katherine (OS/ASPA) <Katherine.McKeogh@hhs.gov>; Block, Molly <Molly.Block@fda.hhs.gov>; Heck, Mia (HHS/OASH)

<Mia.Heck@hhs.gov>; Broido, Tara (HHS/OASH) <Tara.Broido@hhs.gov>; Caliguiri, Laura (FDA/OC)

<Laura.Caliguiri@fda.hhs.gov>

Subject: RE: Washington Post

Please circulate those statements for review on this chain as well.

From: Cacco, Stephanie <Stephanie.Cacomo@fda.hhs.gov>

Sent: Wednesday, April 1, 2020 1:35 PM

To: Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>; Fetalvo, Ninio J. EOP/OVP (b)(6); O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>; Deere, Judd P. EOP/WHO

<(b)(6)>

Cc: Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>; Hall, Bill (OS) <bill.hall@hhs.gov>; McKeogh, Katherine (OS) <Katherine.McKeogh@hhs.gov>; Block, Molly <Molly.Block@fda.hhs.gov>; Heck, Mia (OS) <Mia.Heck@hhs.gov>; Broido, Tara (OS) <Tara.Broido@hhs.gov>; Caligui, Laura <Laura.Caligui@fda.hhs.gov>

Subject: RE: Washington Post

Yes—this is a bit similar to the NYT story last week, but much harsher of FDA. Narrative is being driven a bit by the lab community, specifically academic/research labs.

We are putting Drs. Shuren and Stenzel on the phone for a deep background phone call this evening at 6pm. We will complement with on the record responses that align with statement we issued on Monday.

Stephanie Cacco

Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: 301.348.1956
Cell: (b)(6)
stephanie.cacomo@fda.hhs.gov

From: Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>

Sent: Wednesday, April 1, 2020 1:28 PM

To: Fetalvo, Ninio J. EOP/OVP <(b)(6)>; O'Malley, Devin M. EOP/OVP

<(b)(6)>; Deere, Judd P. EOP/WHO <(b)(6)>

Cc: Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>; Hall, Bill (OS) <bill.hall@hhs.gov>; McKeogh, Katherine (OS) <Katherine.McKeogh@hhs.gov>; Block, Molly <Molly.Block@fda.hhs.gov>; Cacco, Stephanie <Stephanie.Cacomo@fda.hhs.gov>; Heck, Mia (OS) <Mia.Heck@hhs.gov>; Broido, Tara (OS) <Tara.Broido@hhs.gov>

Subject: RE: Washington Post

Thanks, Ninio.

(b)(5)

[REDACTED]

[REDACTED]

Thanks all.

DRAFT PRE-DECISIONAL DELIBERATIVE

From: Fetalvo, Ninio J. EOP/OVP <(b)(6)>

Sent: Wednesday, April 1, 2020 1:25 PM

To: Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>; O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>; Deere, Judd P. EOP/WHO <Judson.P.Deere@who.eop.gov>

Cc: Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>; McKeogh, Katherine (OS/ASPA) <Katherine.McKeogh@hhs.gov>; Molly.Block@fda.hhs.gov; Cacco, Stephanie (FDA/OC)

<Stephanie.Caccomo@fda.hhs.gov>; Heck, Mia (HHS/OASH) <Mia.Heck@hhs.gov>; Broido, Tara (HHS/OASH) <Tara.Broido@hhs.gov>

Subject: RE: Washington Post

(b) (5) [REDACTED] How will the below questions be handled?

From: Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>

Sent: Wednesday, April 1, 2020 1:19 PM

To: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>; Fetalvo, Ninio J. EOP/OVP

(b)(6) [REDACTED] @ [REDACTED] Deere, Judd P. EOP/WHO <Judson.P.Deere@who.eop.gov>

Cc: Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>; McKeogh, Katherine (OS/ASPA) <Katherine.McKeogh@hhs.gov>; Molly.Block@fda.hhs.gov; Caccomo, Stephanie (FDA/OC) <Stephanie.Caccomo@fda.hhs.gov>; Heck, Mia (HHS/OASH) <Mia.Heck@hhs.gov>; Broido, Tara (HHS/OASH) <Tara.Broido@hhs.gov>

Subject: FW: Washington Post

Hi Devin, Ninio and Judd—The Washington Post (Bob O'Harrow and Neena Satija) is working on a story about testing again....this one seems to be related more to the FDA. Not sure if they have reached out to you.

(b) (5) [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Thanks and happy to chat.

DRAFT PRE-DECISIONAL DELIBERATIVE COMMUNICATION

From: O'Harrow, Robert <Robert.OHarrow@washpost.com>

Sent: Tuesday, March 31, 2020 12:38 PM

To: FDA Office of Media Affairs <FDAOMA@FDA.HHS.GOV>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Manchester, Brittney <Brittney.Manchester@fda.hhs.gov>; McKinney, James <James.McKinney@fda.hhs.gov>

Cc: Satija, Neena <Neena.Satija@washpost.com>; Boburg, Shawn <Shawn.Boburg@washpost.com>

Subject: Washington Post

Hi. I'm Robert O'Harrow at The Post. I am working with my investigative colleagues Neena Satija and Shawn Boburg on a story about coronavirus testing.

We have built an extensive timeline of events, collected scores of emails from scientists at FDA, CDC, public health, academic and hospital laboratories. In addition we have conducted numerous interviews.

We are trying to understand how events unfolded and who made the decisions.

It is clear that the FDA decided early in the crisis to grant EUA approval to just one test, the CDC assay, and only allow public health laboratories to employ it. In doing so, the FDA prevented other viable tests from being used to diagnose Americans for the coronavirus.

After the CDC test failed on Feb. 8, the FDA stood by its decision to use just one test, despite having the authority to use other tests and loosen the approval requirements (as it ultimately decided to do on Feb. 29.)

Even as the number of infected people soared, Tim Stenzel, director of the office of Vitro Diagnostics and Radiological Health at FDA, spent most of a week at CDC, attending meetings about the test and touring the facilities. He did so while public health and clinical lab scientists were imploring the FDA to take swifter action to loosen regulatory requirements, according to the emails we have obtained, along with letters sent to Congress and the FDA.

We have a few questions:

1. Why did the FDA initially choose to use only the CDC test and allow only public health labs to use it?

2. Why did Dr. Stenzel decide on Friday Feb. 21 to go to Atlanta for discussions about the CDC test -- and stay there for most of the following week?

3. Stenzel was told to go to Atlanta, according to our documents and interviews.

Who told him to go to CDC?

What was Jeff Shuren's role in that decision?

4. Why did FDA choose to send Stenzel to CDC and focus on the CDC test exclusively, a choice that delayed the kind of decision the agency made on Feb. 29?

We are open to discussing our story in detail.

We are hoping to publish in the coming days, so please get back to us by noon tomorrow.

m) (b)(6)

Thank you,
Robert

Robert O'Harrow Jr.
Washington Post Staff Writer

m) (b)(6)

From: Fetalvo, Ninio J. EOP/OVP (b)(6)]
Sent: 4/4/2020 4:22:29 PM
To: Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]
CC: DL OVP Comms COVID (b)(6)]; Oakley, Caitlin B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8feed045e954557aa1e0052f925865f-HHS-Caitlin]; McKeogh, Katherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3facab3fd03480f8553892121fd2009-HHS-Katheri]; Hall, Bill (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e56218361cd4ffbaccdd06ac2d7b809d-HHS-bill.ha]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Robinson, Michael J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4118fde5239947c6bccbdb4cb7488fa-HHS-michael]; Block, Molly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e32ca68078848889751e7ec26910142-Molly.Block]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
Subject: Re: WaPo Inquiry on FDA and Rudy Giuliani - EARLY PM DEADLINE

Ok

—
Ninio J.H. Fetalvo
Office of the Vice President
(b)(6)

On Apr 4, 2020, at 3:27 PM, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov> wrote:

Checking back on this. OK to share responses back with reporter? Thanks!

From: Felberbaum, Michael
Sent: Saturday, April 04, 2020 1:38 PM
To: DL OVP Comms COVID (b)(6)
Cc: Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>; McKeogh, Katherine (OS) <Katherine.McKeogh@hhs.gov>; Hall, Bill (OS) <bill.hall@hhs.gov>; Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>; Robinson, Michael J (OS) <michael.robinson@hhs.gov>; Block, Molly <Molly.Block@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: WaPo Inquiry on FDA and Rudy Giuliani - EARLY PM DEADLINE

Hi all –

WaPo is working on a larger story about Rudy Giuliani and some of the things he has been saying about coronavirus in recent days, including him advocating two specific possible treatments for covid-19, including the use of antimalarial drugs for the disease and the possible use of placental stem cell therapy.

For a small part of their bigger story, they are asking whether White House or the coronavirus task force made any requests of the FDA prior to the issuance of that EUA? Did Rudy Giuliani have any contact with the FDA? Did the president's frequently stated praise for this treatment play any role in the issuance of the EUA? Did the White House/task force or Giuliani have any contact with the FDA over the granted Investigational New Drug status to a stem

cell therapy developed by a company called Celularity this approval? Did Giuliani's public praise for it play any role in the approval?

FDA has cleared following response, which is similar to what we've provided to NYT and Reuters.

As is true with any public health emergency, there's tremendous interest among all parties to identify and implement potential short- and long-term solutions to address this pandemic impacting people around the country and the world.

The FDA's role is to make independent, science-based decisions to bring new therapies to sick patients as quickly as possible, while at the same time supporting research to further evaluate whether these medical countermeasures are safe and effective for treating patients infected with this novel virus.

EUA:

The EUA allowing these specific drugs to be donated to the Strategic National Stockpile and used for certain hospitalized patients with COVID-19 was prepared by expert FDA career staff and reflects extensive discussions with experts at CDC, NIH, and BARDA who are involved in pandemic response.

During the evaluation of the criteria under which to issue an EUA, it was determined, based on the scientific evidence available, that it is reasonable to believe that the specific drugs may be effective in treating COVID-19, and that, given there are no adequate, approved, or available alternative treatments, the known and potential benefits to treat this serious or life-threatening virus outweigh the known and potential risks when used under the conditions described in the EUA.

IND:

By law, the FDA generally cannot confirm or deny the existence of or comment on any pending investigational new drug (IND) applications.

The FDA's decision to grant an Investigational Drug Application, including for products such as stem cell therapies, is always based on an internal scientific review that evaluates preclinical data, information about the investigator, the drug's composition and manufacturing, as well as plans for the studies to be conducted, to determine whether it is reasonably safe to move forward with testing the drug in humans.

The reporter has a late afternoon deadline, so please let me know if you have any questions/comments ASAP.
Thanks,

Michael

Michael Felberbaum
Senior Advisor

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-9548 / Cell: (b)(6)
michael.felberbaum@fda.hhs.gov

<image002.png>

<image004.jpg>

<image006.jpg>

<image008.jpg>

<image010.jpg>

<image012.jpg>

From: Fetalvo, Ninio J. EOP/OVP (b)(6)
Sent: 3/31/2020 2:24:17 PM
To: Caccamo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
CC: Love, Kelly A. EOP/OVP (b)(6); Bowman, Lauren K. EOP/WHO [Lauren.K.Bowman@who.eop.gov]; Porter, Macaulay V. EOP/OVP (b)(6)
Subject: FW: hey ninio --

Stephanie—We have a national radio request below. Is this something Dr. Hahn could speak to? Thank you!

From: Portnoy, Steven <PortnoyS@cbsnews.com>
Sent: Tuesday, March 31, 2020 2:11 PM
To: Fetalvo, Ninio J. EOP/OVP (b)(6)
Cc: Sherman, Jennifer (HHS/OASH) <Jennifer.Sherman@hhs.gov>; Porter, Macaulay V. EOP/OVP <Macaulay.V.Porter@ovp.eop.gov>; Bowman, Lauren K. EOP/WHO <Lauren.K.Bowman@who.eop.gov>; Love, Kelly A. EOP/OVP (b)(6)
Subject: [EXTERNAL] RE: hey ninio --

Thanks Ninio.

We're looking to help the audience understand the updated guidance the task force is discussing today, how quickly the rapid test Abbott unveiled this week will be available in doctors' offices, and how much researchers now understand (that they didn't just weeks ago) about morbidity/mortality and spread.

We'd push the interview out in full to all 600+ stations, and on our new [coronavirus podcast](#).

From: Fetalvo, Ninio J. EOP/OVP (b)(6)
Sent: Tuesday, March 31, 2020 2:05 PM
To: Portnoy, Steven <PortnoyS@cbsnews.com>
Cc: Sherman, Jennifer (HHS/OASH) <Jennifer.Sherman@hhs.gov>; Porter, Macaulay V. EOP/OVP (b)(6); Bowman, Lauren K. EOP/WHO <Lauren.K.Bowman@who.eop.gov>; Love, Kelly A. EOP/OVP (b)(6)
Subject: RE: hey ninio --

External Email

Looping in Kelly. If you provide us with the specific topics, we can find the most appropriate guest for you.

From: Portnoy, Steven <PortnoyS@cbsnews.com>
Sent: Tuesday, March 31, 2020 2:03 PM
To: Fetalvo, Ninio J. EOP/OVP (b)(6)
Cc: Sherman, Jennifer (HHS/OASH) <Jennifer.Sherman@hhs.gov>; Porter, Macaulay V. EOP/OVP (b)(6); Bowman, Lauren K. EOP/WHO <Lauren.K.Bowman@who.eop.gov>
Subject: [EXTERNAL] RE: hey ninio --

Dr. Adams would be good.

But if we could get the subject matter experts -- Dr. Birx or Dr. Fauci -- I imagine they'd have more specific answers to our questions on virology and spread.

FYI, sharing latest Nielsen numbers.

WTOP (CBS) alone reaches a million listeners a week, just in DC. Far bigger than anything on cable...

ratings, on the bottom of each market page.

STATIONRATINGS.COM

Washington, DC Rank: 7

6+ Population: 5,019,400
Ethnic Composition: Black - 26.83% Hispanic - 16%
Market Swept: 13x/year

Back

Station	Format	Owner/LMA	Hol18	Jan19	Feb19	Cume
WTOP-FM / WTLF-FM	News	Hubbard Broadcasting, Inc.	6.9	7.4	7.8	1,013,500
WAMU-FM	News/Talk	American University	6.5	7.3	7.8	692,000
WMAL-FM	News/Talk	Cumulus Media, Inc.	5.0	6.9	7.3	336,000
WMMJ-FM	Urban AC	Radio One	7.4	7.5	6.7	683,300
WASH-FM	Adult Contemporary	iHeartMedia, Inc.	12.9	6.7	6.2	1,099,600
WHUR-FM	Urban AC	Howard University	5.8	6.0	5.8	696,600

From: Fetalvo, Ninio J. EOP/OVP <(b)(6)>
Sent: Tuesday, March 31, 2020 12:26 PM
To: Portnoy, Steven <PortnoyS@cbsnews.com>
Cc: Sherman, Jennifer (HHS/OASH) <Jennifer.Sherman@hhs.gov>; Porter, Macaulay V. EOP/OVP <(b)(6)>; Bowman, Lauren K. EOP/WHO <Lauren.K.Bowman@who.eop.gov>
Subject: RE: hey ninio --

External Email

Looping in Jenn from the Surgeon General's team. I know they are working on finding a time sometime this week.

From: Portnoy, Steven <PortnoyS@cbsnews.com>
Sent: Tuesday, March 31, 2020 12:25 PM
To: Fetalvo, Ninio J. EOP/OVP <(b)(6)>
Subject: [EXTERNAL] hey ninio --

We'd still hope to work out a quick hit with a task force member today.. but if that's not possible, can we schedule something for tomorrow?

Thanks!

Steven Portnoy
CBS News Radio
White House Correspondent
202-457-4453 | cell (b)(6)
@stevenportnoy

From: Fetalvo, Ninio J. EOP/OVP (b)(6)
Sent: 4/1/2020 1:42:24 PM
To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Oakley, Caitlin B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8feed045e954557aa1e0052f925865f-HHS-Caitlin]; O'Malley, Devin M. EOP/OVP [Devin.M.O'Malley@ovp.eop.gov]; Deere, Judd P. EOP/WHO (b)(6)
CC: Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Hall, Bill (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e56218361cd4ffbaccdd06ac2d7b809d-HHS-bill.ha]; McKeogh, Katherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3facab3fd03480f8553892121fd2009-HHS-Katheri]; Block, Molly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e32ca68078848889751e7ec26910142-Molly.Block]; Heck, Mia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=656b2fa5aca84a18851397d417a16672-HHS-Mia.Hec]; Broido, Tara (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b1ed7d3dee614eda879e4e5e8641601b-HHS-Tara.Br]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]
Subject: RE: Washington Post

Please circulate those statements for review on this chain as well.

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Wednesday, April 1, 2020 1:35 PM
To: Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>; Fetalvo, Ninio J. EOP/OVP (b)(6); O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>; Deere, Judd P. EOP/WHO (b)(6)
Cc: Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>; Hall, Bill (OS) <bill.hall@hhs.gov>; McKeogh, Katherine (OS) <Katherine.McKeogh@hhs.gov>; Block, Molly <Molly.Block@fda.hhs.gov>; Heck, Mia (OS) <Mia.Heck@hhs.gov>; Broido, Tara (OS) <Tara.Broido@hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Subject: RE: Washington Post

Yes—this is a bit similar to the NYT story last week, but much harsher of FDA. Narrative is being driven a bit by the lab community, specifically academic/research labs.

We are putting Drs. Shuren and Stenzel on the phone for a deep background phone call this evening at 6pm. We will complement with on the record responses that align with statement we issued on Monday.

Stephanie Caccomo

Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: 301.348.1956
Cell: (b)(6)
stephanie.caccomo@fda.hhs.gov

From: Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>
Sent: Wednesday, April 1, 2020 1:28 PM
To: Fetalvo, Ninio J. EOP/OVP (b)(6); O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>; Deere, Judd P. EOP/WHO (b)(6)

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FDA-OC-2020-1977/2020-4765-001019

MULTI-HHS-FDA-20-0400, 20-0415-C-000027

Cc: Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>; Hall, Bill (OS) <bill.hall@hhs.gov>; McKeogh, Katherine (OS) <Katherine.McKeogh@hhs.gov>; Block, Molly <Molly.Block@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Heck, Mia (OS) <Mia.Heck@hhs.gov>; Broido, Tara (OS) <Tara.Broido@hhs.gov>
Subject: RE: Washington Post

Thanks, Ninio.

(b) (5)

Thanks all.

DRAFT PRE-DECISIONAL DELIBERATIVE

From: Fetalvo, Ninio J. EOP/OVP (b)(6) >
Sent: Wednesday, April 1, 2020 1:25 PM
To: Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>; O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>; Deere, Judd P. EOP/WHO <(b)(6)>
Cc: Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>; McKeogh, Katherine (OS/ASPA) <Katherine.McKeogh@hhs.gov>; Molly.Block@fda.hhs.gov; Caccomo, Stephanie (FDA/OC) <Stephanie.Caccomo@fda.hhs.gov>; Heck, Mia (HHS/OASH) <Mia.Heck@hhs.gov>; Broido, Tara (HHS/OASH) <Tara.Broido@hhs.gov>
Subject: RE: Washington Post

(b) (5)

From: Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>
Sent: Wednesday, April 1, 2020 1:19 PM
To: O'Malley, Devin M. EOP/OVP <(b)(6)>; Fetalvo, Ninio J. EOP/OVP (b)(6); Deere, Judd P. EOP/WHO <(b)(6)>
Cc: Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>; McKeogh, Katherine (OS/ASPA) <Katherine.McKeogh@hhs.gov>; Molly.Block@fda.hhs.gov; Caccomo, Stephanie (FDA/OC) <Stephanie.Caccomo@fda.hhs.gov>; Heck, Mia (HHS/OASH) <Mia.Heck@hhs.gov>; Broido, Tara (HHS/OASH) <Tara.Broido@hhs.gov>
Subject: FW: Washington Post

Hi Devin, Ninio and Judd—The Washington Post (Bob O'Harrow and Neena Satija) is working on a story about testing again....this one seems to be related more to the FDA. Not sure if they have reached out to you.

(b) (5)

(b) (5)

Thanks and happy to chat.

DRAFT PRE-DECISIONAL DELIBERATIVE COMMUNICATION

From: O'Harrow, Robert <Robert.OHarrow@washpost.com>

Sent: Tuesday, March 31, 2020 12:38 PM

To: FDA Office of Media Affairs <FDAOMA@FDA.HHS.GOV>; Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; Manchester, Brittney <Brittney.Manchester@fda.hhs.gov>; McKinney, James <James.McKinney@fda.hhs.gov>

Cc: Satija, Neena <Neena.Satija@washpost.com>; Boburg, Shawn <Shawn.Boburg@washpost.com>

Subject: Washington Post

Hi. I'm Robert O'Harrow at The Post. I am working with my investigative colleagues Neena Satija and Shawn Boburg on a story about coronavirus testing.

We have built an extensive timeline of events, collected scores of emails from scientists at FDA, CDC, public health, academic and hospital laboratories. In addition we have conducted numerous interviews.

We are trying to understand how events unfolded and who made the decisions.

It is clear that the FDA decided early in the crisis to grant EUA approval to just one test, the CDC assay, and only allow public health laboratories to employ it. In doing so, the FDA prevented other viable tests from being used to diagnose Americans for the coronavirus.

After the CDC test failed on Feb. 8, the FDA stood by its decision to use just one test, despite having the authority to use other tests and loosen the approval requirements (as it ultimately decided to do on Feb. 29.)

Even as the number of infected people soared, Tim Stenzel, director of the office of Vitro Diagnostics and Radiological Health at FDA, spent most of a week at CDC, attending meetings about the test and touring the facilities. He did so while public health and clinical lab scientists were imploring the FDA to take swifter action to loosen regulatory requirements, according to the emails we have obtained, along with letters sent to Congress and the FDA.

We have a few questions:

1. Why did the FDA initially choose to use only the CDC test and allow only public health labs to use it?

2. Why did Dr. Stenzel decide on Friday Feb. 21 to go to Atlanta for discussions about the CDC test -- and stay there for most of the following week?

3. Stenzel was told to go to Atlanta, according to our documents and interviews.

Who told him to go to CDC?

What was Jeff Shuren's role in that decision?

4. Why did FDA choose to send Stenzel to CDC and focus on the CDC test exclusively, a choice that delayed the kind of decision the agency made on Feb. 29?

We are open to discussing our story in detail.

We are hoping to publish in the coming days, so please get back to us by noon tomorrow.

m) (b)(6)

Thank you,
Robert

Robert O'Harrow Jr.
Washington Post Staff Writer
m) (b)(6)

From: Fetalvo, Ninio J. EOP/OVP [(b)(6)]
Sent: 4/1/2020 2:10:29 PM
To: Cacco, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
Subject: RE: INGRAHAM ANGLE TONIGHT AT 10PM ET - FDA COMMISSIONER HAHN FROM DC LIVE SHOTS STUDIO

Can you send me specific topics when you have them so I can add to the calendar invite for the prep?

From: Cacco, Stephanie <Stephanie.Cacco@fda.hhs.gov>
Sent: Wednesday, April 1, 2020 1:59 PM
To: Conti, Andrew <Andrew.conti@FOXNEWS.COM>; Daravi, Roma S. EOP/WHO <Roma.S.Daravi2@who.eop.gov>
Cc: Fetalvo, Ninio J. EOP/OVP [(b)(6)]; Love, Kelly A. EOP/OVP <[(b)(6)]>; Henning, Alexa A. EOP/WHO <Katherine.A.Henning@who.eop.gov>; Fox, Samantha <Samantha.Fox@FOXNEWS.COM>; Cofini, Roman <roman.cofini@FOXNEWS.COM>
Subject: RE: INGRAHAM ANGLE TONIGHT AT 10PM ET - FDA COMMISSIONER HAHN FROM DC LIVE SHOTS STUDIO

Hi Andrew-

Thanks for connecting. Per our discussion, here's the press release on the coronavirus treatment accelerator program.
><https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-continues-accelerate-development-novel-therapies-covid-19><

Stephanie Cacco

Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: 301.348.1956
Cell: [(b)(6)]
stephanie.cacco@fda.hhs.gov

From: Conti, Andrew <Andrew.conti@FOXNEWS.COM>
Sent: Wednesday, April 1, 2020 9:36 AM
To: Cacco, Stephanie <Stephanie.Cacco@fda.hhs.gov>; Daravi, Roma S. EOP/WHO <Roma.S.Daravi2@who.eop.gov>
Cc: Fetalvo, Ninio J. EOP/OVP <[(b)(6)]>; Love, Kelly A. EOP/OVP <[(b)(6)]>; Henning, Alexa A. EOP/WHO <Katherine.A.Henning@who.eop.gov>; Fox, Samantha <Samantha.Fox@FOXNEWS.COM>; Cofini, Roman <roman.cofini@FOXNEWS.COM>
Subject: INGRAHAM ANGLE TONIGHT AT 10PM ET - FDA COMMISSIONER HAHN FROM DC LIVE SHOTS STUDIO

Hi everyone-we are all set for tonight's interview with Laura Ingraham at 10pm. As mentioned, Live Shots studio is all set. Please Arrive by 9:40p. The FDA Commissioner will lead the show at 10p. I will connect you with one of our producers mid afternoon via this email who will provide more editorial guidance. Our primetime booking producer Roman is on this email and can assist with any logistics. Roman's cell is 917-887-2104. More detail to follow. Thanks!

Studio info:

Liveshots DC
400 North Capitol Street, NW
Suite 366
Washington DC 20001
PH: [(b)(6)]
lsdc366@gmail.com
Contact at live shots is Steve Clark

From: Conti, Andrew <Andrew.conti@FOXNEWS.COM>
Sent: Tuesday, March 31, 2020 8:07 PM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Daravi, Roma S. EOP/WHO <Roma.S.Daravi2@who.eop.gov>
Cc: Fetalvo, Ninio J. EOP/OVP (b)(6) @ (b)(6) Love, Kelly A. EOP/OVP <Kelly.A.Love@ovp.eop.gov>; Henning, Alexa A. EOP/WHO <Katherine.A.Henning@who.eop.gov>; Fox, Samantha <Samantha.Fox@FOXNEWS.COM>; Cofini, Roman <roman.cofini@FOXNEWS.COM>
Subject: Re: INGRAHAM ANGLE TOMORROW AT 10PM

Absolutely. Let's reconnect tomorrow. I will have much more detail. Thanks!

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Tuesday, March 31, 2020 6:41:47 PM
To: Conti, Andrew <Andrew.conti@FOXNEWS.COM>; Daravi, Roma S. EOP/WHO <Roma.S.Daravi2@who.eop.gov>
Cc: Fetalvo, Ninio J. EOP/OVP (b)(6); Love, Kelly A. EOP/OVP <(b)(6)>; Henning, Alexa A. EOP/WHO <Katherine.A.Henning@who.eop.gov>; Fox, Samantha <Samantha.Fox@FOXNEWS.COM>; Cofini, Roman <roman.cofini@FOXNEWS.COM>
Subject: [EXTERNAL] RE: INGRAHAM ANGLE TOMORROW AT 10PM

Thanks Andrew, happy to connect when you have a few minutes. Thank you!

Stephanie Caccomo

Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: 301.348.1956
Cell: (b)(6)
stephanie.caccomo@fda.hhs.gov

From: Conti, Andrew <Andrew.conti@FOXNEWS.COM>
Sent: Tuesday, March 31, 2020 5:36 PM
To: Daravi, Roma S. EOP/WHO <Roma.S.Daravi2@who.eop.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Cc: Fetalvo, Ninio J. EOP/OVP <(b)(6)>; Love, Kelly A. EOP/OVP <(b)(6)>; Henning, Alexa A. EOP/WHO <Katherine.A.Henning@who.eop.gov>; Fox, Samantha <Samantha.Fox@FOXNEWS.COM>; Cofini, Roman <roman.cofini@FOXNEWS.COM>
Subject: Re: INGRAHAM ANGLE TOMORROW AT 10PM

Hi everyone. Thanks much. Looking forward to tomorrow's interview (wed, 4/1) on the Ingraham Angle, 10p et with FDA Commissioner Hahn. Interview from live shots studio, 400 north capitol, 3rd floor, suite 366 in dc. Live interview at 10p. Arrival by 9:40p please. I will reconnect with additional detail. Thanks!

Andrew

(b)(6) cell

From: Daravi, Roma S. EOP/WHO <Roma.S.Daravi2@who.eop.gov>
Sent: Tuesday, March 31, 2020 5:29:01 PM
To: Conti, Andrew <Andrew.conti@FOXNEWS.COM>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Cc: Fetalvo, Ninio J. EOP/OVP <(b)(6)>; Love, Kelly A. EOP/OVP <(b)(6)>; Henning, Alexa A. EOP/WHO <Katherine.A.Henning@who.eop.gov>
Subject: [EXTERNAL] RE: INGRAHAM ANGLE TOMORROW AT 10PM

Looping Stephanie from Dr. Hahn's team.

From: Conti, Andrew <Andrew.conti@FOXNEWS.COM>

Sent: Tuesday, March 31, 2020 5:24 PM

To: Daravi, Roma S. EOP/WHO <Roma.S.Daravi2@who.eop.gov>

Cc: Fetalvo, Ninio J. EOP/OVP <(b)(6)@>; Love, Kelly A. EOP/OVP <(b)(6)>

Henning, Alexa A. EOP/WHO <Katherine.A.Henning@who.eop.gov>

Subject: [EXTERNAL] Re:

That's fantastic, thanks, be right back. Live in the 10 PM hour? Live Shots Studio DC? Unfortunately we can't pre-tape right now.

From: Daravi, Roma S. EOP/WHO <Roma.S.Daravi2@who.eop.gov>

Sent: Tuesday, March 31, 2020 5:20:38 PM

To: Conti, Andrew <Andrew.conti@FOXNEWS.COM>

Cc: Fetalvo, Ninio J. EOP/OVP <(b)(6)> (b)(6) Love, Kelly A. EOP/OVP <(b)(6)>;

Henning, Alexa A. EOP/WHO <Katherine.A.Henning@who.eop.gov>

Subject: [EXTERNAL] RE:

Dr. Hahn can be available for Laura tomorrow night. Let me know if this works and we will loop you with his team. Thank you again.

This message and its attachments may contain legally privileged or confidential information. It is intended solely for the named addressee. If you are not the addressee indicated in this message (or responsible for delivery of the message to the addressee), you may not copy or deliver this message or its attachments to anyone. Rather, you should permanently delete this message and its attachments and kindly notify the sender by reply e-mail. Any content of this message and its attachments that does not relate to the official business of Fox News or Fox Business must not be taken to have been sent or endorsed by either of them. No representation is made that this email or its attachments are without defect.

From: O'Malley, Devin M. EOP/OVP [Devin.M.O'Malley@ovp.eop.gov]
Sent: 3/29/2020 1:58:23 PM
To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
CC: Miller, Katie R. EOP/OVP [Katie.R.Miller@ovp.eop.gov]; Fetalvo, Ninio J. EOP/OVP (b)(6); Manchester, Brittney [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bd6ca86f5a3f43ffb295122f23a95770-Brittney.Ma]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]
Subject: Re: flag--media response re: n95 sterilization

(b) (5)

Sent from my iPhone

On Mar 29, 2020, at 1:34 PM, Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov> wrote:

Hi folks—

Flagging for you that we want to get some information for reporters on an issue that POTUS raised re: N95s. Basically, our team is working quickly!

POTUS tweet:

Hope the FDA can approve Mask Sterilization equipment ASAP. As per Governor

@MikeDeWine

, there is a company in Ohio,

@Battelle

, which has equipment that can sterilize masks quickly.

Response:

(b) (5)

Stephanie Caccomo

Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: 301.348.1956

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FDA-OC-2020-1977/2020-4765-001026

MULTI-HHS-FDA-20-0400, 20-0415-C-000034

Cell: 240.762.8873
stephanie.caccomo@fda.hhs.gov

From: Fetalvo, Ninio J. EOP/OVP [(b)(6)]
Sent: 3/30/2020 8:28:40 AM
To: Cacco, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
CC: Love, Kelly A. EOP/OVP [(b)(6)]; Henning, Alexa A. EOP/WHO [Katherine.A.Henning@who.eop.gov]; Daravi, Roma S. EOP/WHO [Roma.S.Daravi2@who.eop.gov]
Subject: Re: One America for Dr. Hahn

Thank you. + others for awareness.

—
Ninio J.H. Fetalvo
Office of the Vice President

[(b)(6)]

On Mar 30, 2020, at 8:01 AM, Cacco, Stephanie <Stephanie.Cacco@fda.hhs.gov> wrote:

Hey Ninio! Just following up on this interview with Chanel. We've set aside time for him tomorrow to tape. We plan to use HHS, if that works.

She sent over Qs (only the first one we can't answer b/c we don't track).

Basics:

Q. How many Americans with CoVid-19 have taken HydroxyC/Chloroquine to date? How are we tracking this number?

Q. March 24th, Chloroquine sent to NY - how many New Yorkers have taken it; is NY working with the admin/FDA by sharing data on its use of Chloroquine?

Admin/FDA Specific Details:

Q. Bayer donated 3 million Chloroquine tablets to the US; Bayer says it will continue to work closely with the Admin in its efforts to fight the virus; expand on what this looks like?

Q. How long would be prudent for FDA to judge efficacy of H/Chloroquine for treating coronavirus?

- And why did Nevada's governor ban its use?

Q. France and S. Korea's track records with HydroxyC and Chloroquine - what are we learning from them... What is the FDA looking for as signals to move forward with this drug as possible recommended treatment?

Stephanie Caccomo

Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: 301.348.1956
Cell: (b)(6)
stephanie.caccomo@fda.hhs.gov

From: Fetalvo, Ninio J. EOP/OVP (b)(6)
Sent: 3/27/2020 10:46:25 AM
To: Cacco, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
CC: Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Henning, Alexa A. EOP/WHO [Katherine.A.Henning@who.eop.gov]; Daravi, Roma S. EOP/WHO [Roma.S.Daravi2@who.eop.gov]; Love, Kelly A. EOP/OVP (b)(6)
Subject: RE: [EXTERNAL] TaskForce on Chloroquine/HydroxyChloroquine

++ Yes, we recommend.

From: Cacco, Stephanie <Stephanie.Cacco@fda.hhs.gov>
Sent: Friday, March 27, 2020 10:43 AM
To: Fetalvo, Ninio J. EOP/OVP (b)(6)
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: FW: [EXTERNAL] TaskForce on Chloroquine/HydroxyChloroquine

Question—I'm not familiar with this correspondent, do you generally recommend we proceed with this outlet/correspondent?

Stephanie Cacco
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: 301.348.1956
Cell: (b)(6)
stephanie.cacco@fda.hhs.gov

From: Chanel Rion <Chanel.Rion@oann.com>
Sent: Friday, March 27, 2020 10:32 AM
To: Cacco, Stephanie <Stephanie.Cacco@fda.hhs.gov>
Subject: Re: [EXTERNAL] TaskForce on Chloroquine/HydroxyChloroquine

Hi Stephanie!

My questions to Dr. Hahn are short and logistical ones. My cameraman and I are mobile and ready to deploy anytime that is convenient. We can interview in a standup, sit down, or hallway just to give a sense of how un-intrusive to his schedule we can be.

If there are other concerns that hinder our access to him, please let me know. I understand you guys are slammed with imperative work at an imperative time. Thank you for all you do and I hope we can work something out as soon as possible.

Best,

Chanel Rion

AMERICAN
OVERSIGHT
Chief White House Correspondent

FDA-OC-2020-1977/2020-4765-001030

MULTI-HHS-FDA-20-0400, 20-0415-C-000038

One America News Network

101 Constitution Ave. NW
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Chanel's Broadcasts: ><https://www.youtube.com/playlist?list=PLaJp7NK1-soc9bSnbkyDLJIOckvbkC4e7><

STREAM OAN | ><http://shorturl.at/jsJW5><
OAN FACEBOOK | ><http://shorturl.at/yEIN6><
OAN TWITTER | ><https://twitter.com/OANN><
OAN YOUTUBE | ><http://shorturl.at/dhV29><

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Thursday, March 26, 2020 12:18:56 PM
To: Fetalvo, Ninio J. EOP/OVP; Chanel Rion; Daravi, Roma S. EOP/WHO
Cc: Henning, Alexa A. EOP/WHO; Love, Kelly A. EOP/OVP; Felberbaum, Michael
Subject: RE: [EXTERNAL] TaskForce on Chloroquine/HydroxyChloroquine

Hi Chanel- we will follow-up. Thanks!

Stephanie Caccomo
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: 301.348.1956
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stephanie.caccomo@fda.hhs.gov

From: Fetalvo, Ninio J. EOP/OVP <(b)(6)>
Date: March 26, 2020 at 11:58:16 AM EDT
To: Chanel Rion <Chanel.Rion@oann.com>, Daravi, Roma S. EOP/WHO <Roma.S.Daravi2@who.eop.gov>
Cc: Henning, Alexa A. EOP/WHO <Katherine.A.Henning@who.eop.gov>, Love, Kelly A. EOP/OVP <(b)(6)>, Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: RE: [EXTERNAL] TaskForce on Chloroquine/HydroxyChloroquine

Thanks Chanel. I'm looping in Stephanie Caccomo from Dr. Hahn's team to help facilitate.

From: Chanel Rion <Chanel.Rion@oann.com>
Sent: Thursday, March 26, 2020 10:43 AM
To: Daravi, Roma S. EOP/WHO <Roma.S.Daravi2@who.eop.gov>

AMERICAN
OVERSIGHT

FDA-OC-2020-1977/2020-4765-001031

MULTI-HHS-FDA-20-0400, 20-0415-C-000039

Cc: Henning, Alexa A. EOP/WHO <Katherine.A.Henning@who.eop.gov>; Fetalvo, Ninio J. EOP/OVP

(b)(6); Love, Kelly A. EOP/OVP (b)(6)

Subject: Re: [EXTERNAL] TaskForce on Chloroquine/HydroxyChloroquine

Thank you, Roma!

Hi Ninio and Kelly, please let me know what we can arrange - my request is a flexible but time sensitive one. Flexible in that we're ready to deploy 24/7. Time sensitive in that I need something by Monday (we can work something out on the weekend as well if this would be more convenient).

10 minute sit downs with Secretary Azar and/or Dr. Hahn and/or senior Taskforce members strictly on the logistics and latest opinions regarding Chloroquine and Hydroxychloroquine is all we need.

I can also send questions ahead of time for your approval if this would help.

This is not a hostile interview. It's a straightforward highlighting of the Administration's perspective on hopeful solutions and the logistics attached to implementing them in this imperative time.

Best,

Chanel Rion

Chief White House Correspondent

One America News Network

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Washington, D.C. 20001

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Twitter: @ChanelRion

Chanel's Broadcasts: >>[<<https://www.youtube.com/playlist?list=PLaJp7NK1-soc9bSnbkyDLJIOckvbkC4e7](https://www.youtube.com/playlist?list=PLaJp7NK1-soc9bSnbkyDLJIOckvbkC4e7)<<

STREAM OAN | >>[<<http://shorturl.at/jsJW5](http://shorturl.at/jsJW5)<<;

OAN FACEBOOK | >>[<<http://shorturl.at/yEIN6](http://shorturl.at/yEIN6)<<;

OAN TWITTER | >>[<<https://twitter.com/OANN](https://twitter.com/OANN)<<;

OAN YOUTUBE | >>[<<http://shorturl.at/dhV29](http://shorturl.at/dhV29)<<;

From: Daravi, Roma S. EOP/WHO <Roma.S.Daravi2@who.eop.gov>

Sent: Thursday, March 26, 2020 9:30:46 AM

To: Chanel Rion

Cc: Henning, Alexa A. EOP/WHO; Fetalvo, Ninio J. EOP/OVP; Love, Kelly A. EOP/OVP

Subject: Re: [EXTERNAL] TaskForce on Chloroquine/HydroxyChloroquine

Hi Chanel - adding Ninio and Kelly on this.

> On Mar 26, 2020, at 9:29 AM, Chanel Rion <Chanel.Rion@oann.com> wrote:

>

> Good morning, Roma!

>

> I'm collaborating with our New York Bureau on a mini documentary special on drugs that show signs of hope from Coronavirus; they're covering the on the ground NYC side of things, and I need to cover this from an official Administration standpoint.

>

> How can I get a hold of Dr. Hahn, Secretary Azar, or VP for a sit down on this? Is anyone from the TaskForce able or willing to participate or weigh in on this?

>

> Best,

>

> Sent from my iPhone

From: O'Malley, Devin M. EOP/OVP [Devin.M.O'Malley@ovp.eop.gov]
Sent: 3/27/2020 12:02:20 AM
To: Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]
CC: Fetalvo, Ninio J. EOP/OVP (b)(6); Hall, Bill (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e56218361cd4ffbacdd06ac2d7b809d-HHS-bill.ha]; McKeogh, Katherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3facab3fd03480f8553892121fd2009-HHS-Katheri]; Oakley, Caitlin B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8feed045e954557aa1e0052f925865f-HHS-Caitlin]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Robinson, Michael J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4118fde5239947c6bccbdb4cb7488fa-HHS-michael]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
Subject: Re: FDA Interview Request - Politico - COVID Oracle Project

(b) (5)

Sent from my iPhone

On Mar 26, 2020, at 11:20 PM, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov> wrote:

Following up on this. Thanks!

From: Felberbaum, Michael
Sent: Thursday, March 26, 2020 9:04 PM
To: 'Devin.M.O'Malley@ovp.eop.gov' <Devin.M.O'Malley@ovp.eop.gov>; (b)(6)
<(b)(6)>
Cc: Hall, Bill (OS) <bill.hall@hhs.gov>; McKeogh, Katherine (OS) <Katherine.McKeogh@hhs.gov>; Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>; Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>; Robinson, Michael J (OS) <michael.robinson@hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: FDA Interview Request - Politico - COVID Oracle Project

Hi Devin and Ninio,

Hope you're doing well. Please see the below inquiry we received from Politico and our proposed/cleared written response. Let me know if you have any questions/concerns.

Thanks,

Michael

Reporter: Sarah Oweremohle

Organization: Politico

Phone #(s): N/A

Subject: COVID Oracle Project

Deadline: 7 a.m., Friday, March 27

Spokesperson: Michael Felberbaum, FDA Office of Media Affairs, in written response

Additional information: Politico is working on a story saying they heard that the administration's interest in chloroquine/hydroxychloroquine and a subsequent project with Oracle has involved FDA heavily, including involvement by FDA's Principal Deputy Commissioner Amy Abernethy. And they've also heard there is frustration with how much it is consuming FDA officials' time and the claims the President has been making about its potential effectiveness. (b) (5)

Proposed Response:

(b) (5)

Michael Felberbaum
Senior Advisor

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-9548 / Cell: (b)(6)
michael.felberbaum@fda.hhs.gov

<image002.png>

<image004.jpg>

<image006.jpg>

<image008.jpg>

<image010.jpg>

<image012.jpg>

From: O'Malley, Devin M. EOP/OVP [Devin.M.O'Malley@ovp.eop.gov]
Sent: 3/26/2020 6:04:11 PM
To: Cacco, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Fetalvo, Ninio J. EOP/OVP (b)(6)
CC: Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Hall, Bill (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e56218361cd4ffbaccdd06ac2d7b809d-HHS-bill.ha]; McKeogh, Katherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3facab3fd03480f8553892121fd2009-HHS-Katheri]
Subject: RE: flag for urgent review--USAToday, negative testing story

(b) (5)

From: Cacco, Stephanie <Stephanie.Cacco@fda.hhs.gov>
Sent: Thursday, March 26, 2020 5:59 PM
To: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>; Fetalvo, Ninio J. EOP/OVP <(b)(6)>
Cc: Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>; Hall, Bill (OS) <bill.hall@hhs.gov>; McKeogh, Katherine (OS) <Katherine.McKeogh@hhs.gov>
Subject: flag for urgent review--USAToday, negative testing story

Hey folks—flagging below for you. USAToday is hitting us on testing. We asked to do background/deep background chat, which they declined. So providing below on the record.

Ok to send—we are past deadline at this point. Thank you!!

Outlet: Brett Murphy, USA Today

Deadline: ASAP

Questions and Answers:

This story will be about the delays in a reliable, accessible testing, especially during the several weeks in February after it was known that the CDC kit was faulty. We will be citing the consensus of experts and scientists who fault federal health agencies, including the FDA, for shirking its responsibility to protect Americans. Laboratories around the country were hamstrung and frustrated that they couldn't work to head off the outbreak. We will be drawing a straight line between those early failures and the current resource shortages at hospitals and labs around the country.

The reporting is based on interviews with dozens of scientists and public health experts—including former FDA commissioners and lab directors—as well as email communications between laboratories and hospitals across the country.

Here are some more specific questions:

- *The FDA chose one of the most restrictive approaches possible by limiting who and how could begin developing tests, even after the CDC assay was determined to be faulty. Using its emergency authority to place restrictions on private labs that do not apply in normal circumstances, the FDA ignored initial calls from public and private labs to let them develop their own tests until the end of February. What made the FDA finally decide to lift the restrictions?*
- *The immediate timing of those restrictions, with the lack of onramp for the private sector or laboratories, marked a departure from the government's response in prior disease outbreaks. Unlike past outbreaks, FDA told universities and private labs they would have to wait in line behind the public health labs before they got the CDC's test kits. If any scientists wanted to*

develop their own tests or adopt the WHO's, they would need to submit separate, 67-page applications. Why did the FDA choose this course and not the less restrictive strategies of the past?

Response: There is no 67-page application—that is inaccurate. Additionally, the FDA never told universities and private labs they would have to “wait in line.” That is not an accurate characterization of any conversation FDA had with test developers.

- *The FDA, an arm of the Department of Health and Human Services, regulates according to laws passed by congress and guidance laid out by the administration. How much of these emergency decisions are up to the FDA versus the administration?*
- *The Trump administration has said publicly that the lack of flexibility in the early days was because of a framework created by previous administrations. What specific restrictions were due to previous administrations? What prevented the FDA from lifting them earlier?*

Response:

(b) (5)

(b) (5)

Thank you!

Stephanie Cacco
Press Officer

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stephanie.caccommo@fda.hhs.gov

1 - When did the FDA staff -- Jeff Shuren, or others -- first bring up to Dr. Hahn the notion of loosening the restrictions on LDT's, via a change in enforcement discretion policy? I am referring to that "Saturday thing," as we have called it -- the Feb. 29 announcement that institutional labs and commercial labs could go ahead and come up with a coronavirus test and then have it validated with the FDA later on.

I have from our conversations that Dr. Hahn wasn't aware until the ACLA wrote to him, that the labs needed some action from FDA to start making the tests. I have that date as Monday, Feb. 24 -- and that Dr. Hahn lifted the restrictions in just 5 days later.

I am asking this specifically, because HHS people are telling our White House reporters that nobody in the FDA told them this was important to do -- and that it should have been done earlier.

2 - Which brings me to the other question: People have told us that of course doctor Hahn or the participants in the daily FDA-HHS calls -- Keegan Lenihan, Stacy Amin and Anna Abrams -- would have raised it as a possible step to take. Or, these sources say, even if FDA didn't mention it, it should have been obvious to HHS that this would be a good idea.

From: Fetalvo, Ninio J. EOP/OVP (b)(6)
Sent: 3/23/2020 7:54:17 PM
To: Henning, Alexa A. EOP/WHO [Katherine.A.Henning@who.eop.gov]; Love, Kelly A. EOP/OVP (b)(6); Hahn, Julia A. EOP/WHO [Julia.A.Hahn@who.eop.gov]; Miller, Katie R. EOP/OVP [Katie.R.Miller@ovp.eop.gov]; Daravi, Roma S. EOP/WHO [Roma.S.Daravi2@who.eop.gov]; O'Malley, Devin M. EOP/OVP [Devin.M.O'Malley@ovp.eop.gov]; Gidley, Hogan H. EOP/WHO [Hogan.Gidley@who.eop.gov]; McGuffee, Tyler A. EOP/OVP (b)(6); Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Montesi, Janet (b)(6); Litzow, Elizabeth (b)(6); Baker, Brittany G. EOP/WHO [Brittany.G.Baker@who.eop.gov]; Caccamo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Caliguirri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Conrad, Patricia L (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e30cd6224aeb49c795844f43fd78a049-HHS-conradp]; Sherman, Jennifer (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=96ea669491654aba8d4ea6816279e040-HHS-Jennife]

Subject: Principal Media Prep: Primetime/Morning/Daytime Shows
Location: Dial-In: (202) 395-6392 | Code: (b)(6)

Start: 3/23/2020 8:15:00 PM
End: 3/23/2020 8:45:00 PM
Show Time As: Tentative

Recurrence: (none)

Hi all—

This will be a media prep for any principals doing primetime/morning/daytime shows. Please forward this invite to your respective principal's scheduler.

(b)(5)



If you have any conflicts, please let us know asap.

Thank you,
Ninio

From: O'Malley, Devin M. EOP/OVP [Devin.M.O'Malley@ovp.eop.gov]
Sent: 3/21/2020 2:35:09 PM
To: Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
CC: Robinson, Michael J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4118fde5239947c6bccb4bd4cb7488fa-HHS-michael]; Fetalvo, Ninio J. EOP/OVP (b)(6); Weber, Mark (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a80e62b41b2d4981af48d6cabbd923e9-HHS-Mark.We]; Oakley, Caitlin B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8feed045e954557aa1e0052f925865f-HHS-Caitlin]; McKeogh, Katherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3facab3fd03480f8553892121fd2009-HHS-Katheri]; Hall, Bill (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e56218361cd4ffbacdd06ac2d7b809d-HHS-bill.ha]; Myrie, Simone (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0ae0858be3ac46f8a346c6e6316fe36d-HHS-Simone.]; Lemar, Naweed (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d5cb1dd2b784e6ca62cc6938b485db9-HHS-Naweed.]; Daniels, Carla L (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec0430c977294a79b2b2d8f42f75992d-HHS-Carla.D]; Formoso, Paula (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ef23a919842c4da7a77b27d1c9cd739a-HHS-Paula.F]; Bradley, Tasha (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=21f77c6d1e2044f58de4fc02145fd32-HHS-Tasha.B]; OS HHSPress (HHS/ASPA) (b)(6)
Subject: RE: UPDATE: CLEARANCE_0302: FDA "Coronavirus (COVID-19) Update: FDA Issues first Emergency Use Authorization for Point of Care Diagnostic"

Yes.

From: Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>
Sent: Saturday, March 21, 2020 2:30 PM
To: Caccomo, Stephanie (FDA/OC) <Stephanie.Caccomo@fda.hhs.gov>; O'Malley, Devin M. EOP/OVP (b)(6)
Cc: Robinson, Michael J (HHS/ASPA) <michael.robinson@hhs.gov>; Fetalvo, Ninio J. EOP/OVP (b)(6); Weber, Mark (HHS/ASPA) <Mark.Weber@hhs.gov>; Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>; McKeogh, Katherine (OS/ASPA) <Katherine.McKeogh@hhs.gov>; Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>; Myrie, Simone (OS/ASPA) <Simone.Myrie@hhs.gov>; Lemar, Naweed (OS/ASPA) <Naweed.Lemar@hhs.gov>; Daniels, Carla (HHS/ASPA) <Carla.Daniels@hhs.gov>; Formoso, Paula (HHS/ASPA) <Paula.Formoso@hhs.gov>; Bradley, Tasha (OS/ASPA) <Tasha.Bradley@hhs.gov>; OS HHSPress (HHS/ASPA) (b)(6)
Subject: RE: UPDATE: CLEARANCE_0302: FDA "Coronavirus (COVID-19) Update: FDA Issues first Emergency Use Authorization for Point of Care Diagnostic"

Are we cleared to release?

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Saturday, March 21, 2020 2:15 PM

To: Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>

Cc: Robinson, Michael J (HHS/ASPA) <michael.robinson@hhs.gov>; Fetalvo, Ninio J. EOP/OVP

<(b)(6)>; Weber, Mark (HHS/ASPA) <Mark.Weber@hhs.gov>; Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>; McKeogh, Katherine (OS/ASPA) <Katherine.McKeogh@hhs.gov>; Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>; Myrie, Simone (OS/ASPA) <Simone.Myrie@hhs.gov>; Lemar, Naweed (OS/ASPA) <Naweed.Lemar@hhs.gov>; Daniels, Carla (HHS/ASPA) <Carla.Daniels@hhs.gov>; Formoso, Paula (HHS/ASPA) <Paula.Formoso@hhs.gov>; Bradley, Tasha (OS/ASPA) <Tasha.Bradley@hhs.gov>; OS HHSPress (HHS/ASPA) <(b)(6)>

Subject: RE: UPDATE: CLEARANCE_0302: FDA "Coronavirus (COVID-19) Update: FDA Issues first Emergency Use Authorization for Point of Care Diagnostic"

It's a small order. I heard less than 50k. Not quite sure where tests going but can ask folks if we have that info.

Are we okay to issue press release while I check if we have that information?

Stephanie Caccamo

Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: 301.348.1956
Cell: (b)(6)
stephanie.caccamo@fda.hhs.gov

From: Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>

Sent: Saturday, March 21, 2020 2:06 PM

To: O'Malley, Devin M. EOP/OVP <(b)(6)>

Cc: Robinson, Michael J (OS) <michael.robinson@hhs.gov>; Fetalvo, Ninio J. EOP/OVP <(b)(6)>; Weber, Mark (OS) <Mark.Weber@hhs.gov>; Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>; McKeogh, Katherine (OS) <Katherine.McKeogh@hhs.gov>; Hall, Bill (OS) <bill.hall@hhs.gov>; Myrie, Simone (OS) <Simone.Myrie@hhs.gov>; Lemar, Naweed (OS) <Naweed.Lemar@hhs.gov>; Daniels, Carla L (OS) <Carla.Daniels@hhs.gov>; Formoso, Paula (OS) <Paula.Formoso@hhs.gov>; Bradley, Tasha (OS) <Tasha.Bradley@hhs.gov>; OS HHSPress (HHS/ASPA) <(b)(6)>; Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>

Subject: RE: UPDATE: CLEARANCE_0302: FDA "Coronavirus (COVID-19) Update: FDA Issues first Emergency Use Authorization for Point of Care Diagnostic"

+ Stephanie with FDA

From: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>

Sent: Saturday, March 21, 2020 2:04 PM

To: Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>

Cc: Robinson, Michael J (HHS/ASPA) <michael.robinson@hhs.gov>; Fetalvo, Ninio J. EOP/OVP

<(b)(6)>; Weber, Mark (HHS/ASPA) <Mark.Weber@hhs.gov>; Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>; McKeogh, Katherine (OS/ASPA) <Katherine.McKeogh@hhs.gov>; Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>; Myrie, Simone (OS/ASPA) <Simone.Myrie@hhs.gov>; Lemar, Naweed (OS/ASPA) <Naweed.Lemar@hhs.gov>; Daniels, Carla (HHS/ASPA) <Carla.Daniels@hhs.gov>; Formoso, Paula (HHS/ASPA)

<Paula.Formoso@hhs.gov>; Bradley, Tasha (OS/ASPA) <Tasha.Bradley@hhs.gov>; OS HHSPress (HHS/ASPA)

(b) (6) <[REDACTED]>

Subject: RE: UPDATE: CLEARANCE_0302: FDA "Coronavirus (COVID-19) Update: FDA Issues first Emergency Use Authorization for Point of Care Diagnostic"

One clarification, (b) (5) <[REDACTED]>

From: Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>

Sent: Saturday, March 21, 2020 1:52 PM

To: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>

Cc: Robinson, Michael J (HHS/ASPA) <michael.robinson@hhs.gov>; Fetalvo, Ninio J. EOP/OVP

(b)(6) <[REDACTED]>; Weber, Mark (HHS/ASPA) <Mark.Weber@hhs.gov>; Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>; McKeogh, Katherine (OS/ASPA) <Katherine.McKeogh@hhs.gov>; Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>; Myrie, Simone (OS/ASPA) <Simone.Myrie@hhs.gov>; Lemar, Naweed (OS/ASPA) <Naweed.Lemar@hhs.gov>; Daniels, Carla (HHS/ASPA) <Carla.Daniels@hhs.gov>; Formoso, Paula (HHS/ASPA) <Paula.Formoso@hhs.gov>; Bradley, Tasha (OS/ASPA) <Tasha.Bradley@hhs.gov>; OS HHSPress (HHS/ASPA)

(b)(6) <[REDACTED]>

Subject: RE: UPDATE: CLEARANCE_0302: FDA "Coronavirus (COVID-19) Update: FDA Issues first Emergency Use Authorization for Point of Care Diagnostic"

Please see attached – updates in yellow. Please let us know if we can proceed – at this point, can wait until press conference is over. Thanks.

From: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>

Sent: Saturday, March 21, 2020 12:39 PM

To: Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>

Cc: Robinson, Michael J (HHS/ASPA) <michael.robinson@hhs.gov>; Fetalvo, Ninio J. EOP/OVP

(b)(6) <[REDACTED]>; Weber, Mark (HHS/ASPA) <Mark.Weber@hhs.gov>; Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>; McKeogh, Katherine (OS/ASPA) <Katherine.McKeogh@hhs.gov>; Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>; Myrie, Simone (OS/ASPA) <Simone.Myrie@hhs.gov>; Lemar, Naweed (OS/ASPA) <Naweed.Lemar@hhs.gov>; Daniels, Carla (HHS/ASPA) <Carla.Daniels@hhs.gov>; Formoso, Paula (HHS/ASPA) <Paula.Formoso@hhs.gov>; Bradley, Tasha (OS/ASPA) <Tasha.Bradley@hhs.gov>; OS HHSPress (HHS/ASPA) <(b)(6)@hhs.gov>

Subject: RE: UPDATE: CLEARANCE_0302: FDA "Coronavirus (COVID-19) Update: FDA Issues first Emergency Use Authorization for Point of Care Diagnostic"

(b) (5) <[REDACTED]>

From: Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>

Sent: Saturday, March 21, 2020 12:38 PM

To: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>

Cc: Robinson, Michael J (HHS/ASPA) <michael.robinson@hhs.gov>; Fetalvo, Ninio J. EOP/OVP

(b)(6) <[REDACTED]>; Weber, Mark (HHS/ASPA) <Mark.Weber@hhs.gov>; Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>; McKeogh, Katherine (OS/ASPA) <Katherine.McKeogh@hhs.gov>; Hall, Bill (HHS/ASPA)

<bill.hall@hhs.gov>; Myrie, Simone (OS/ASPA) <Simone.Myrie@hhs.gov>; Lemar, Naweed (OS/ASPA) <Naweed.Lemar@hhs.gov>; Daniels, Carla (HHS/ASPA) <Carla.Daniels@hhs.gov>; Formoso, Paula (HHS/ASPA) <Paula.Formoso@hhs.gov>; Bradley, Tasha (OS/ASPA) <Tasha.Bradley@hhs.gov>; OS HHSPress (HHS/ASPA) <(b)(6)@hhs.gov>

Subject: RE: UPDATE: CLEARANCE_0302: FDA "Coronavirus (COVID-19) Update: FDA Issues first Emergency Use Authorization for Point of Care Diagnostic"

(b) (5)

From: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>

Sent: Saturday, March 21, 2020 12:35 PM

To: Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>

Cc: Robinson, Michael J (HHS/ASPA) <michael.robinson@hhs.gov>; Fetalvo, Ninio J. EOP/OVP

<(b)(6)>; Weber, Mark (HHS/ASPA) <Mark.Weber@hhs.gov>; Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>; McKeogh, Katherine (OS/ASPA) <Katherine.McKeogh@hhs.gov>; Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>; Myrie, Simone (OS/ASPA) <Simone.Myrie@hhs.gov>; Lemar, Naweed (OS/ASPA) <Naweed.Lemar@hhs.gov>; Daniels, Carla (HHS/ASPA) <Carla.Daniels@hhs.gov>; Formoso, Paula (HHS/ASPA) <Paula.Formoso@hhs.gov>; Bradley, Tasha (OS/ASPA) <Tasha.Bradley@hhs.gov>; OS HHSPress (HHS/ASPA) <(b)(6)@hhs.gov>

Subject: RE: UPDATE: CLEARANCE_0302: FDA "Coronavirus (COVID-19) Update: FDA Issues first Emergency Use Authorization for Point of Care Diagnostic"

Thank you. (b) (5)

From: Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>

Sent: Saturday, March 21, 2020 12:33 PM

To: O'Malley, Devin M. EOP/OVP <(b)(6)>

Cc: Robinson, Michael J (HHS/ASPA) <michael.robinson@hhs.gov>; Fetalvo, Ninio J. EOP/OVP

<(b)(6)>; Weber, Mark (HHS/ASPA) <Mark.Weber@hhs.gov>; Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>; McKeogh, Katherine (OS/ASPA) <Katherine.McKeogh@hhs.gov>; Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>; Myrie, Simone (OS/ASPA) <Simone.Myrie@hhs.gov>; Lemar, Naweed (OS/ASPA) <Naweed.Lemar@hhs.gov>; Daniels, Carla (HHS/ASPA) <Carla.Daniels@hhs.gov>; Formoso, Paula (HHS/ASPA) <Paula.Formoso@hhs.gov>; Bradley, Tasha (OS/ASPA) <Tasha.Bradley@hhs.gov>; OS HHSPress (HHS/ASPA) <(b)(6)>

Subject: RE: UPDATE: CLEARANCE_0302: FDA "Coronavirus (COVID-19) Update: FDA Issues first Emergency Use Authorization for Point of Care Diagnostic"

(b) (5)

(b) (5)

From: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>

Sent: Saturday, March 21, 2020 12:28 PM

To: Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>

Cc: Robinson, Michael J (HHS/ASPA) <michael.robinson@hhs.gov>; Fetalvo, Ninio J. EOP/OVP

<(b)(6)>; Weber, Mark (HHS/ASPA) <Mark.Weber@hhs.gov>; Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>; McKeogh, Katherine (OS/ASPA) <Katherine.McKeogh@hhs.gov>; Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>; Myrie, Simone (OS/ASPA) <Simone.Myrie@hhs.gov>; Lemar, Naweed (OS/ASPA) <Naweed.Lemar@hhs.gov>; Daniels, Carla (HHS/ASPA) <Carla.Daniels@hhs.gov>; Formoso, Paula (HHS/ASPA) <Paula.Formoso@hhs.gov>; Bradley, Tasha (OS/ASPA) <Tasha.Bradley@hhs.gov>; OS HHSPress (HHS/ASPA) <(b)(6)@hhs.gov>

Subject: RE: UPDATE: CLEARANCE_0302: FDA "Coronavirus (COVID-19) Update: FDA Issues first Emergency Use Authorization for Point of Care Diagnostic"

(b) (5)

From: Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>

Sent: Saturday, March 21, 2020 12:25 PM

To: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>

Cc: Robinson, Michael J (HHS/ASPA) <michael.robinson@hhs.gov>; Fetalvo, Ninio J. EOP/OVP

<(b)(6)>; Weber, Mark (HHS/ASPA) <Mark.Weber@hhs.gov>; Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>; McKeogh, Katherine (OS/ASPA) <Katherine.McKeogh@hhs.gov>; Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>; Myrie, Simone (OS/ASPA) <Simone.Myrie@hhs.gov>; Lemar, Naweed (OS/ASPA) <Naweed.Lemar@hhs.gov>; Daniels, Carla (HHS/ASPA) <Carla.Daniels@hhs.gov>; Formoso, Paula (HHS/ASPA) <Paula.Formoso@hhs.gov>; Bradley, Tasha (OS/ASPA) <Tasha.Bradley@hhs.gov>; OS HHSPress (HHS/ASPA) <(b)(6)@hhs.gov>

Subject: Re: UPDATE: CLEARANCE_0302: FDA "Coronavirus (COVID-19) Update: FDA Issues first Emergency Use Authorization for Point of Care Diagnostic"

(b) (5)

On Mar 21, 2020, at 12:23 PM, O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov> wrote:

(b) (5)

From: Robinson, Michael J (HHS/ASPA) <michael.robinson@hhs.gov>

Sent: Saturday, March 21, 2020 12:22 PM

To: O'Malley, Devin M. EOP/OVP <(b)(6)> Fetalvo, Ninio J. EOP/OVP

<(b)(6)>

Cc: Weber, Mark (HHS/ASPA) <Mark.Weber@hhs.gov>; Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; Oakley,

Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>; McKeogh, Katherine (OS/ASPA) <Katherine.McKeogh@hhs.gov>; Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>; Myrie, Simone (OS/ASPA) <Simone.Myrie@hhs.gov>; Lemar, Naweed (OS/ASPA) <Naweed.Lemar@hhs.gov>; Daniels, Carla (HHS/ASPA) <Carla.Daniels@hhs.gov>; Formoso, Paula (HHS/ASPA) <Paula.Formoso@hhs.gov>; Bradley, Tasha (OS/ASPA) <Tasha.Bradley@hhs.gov>; OS HHSPress (HHS/ASPA) <(b)(6)@hhs.gov>

Subject: RE: UPDATE: CLEARANCE_0302: FDA "Coronavirus (COVID-19) Update: FDA Issues first Emergency Use Authorization for Point of Care Diagnostic"

(b) (5)

From: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>

Sent: Saturday, March 21, 2020 12:20 PM

To: Robinson, Michael J (HHS/ASPA) <michael.robinson@hhs.gov>; Fetalvo, Ninio J. EOP/OVP

<(b)(6)>

Cc: Weber, Mark (HHS/ASPA) <Mark.Weber@hhs.gov>; Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>; McKeogh, Katherine (OS/ASPA) <Katherine.McKeogh@hhs.gov>; Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>; Myrie, Simone (OS/ASPA) <Simone.Myrie@hhs.gov>; Lemar, Naweed (OS/ASPA) <Naweed.Lemar@hhs.gov>; Daniels, Carla (HHS/ASPA) <Carla.Daniels@hhs.gov>; Formoso, Paula (HHS/ASPA) <Paula.Formoso@hhs.gov>; Bradley, Tasha (OS/ASPA) <Tasha.Bradley@hhs.gov>; OS HHSPress (HHS/ASPA)

<(b)(6)>

Subject: RE: UPDATE: CLEARANCE_0302: FDA "Coronavirus (COVID-19) Update: FDA Issues first Emergency Use Authorization for Point of Care Diagnostic"

(b) (5)

From: Robinson, Michael J (HHS/ASPA) <michael.robinson@hhs.gov>

Sent: Saturday, March 21, 2020 11:23 AM

To: O'Malley, Devin M. EOP/OVP <(b)(6)@hhs.gov>; Fetalvo, Ninio J. EOP/OVP

<(b)(6)>

Cc: Weber, Mark (HHS/ASPA) <Mark.Weber@hhs.gov>; Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>; McKeogh, Katherine (OS/ASPA) <Katherine.McKeogh@hhs.gov>; Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>; Myrie, Simone (OS/ASPA) <Simone.Myrie@hhs.gov>; Lemar, Naweed (OS/ASPA) <Naweed.Lemar@hhs.gov>; Daniels, Carla (HHS/ASPA) <Carla.Daniels@hhs.gov>; Formoso, Paula (HHS/ASPA) <Paula.Formoso@hhs.gov>; Bradley, Tasha (OS/ASPA) <Tasha.Bradley@hhs.gov>; OS HHSPress (HHS/ASPA)

<(b)(6)@hhs.gov>

Subject: RE: UPDATE: CLEARANCE_0302: FDA "Coronavirus (COVID-19) Update: FDA Issues first Emergency Use Authorization for Point of Care Diagnostic"

Importance: High

Hi Ninio and Devin

(b) (5)

V/r,

From: Barry, Daniel J (HHS/OGC) <daniel.barry@hhs.gov>

Sent: Saturday, March 21, 2020 11:14 AM

Subject: Re: UPDATE: CLEARANCE_0302: FDA "Coronavirus (COVID-19) Update: FDA Issues first Emergency Use Authorization for Point of Care Diagnostic"

(b) (5). Thanks, Dan

From: OS HHSPress (HHS/ASPA)

Sent: Saturday, March 21, 2020 10:57 AM

Subject: UPDATE: CLEARANCE_0302: FDA "Coronavirus (COVID-19) Update: FDA Issues first Emergency Use Authorization for Point of Care Diagnostic"

Importance: High

A quote has been added to this statement

To ensure you have time to review, please reply before 11:30

V/r,

From: (b)(6)

Sent: Saturday, March 21, 2020 9:39 AM

To: Campbell, Taylor (OS/OASH) <Taylor.Campbell@hhs.gov>; OS - ASPA - Clearance <OS.ASPA-Clearance@hhs.gov>; OS OGC-IO ControlDesk (HHS/OS/OGC) <ControlDesk.OCIO@hhs.gov>; Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov>; Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; Caliguiri, Laura (FDA/OC) <Laura.Caliguiri@fda.hhs.gov>; Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Steele, Danielle (HHS/IOS) <Danielle.Steele@hhs.gov>; White, Caroline (HHS/OGC) <Caroline.White@hhs.gov>; Stimson, Brian (HHS/OGC) <Brian.Stimson@hhs.gov>; Charrow, Robert (HHS/OGC) <Robert.Charrow@hhs.gov>; Keveney, Sean (HHS/OGC) <Sean.Keveney@hhs.gov>; Chang, William (HHS/OGC) <William.Chang@hhs.gov>; Barry, Daniel J (HHS/OGC) <daniel.barry@hhs.gov>; Amin, Stacy (FDA/OC) <Stacy.Amin@fda.hhs.gov>; ASPRCOMMS <ASPRCOMMS@hhs.gov>; ASPRMEDIA (OS/ASPR/COO) <ASPRMEDIA@hhs.gov>; Routh, Jennifer (NIH/NIAID) [E] <(b)(6)>; Conrad, Patricia (NIH/NIAID) [E] <(b)(6)>; Billet, Courtney (NIH/NIAID) [E] <(b)(6)>; Wojtowicz, Emma (NIH/OD) [E] <(b)(6)>; Akinso, Woleola (NIH/OD) [E] <(b)(6)>; Fine, Amanda (NIH/OD) [E] <(b)(6)>; Fritz, Craig (NIH/OD) [E] <(b)(6)>; Myles, Renate (NIH/OD) [E] <(b)(6)>; Broido, Tara (HHS/OASH) <Tara.Broido@hhs.gov>; Channer, Amber (OS/OASH) <Amber.Channer@hhs.gov>; Heck, Mia (HHS/OASH) <Mia.Heck@hhs.gov>; Kotwicki, Lauren (HHS/OASH) <Lauren.Kotwicki@hhs.gov>; Migliaccio-Grabill, Kate (HHS/OASH) <Kate.Migliaccio-Grabill@hhs.gov>; Sherman, Jennifer (HHS/OASH) <Jennifer.Sherman@hhs.gov>; Bonds, Michelle E. (CDC/OD/OADC) <meb0@cdc.gov>; Galatas, Kate (CDC/OD/OADC) <kkg2@cdc.gov>; Heldman, Amy B. (CDC/OD/OADC) <evd4@cdc.gov>; Patrick, Kera (CDC/OD/OADC)

<ihn7@cdc.gov>; CDC OADC ASPA Clearance <OADCASPAclearance@cdc.gov>

Cc: Caccamo, Stephanie (FDA/OC) <Stephanie.Caccamo@fda.hhs.gov>; Finnen, April (FDA/OC)

<April.Finnen@fda.hhs.gov>; OCOEAOMA-Press (FDA) <(b)(6)>; OS HHSPress (HHS/ASPA)

(b)(6)

Subject: CLEARANCE_0302: FDA "Coronavirus (COVID-19) Update: FDA Issues first Emergency Use Authorization for Point of Care Diagnostic"

URGENT

Agency/Office: FDA

Subject: *Coronavirus (COVID-19) Update: FDA Issues first Emergency Use Authorization for Point of Care Diagnostic*

(b) (5)

V/r,

Mike Robinson
Strategic Planning, ASPA

202-690-6885 –desk
(b)(6) –mobile

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BY LAW:**

This information has not been publically disclosed and may be privileged and confidential. This document must not be disseminated, distributed, or copied to persons not authorized to receive the information. Unauthorized disclosure may result in prosecution to the full extent of the law.

From: O'Malley, Devin M. EOP/OVP [Devin.M.O'Malley@ovp.eop.gov]
Sent: 3/19/2020 2:05:38 PM
To: Caccamo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Hall, Bill (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e56218361cd4ffbaccdd06ac2d7b809d-HHS-bill.ha]; Miller, Katie R. EOP/OVP [Katie.R.Miller@ovp.eop.gov]; Fetalvo, Ninio J. EOP/OVP (b)(6)
CC: Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Oakley, Caitlin B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8feed045e954557aa1e0052f925865f-HHS-Caitlin]; McKeogh, Katherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3facab3fd03480f8553892121fd2009-HHS-Katheri]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]
Subject: RE: FDA release on chloroquine

(b) (5)

From: Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>
Sent: Thursday, March 19, 2020 2:01 PM
To: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>; Hall, Bill (OS) <bill.hall@hhs.gov>; Miller, Katie R. EOP/OVP <Katie.R.Miller@ovp.eop.gov>; Fetalvo, Ninio J. EOP/OVP (b)(6) >
Cc: Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>; Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>; McKeogh, Katherine (OS) <Katherine.McKeogh@hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: RE: FDA release on chloroquine

(b) (5)

. Just clarifying.

Stephanie Caccamo

Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: 301.348.1956
Cell: (b)(6)
stephanie.caccamo@fda.hhs.gov

Date: March 19, 2020 at 1:53:15 PM EDT

To: Cacco, Stephanie <Stephanie.Cacco@fda.hhs.gov>, Hall, Bill (OS) <bill.hall@hhs.gov>, Miller, Katie R. EOP/OVP <Katie.R.Miller@ovp.eop.gov>, Fetalvo, Ninio J. EOP/OVP

<(b)(6)>

Cc: Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>, Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>, McKeogh, Katherine (OS) <Katherine.McKeogh@hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>

Subject: RE: FDA release on chloroquine

One more: (b) (5)

”

To: (b) (5)

From: Cacco, Stephanie <Stephanie.Cacco@fda.hhs.gov>

Sent: Thursday, March 19, 2020 1:37 PM

To: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>; Hall, Bill (OS) <bill.hall@hhs.gov>; Miller, Katie R. EOP/OVP <Katie.R.Miller@ovp.eop.gov>; Fetalvo, Ninio J. EOP/OVP <(b)(6)>

Cc: Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>; Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>; McKeogh, Katherine (OS) <Katherine.McKeogh@hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>

Subject: RE: FDA release on chloroquine

Will do. With that edit, can we issue?

Stephanie Cacco

Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: 301.348.1956
Cell: (b)(6)
stephanie.cacco@fda.hhs.gov

From: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>

Sent: Thursday, March 19, 2020 1:35 PM

To: Hall, Bill (OS) <bill.hall@hhs.gov>; Miller, Katie R. EOP/OVP <Katie.R.Miller@ovp.eop.gov>; Fetalvo, Ninio J. EOP/OVP <(b)(6)>

Cc: Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>; Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>; McKeogh, Katherine (OS) <Katherine.McKeogh@hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Cacco, Stephanie <Stephanie.Cacco@fda.hhs.gov>

Subject: RE: FDA release on chloroquine

This release goes right into the quote from (b) (5) about “today’s actions,” (b) (5)

From: Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>

Sent: Thursday, March 19, 2020 1:24 PM

To: O'Malley, Devin M. EOP/OVP <(b)(6)>; Miller, Katie R. EOP/OVP <(b)(6)>; Fetalvo, Ninio J. EOP/OVP <(b)(6)>

Cc: Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>; McKeogh, Katherine (OS/ASPA) <Katherine.McKeogh@hhs.gov>; Caliguiri, Laura (FDA/OC)

<Laura.Caliguiri@fda.hhs.gov>; Caccamo, Stephanie (FDA/OC) <Stephanie.Caccamo@fda.hhs.gov>

Subject: FDA release on chloroquine

All...FDA is ready to issue this. Please let us know if we have the green light. Bill

William Hall

Deputy Assistant Secretary for Public Affairs (Public Health)

Office of the Assistant Secretary for Public Affairs

U.S. Department of Health & Human Services

Washington, DC

Direct: 202-690-6344

Mobile: (b)(6)

Email: bill.hall@hhs.gov

>>>www.hhs.gov<<<



From: O'Malley, Devin M. EOP/OVP [Devin.M.O'Malley@ovp.eop.gov]
Sent: 4/14/2020 1:23:48 PM
To: Caccamo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Heck, Mia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=656b2fa5aca84a18851397d417a16672-HHS-Mia.Hec]
CC: Fetalvo, Ninio J. EOP/OVP (b)(6) Block, Molly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e32ca68078848889751e7ec26910142-Molly.Block]; McKeogh, Katherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3facab3fd03480f8553892121fd2009-HHS-Katheri]; Oakley, Caitlin B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8feed045e954557aa1e0052f925865f-HHS-Caitlin]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]
Subject: RE: [EXTERNAL] Re: Dr. Giroir interview request from megan twohey, new york times

Ok I spoke with her and pointed her to the press briefings, which largely address her questions.

From: Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>
Sent: Tuesday, April 14, 2020 1:23 PM
To: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>; Heck, Mia (OS) <Mia.Heck@hhs.gov>
Cc: Fetalvo, Ninio J. EOP/OVP (b)(6); Block, Molly <Molly.Block@fda.hhs.gov>; McKeogh, Katherine (OS) <Katherine.McKeogh@hhs.gov>; Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>; Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>
Subject: RE: [EXTERNAL] Re: Dr. Giroir interview request from megan twohey, new york times

We sent reporter to task force for her outstanding Qs, which at this time I understand to be question about how serology test companies are consulting the WHTF. Plus, what other government-wide efforts are underway for serology tests. She already knows about FDA's policies on serology and NIH validation effort, so she's looking for anything else that should be shared with her. Not aware of any other efforts, so later Q might be easy.

Stephanie Caccamo
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: 301.348.1956
Cell: (b)(6)
stephanie.caccamo@fda.hhs.gov

From: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>
Sent: Tuesday, April 14, 2020 10:22 AM
To: Heck, Mia (OS) <Mia.Heck@hhs.gov>
Cc: Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; Fetalvo, Ninio J. EOP/OVP (b)(6) Block, Molly <Molly.Block@fda.hhs.gov>; McKeogh, Katherine (OS) <Katherine.McKeogh@hhs.gov>; Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>; Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>
Subject: RE: [EXTERNAL] Re: Dr. Giroir interview request from megan twohey, new york times

I was under the impression you had already punted to the TF. Here are where her questions stand. Again, I think many of these (I highlighted them) fall under the ambit of FDA:

(b) (5)
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FDA-OC-2020-1977/2020-4765-001053

MULTI-HHS-FDA-20-0400, 20-0415-C-000061

(b) (5)

From: Heck, Mia (HHS/OASH) <Mia.Heck@hhs.gov>

Sent: Tuesday, April 14, 2020 7:53 AM

To: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>

Cc: Caccomo, Stephanie (FDA/OC) <Stephanie.Caccomo@fda.hhs.gov>; Fetalvo, Ninio J. EOP/OVP <Ninio.J.Fetalvo@ovp.eop.gov>; Block, Molly (FDA/OC) <Molly.Block@fda.hhs.gov>; McKeogh, Katherine (OS/ASPA) <Katherine.McKeogh@hhs.gov>; Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>; Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>

Subject: Re: [EXTERNAL] Re: Dr. Giroir interview request from megan twohey, new york times

Good morning,

(b) (5)

Mia

On Apr 13, 2020, at 5:46 PM, O'Malley, Devin M. EOP/OVP <(b)(6)> wrote:

Thank you, Stephanie!

Moving forward, please refer people to the Task Force/OVP, not to specific Task Force principals.

Thanks, all!
Devin

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>

Sent: Monday, April 13, 2020 4:13 PM

To: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>; Fetalvo, Ninio J. EOP/OVP

<(b)(6)>; Block, Molly <Molly.Block@fda.hhs.gov>

Cc: Heck, Mia (OS) <Mia.Heck@hhs.gov>; McKeogh, Katherine (OS) <Katherine.McKeogh@hhs.gov>; Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>; Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>

Subject: RE: [EXTERNAL] Re: Dr. Giroir interview request from megan twohey, new york times

Hi folks-

I connected with Megan Twohey, we are following up with her on a technical Q FDA/CMS overlap issue on lab regulation.

Her question on oversight though is more specific to the WHTF—(b)(6)

Stephanie Caccomo

Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: 301.348.1956
Cell: (b)(6)
stephanie.caccomo@fda.hhs.gov

From: Caccomo, Stephanie

Sent: Monday, April 13, 2020 3:05 PM

To: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>; Fetalvo, Ninio J. EOP/OVP

<(b)(6)> Block, Molly <Molly.Block@fda.hhs.gov>

Cc: Heck, Mia (OS) <Mia.Heck@hhs.gov>; McKeogh, Katherine (OS) <Katherine.McKeogh@hhs.gov>; Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>; Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>

Subject: RE: [EXTERNAL] Re: Dr. Giroir interview request from megan twohey, new york times

Megan came to us with questions about the validation project. That is a government-wide project which Admiral Giroir has mentioned in a WH press briefing. FDA is not rolling out the use of these tests or overseeing DPA. And the validation project is out of NIH. Under our COVID-19 diagnostics policy, these tests are available now, or can pursue an EUA (1 to date, more to come soon).

Looping in our HHS colleagues so we can connect and get back to you on best approach

Stephanie Caccomo

Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: 301.348.1956
Cell: (b)(6)
stephanie.caccomo@fda.hhs.gov

From: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>

Sent: Monday, April 13, 2020 2:46 PM

To: Fetalvo, Ninio J. EOP/OVP <(b)(6)>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>;

Block, Molly <Molly.Block@fda.hhs.gov>

Cc: Heck, Mia (OS) <Mia.Heck@hhs.gov>

Subject: RE: [EXTERNAL] Re: Dr. Giroir interview request from megan twohey, new york times

Dropping the reporter and adding FDA.

(b)(5)

Thanks!

Devin

From: Twohey, Megan <megan.twohey@nytimes.com>

Sent: Monday, April 13, 2020 2:35 PM

To: Fetalvo, Ninio J. EOP/OVP <(b)(6)>

Cc: Heck, Mia (HHS/OASH) <Mia.Heck@hhs.gov>; O'Malley, Devin M. EOP/OVP (b)(6);
Love, Kelly A. EOP/OVP <(b)(6)>
Subject: [EXTERNAL] Re: Dr. Giroir interview request from megan twohey, new york times

Thanks so much.

It would be great to connect with AMB Birx and/or otherwise get answers to these questions today

Best,
Megan

Megan Twohey
Reporter
The New York Times
cell: (b)(6)
megan.twohey@nytimes.com

On Mon, Apr 13, 2020 at 2:17 PM Heck, Mia (HHS/OASH) <Mia.Heck@hhs.gov> wrote:

Hi Megan,

AMB Birx is best person to speak to regarding your questions; let me know if you need me to help you connect with someone on her team.

Mia

From: Twohey, Megan <megan.twohey@nytimes.com>

Sent: Monday, April 13, 2020 12:25 PM

To: ASH Media <ASHMedia@hhs.gov>

Subject: Re: Dr. Giroir interview request from megan twohey, new york times

Hi Ashmedia,

Are you the correct person to contact for an interview request of Dr. Giroir? If not, can you kindly direct me to the best person?

Last Friday, Fauci said on CNN that providers of the antibody tests had been consulting with the White House Task Force and had cleared hurdles in terms of validating the accuracy and validation of their tests.

When I asked the FDA about this--whether the companies with antibody tests are required to consult with the White House Task Force? and whether the task force was doing oversight of these companies in any way?--the FDA said that Admiral Giroir would be the best person to speak with.

In addition to these questions, I'd like to be able to explain to our readers:

--What specifically the federal government is doing to organize and oversee the roll out of these antibody tests? The FDA has a process for issuing emergency authorization to certain private test companies and registering other companies that are manufacturing the tests. The NIH is doing some validating of the tests. Are there any other things happening at the federal level?

--Is the federal government coordinating the roll out of antibody testing with the states in any way? Governor Cuomo has suggested the federal government would need to use the Defense Production Act in order to get antibody testings manufactured at capacity. Is that something that the federal government is considering?

I'd love to get answers as soon as possible.

My deadline is close of business. Please let me know.

Best,
Megan

Megan Twohey
Reporter
The New York Times
cell: (b)(6)
megan.twohey@nytimes.com

On Mon, Apr 13, 2020 at 7:21 AM Twohey, Megan <megan.twohey@nytimes.com> wrote:

Good morning,

Megan Twohey here, with The New York Times.

I am working on a story about the antibody tests coming on the market here in the US and have been told that Dr. Giroir is the best person in the administration to talk to about them.

Is he available for a quick phone interview today?

Please let me know.

Best,
Megan

Megan Twohey
Reporter
The New York Times
cell: (b)(6)
megan.twohey@nytimes.com

From: O'Malley, Devin M. EOP/OVP [Devin.M.O'Malley@ovp.eop.gov]
Sent: 3/13/2020 8:46:54 AM
To: Hall, Bill (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e56218361cd4ffbaccdd06ac2d7b809d-HHS-bill.ha]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Oakley, Caitlin B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8feed045e954557aa1e0052f925865f-HHS-Caitlin]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
Subject: Please provide one final review

Let me know if you have any red flags:

(b) (5)

(b) (5)

Devin M. O'Malley

(b)(6)

From: O'Malley, Devin M. EOP/OVP [Devin.M.O'Malley@ovp.eop.gov]
Sent: 3/13/2020 7:48:56 AM
To: Galatas, Kate (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0a0623b3cb34f86a2f6f9d14afe115e-HHS-kkg2-cd]; Caccamo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]
CC: Hall, Bill (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e56218361cd4ffbaccdd06ac2d7b809d-HHS-bill.ha]; Bonds, Michelle E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=55bb1c6e16fc49c6840de58f10bce69f-HHS-meb0-cd]; Oakley, Caitlin B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8feed045e954557aa1e0052f925865f-HHS-Caitlin]; Miller, Katie R. EOP/OVP [Katie.R.Miller@ovp.eop.gov]; Love, Kelly A. EOP/OVP (b)(6)
Subject: RE: Releases

(b) (5) No worries if not.

From: Galatas, Kate (CDC/OD/OADC) <kkg2@cdc.gov>
Sent: Friday, March 13, 2020 7:48 AM
To: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>; Caccamo, Stephanie (FDA/OC) <Stephanie.Caccamo@fda.hhs.gov>; Caliguiri, Laura (FDA/OC) <Laura.Caliguiri@fda.hhs.gov>; Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>
Cc: Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>; Bonds, Michelle E. (CDC/OD/OADC) <meb0@cdc.gov>; Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>; Miller, Katie R. EOP/OVP <(b)(6)>; Love, Kelly A. EOP/OVP <(b)(6)>
Subject: Re: Releases

We are having a telebriefing at 1pm today — we don't have current plans to issue a press release about testing, unless you're suggesting we do that. Undoubtedly we will be asked about this today and will be ready to respond on the telebriefing.

Take care,
Kate

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From: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>
Sent: Friday, March 13, 2020 7:37:44 AM
To: Caccamo, Stephanie (FDA/OC) <Stephanie.Caccamo@fda.hhs.gov>; Caliguiri, Laura (FDA/OC) <Laura.Caliguiri@fda.hhs.gov>; Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>
Cc: Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>; Galatas, Kate (CDC/OD/OADC) <kkg2@cdc.gov>; Bonds, Michelle E. (CDC/OD/OADC) <meb0@cdc.gov>; Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>; Miller, Katie R. EOP/OVP <Katie.R.Miller@ovp.eop.gov>; Love, Kelly A. EOP/OVP <(b)(6)>
Subject: RE: Releases

(b) (5)

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Friday, March 13, 2020 6:34 AM
To: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>
Cc: Hall, Bill (OS) <bill.hall@hhs.gov>; Galatas, Kate (CDC) <kkg2@cdc.gov>; Bonds, Michelle E (CDC) <meb0@cdc.gov>; Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>; Miller, Katie R. EOP/OVP <Katie.R.Miller@ovp.eop.gov>; Love, Kelly A. EOP/OVP <Kelly.A.Love@ovp.eop.gov>
Subject: RE: Releases

Noted. Will push soon

Stephanie Caccomo
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: 301.348.1956
Cell: (b)(6)
stephanie.caccomo@fda.hhs.gov

From: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>
Date: March 13, 2020 at 3:59:21 AM EDT
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>
Cc: Hall, Bill (OS) <bill.hall@hhs.gov>, Galatas, Kate (CDC) <kkg2@cdc.gov>, Bonds, Michelle E (CDC) <meb0@cdc.gov>, Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>, Miller, Katie R. EOP/OVP <Katie.R.Miller@ovp.eop.gov>, Love, Kelly A. EOP/OVP <(b)(6)>
Subject: RE: Releases
Importance: High

Hi all-

Here is the plan:

(b) (5)

Thanks for your coordination on this; I think it will prove to be more effective.

Devin

(b) (5)

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FDA-OC-2020-1977/2020-4765-001061

MULTI-HHS-FDA-20-0400, 20-0415-C-000069

(b) (5)

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>

Sent: Friday, March 13, 2020 12:06 AM

To: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>;
Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>

Cc: Hall, Bill (OS) <bill.hall@hhs.gov>; Galatas, Kate (CDC) <kkg2@cdc.gov>; Bonds, Michelle E (CDC) <meb0@cdc.gov>;
Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>

Subject: RE: Releases

Hi Devin—

Attaching our draft release. These actions happened this evening (within the last hour), so they can be discussed in AM TV programs. Please feel free to call if you need any walk through on any of this.

Stephanie Caccomo

Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: 301.348.1956
Cell: (b)(6)
stephanie.caccomo@fda.hhs.gov

From: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>

Sent: Thursday, March 12, 2020 10:56 PM

To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>

Cc: Hall, Bill (OS) <bill.hall@hhs.gov>; Galatas, Kate (CDC) <kkg2@cdc.gov>; Bonds, Michelle E (CDC) <meb0@cdc.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>

Subject: RE: Releases

Checking in on where folks are at with their releases.

(b) (5)

That means we'd have to be ready to go by 8:00 am or so. People going on TV can refer to it as "announcements coming this morning."

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>

Sent: Thursday, March 12, 2020 8:32 PM

To: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>; Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>

Cc: Hall, Bill (OS) <bill.hall@hhs.gov>; Galatas, Kate (CDC) <kkg2@cdc.gov>; Bonds, Michelle E (CDC) <meb0@cdc.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>

Subject: RE: Releases

Here is where we are: We are buttoning up on our end, going through our clearance, have flagged for ASPA it is coming tonight – likely late and targeting, depending on timing, tonight if possible or as early as possible am (before 8am).

From: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>

Sent: Thursday, March 12, 2020 8:27 PM

To: Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>

Cc: Hall, Bill (OS) <bill.hall@hhs.gov>; Galatas, Kate (CDC) <kkg2@cdc.gov>; Bonds, Michelle E (CDC) <meb0@cdc.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>

Subject: RE: Releases

Thank you. Put NIH on by accident. Taking them off now.

From: Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>

Sent: Thursday, March 12, 2020 8:25 PM

To: O'Malley, Devin M. EOP/OVP <(b)(6)>

Cc: Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>; Stover, Kathy (NIH/NIAID) [E] <(b)(6)>; Conrad, Patricia

(NIH/NIAID) [E] <(b)(6)>; Galatas, Kate (CDC/OD/OADC) <kkg2@cdc.gov>; Bonds, Michelle E.

(CDC/OD/OADC) <meb0@cdc.gov>; Caccomo, Stephanie (FDA/OC) <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura (FDA/OC) <Laura.Caliguiri@fda.hhs.gov>

Subject: Re: Releases

+ Stephanie and Laura w/ FDA

On Mar 12, 2020, at 8:20 PM, O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov> wrote:

Hi CDC and FDA-

1 (b) (5) [REDACTED].

Can you let me know how the drafting of materials is going? I know that, in FDA's case, the release hinges on some things happening overnight. That said, would you all have a sense of timing?

Thanks!

Devin

Devin M. O'Malley

(b)(6) [REDACTED]

From: O'Malley, Devin M. EOP/OVP [Devin.M.O'Malley@ovp.eop.gov]
Sent: 3/13/2020 9:01:47 AM
To: Hall, Bill (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e56218361cd4ffbaccdd06ac2d7b809d-HHS-bill.ha]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Oakley, Caitlin B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8feed045e954557aa1e0052f925865f-HHS-Caitlin]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
Subject: RE: Please provide one final review

(b) (5)

From: Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>
Sent: Friday, March 13, 2020 8:49 AM
To: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>; Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>; Caliguiri, Laura (FDA/OC) <Laura.Caliguiri@fda.hhs.gov>; Caccomo, Stephanie (FDA/OC) <Stephanie.Caccomo@fda.hhs.gov>
Subject: RE: Please provide one final review

(b) (5)

From: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>
Sent: Friday, March 13, 2020 8:47 AM
To: Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>; Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>; Caliguiri, Laura (FDA/OC) <Laura.Caliguiri@fda.hhs.gov>; Caccomo, Stephanie (FDA/OC) <Stephanie.Caccomo@fda.hhs.gov>
Subject: Please provide one final review

Let me know if you have any red flags:

(b) (5)

(b) (5)

Devin M. O'Malley

(b)(6)

From: O'Malley, Devin M. EOP/OVP [Devin.M.O'Malley@ovp.eop.gov]
Sent: 3/13/2020 10:48:07 AM
To: Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Hall, Bill (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e56218361cd4ffbaccdd06ac2d7b809d-HHS-bill.ha]; Oakley, Caitlin B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8feed045e954557aa1e0052f925865f-HHS-Caitlin]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
Subject: RE: Please provide one final review

(b) (5)

From: Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>
Sent: Friday, March 13, 2020 10:47 AM
To: O'Malley, Devin M. EOP/OVP <(b)(6)>; Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>; Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>; Caliguiri, Laura (FDA/OC) <Laura.Caliguiri@fda.hhs.gov>; Caccomo, Stephanie (FDA/OC) <Stephanie.Caccomo@fda.hhs.gov>
Subject: RE: Please provide one final review

Hey Devin – did your release go out?

From: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>
Sent: Friday, March 13, 2020 9:25 AM
To: Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>; Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>; Caliguiri, Laura (FDA/OC) <Laura.Caliguiri@fda.hhs.gov>; Caccomo, Stephanie (FDA/OC) <Stephanie.Caccomo@fda.hhs.gov>
Subject: RE: Please provide one final review

Good stuff, thanks!

From: Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>
Sent: Friday, March 13, 2020 9:24 AM
To: O'Malley, Devin M. EOP/OVP <(b)(6)>; Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>; Caliguiri, Laura (FDA/OC) <Laura.Caliguiri@fda.hhs.gov>; Caccomo, Stephanie (FDA/OC) <Stephanie.Caccomo@fda.hhs.gov>
Subject: RE: Please provide one final review

(b) (5)

From: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>
Sent: Friday, March 13, 2020 9:09 AM
To: Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>; Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>; Caliguiri, Laura (FDA/OC) <Laura.Caliguiri@fda.hhs.gov>; Caccomo, Stephanie (FDA/OC) <Stephanie.Caccomo@fda.hhs.gov>
Subject: RE: Please provide one final review

(b) (5)

From: Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>

Sent: Friday, March 13, 2020 9:06 AM

To: O'Malley, Devin M. EOP/OVP <(b)(6)>; Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>; Caliguiri, Laura (FDA/OC) <Laura.Caliguiri@fda.hhs.gov>; Caccomo, Stephanie (FDA/OC) <Stephanie.Caccomo@fda.hhs.gov>

Subject: RE: Please provide one final review

It's the bridge where HHS partners with industry to carry a research discovery to a point where a product is ready for FDA approval (or an EUA in an emergency).

From: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>

Sent: Friday, March 13, 2020 9:02 AM

To: Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>; Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>; Caliguiri, Laura (FDA/OC) <Laura.Caliguiri@fda.hhs.gov>; Caccomo, Stephanie (FDA/OC) <Stephanie.Caccomo@fda.hhs.gov>

Subject: RE: Please provide one final review

(b) (5)

From: Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>

Sent: Friday, March 13, 2020 8:49 AM

To: O'Malley, Devin M. EOP/OVP <(b)(6)>; Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>; Caliguiri, Laura (FDA/OC) <Laura.Caliguiri@fda.hhs.gov>; Caccomo, Stephanie (FDA/OC) <Stephanie.Caccomo@fda.hhs.gov>

Subject: RE: Please provide one final review

(b) (5)

From: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>

Sent: Friday, March 13, 2020 8:47 AM

To: Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>; Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>; Caliguiri, Laura (FDA/OC) <Laura.Caliguiri@fda.hhs.gov>; Caccomo, Stephanie (FDA/OC) <Stephanie.Caccomo@fda.hhs.gov>

Subject: Please provide one final review

Let me know if you have any red flags:

(b) (5)

(b) (5)

Devin M. O'Malley

(b)(6)

From: O'Malley, Devin M. EOP/OVP [Devin.M.O'Malley@ovp.eop.gov]
Sent: 4/10/2020 2:02:44 PM
To: Block, Molly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e32ca68078848889751e7ec26910142-Molly.Block]; Manchester, Brittney [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bd6ca86f5a3f43ffb295122f23a95770-Brittney.Ma]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; DL OVP Comms COVID [DL.OVP.CommsCOVID@ovp.eop.gov]
CC: Robinson, Michael J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4118fde5239947c6bccbdbd4cb7488fa-HHS-michael]; Oakley, Caitlin B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8feed045e954557aa1e0052f925865f-HHS-Caitlin]; McKeogh, Katherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3facab3fd03480f8553892121fd2009-HHS-Katheri]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Hall, Bill (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e56218361cd4ffbaccdd06ac2d7b809d-HHS-bill.ha]; Caccamo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
Subject: RE: FDA Media Request: CBS News 60 Minutes - PPE specific to COVID-19

It's fine. (b) (5) it addresses everything well.

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Friday, April 10, 2020 2:01 PM
To: Manchester, Brittney <Brittney.Manchester@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; DL OVP Comms COVID (b) (6) O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>
Cc: Robinson, Michael J (OS) <michael.robinson@hhs.gov>; Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>; McKeogh, Katherine (OS) <Katherine.McKeogh@hhs.gov>; Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>; Hall, Bill (OS) <bill.hall@hhs.gov>; Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>
Subject: RE: FDA Media Request: CBS News 60 Minutes - PPE specific to COVID-19

Re-upping this inquiry. Can we get guidance? Thanks!

Happy to chat offline about this as well.

Molly

From: Manchester, Brittney <Brittney.Manchester@fda.hhs.gov>
Sent: Thursday, April 9, 2020 5:08 PM
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; DL OVP Comms COVID (b) (6)
Cc: Robinson, Michael J (OS) <michael.robinson@hhs.gov>; Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>; McKeogh, Katherine (OS) <Katherine.McKeogh@hhs.gov>; Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>; Hall, Bill (OS) <bill.hall@hhs.gov>; Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; Block, Molly <Molly.Block@fda.hhs.gov>
Subject: RE: FDA Media Request: CBS News 60 Minutes - PPE specific to COVID-19

Hello,

Checking in on review of the below.

AMERICAN
OVERSIGHT

FDA-OC-2020-1977/2020-4765-001070

MULTI-HHS-FDA-20-0400, 20-0415-C-000078

Thank you,
Brittney

Brittney Manchester
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: 301-796-1026 | (b)(6)
brittney.manchester@fda.hhs.gov



From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Sent: Thursday, April 9, 2020 10:31 AM
To: DL OVP Comms COVID <(b)(6)> @<(b)(6)>
Cc: Manchester, Brittney <Brittney.Manchester@fda.hhs.gov>; Robinson, Michael J (OS) <michael.robinson@hhs.gov>; Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>; McKeogh, Katherine (OS) <Katherine.McKeogh@hhs.gov>; Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>; Hall, Bill (OS) <bill.hall@hhs.gov>; Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; Block, Molly <Molly.Block@fda.hhs.gov>
Subject: FDA Media Request: CBS News 60 Minutes - PPE specific to COVID-19

Hello,

Sending the below request on behalf of my colleague Brittney.

Thanks,

Michael

Reporter: Sam Hornblower

Media Outlet: CBS News – 60 Minutes

FDA Spokespersons: FDA spokesperson via written response

Subject: PPE specific to COVID-19

Deadline: Today, April 9, 3PM

Expected place of publication (print, online, broadcast): Broadcast

Expected date of publication/airing: April 12

Background:

Sam is an associate producer at CBS News - 60 Minutes. The outlet is working on a story about PPE specific to COVID-19.

Questions:

1. What happened to the recalled products with Cardinal Health? We want to keep an eye on those Cardinal gowns - I assume they could be useful as isolation gowns at this point.

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2. I want to see what we can learn about the issue of FDA efforts on the issue of global shortages of PPE. And states competing for it within the states, hoarding, how this is affecting the market etc.

(b) (5)

(b) (5)

3. And also any ongoing efforts related to watch for counterfeit PPE or misbranded PPE as hospitals turn to non traditional sourcing. The FDA considers the sale and promotion of fraudulent COVID-19 products to be a threat to the public health. We have an aggressive surveillance program that routinely monitors online sources for health fraud products, especially during a significant public health issue such as this one.

(b) (5)

(b) (5)

4. With respect to new American based companies coming into the picture who are rapidly jump in and get new factories online to alleviate the PPE shortage. I want to make sure that we don't highlight anything that isn't appropriate. These are regulated medical devices. If not done right it could be worse than nothing at all. So if there are examples of new facilities doing it right and getting FDA approval with correct specs etc. - PPE medical gear that is approved By FDA in record time so that they can get to hospitals that need them (since imports are all but foreclosed). Is there a way you could inform me about such examples?

(b) (5)

(b) (5)

From: O'Malley, Devin M. EOP/OVP [Devin.M.O'Malley@ovp.eop.gov]
Sent: 5/14/2020 9:38:02 AM
To: Caccamo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
CC: Block, Molly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e32ca68078848889751e7ec26910142-Molly.Block]; DL OVP Comms COVID [DL.OVP.CommsCOVID@ovp.eop.gov]; Syrek, Tori Q. EOP/WHO [Tori.Q.Syrek@who.eop.gov]; Miller, Katie R. EOP/OVP [Katie.R.Miller@ovp.eop.gov]; Yanick, Brittany M. EOP/WHO [Brittany.M.Yanick@who.eop.gov]; Caputo, Michael R (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dac6080dfebe436da01db07986b63377-HHS-Michael]; Traverse, Brad (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=392182fc98ba4510a6be159a867997f6-HHS-Brad.Tr]; Nance, Claire Y. EOP/WHO [Claire.Y.Nance2@who.eop.gov]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Hall, Bill (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e56218361cd4ffbacdd06ac2d7b809d-HHS-bill.ha]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]
Subject: RE: FDA Announcement Heads Ups 5/13/20

Good. We should definitely go after.

From: Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>
Sent: Thursday, May 14, 2020 9:32 AM
To: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>
Cc: Block, Molly <Molly.Block@fda.hhs.gov>; DL OVP Comms COVID <(b)(6)>; Syrek, Tori Q. EOP/WHO <Tori.Q.Syrek@who.eop.gov>; Miller, Katie R. EOP/OVP <Katie.R.Miller@ovp.eop.gov>; Yanick, Brittany M. EOP/WHO <Brittany.M.Yanick@who.eop.gov>; Caputo, Michael R (OS) <Michael.Caputo@hhs.gov>; Traverse, Brad (OS) <Brad.Traverse@hhs.gov>; Nance, Claire Y. EOP/WHO <Claire.Y.Nance2@who.eop.gov>; Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>; Hall, Bill (OS) <bill.hall@hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Subject: RE: FDA Announcement Heads Ups 5/13/20

(b) (5)

Stephanie Caccamo

Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: 301.348.1956
Cell: (b)(6)
stephanie.caccamo@fda.hhs.gov

From: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>
Sent: Thursday, May 14, 2020 9:02 AM
To: Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>
Cc: Block, Molly <Molly.Block@fda.hhs.gov>; DL OVP Comms COVID <(b)(6)>; Syrek, Tori Q. EOP/WHO <Tori.Q.Syrek@who.eop.gov>; Miller, Katie R. EOP/OVP <Katie.R.Miller@ovp.eop.gov>; Yanick, Brittany M. EOP/WHO <Brittany.M.Yanick@who.eop.gov>; Caputo, Michael R (OS) <Michael.Caputo@hhs.gov>; Traverse, Brad (OS) <Brad.Traverse@hhs.gov>; Nance, Claire Y. EOP/WHO <Claire.Y.Nance2@who.eop.gov>; Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>; Hall, Bill (OS) <bill.hall@hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Subject: Re: FDA Announcement Heads Ups 5/13/20

Who is going first?

Sent from my iPhone

On May 14, 2020, at 8:50 AM, Cacco, Stephanie <Stephanie.Cacomo@fda.hhs.gov> wrote:

(b) (5)

Happy to chat through strategy. Comms should be coming your way for review by this afternoon. We would like to issue today.

Stephanie Cacomo

Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: 301.348.1956
Cell: (b)(6)
stephanie.cacomo@fda.hhs.gov

From: Block, Molly <Molly.Block@fda.hhs.gov>

Sent: Wednesday, May 13, 2020 5:18 PM

To: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>; DL OVP Comms COVID

(b)(6) <(b)(6)>; Syrek, Tori Q. EOP/WHO <Tori.Q.Syrek@who.eop.gov>; Miller, Katie R. EOP/OVP <Katie.R.Miller@ovp.eop.gov>; Yanick, Brittany M. EOP/WHO <Brittany.M.Yanick@who.eop.gov>; Caputo, Michael R (OS) <Michael.Caputo@hhs.gov>; Traverse, Brad (OS) <Brad.Traverse@hhs.gov>; Nance, Claire Y. EOP/WHO <Claire.Y.Nance2@who.eop.gov>

Cc: Cacco, Stephanie <Stephanie.Cacomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>

Subject: FDA Announcement Heads Ups 5/13/20

Upcoming Announcements:

- MOU with USDA regarding the potential use of the defense production act with regard to FDA Regulated Food During the COVID-19 Pandemic
- Federal judge enters temporary injunction against Xephyr LLC doing business as N-Ergetics, preventing sale of Colloidal Silver Products for COVID-19
 - Maybe tonight/tomorrow (waiting for Judge to file in OK)

Today's Announcements

- Coronavirus Daily Roundup for 5/13/20 (topics: town hall on 3D printing, thermal imaging resources, diagnostics update)

Media

- None

Interview Requests:

- NBC TODAY Show
 - Watching Dr. Hahn's testimony now, would love the chance to explore how we can safely have him join us live tomorrow. We would be happy to facilitate via Skype or FaceTime.
- Cavuto

- I wanted to reach out to see if Dr. Hahn or Dr. Peter Marks would be available to join Neil Cavuto's show on Fox News this Saturday (5/16) at any point between 10AM-12PM ET. We're interested in discussing the latest on COVID-19 vaccine development, the FDA giving Moderna's vaccine a fast-track status, and other news of the day.
- NPR (morning edition / all things considered)

From: Fetalvo, Ninio (CMS/OC) [Ninio.Fetalvo@cms.hhs.gov]
Sent: 5/15/2020 12:00:33 PM
To: Foster, Timothy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=305ac986fff64e3abf3e57c20991bd33-HHS-Timothy]; Hayes, Jonathan H (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=09728a0143b84029ae2453fd78d6e02d-HHS-Jonatha]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Waters, Cicely (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fba91b63e0524bdda033348880b10ed0-HHS-Cicely.]; block.molly@epa.gov; Michael, Gretchen (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9124cfb0a9114613a44e2269824f94e6-HHS-Gretche]; Kane, Elleen (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6233166344c4d4f8cb4057a8c91d30e-HHS-Elleen.]; Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Morse, Sara N (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4080ee237c084683ae674366e5cde21d-HHS-Sara.Mo]; Pence, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3f21407a02d44cd4901bcce26f9b3074-HHS-Laura.P]; Galatas, Kate (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0a0623b3cb34f86a2f6f9d14afe115e-HHS-kkg2-cd]; CDC IMS JIC OADC LNO -2 [eocevent202@cdc.gov]; Bonds, Michelle E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=55bb1c6e16fc49c6840de58f10bce69f-HHS-meb0-cd]; Heldman, Amy B (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9d1540bef81a43a594d474b947645915-HHS-evd4-cd]; McGowan, Robert K (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e6175b088b1d49a4bfa2de3862800d4a-HHS-omc2-cd]; Rich, Michawn M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=74df5e4343744d2eb5ecfdb2e9dacf26-HHS-qig3-cd]; Brandt, Kimberly (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c27a38a5cf444a9eb4db07014d44f848-HHS-Kimberl]; Brookes, Brady (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=be9baf245ae491baa1c01e7e03ad9e4-HHS-Brady.B]; Corry, Thomas (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=231d7059d86a4849b57446fb3b682a17-HHS-Thomas.]; Bell, Damian (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=786ee55e696149b1a3aee1be64e83e5b-HHS-Damian.]; Brady, William (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=20a0af371df94b4fbee7821e5892048-HHS-William]; Callahan, Kenneth (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec339fe2bb494b829a3cb4b638466afb-HHS-Kenneth]; Caligui, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Caccamo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Trueman, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9385c36713d64340ac51bc3e72864402-HHS-Laura.T]; Johnston, Darcie (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0e6d7dbb72d4d6eb84029c0547f7458-HHS-Darcie.]; Stannard, Paula (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=447102489a24495bb9004e524dda1589-HHS-Paula.S]; Conrad, Patricia L (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e30cd6224aeb49c795844f43fd78a049-HHS-conradp]; Billet, Courtney R (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=04ddfe30e6154dd5ab720f23eb6070df-HHS-billetec]; Shuy, Caitrin (OS)
[o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=875ab76b6ae34c4cad510d8e5ceddf9b-HHS-Caitrin]; Stover, Kathy A (NIH)
[o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=b2c949970bc3434e8e0b42fd9404e774-HHS-kathy.s]; Routh, Jennifer M
(NIH) [o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=1e8ec9d097ff40ec9672a45be2a7d906-HHS-jennife]; Heck, Mia (OS)
[o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=656b2fa5aca84a18851397d417a16672-HHS-Mia.Hec]; Sherman, Jennifer
(OS) [o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=96ea669491654aba8d4ea6816279e040-HHS-Jennife]; Kellogg, Rachel (OS)
[o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=6dc3e53a06f5451cad9facbb50d54576-HHS-Rachel.]; Zebley, Kyle (OS)
[o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=d79ac6af2e1b49089fca453b39ebddde-HHS-Kyle.Ze]; Stimson, Brian (OS)
[o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=21fcf1b527694276af1ccdb7db495042-HHS-Brian.S]; Jenny, Brenna (OS)
[o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=b9c67f9e773345d99578e032e2e8b5a6-HHS-Brenna.]; Schaeffer, Alison M
(OS) [o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=4141e15908124849b7b905ba381abe85-HHS-Alison.]; Thomas, Gloria D (OS)
[o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=9198d045d3b247779f604deb26d8a2e5-HHS-Gloria.]; Fulmer, Brendan (OS)
[o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=3a4f4f84b75243b3af90cf1ea4fe1ada-HHS-Brendan]; Ezernack, Paige (OS)
[o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=872e1cb77bfe440596caae115cd6515c-HHS-Paige.E]; Myles, Renate H (NIH)
[o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=04a3e5f0ac384bd6b70bd9cdee9082f2-HHS-mylesr-]; Burklow, John T (NIH)
[o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=20d9290a05474f989153cf26a5a4e669-HHS-Burklow]; Fine, Amanda B (NIH)
[o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=2df9b8b64006465d943d2f283ad87d1d-HHS-amanda.]; Fritz, Craig M (NIH)
[o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=aae2df341fec455db972cce10f0749e5-HHS-craig.f]; Wojtowicz, Emma M
(NIH) [o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=fc3ba2cdc9394d43af6d048bfd568b69-HHS-emma.wo]; Akinso, Woleola O
(NIH) [o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ecd2eb000f5743ef81d334a38b32b4bd-HHS-akinsow]; Beckham, Tammy (OS)
[o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=8b3c038e4917469dbb5666f0464192b3-HHS-Tammy.B]; Avula, Deepa
(SAMHSA) [o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=1769053a2788410c9a49686112266ad9-HHS-Deepa.A]; Lepore, Loretta A
(CDC) [o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=713d163ed33643caa6caec3a00adf141-HHS-phf7-cd]; Thorman, Caroline
(ACF) [o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=61ab62aed42f45c4bdd1bd5419b5afcc-HHS-Carolin]; Block, Molly
[o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0e32ca68078848889751e7ec26910142-Molly.Block]; Marks, Caryn L (OS)
[o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=8e8a41c617994afa80efdda08b4c6053-HHS-Caryn.M]; Overstreet, Elizabeth
(OS) [o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=425b9f564782488395620134c9bc776f-HHS-Elizabe]
CC: ASPA-Deputies [ASPA-Deputies@hhs.gov]; Bird, Catherine (OS) [o=ExchangeLabs/ou=Exchange Administrative
Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=add7a78c8cec414c963d6b8213b7598a-HHS-Catheri]; Brennan,
Patrick (OS) [o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e87181146141b1ba0978553d9ff156-HHS-Patrick]
Subject: RE: FOR REVIEW BY NOON TOMORROW: HHS FACTSHEET 5.15



HHS fact sheet
WH 5.15 cms.docx

CMS edits attached.

CONFIDENTIAL. DELIBERATIVE. PRE-DECISIONAL.

From: Foster, Timothy (OS/ASPA) <Timothy.Foster@hhs.gov>

Sent: Thursday, May 14, 2020 10:08 PM

To: Hayes, Jonathan (OS/ASPR/IO) <Jonathan.Hayes@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Waters, Cicely (OS/ASPR/OEA) <Cicely.Waters@hhs.gov>; block.molly@epa.gov; Michael, Gretchen (OS/ASPR/OEA) <Gretchen.Michael@hhs.gov>; Kane, Elleen (OS/ASPR/OEA) <Elleen.Kane@hhs.gov>; Arbes, Sarah (HHS/ASL) <Sarah.Arbes@hhs.gov>; Morse, Sara (HHS/ASL) <Sara.Morse@hhs.gov>; Pence, Laura (HHS/ASL) <Laura.Pence@hhs.gov>; Galatas, Kate (CDC/OD/OADC) <kkg2@cdc.gov>; CDC IMS JIC OADC LNO -2 <eocevent202@cdc.gov>; Bonds, Michelle E. (CDC/OD/OADC) <meb0@cdc.gov>; Heldman, Amy B. (CDC/OD/OADC) <evd4@cdc.gov>; McGowan, Robert (Kyle) (CDC/OD/OCS) <omc2@cdc.gov>; Rich, Michawn (CDC/OD) <qig3@cdc.gov>; Brandt, Kimberly (CMS/OA) <Kimberly.Brandt1@cms.hhs.gov>; Brookes, Brady (CMS/OA) <Brady.Brookes@cms.hhs.gov>; Corry, Thomas (CMS/OA) <Thomas.Corry@cms.hhs.gov>; Bell, Damian (CMS/OC) <Damian.Bell@cms.hhs.gov>; Brady, Will (HHS/IOS) <William.Brady@hhs.gov>; Callahan, Kenneth (HHS/IOS) <Kenneth.Callahan@hhs.gov>; Caliguiri, Laura (FDA/OC) <Laura.Caliguiri@fda.hhs.gov>; Felberbaum, Michael (FDA/OC) <Michael.Felberbaum@fda.hhs.gov>; Caccamo, Stephanie (FDA/OC) <Stephanie.Caccamo@fda.hhs.gov>; Trueman, Laura (HHS/IEA) <Laura.Trueman@hhs.gov>; Johnston, Darcie (HHS/IEA) <Darcie.Johnston@hhs.gov>; Stannard, Paula (HHS/IOS) <Paula.Stannard@hhs.gov>; Conrad, Patricia (NIH/NIAID) [E] (b)(6); Billet, Courtney (NIH/NIAID) [E] (b)(6); Shuy, Caitrin (HHS/ASFR) <Caitrin.Shuy@hhs.gov>; Stover, Kathy (NIH/NIAID) [E] (b)(6); Routh, Jennifer (NIH/NIAID) [E] (b)(6); Heck, Mia (HHS/OASH) <Mia.Heck@hhs.gov>; Sherman, Jennifer (HHS/OASH) <Jennifer.Sherman@hhs.gov>; Kellogg, Rachel (HHS/OASH) <Rachel.Kellogg@hhs.gov>; Zebley, Kyle (HHS/OS/OGA) <Kyle.Zebley@hhs.gov>; Stimson, Brian (HHS/OGC) <Brian.Stimson@hhs.gov>; Jenny, Brenna (HHS/OGC) <Brenna.Jenny@hhs.gov>; Schaeffer, Alison (HHS/OS/OGA) <Alison.Schaeffer@hhs.gov>; Thomas, Gloria (HHS/OS/OGA) <Gloria.Thomas@hhs.gov>; Fulmer, Brendan (HHS/IOS) <Brendan.Fulmer@hhs.gov>; Ezernack, Paige (OS/ASPR/SPPR) <Paige.Ezernack@hhs.gov>; Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>; Burklow, John (NIH/OD) [E] (b)(6); Fine, Amanda (NIH/OD) [E] (b)(6); Fritz, Craig (NIH/OD) [E] (b)(6); Wojtowicz, Emma (NIH/OD) [E] (b)(6); Akinso, Woleola (NIH/OD) [E] (b)(6); Beckham, Tammy (HHS/OASH) <Tammy.Beckham@hhs.gov>; Avula, Deepa (SAMHSA/OFR) <Deepa.Avula@samhsa.hhs.gov>; Lepore, Loretta (CDC/OD/OCS) <phf7@cdc.gov>; Thorman, Caroline (ACF) <Caroline.Thorman@acf.hhs.gov>; Fetalvo, Ninio (CMS/OC) <Ninio.Fetalvo@cms.hhs.gov>; Block, Molly (FDA/OC) <Molly.Block@fda.hhs.gov>; Marks, Caryn (HHS/IEA) <Caryn.Marks@hhs.gov>; Overstreet, Elizabeth (OS/ASFR) <Elizabeth.Overstreet@hhs.gov>

Cc: ASPA-Deputies <ASPA-Deputies@hhs.gov>; Bird, Catherine (OS/IOS) <Catherine.Bird@hhs.gov>; Brennan, Patrick (OS/ASPA) <Patrick.Brennan@hhs.gov>

Subject: FOR REVIEW BY NOON TOMORROW: HHS FACTSHEET 5.15

All,

(b) (5)

Please respond with any updates, comments, or edits to Patrick Brennan and me by 12:00 PM noon, tomorrow, May 15.

<< File: HHS fact sheet WH 5.15.docx >>

Timothy Foster
Advisor, Strategic Communications
Office of the Assistant Secretary for Public Affairs
U.S. Department of Health and Human Services
Timothy.Foster@HHS.Gov

(b)(6)

Predecisional/deliberative communication

From: O'Malley, Devin M. EOP/OVP [Devin.M.O'Malley@ovp.eop.gov]
Sent: 5/6/2020 7:41:30 PM
To: Caccamo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
CC: Manchester, Brittney [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bd6ca86f5a3f43ffb295122f23a95770-Brittney.Ma]
Subject: RE: Flag: (b) (5)

ok

From: Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>
Sent: Wednesday, May 6, 2020 5:39 PM
To: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>
Cc: Manchester, Brittney <Brittney.Manchester@fda.hhs.gov>
Subject: RE: Flag: (b) (5)

Hey Devin! Just a quick update. We are continuing with our planned pitch for WSJ tomorrow, (b) (5). Happy to work through strategy if there are any questions/concerns we can address, let us know.

Thank you!

Stephanie Caccamo
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: 301.348.1956
Cell: (b)(6)
stephanie.caccamo@fda.hhs.gov

From: Caccamo, Stephanie
Sent: Tuesday, May 5, 2020 10:58 AM
To: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>
Cc: DL OVP Comms COVID <(b)(6)> Caliguri, Laura <Laura.Caliguri@fda.hhs.gov>; Block, Molly <Molly.Block@fda.hhs.gov>; Manchester, Brittney <Brittney.Manchester@fda.hhs.gov>; Spring, Christina M (CDC) <dsa9@cdc.gov>; Burden, Bernadette (CDC) <btb8@cdc.gov>; Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>; Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>; McKeogh, Katherine (OS) <Katherine.McKeogh@hhs.gov>; Hall, Bill (OS) <bill.hall@hhs.gov>
Subject: RE: (b) (5)

(b) (5). We also want to complement the WSJ pitch with a very short proactive statement. We're working on that now and will get a draft to you later today/early tomorrow. Happy to chat through any of this, thanks!

Stephanie Caccamo
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: 301.348.1956
Cell: (b)(6)
stephanie.caccamo@fda.hhs.gov

From: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>

Sent: Monday, May 4, 2020 10:26 PM

To: Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>

Cc: DL OVP Comms COVID <(b)(6)> @ <(b)(6)> Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Block, Molly <Molly.Block@fda.hhs.gov>; Manchester, Brittney <Brittney.Manchester@fda.hhs.gov>; Spring, Christina M (CDC) <dsa9@cdc.gov>; Burden, Bernadette (CDC) <btb8@cdc.gov>; Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>; Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>; McKeogh, Katherine (OS) <Katherine.McKeogh@hhs.gov>; Hall, Bill (OS) <bill.hall@hhs.gov>

Subject: Re: (b) (5)

(b) (5)

Sent from my iPhone

On May 4, 2020, at 7:31 PM, Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov> wrote:

Hi all--

Flagging a joint FDA/CDC media interview opportunity (b) (5)

(b) (5)

Stephanie Caccomo

Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: 301.348.1956
Cell: (b)(6)
stephanie.caccomo@fda.hhs.gov

<(b) (5) docx>

From: O'Malley, Devin M. EOP/OVP [Devin.M.O'Malley@ovp.eop.gov]
Sent: 5/6/2020 3:48:04 PM
To: Block, Molly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e32ca68078848889751e7ec26910142-Molly.Block]; Caccamo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
Subject: RE: CLEARANCE_0546: FDA "FDA Continues to Combat Fraudulent COVID-19 Medical Products"

ok

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Wednesday, May 6, 2020 2:43 PM
To: Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>
Subject: RE: CLEARANCE_0546: FDA "FDA Continues to Combat Fraudulent COVID-19 Medical Products"

Wanted to check on the status here.

From: Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>
Sent: Wednesday, May 6, 2020 11:33 AM
To: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>; Block, Molly <Molly.Block@fda.hhs.gov>
Subject: RE: CLEARANCE_0546: FDA "FDA Continues to Combat Fraudulent COVID-19 Medical Products"

Hey Devin—

We've tightened this up a bit. Appreciate your feedback on this one. Thank you!

Stephanie Caccamo

Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: 301.348.1956
Cell: (b)(6)
stephanie.caccamo@fda.hhs.gov

From: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>
Sent: Friday, May 1, 2020 12:14 PM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>
Subject: FW: CLEARANCE_0546: FDA "FDA Continues to Combat Fraudulent COVID-19 Medical Products"

(b) (5) ?

From: Robinson, Michael J (HHS/ASPA) <michael.robinson@hhs.gov>
Sent: Friday, May 1, 2020 11:38 AM
To: O'Malley, Devin M. EOP/OVP (b)(6); Fetalvo, Ninio J. EOP/OVP (b)(6) @ (b)(6); Yanick, Brittany M. EOP/WHO <Brittany.M.Yanick@who.eop.gov>; Syrek, Tori Q. EOP/WHO <Tori.Q.Syrek@who.eop.gov>

Cc: Weber, Mark (HHS/ASPA) <Mark.Weber@hhs.gov>; Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>; Caputo, Michael (HHS/ASPA) <Michael.Caputo@hhs.gov>; McKeogh, Katherine (OS/ASPA) <Katherine.McKeogh@hhs.gov>; Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>; Myrie, Simone (OS/ASPA) <Simone.Myrie@hhs.gov>; Lemar, Naweed (OS/ASPA) <Naweed.Lemar@hhs.gov>; Daniels, Carla (HHS/ASPA) <Carla.Daniels@hhs.gov>; Formoso, Paula (HHS/ASPA) <Paula.Formoso@hhs.gov>; Bradley, Tasha (OS/ASPA) <Tasha.Bradley@hhs.gov>; OS HHSPress (HHS/ASPA) <(b)(6)@hhs.gov>; Pratt, Michael (OS/ASPA) <Michael.Pratt@hhs.gov>

Subject: FW: CLEARANCE_0546: FDA "FDA Continues to Combat Fraudulent COVID-19 Medical Products"

Hello

Attached is for your urgent approval; it has been cleared w/n HHS

Respectfully,

From: OS HHSPress (HHS/ASPA) <(b)(6)@hhs.gov>

Sent: Thursday, April 30, 2020 9:39 PM

Subject: CLEARANCE_0546: FDA "FDA Continues to Combat Fraudulent COVID-19 Medical Products"

(b) (5)

V/r,

Mike Robinson

AMERICAN
OVERSIGHT

FDA-OC-2020-1977/2020-4765-001087

MULTI-HHS-FDA-20-0400, 20-0415-C-000095

Strategic Planning, ASPA

202-690-6885 –desk

(b)(6) –mobile

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BY LAW:***

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From: Fetalvo, Ninio J. EOP/OVP (b)(6)]
Sent: 4/22/2020 3:30:38 PM
To: Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]
CC: DL OVP Comms COVID (b)(6) Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Hall, Bill (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e56218361cd4ffbaccdd06ac2d7b809d-HHS-bill.ha]; Robinson, Michael J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4118fde5239947c6bccbdbd4cb7488fa-HHS-michael]; Oakley, Caitlin B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8feed045e954557aa1e0052f925865f-HHS-Caitlin]; McKeogh, Katherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3facab3fd03480f8553892121fd2009-HHS-Katheri]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Block, Molly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e32ca68078848889751e7ec26910142-Molly.Block]
Subject: Re: FOR INPUT BY 6 PM: WSJ Inquiry for FDA on groups influencing COVID policy/actions

Ok

—
Ninio J.H. Fetalvo
Office of the Vice President
(b)(6)

On Apr 22, 2020, at 3:26 PM, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov> wrote:

Seeking input/clearance by 6 p.m. for WSJ is working on a story about a group of scientists led by Tom Cahill in Boston, calling themselves "scientists to stop covid-19", and their deep work behind the scenes to influence policy related to the pandemic. The upshot of the story is that this group is helping governmental entities, including the FDA, slash red tape. The story is not focused on FDA, but likely will have some mention.

Proposed FDA response (we are not going to confirm/discuss any specifics he raises):

(b) (5)

Additional information from the reporter for your awareness:

The reporter understands the group (which includes former Merck CEO Ed Scolnick) has had many conversations with the FDA, including with Janet Woodcock and Stephen Hahn. They've also had influence with some changes related to FDA policy and getting the FDA to speed up approval of drugs/manufacturing. In particular, in the case of Regeneron, the group asked Tommy Hicks Jr. (co-chair of the RNC) to help get Renegeron permission to move some manufacturing to Limerick (Ireland) so they would have more capacity in the U.S. for covid drugs. This would have been a months-long approval process, but after Mr. Hicks got involved, the FDA called Regeneron the same day and said they would have permission. The reporter did note that the group, particularly Mr. Scolnick, was frustrated with the pace of the FDA early

on. He said, on a call with FDA staff, a few weeks ago: "You don't know a f---ing thing you're talking about. You're the problem here."

Thanks!

Michael

Michael Felberbaum

Senior Advisor

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-9548 / Cell: (b) (6)
michael.felberbaum@fda.hhs.gov

<image013.png>

<image014.jpg>

<image015.jpg>

<image016.jpg>

<image017.jpg>

<image018.jpg>

From: O'Malley, Devin M. EOP/OVP [Devin.M.O'Malley@ovp.eop.gov]
Sent: 4/23/2020 7:36:23 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]
CC: Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Block, Molly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e32ca68078848889751e7ec26910142-Molly.Block]; Caccamo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Oakley, Caitlin B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8feed045e954557aa1e0052f925865f-HHS-Caitlin]; McKeogh, Katherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3facab3fd03480f8553892121fd2009-HHS-Katheri]; Hall, Bill (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e56218361cd4ffbacdd06ac2d7b809d-HHS-bill.ha]; Robinson, Michael J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4118fde5239947c6bccbdb4cb7488fa-HHS-michael]
Subject: RE: PLEASE SEE ASAP -- PAST DEADLINE: FDA Media Inquiry -- Vanity Fair --

(b) (5)

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Thursday, April 23, 2020 7:34 PM
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Cc: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Block, Molly <Molly.Block@fda.hhs.gov>; Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>; Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>; McKeogh, Katherine (OS) <Katherine.McKeogh@hhs.gov>; Hall, Bill (OS) <bill.hall@hhs.gov>; Robinson, Michael J (OS) <michael.robinson@hhs.gov>
Subject: Re: PLEASE SEE ASAP -- PAST DEADLINE: FDA Media Inquiry -- Vanity Fair --

+Stacy

Sent from my iPhone

On Apr 23, 2020, at 7:32 PM, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov> wrote:

Hi Devin, I appreciate your feedback but does not hit the point we're trying to make – she's using the word support and it's not about support, it was about considerations. How about the following?

(b) (5)

AMERICAN
OVERSIGHT

FDA-OC-2020-1977/2020-4765-001091

MULTI-HHS-FDA-20-0400, 20-0415-C-000099

(b) (5)

From: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>
Sent: Thursday, April 23, 2020 7:14 PM
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Block, Molly <Molly.Block@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>; Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>; McKeogh, Katherine (OS) <Katherine.McKeogh@hhs.gov>; Hall, Bill (OS) <bill.hall@hhs.gov>; Robinson, Michael J (OS) <michael.robinson@hhs.gov>
Subject: RE: PLEASE SEE ASAP -- PAST DEADLINE: FDA Media Inquiry -- Vanity Fair --

(b) (5)

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Sent: Thursday, April 23, 2020 7:06 PM
To: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>
Cc: DL OVP Comms COVID <(b)(6)>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Block, Molly <Molly.Block@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>; Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>; McKeogh, Katherine (OS) <Katherine.McKeogh@hhs.gov>; Hall, Bill (OS) <bill.hall@hhs.gov>; Robinson, Michael J (OS) <michael.robinson@hhs.gov>
Subject: RE: PLEASE SEE ASAP -- PAST DEADLINE: FDA Media Inquiry -- Vanity Fair --

Katherine Eban

From: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>
Sent: Thursday, April 23, 2020 7:05 PM
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: DL OVP Comms COVID <(b)(6)>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Block, Molly <Molly.Block@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>; Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>; McKeogh, Katherine (OS) <Katherine.McKeogh@hhs.gov>; Hall, Bill (OS) <bill.hall@hhs.gov>; Robinson, Michael J (OS) <michael.robinson@hhs.gov>
Subject: RE: PLEASE SEE ASAP -- PAST DEADLINE: FDA Media Inquiry -- Vanity Fair --

Who is the reporter?

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Sent: Thursday, April 23, 2020 7:04 PM
To: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>
Cc: DL OVP Comms COVID <(b)(6)>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Block, Molly <Molly.Block@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>; Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>; McKeogh, Katherine (OS) <Katherine.McKeogh@hhs.gov>; Hall, Bill (OS)

<bill.hall@hhs.gov>; Robinson, Michael J (OS) <michael.robinson@hhs.gov>

Subject: PLEASE SEE ASAP -- PAST DEADLINE: FDA Media Inquiry -- Vanity Fair --

Importance: High

Hi Devin,

Sorry for the rush here, but trying to get this response back to the reporter ASAP – we are past 7 p.m. deadline. From reporter -- they are writing about a Trump administration plan that was being established over the last six weeks to disseminate chloroquine drugs widely through drugstores with the use of an app designed by Oracle.

- **FEMA documentation from early April appears to suggest that FDA commissioner Stephen Hahn supported making chloroquine drugs from the Strategic National Stockpile available to COVID-19 patients more widely, outside of hospital settings. Can the FDA comment on whether Commissioner Hahn supported an administration plan to distribute chloroquine drugs for treatment of COVID-19 patients to drugstores as well as hospitals?**

(b) (5)

- **Vanity Fair will report that in mid-to-late March, the FDA's chief counsel Stacy Amin worked to execute a White House plan that would have BARDA sponsor a chloroquine IND, and then have President Trump announce the use of an Oracle app that would help patients access chloroquine drugs and collect data on their treatment. Can the FDA comment on the nature of this plan, and whether the FDA had to waive any regulations in order to work towards execution of it?**

(b) (5)

Thanks,

Michael

Michael Felberbaum
Senior Advisor

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-9548 / Cell: (b)(6)
michael.felberbaum@fda.hhs.gov

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<image003.jpg>

<image004.jpg>

<image005.jpg>

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OVERSIGHT

FDA-OC-2020-1977/2020-4765-001093

MULTI-HHS-FDA-20-0400, 20-0415-C-000101

<image006.jpg>

From: O'Malley, Devin M. EOP/OVP [Devin.M.O'Malley@ovp.eop.gov]
Sent: 4/23/2020 10:24:15 AM
To: Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Block, Molly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e32ca68078848889751e7ec26910142-Molly.Block]; Fetalvo, Ninio J. EOP/OVP (b)(6); Miller, Katie R. EOP/OVP [Katie.R.Miller@ovp.eop.gov]; Gilmartin, Kayleigh M. EOP/WHO [Kayleigh.McEnany@who.eop.gov]; Farah, Alyssa A. EOP/WHO [Alyssa.A.Farah@who.eop.gov]
CC: Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]
Subject: RE: FDA Announcements Heads Up 4/22/2020

I'm good. What is the timing on it?

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Sent: Thursday, April 23, 2020 10:21 AM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>; Block, Molly <Molly.Block@fda.hhs.gov>; Fetalvo, Ninio J. EOP/OVP <(b)(6)>; Miller, Katie R. EOP/OVP <Katie.R.Miller@ovp.eop.gov>; Gilmartin, Kayleigh M. EOP/WHO <Kayleigh.McEnany@who.eop.gov>; Farah, Alyssa A. EOP/WHO <Alyssa.A.Farah@who.eop.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: RE: FDA Announcements Heads Up 4/22/2020

Devin
Call me or Keagan if you would like to discuss.
Laura

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Wednesday, April 22, 2020 10:17 PM
To: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>; Block, Molly <Molly.Block@fda.hhs.gov>; Fetalvo, Ninio J. EOP/OVP <(b)(6)>; Miller, Katie R. EOP/OVP <Katie.R.Miller@ovp.eop.gov>; Gilmartin, Kayleigh M. EOP/WHO <Kayleigh.McEnany@who.eop.gov>; Farah, Alyssa A. EOP/WHO <Alyssa.A.Farah@who.eop.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: RE: FDA Announcements Heads Up 4/22/2020

(b) (5)

Stephanie Caccomo
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: 301.348.1956
Cell: (b)(6)
stephanie.caccomo@fda.hhs.gov

From: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>
Sent: Wednesday, April 22, 2020 10:10 PM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Fetalvo, Ninio J. EOP/OVP <(b)(6)>; Miller, Katie R.

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OVERSIGHT

FDA-OC-2020-1977/2020-4765-001095

MULTI-HHS-FDA-20-0400, 20-0415-C-000103

EOP/OVP <(b)(6)>; Gilmartin, Kayleigh M. EOP/WHO <Kayleigh.McEnany@who.eop.gov>; Farah, Alyssa A. EOP/WHO <Alyssa.A.Farah@who.eop.gov>
Cc: Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Subject: RE: FDA Announcements Heads Up 4/22/2020

What's the hydroxy statement going to say?

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Wednesday, April 22, 2020 4:40 PM
To: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>; DL OVP Comms COVID <(b)(6)>; Syrek, Tori Q. EOP/WHO <Tori.Q.Syrek@who.eop.gov>; Fetalvo, Ninio J. EOP/OVP <(b)(6)>; Miller, Katie R. EOP/OVP <Katie.R.Miller@ovp.eop.gov>; Love, Kelly A. EOP/OVP <(b)(6)>; Porter, Macaulay V. EOP/OVP <(b)(6)>
Cc: Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Subject: FDA Announcements Heads Up 4/22/2020

Upcoming Announcements:

- Likely today: FDA Continues to Ensure Safe Hand Sanitizer is Available During COVID-19
- Likely tomorrow: Drug Safety Communication about chloroquine and hydroxychloroquine press statement
- TBD this week: FDA updates on efforts to swiftly facilitate the import of crucial COVID-19 medical products and combat fraud

Today's Announcements

1. Daily Roundup: FDA actions on remote monitoring EUAs, warning letters on fraudulent products and more in its ongoing response to the COVID-19 pandemic.

Today's Media

1. 6:52 – 6:57 AM ET: Fox & Friends
2. 7:07 – 7:11 AM ET: CBS This Morning

Upcoming Media

1. 8:00 PM Hour (10 Minutes): CNN Town Hall with Anderson Cooper and Sanjay Gupta
2. 8:30 PM ET pre-tape: FOX News @ Night with Shannon Bream
3. 8:00 – 8:15 AM: BioCentury podcast with Steve Usdin (treatments/vaccine development)

New Outstanding Media Requests

TV:

1. MSNBC SPECIAL REPORT: TESTING & THE ROAD TO REOPENING (4/23/20)
 - a. Note: We will make ANY timing work for Dr. Hahn tomorrow with a pre-taped interview, or live between 10 PM - 11:30 PM.
 - b. Hosted by Brian Williams and Nicolle Wallace
2. America Newsroom HQ
 - a. Saturday: 12 – 3:00 PM
 - b. Sunday: 1:00 pm hour
 - c. Topics: COVID-19 response, preparedness and future treatment
3. Mornings with Maria
 - a. Ask: Monday, April 27, 2020
4. The Story with Martha MacCallum
 - a. Ask: Could we potentially have him join us later this week (April 23/24) or Monday?
5. Lou Dobbs
 - a. Ask: If Commissioner Stephen Hahn could join Lou next week to discuss testing. Giving companies the ability for more testing, home testing etc.

6. Cox Media

- a. Topics: Collecting plasma from patients who have recovered from COVID-19
- b. Reach: 33 television stations in 20 markets, 54 radio stations in 10 markets
- 7. The Daily Briefing with Dana Perino
 - a. Topic: Drug testing in the U.S.
- 8. Axios (HBO)
 - a. Topics: What it would take to relax stay-at-home orders and other restrictions, Coronavirus Treatment Acceleration Program, future of antibody testing, potential drugs and treatments
- 9. Cavuto (Weekday 4pm show and Saturday show)
 - a. Topics: We are interested in discussing the FDA's authorization of the first test for patients at home sample collection. Please let me know if there is anything we can work out for today or this week remotely (studio, skype or phoner) as well.
- 10. Associated Press
 - a. Ask: Would Dr. Hahn be available for an interview with AP Video today via ZOOM or Skype? The interview would be TAPED and last no more than 15 minutes.
- 11. CNBC
 - a. What: Mini-documentary about the various potential treatments for COVID-19 and their effects on the pharmaceutical sector
 - b. Topics: FDA's new Coronavirus Treatment Acceleration Program and the necessary steps for a treatment to be approved by the FDA
- 12. TODAY Show – standing offer

Radio

- 1. Piscopo in the Morning
- 2. KSL
- 3. NPR
- 4. Breitbart Sunday News (May 3, 2020)

Print

- 1. Rolling Stone
 - a. What: Magazine feature about the federal response to the coronavirus outbreak.
 - b. Topics: Several high-profile sources (academics, former government administrators) have been critical of the FDA's response, in particular of the long delay before allowing large commercial labs with high throughput to begin testing, and I wanted to give Hahn a chance to respond. It would also be helpful to get his explanation for what happened with CDC testing.

From: O'Malley, Devin M. EOP/OVP [Devin.M.O'Malley@ovp.eop.gov]
Sent: 4/23/2020 5:35:49 PM
To: Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]
CC: DL OVP Comms COVID (b)(6); Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Oakley, Caitlin B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8feed045e954557aa1e0052f925865f-HHS-Caitlin]; McKeogh, Katherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3facab3fd03480f8553892121fd2009-HHS-Katheri]; Hall, Bill (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e56218361cd4ffbaccdd06ac2d7b809d-HHS-bill.ha]; Robinson, Michael J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4118fde5239947c6bccbdbd4cb7488fa-HHS-michael]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Block, Molly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e32ca68078848889751e7ec26910142-Molly.Block]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
Subject: Re: FOR INPUT BY 6PM: WSJ inquiry for FDA on Dr. Bright

(b) (5)

Sent from my iPhone

On Apr 23, 2020, at 5:05 PM, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov> wrote:

Hello,

For input/clearance by 6 p.m., if possible.

WSJ is working on a story about the removal of Dr. Rick Bright from BARDA. In their reporting, sources are saying that Dr. Hahn (along with Birx, Fauci, Jerome Adams and others) had in private conversations questioned the use of anti-malarial drugs in treating coronavirus, citing the lack of clinical evidence on their effectiveness.

(b) (5)

Proposed response:

(b) (5)

Thanks,

Michael

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FDA-OC-2020-1977/2020-4765-001098

MULTI-HHS-FDA-20-0400, 20-0415-C-000106

Michael Felberbaum

Senior Advisor

Office of Media Affairs
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Tel: 240-402-9548 / Cell: (b) (6)
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From: Fetalvo, Ninio (CMS/OC) [Ninio.Fetalvo@cms.hhs.gov]
Sent: 5/22/2020 11:29:22 AM
To: Foster, Timothy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=305ac986fff64e3abf3e57c20991bd33-HHS-Timothy]; Hayes, Jonathan H (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=09728a0143b84029ae2453fd78d6e02d-HHS-Jonatha]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Waters, Cicely (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fba91b63e0524bdda033348880b10ed0-HHS-Cicely.]; block.molly@epa.gov; Michael, Gretchen (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9124cfb0a9114613a44e2269824f94e6-HHS-Gretche]; Kane, Elleen (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6233166344c4d4f8cb4057a8c91d30e-HHS-Elleen.]; Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Morse, Sara N (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4080ee237c084683ae674366e5cde21d-HHS-Sara.Mo]; Pence, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3f21407a02d44cd4901bcce26f9b3074-HHS-Laura.P]; Galatas, Kate (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0a0623b3cb34f86a2f6f9d14afe115e-HHS-kkg2-cd]; CDC IMS JIC OADC LNO -2 [eocevent202@cdc.gov]; Bonds, Michelle E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=55bb1c6e16fc49c6840de58f10bce69f-HHS-meb0-cd]; Heldman, Amy B (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9d1540bef81a43a594d474b947645915-HHS-evd4-cd]; McGowan, Robert K (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e6175b088b1d49a4bfa2de3862800d4a-HHS-omc2-cd]; Rich, Michawn M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=74df5e4343744d2eb5ecfdb2e9dacf26-HHS-qig3-cd]; Brandt, Kimberly (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c27a38a5cf444a9eb4db07014d44f848-HHS-Kimberl]; Brookes, Brady (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=be9baf6245ae491baa1c01e7e03ad9e4-HHS-Brady.B]; Corry, Thomas (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=231d7059d86a4849b57446fb3b682a17-HHS-Thomas.]; Bell, Damian (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=786ee55e696149b1a3aee1be64e83e5b-HHS-Damian.]; Brady, William (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=20a0af371df94b4fbee7821e5892048-HHS-William]; Callahan, Kenneth (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec339fe2bb494b829a3cb4b638466afb-HHS-Kenneth]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Caccamo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Trueman, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9385c36713d64340ac51bc3e72864402-HHS-Laura.T]; Johnston, Darcie (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0e6d7dbb72d4d6eb84029c0547f7458-HHS-Darcie.]; Stannard, Paula (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=447102489a24495bb9004e524dda1589-HHS-Paula.S]; Conrad, Patricia L (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e30cd6224aeb49c795844f43fd78a049-HHS-conradp]; Billet, Courtney R (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group

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[o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=8b3c038e4917469dbb5666f0464192b3-HHS-Tammy.B]; Avula, Deepa (SAMHSA) [o=ExchangeLabs/ou=Exchange Administrative Group
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[o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=8e8a41c617994afa80efdda08b4c6053-HHS-Caryn.M]; Overstreet, Elizabeth (OS) [o=ExchangeLabs/ou=Exchange Administrative Group
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[o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=769f79cdeb50401c8bee4f227b113ceb-HHS-John.Am]
ASPA-Deputies [ASPA-Deputies@hhs.gov]; Bird, Catherine (OS) [o=ExchangeLabs/ou=Exchange Administrative

Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=add7a78c8cec414c963d6b8213b7598a-HHS-Catheri]; Brennan, Patrick (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e87181146141b1ba0978553d9ff156-HHS-Patrick]

Subject: RE: FOR REVIEW BY NOON TOMORROW: HHS FACTSHEET 5.21

Attachments: FOR UPDATE HHS Fact Sheet 5.21.20 cms.docx



FOR UPDATE
HHS Fact Sheet ...

CMS edits and comments attached.

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From: Foster, Timothy (OS/ASPA) <Timothy.Foster@hhs.gov>

Sent: Thursday, May 21, 2020 8:50 PM

To: Hayes, Jonathan (OS/ASPR/IO) <Jonathan.Hayes@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Waters, Cicely (OS/ASPR/OEA) <Cicely.Waters@hhs.gov>; block.molly@epa.gov; Michael, Gretchen (OS/ASPR/OEA) <Gretchen.Michael@hhs.gov>; Kane, Elleen (OS/ASPR/OEA) <Elleen.Kane@hhs.gov>; Arbes, Sarah (HHS/ASL) <Sarah.Arbes@hhs.gov>; Morse, Sara (HHS/ASL) <Sara.Morse@hhs.gov>; Pence, Laura (HHS/ASL) <Laura.Pence@hhs.gov>; Galatas, Kate (CDC/OD/OADC) <kkg2@cdc.gov>; CDC IMS JIC OADC LNO -2 <eocevent202@cdc.gov>; Bonds, Michelle E. (CDC/OD/OADC) <meb0@cdc.gov>; Heldman, Amy B. (CDC/OD/OADC) <evd4@cdc.gov>; McGowan, Robert (Kyle) (CDC/OD/OCS) <omc2@cdc.gov>; Rich, Michawn (CDC/OD) <qig3@cdc.gov>; Brandt, Kimberly (CMS/OA) <Kimberly.Brandt1@cms.hhs.gov>; Brookes, Brady (CMS/OA) <Brady.Brookes@cms.hhs.gov>; Corry, Thomas (CMS/OA) <Thomas.Corry@cms.hhs.gov>; Bell, Damian (CMS/OC) <Damian.Bell@cms.hhs.gov>; Brady, Will (HHS/IOS) <William.Brady@hhs.gov>; Callahan, Kenneth (HHS/IOS) <Kenneth.Callahan@hhs.gov>; Caliguri, Laura (FDA/OC) <Laura.Caliguri@fda.hhs.gov>; Felberbaum, Michael (FDA/OC) <Michael.Felberbaum@fda.hhs.gov>; Caccamo, Stephanie (FDA/OC) <Stephanie.Caccamo@fda.hhs.gov>; Trueman, Laura (HHS/IEA) <Laura.Trueman@hhs.gov>; Johnston, Darcie (HHS/IEA) <Darcie.Johnston@hhs.gov>; Stannard, Paula (HHS/IOS) <Paula.Stannard@hhs.gov>; Conrad, Patricia (NIH/NIAID) [E] (b)(6); Billet, Courtney (NIH/NIAID) [E] (b)(6); Shuy, Caitrin (HHS/ASFR) <Caitrin.Shuy@hhs.gov>; Stover, Kathy (NIH/NIAID) [E] (b)(6); Routh, Jennifer (NIH/NIAID) [E] (b)(6); Heck, Mia (HHS/OASH) <Mia.Heck@hhs.gov>; Sherman, Jennifer (HHS/OASH) <Jennifer.Sherman@hhs.gov>; Kellogg, Rachel (HHS/OASH) <Rachel.Kellogg@hhs.gov>; Zebley, Kyle (HHS/OS/OGA) <Kyle.Zebley@hhs.gov>; Stimson, Brian (HHS/OGC) <Brian.Stimson@hhs.gov>; Jenny, Brenna (HHS/OGC) <Brenna.Jenny@hhs.gov>; Schaeffer, Alison (HHS/OS/OGA) <Alison.Schaeffer@hhs.gov>; Thomas, Gloria (HHS/OS/OGA) <Gloria.Thomas@hhs.gov>; Fulmer, Brendan (HHS/IOS) <Brendan.Fulmer@hhs.gov>; Ezernack, Paige (OS/ASPR/SPPR) <Paige.Ezernack@hhs.gov>; Myles, Renate (NIH/OD) [E] (b)(6); Burklow, John (NIH/OD) [E] (b)(6); Fine, Amanda (NIH/OD) [E] (b)(6); Fritz, Craig (NIH/OD) [E] (b)(6); Wojtowicz, Emma (NIH/OD) [E] (b)(6); Akinso, Woleola (NIH/OD) [E] (b)(6); Beckham, Tammy (HHS/OASH) <Tammy.Beckham@hhs.gov>; Avula, Deepa (SAMHSA/OFR) <Deepa.Avula@samhsa.hhs.gov>; Lepore, Loretta (CDC/OD/OCS) <phf7@cdc.gov>; Thorman, Caroline (ACF) <Caroline.Thorman@acf.hhs.gov>; Fetalvo, Ninio (CMS/OC) <Ninio.Fetalvo@cms.hhs.gov>; Block, Molly (FDA/OC) <Molly.Block@fda.hhs.gov>; Marks, Caryn (HHS/IEA) <Caryn.Marks@hhs.gov>; Overstreet, Elizabeth (OS/ASFR) <Elizabeth.Overstreet@hhs.gov>; Moughalian, Jen (HHS/ASFR) <Jen.Moughalian@hhs.gov>; Amin, John (HHS/ASFR) (CTR) <John.Amin@hhs.gov>

Cc: ASPA-Deputies <ASPA-Deputies@hhs.gov>; Bird, Catherine (OS/IOS) <Catherine.Bird@hhs.gov>; Brennan, Patrick (OS/ASPA) <Patrick.Brennan@hhs.gov>

Subject: FOR REVIEW BY NOON TOMORROW: HHS FACTSHEET 5.21

(b) (5)

Please respond with any updates, comments, or edits to Patrick Brennan and me by 12:00 PM noon, tomorrow, May 22.

<< File: FOR UPDATE HHS Fact Sheet 5.21.20.docx >>

Timothy Foster
Advisor, Strategic Communications
Office of the Assistant Secretary for Public Affairs
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(b)(6) (m)

Predecisional/deliberative communication

From: Fetalvo, Ninio (CMS/OC) [Ninio.Fetalvo@cms.hhs.gov]
Sent: 6/15/2020 4:04:45 PM
To: Robinson, Wilma (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8cb06883191e4f6e8d324d78743b27ad-HHS-Wilma.R]; OS - ASPA - Opioids [OS-ASPA-Opioids@hhs.gov]; Moughalian, Jen C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1227fced76ad4092bb5f1395d24c0d74-HHS-Jen.Mou]; Hayes, Jonathan H (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=09728a0143b84029ae2453fd78d6e02d-HHS-Jonatha]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Waters, Cicely (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fba91b63e0524bdda033348880b10ed0-HHS-Cicely.]; block.molly@epa.gov; Michael, Gretchen (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9124cfb0a9114613a44e2269824f94e6-HHS-Gretche]; Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Morse, Sara N (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4080ee237c084683ae674366e5cde21d-HHS-Sara.Mo]; Pence, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3f21407a02d44cd4901bcce26f9b3074-HHS-Laura.P]; Galatas, Kate (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0a0623b3cb34f86a2f6f9d14afe115e-HHS-kkg2-cd]; CDC IMS JIC OADC LNO - 2 [eocevent202@cdc.gov]; Bonds, Michelle E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=55bb1c6e16fc49c6840de58f10bce69f-HHS-meb0-cd]; Heldman, Amy B (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9d1540bef81a43a594d474b947645915-HHS-evd4-cd]; McGowan, Robert K (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e6175b088b1d49a4bfa2de3862800d4a-HHS-omc2-cd]; Oury, Rachael (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=de9a6ee608e74e35b822b2dcc143c639-HHS-qkc3-cd]; Brandt, Kimberly (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c27a38a5cf444a9eb4db07014d44f848-HHS-Kimberl]; Brookes, Brady (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=be9baf245ae491baa1c01e7e03ad9e4-HHS-Brady.B]; Corry, Thomas (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=231d7059d86a4849b57446fb3b682a17-HHS-Thomas.]; Bell, Damian (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=786ee55e696149b1a3aee1be64e83e5b-HHS-Damian.]; Brady, William (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=20a0af371df94b4fbee7821e5892048-HHS-William]; Callahan, Kenneth (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec339fe2bb494b829a3cb4b638466afb-HHS-Kenneth]; Caligui, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Caccamo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Trueman, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9385c36713d64340ac51bc3e72864402-HHS-Laura.T]; Johnston, Darcie (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0e6d7dbb72d4d6eb84029c0547f7458-HHS-Darcie.]; Stannard, Paula (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=447102489a24495bb9004e524dda1589-HHS-Paula.S]; Conrad, Patricia L (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e30cd6224aeb49c795844f43fd78a049-HHS-conradp]; Stover, Kathy A (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=b2c949970bc3434e8e0b42fd9404e774-HHS-kathy.s]; Routh, Jennifer M (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=9198d045d3b247779f604deb26d8a2e5-HHS-Gloria.]; Fulmer, Brendan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=20d9290a05474f989153cf26a5a4e669-HHS-Burklow]; Fine, Amanda B (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=2df9b8b64006465d943d2f283ad87d1d-HHS-amanda.]; Fritz, Craig M (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=aae2df341fec455db972cce10f0749e5-HHS-craig.f]; Wojtowicz, Emma M (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=fc3ba2cdc9394d43af6d048bfd568b69-HHS-emma.wo]; Akinso, Woleola O (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ecd2eb000f5743ef81d334a38b32b4bd-HHS-akinsow]; Beckham, Tammy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=8b3c038e4917469dbb5666f0464192b3-HHS-Tammy.B]; Monroe, Johnathan (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=444fb883930644c5bbeabe0e21ba0054-HHS-Johnath]; Overstreet, Elizabeth (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=425b9f564782488395620134c9bc776f-HHS-Elizabe]; Amin, John (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=e0601902140f426e9c5a139f7134a3c5-HHS-Jim.Par]; Keveney, Sean (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=392a6133e7244f488b3efcc8cb164514-HHS-Sean.Ke]; Schwartz, Erica (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=dd8adca6507d486fb2017138076f4b49-HHS-Nichola]; Brooks, John (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=d8d251ad1ebd447f8378d71031e0dabf-HHS-John.Br]; Steele, Danielle (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=634b96dc13cf48f3971ce676b65e952f-HHS-Daniell]; Medler, Natalie (HHS/ASFR) (CTR) [Natalie.Medler@hhs.gov]; Bird, Catherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=add7a78c8cec414c963d6b8213b7598a-HHS-Catheri]; Agnew, Ann (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=daa06163025f427aa913c47cafaf6589-HHS-Ann.Agn]; Mango, Paul (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=2fe1932caf0249d2a0c6af5fb82c9ec5-HHS-Paul.Ma]; Stecker, Judy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e205440400ab4f629be1faccfe0846fc-HHS-Judy.St] Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Stecker, Judy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e205440400ab4f629be1faccfe0846fc-HHS-Judy.St]; Bird, Catherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=add7a78c8cec414c963d6b8213b7598a-HHS-Catheri]; Mango, Paul (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2fe1932caf0249d2a0c6af5fb82c9ec5-HHS-Paul.Ma]; Agnew, Ann (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=daa06163025f427aa913c47cafaf6589-HHS-Ann.Agn]; Grove, Matthew R (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=74ee04cf984940678e277d7b3390efbc-HHS-Matthew]; Hawkins, Jamar (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bd7c1a4031647ce89237aef4deb5d89-HHS-jamar.h]; Fischbach, Aaron (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8ea33b46039b40e28161700df7dcfd45-HHS-Aaron.F]

Subject: RE: For Review: ONDCP Factsheet--Updated

Attachments: ONDCP COVID Fact Sheet 20200527_STAFF SEC EDITS_CLEAN cms.docx

CMS edits attached

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From: Robinson, Wilma (HHS/IOS) <Wilma.Robinson@hhs.gov>
Sent: Monday, June 15, 2020 2:14 PM
To: OS - ASPA - Opioids <OS-ASPA-Opioids@hhs.gov>; Moughalian, Jen (HHS/ASFR) <Jen.Moughalian@hhs.gov>; Hayes, Jonathan (OS/ASPR/IO) <Jonathan.Hayes@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Waters, Cicely (OS/ASPR/OEA) <Cicely.Waters@hhs.gov>; block.molly@epa.gov; Michael, Gretchen (OS/ASPR/OEA) <Gretchen.Michael@hhs.gov>; Arbes, Sarah (HHS/ASL) <Sarah.Arbes@hhs.gov>; Morse, Sara (HHS/ASL) <Sara.Morse@hhs.gov>; Pence, Laura (HHS/IOS) <Laura.Pence@hhs.gov>; Galatas, Kate (CDC/OD/OADC) <kkg2@cdc.gov>; CDC IMS JIC OADC LNO -2 <eocevent202@cdc.gov>; Bonds, Michelle E. (CDC/OD/OADC) <meb0@cdc.gov>; Heldman, Amy B. (CDC/OD/OADC) <evd4@cdc.gov>; McGowan, Robert (Kyle) (CDC/OD/OCS) <omc2@cdc.gov>; Oury, Rachael (CDC/OD) <QKC3@cdc.gov>; Brandt, Kimberly (CMS/OA) <Kimberly.Brandt1@cms.hhs.gov>; Brookes, Brady (CMS/OA) <Brady.Brookes@cms.hhs.gov>; Corry, Thomas (CMS/OA) <Thomas.Corry@cms.hhs.gov>; Bell, Damian (CMS/OC) <Damian.Bell@cms.hhs.gov>; Brady, Will (HHS/IOS) <William.Brady@hhs.gov>; Callahan, Kenneth (HHS/IOS) <Kenneth.Callahan@hhs.gov>; Caliguiri, Laura (FDA/OC) <Laura.Caliguiri@fda.hhs.gov>; Felberbaum, Michael (FDA/OC) <Michael.Felberbaum@fda.hhs.gov>; Caccamo, Stephanie (FDA/OC) <Stephanie.Caccamo@fda.hhs.gov>; Trueman, Laura (HHS/IEA) <Laura.Trueman@hhs.gov>; Johnston, Darcie (HHS/IEA) <Darcie.Johnston@hhs.gov>; Stannard, Paula (HHS/IOS) <Paula.Stannard@hhs.gov>; Conrad, Patricia (NIH/NIAID) [E] <(b)(6)>; Stover, Kathy (NIH/NIAID) [E] <(b)(6)>; Routh, Jennifer (NIH/NIAID) [E] <(b)(6)>; Sherman, Jennifer (HHS/OASH) <Jennifer.Sherman@hhs.gov>; Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Kellogg, Rachel (HHS/OASH) <Rachel.Kellogg@hhs.gov>; Grigsby, Garrett (HHS/OS/OGA) <Garrett.Grigsby@hhs.gov>; Stimson, Brian (HHS/OGC) <Brian.Stimson@hhs.gov>; Charrow, Robert (HHS/OGC) <Robert.Charrow@hhs.gov>; Thomas, Gloria (HHS/OS/OGA) <Gloria.Thomas@hhs.gov>; Fulmer, Brendan (HHS/IOS) <Brendan.Fulmer@hhs.gov>; Ezernack, Paige (OS/ASPR/SPPR) <Paige.Ezernack@hhs.gov>; Myles, Renate (NIH/OD) [E] <(b)(6)>; Burklow, John (NIH/OD) [E] <(b)(6)>; Fine, Amanda (NIH/OD) [E] <(b)(6)>; Fritz, Craig (NIH/OD) [E] <(b)(6)>; Wojtowicz, Emma (NIH/OD) [E] <(b)(6)>; Akinso, Woleola (NIH/OD) [E] <(b)(6)>; Beckham, Tammy (HHS/OASH) <Tammy.Beckham@hhs.gov>; Monroe, Johnathan (CMS/OC) <Johnathan.Monroe1@cms.hhs.gov>; Overstreet, Elizabeth (OS/ASFR) <Elizabeth.Overstreet@hhs.gov>; Amin, John (HHS/ASFR) (CTR) <John.Amin@hhs.gov>; Parker, Jim (HHS/IOS) <Jim.Parker@hhs.gov>; Fetalvo, Ninio (CMS/OC) <Ninio.Fetalvo@cms.hhs.gov>; Keveney, Sean (HHS/OGC)

FDA-OC-2020-1977/2020-4765-001106

MULTI-HHS-FDA-20-0400, 20-0415-C-000114

<Sean.Keveney@hhs.gov>; Schwartz, Erica (HHS/OASH) <Erica.Schwartz@hhs.gov>; Uehlecke, Nick (HHS/IOS) <Nicholas.Uehlecke@hhs.gov>; Brooks, John (CMS/OA) <John.Brooks@cms.hhs.gov>; Steele, Danielle (HHS/IOS) <Danielle.Steele@hhs.gov>; Medler, Natalie (HHS/ASFR) (CTR) <Natalie.Medler@hhs.gov>; Bird, Catherine (OS/IOS) <Catherine.Bird@hhs.gov>; Agnew, Ann (HHS/IOS) <Ann.Agnew@hhs.gov>; Mango, Paul (HHS/IOS) <Paul.Mango@hhs.gov>; Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov>
Cc: Harrison, Brian (HHS/IOS) <Brian.Harrison@hhs.gov>; Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov>; Bird, Catherine (OS/IOS) <Catherine.Bird@hhs.gov>; Mango, Paul (HHS/IOS) <Paul.Mango@hhs.gov>; Agnew, Ann (HHS/IOS) <Ann.Agnew@hhs.gov>; Grove, Matthew R. (HHS/OS) <Matthew.Grove@HHS.GOV>; Hawkins, Jamar (HHS/OS) <jamar.hawkins@hhs.gov>; Fischbach, Aaron (OS/IOS) <Aaron.Fischbach@hhs.gov>
Subject: FW: For Review: ONDCP Factsheet--Updated

Hi All,

(b) (5)

Thanks,

Staff Sec

Wilma M. Robinson, PhD, MPH
Deputy Executive Secretary
200 Independence Ave. SW
Suite 603
Washington DC 20201

Office Phone: 202-690-5627
Office Cell (b)(6)

From: Staff Secretary <(b)(6)>
Sent: Monday, June 15, 2020 1:29 PM
To: Hicks, Hope C. EOP/WHO <Hope@who.eop.gov>; Kushner, Jared C. EOP/WHO <jck@who.eop.gov>; Gidley, Hogan H. EOP/WHO <Hogan.Gidley@who.eop.gov>; DL Chief of Staff Office (b)(6); Bix, Deborah L. EOP/NSC <Deborah.L.Bix@nsc.eop.gov>; Hahn, Julia A. EOP/WHO <Julia.A.Hahn@who.eop.gov>; Deere, Judd P. EOP/WHO <(b)(6)> imt@who.eop.gov; Conway, Kellyanne E. EOP/WHO <KAC@who.eop.gov>; Philbin, Patrick F. EOP/WHO <Patrick.F.Philbin@who.eop.gov>; Eisenberg, John A. EOP/WHO <John.A.Eisenberg@who.eop.gov>; Pottinger, Matthew F. EOP/WHO <MPottinger@who.eop.gov>; Harrison, Brian (HHS/IOS) <Brian.Harrison@hhs.gov>; Kudlow, Larry A. EOP/WHO <Lawrence.A.Kudlow@who.eop.gov>; Vought, Russell T. EOP/OMB <(b)(6)>; Fauci, Anthony (NIH/NIAID) [E] (b)(6); Short, Marc T. EOP/OVP (b)(6); Miller, Katie R. (ovp.eop.gov) <Katie.R.Miller@ovp.eop.gov>; Miller, Stephen EOP/WHO <Stephen.Miller@who.eop.gov>; Lewis, Oliver CAPT SD (b)(6); Hoelscher, Douglas (who.eop.gov) <Douglas.L.Hoelscher@who.eop.gov>; Pataki, Timothy (who.eop.gov) <Timothy.A.Pataki@who.eop.gov>; Berkowitz, Avraham J. EOP/WHO <avi@who.eop.gov>; DeBacker, Devin A. EOP/WHO <Devin.A.DeBacker@who.eop.gov>; Sandoloski, Sean M. EOP/WHO <Sean.M.Sandoloski@who.eop.gov>; DL NSC NSA FO Staff <(b)(6)>; Farah, Alyssa A. EOP/WHO <Alyssa.A.Farah@who.eop.gov>; Gilmartin, Kayleigh M. EOP/WHO <Kayleigh.McEnany@who.eop.gov>; Rollins, Brooke L. EOP/WHO <Brooke.L.Rollins@who.eop.gov>; (b)(6); Hudson, Renee R. EOP/WHO <Renee.Hudson@who.eop.gov>; Robinson, Wilma (HHS/IOS) <Wilma.Robinson@hhs.gov>; Hahn, Julia A. EOP/WHO <Julia.A.Hahn@who.eop.gov>; Salvi, Mary E. EOP/WHO <Mary.E.Salvi@who.eop.gov>; Chalkey, Richard J. EOP/WHO <Richard.J.Chalkey@who.eop.gov>; McGuffee, Tyler A.

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FDA-OC-2020-1977/2020-4765-001107

MULTI-HHS-FDA-20-0400, 20-0415-C-000115

(ovp.eop.gov) (b)(6); Troutman, Joel D. EOP/WHO <Joel.D.Troutman@who.eop.gov>; Smith, Steven M. EOP/WHO <Steven.M.Smith@who.eop.gov>; Taylor, Elizabeth (who.eop.gov) <Elizabeth.A.Taylor@who.eop.gov>
Cc: Staff Secretary <(b)(6)>
Subject: RE: For Review: ONDCP Factsheet--Updated

Please find an updated factsheet based on feedback received from our circulation last month. Let Staff Sec know **by 6:00 pm today** if you have any edits or comments. If we do not hear from you we will assume your concurrence.

Thanks,

Staff Sec

From: Staff Secretary

Sent: Wednesday, May 27, 2020 3:17 PM

To: Hicks, Hope C. EOP/WHO <Hope@who.eop.gov>; Kushner, Jared C. EOP/WHO <jck@who.eop.gov>; Gidley, Hogan H. EOP/WHO <Hogan.Gidley@who.eop.gov>; DL Chief of Staff Office <(b)(6)> @ (b)(6) Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>; Hahn, Julia A. EOP/WHO <Julia.A.Hahn@who.eop.gov>; Deere, Judd P. EOP/WHO <(b)(6)> imt@who.eop.gov; Conway, Kellyanne E. EOP/WHO <KAC@who.eop.gov>; Philbin, Patrick F. EOP/WHO <pfp2dcp@who.eop.gov>; Eisenberg, John A. EOP/WHO <John.A.Eisenberg@who.eop.gov>; Pottinger, Matthew F. EOP/WHO <MPottinger@who.eop.gov>; 'Harrison, Brian (HHS/IOS)' <Brian.Harrison@hhs.gov>; Kudlow, Larry A. EOP/WHO <Lawrence.A.Kudlow@who.eop.gov>; Vought, Russell T. EOP/OMB <(b)(6)>; Ueland, Eric M. EOP/WHO <Eric.M.Ueland@who.eop.gov>; Fauci, Anthony (NIH/NIAID) [E] <(b)(6)>; Short, Marc T. EOP/OVP <(b)(6)>; Miller, Katie R. EOP/OVP <Katie.R.Miller@ovp.eop.gov>; Miller, Stephen EOP/WHO <Stephen.Miller@who.eop.gov>; Lewis, Oliver CAPT SD <(b)(6)>; Hoelscher, Douglas L. EOP/WHO <Douglas.L.Hoelscher@who.eop.gov>; Pataki, Tim A. EOP/WHO <Timothy.A.Pataki@who.eop.gov>; Berkowitz, Avrahm J. EOP/WHO <avi@who.eop.gov>; DeBacker, Devin A. EOP/WHO <Devin.A.DeBacker@who.eop.gov>; Sandoloski, Sean M. EOP/WHO <Sean.M.Sandoloski@who.eop.gov>; DL NSC NSA FO Staff <(b)(6)>; Farah, Alyssa A. EOP/WHO <Alyssa.A.Farah@who.eop.gov>; Gilmartin, Kayleigh M. EOP/WHO <Kayleigh.McEnany@who.eop.gov>; Rollins, Brooke L. EOP/WHO <Brooke.L.Rollins@who.eop.gov>; (b)(6) <(b)(6)>; Hudson, Renee R. EOP/WHO <Renee.Hudson@who.eop.gov>
Cc: Staff Secretary <(b)(6)> ry@ (b)(6)
Subject: RE: For Review: ONDCP Factsheet--Updated

All,

Please find a revised factsheet from ONDCP. The attached draft has been updated (b)(5)

Please let Staff Sec know **by 10:00 am tomorrow, May 28**, if you have any edits.

Reach out directly with questions.

Thanks,

Staff Sec

From: Staff Secretary <(b)(6)>

Sent: Wednesday, April 8, 2020 6:52 PM

To: Hicks, Hope C. EOP/WHO <Hope@who.eop.gov>; Kushner, Jared C. EOP/WHO <jck@who.eop.gov>; Gidley, Hogan H. EOP/WHO <Hogan.Gidley@who.eop.gov>; Grisham, Stephanie A. EOP/WHO <Stephanie.A.Grisham@who.eop.gov>; DL

FDA-OC-2020-1977/2020-4765-001108

MULTI-HHS-FDA-20-0400, 20-0415-C-000116

Chief of Staff Office (b)(6)@ (b)(6) Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>; Ditto, Jessica E. EOP/WHO <Jessica.E.Ditto@who.eop.gov>; Hahn, Julia A. EOP/WHO <Julia.A.Hahn@who.eop.gov>; Deere, Judd P. EOP/WHO <Judson.P.Deere@who.eop.gov>; imt@who.eop.gov; Conway, Kellyanne E. EOP/WHO <KAC@who.eop.gov>; Philbin, Patrick F. EOP/WHO <Patrick.F.Philbin@who.eop.gov>; Eisenberg, John A. EOP/WHO <John.A.Eisenberg@who.eop.gov>; Pottinger, Matthew F. EOP/WHO <MPottinger@who.eop.gov>; 'Mizelle, Chad' <(b)(6)>; 'Harrison, Brian (HHS/IOS)' <Brian.Harrison@hhs.gov>; Kudlow, Larry A. EOP/WHO <Lawrence.A.Kudlow@who.eop.gov>; Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>; Vought, Russell T. EOP/OMB <(b)(6)>; Ueland, Eric M. EOP/WHO <Eric.M.Ueland@who.eop.gov>; Fauci, Anthony (NIH/NIAID) [E] <(b)(6)>; Short, Marc T. EOP/OVP <(b)(6)>; Miller, Katie R. EOP/OVP <(b)(6)>; Miller, Stephen EOP/WHO <Stephen.Miller@who.eop.gov>; Lewis, Oliver CAPT SD <(b)(6)>; Hoelscher, Douglas L. EOP/WHO <Douglas.L.Hoelscher@who.eop.gov>; Pataki, Tim A. EOP/WHO <Timothy.A.Pataki@who.eop.gov>; Berkowitz, Avrahm J. EOP/WHO <avi@who.eop.gov>; DeBacker, Devin A. EOP/WHO <Devin.A.DeBacker@who.eop.gov>; Sandoloski, Sean M. EOP/WHO <Sean.M.Sandoloski@who.eop.gov>; DL NSC NSA FO Staff <(b)(6)>
Cc: Staff Secretary (b)(6)ry@ (b)(6)
Subject: For Review: ONDCP Factsheet

Attached for your review is a draft factsheet prepared by ONDCP. (b)(6)

Please review and provide any feedback to Staff Sec by **9:00 am tomorrow, April 9.**

Background provided by ONDCP: (b)(5)

Thank you,

Staff Sec

From: O'Malley, Devin M. EOP/OVP (b)(6)
Sent: 3/13/2020 3:59:10 AM
To: Caccamo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]
CC: Hall, Bill (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e56218361cd4ffbaccdd06ac2d7b809d-HHS-bill.ha]; Galatas, Kate (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0a0623b3cb34f86a2f6f9d14afe115e-HHS-kkg2-cd]; Bonds, Michelle E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=55bb1c6e16fc49c6840de58f10bce69f-HHS-meb0-cd]; Oakley, Caitlin B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8feed045e954557aa1e0052f925865f-HHS-Caitlin]; Miller, Katie R. EOP/OVP (b)(6)
Subject: RE: Releases
Importance: High

Hi all-

Here is the plan:

(b) (5)
I am adding Kelly Love to send the emails for the producers of the shows that we will be doing TV with in the AM.

As soon as I get approval on my release (below), we will send out from the Task Force. Please take an opportunity to review the release ASAP.

Thanks for your coordination on this; I think it will prove to be more effective.

Devin

(b) (5)

(b) (5)

From: Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>

Sent: Friday, March 13, 2020 12:06 AM

To: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>

Cc: Hall, Bill (OS) <bill.hall@hhs.gov>; Galatas, Kate (CDC) <kkg2@cdc.gov>; Bonds, Michelle E (CDC) <meb0@cdc.gov>; Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>

Subject: RE: Releases

Hi Devin—

Attaching our draft release. These actions happened this evening (within the last hour), so they can be discussed in AM TV programs. Please feel free to call if you need any walk through on any of this.

Stephanie Caccamo

Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: 301.348.1956
Cell: (b)(6)
stephanie.caccamo@fda.hhs.gov

From: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>

Sent: Thursday, March 12, 2020 10:56 PM

To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>

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FDA-OC-2020-1977/2020-4765-001111

MULTI-HHS-FDA-20-0400, 20-0415-C-000119

Cc: Hall, Bill (OS) <bill.hall@hhs.gov>; Galatas, Kate (CDC) <kkg2@cdc.gov>; Bonds, Michelle E (CDC) <meb0@cdc.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>

Subject: RE: Releases

Checking in on where folks are at with their releases.

I'd like to (b) (5)

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>

Sent: Thursday, March 12, 2020 8:32 PM

To: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>; Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>

Cc: Hall, Bill (OS) <bill.hall@hhs.gov>; Galatas, Kate (CDC) <kkg2@cdc.gov>; Bonds, Michelle E (CDC) <meb0@cdc.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>

Subject: RE: Releases

Here is where we are: We are buttoning up on our end, going through our clearance, have flagged for ASPA it is coming tonight – likely late and targeting, depending on timing, tonight if possible or as early as possible am (before 8am).

From: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>

Sent: Thursday, March 12, 2020 8:27 PM

To: Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>

Cc: Hall, Bill (OS) <bill.hall@hhs.gov>; Galatas, Kate (CDC) <kkg2@cdc.gov>; Bonds, Michelle E (CDC) <meb0@cdc.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>

Subject: RE: Releases

Thank you. Put NIH on by accident. Taking them off now.

From: Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>

Sent: Thursday, March 12, 2020 8:25 PM

To: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>

Cc: Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>; Stover, Kathy (NIH/NIAID) [E] <(b)(6)> Conrad, Patricia (NIH/NIAID) [E] <(b)(6)>; Galatas, Kate (CDC/OD/OADC) <kkg2@cdc.gov>; Bonds, Michelle E. (CDC/OD/OADC) <meb0@cdc.gov>; Caccomo, Stephanie (FDA/OC) <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura (FDA/OC) <Laura.Caliguiri@fda.hhs.gov>

Subject: Re: Releases

+ Stephanie and Laura w/ FDA

On Mar 12, 2020, at 8:20 PM, O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov> wrote:

Hi CDC and FDA-

I've heard from each of you separately that you will have testing-related press releases tomorrow.

Can you let me know how the drafting of materials is going? I know that, in FDA's case, the release hinges on some things happening overnight. That said, would you all have a sense of timing?

Thanks!

Devin

Devin M. O'Malley

(b)(6)

From: Fetalvo, Ninio J. EOP/OVP (b)(6)
Sent: 3/17/2020 10:11:36 AM
To: Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; O'Malley, Devin M. EOP/OVP [Devin.M.O'Malley@ovp.eop.gov]; Miller, Katie R. EOP/OVP [Katie.R.Miller@ovp.eop.gov]
CC: Caccamo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Hall, Bill (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e56218361cd4ffbaccdd06ac2d7b809d-HHS-bill.ha]; MacInnis, Hannah F. EOP/OVP (b)(6)
Subject: RE: 3/16/20 PM Notes from Daily Coronavirus Comms Sync

+Hannah for potential amplification on op-ed

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Sent: Tuesday, March 17, 2020 10:10 AM
To: Fetalvo, Ninio J. EOP/OVP (b)(6); O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>; Miller, Katie R. EOP/OVP <Katie.R.Miller@ovp.eop.gov>
Cc: Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>; Hall, Bill (OS) <bill.hall@hhs.gov>
Subject: RE: 3/16/20 PM Notes from Daily Coronavirus Comms Sync

Can't get into call -all circuits busy – quick update we have enforcement discretion on food inspection guidance coming out today, working through some Q&A on safety/packaging, pushing out support for blood centers and Dr. Hahn's oped on fraud published in USAToday this am.

From: Fetalvo, Ninio J. EOP/OVP (b)(6)
Sent: Monday, March 16, 2020 5:17 PM
To: Fetalvo, Ninio J. EOP/OVP (b)(6)
Cc: Miller, Katie R. EOP/OVP <Katie.R.Miller@ovp.eop.gov>; O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>; Love, Kelly A. EOP/OVP (b)(6)
Subject: 3/16/20 PM Notes from Daily Coronavirus Comms Sync

Notes from Daily Coronavirus Comms Sync
5:00 PM Monday, March 16, 2020

(b) (5)

(b) (5)

(b) (5)

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From: O'Malley, Devin M. EOP/OVP [Devin.M.O'Malley@ovp.eop.gov]
Sent: 4/13/2020 4:40:24 PM
To: Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]
CC: Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]
Subject: RE: FDA Release: COVID Plasma Donation

ok

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Sent: Monday, April 13, 2020 2:57 PM
To: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: FW: FDA Release: COVID Plasma Donation

Devin
Per convo for concurrent review. Planning to release after podium.
Laura

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Sent: Monday, April 13, 2020 2:52 PM
To: 'releases@hhs.gov' <releases@hhs.gov>
Cc: OC OEA OMA-Press <(b)(6)>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Subject: FDA Release: COVID Plasma Donation

URGENT REVIEW REQUESTED.

THIS RELEASE WAS CLEARED FOR FDA BY FDD's CHRISTINE HUNT, DENISE ZAVAGNO AND RUBINA MADNI.

For your review please.

Agency/Office: FDA

Subject: Coronavirus (COVID-19) Update: FDA Encourages Recovered Patients to Donate Plasma for Development of Blood-Related Therapies

Materials:

- Draft statement

Planned release date: Monday, April 13, at 5 p.m.

Driving event: POTUS press briefing remarks

Michael Felberbaum
Senior Advisor

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-9548 / Cell: (b)(6)
michael.felberbaum@fda.hhs.gov

AMERICAN
OVERSIGHT

FDA-OC-2020-1977/2020-4765-001117

MULTI-HHS-FDA-20-0400, 20-0415-C-000125



From: O'Malley, Devin M. EOP/OVP [Devin.M.O'Malley@ovp.eop.gov]
Sent: 3/9/2020 8:45:19 PM
To: Cacco, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Miller, Katie R. EOP/OVP [Katie.R.Miller@ovp.eop.gov]
CC: Caliguri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]
Subject: RE: [CLOSE HOLD] FDA update on inspections

ok

From: Cacco, Stephanie <Stephanie.Cacco@fda.hhs.gov>
Sent: Monday, March 9, 2020 4:51 PM
To: Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>; O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>; Miller, Katie R. EOP/OVP <Katie.R.Miller@ovp.eop.gov>
Cc: Caliguri, Laura <Laura.Caliguri@fda.hhs.gov>
Subject: RE: [CLOSE HOLD] FDA update on inspections

Hi Katie and Devin—

Flagging the most recent version of the FDA statement on foreign inspections. We plan to issue this tomorrow morning, please advise of any concerns. Thank you!!

FOR IMMEDIATE RELEASE

March 10, 2020

Coronavirus Disease 2019 (COVID-19) Update: Foreign Inspections

This statement is attributed to: FDA Commissioner Stephen M. Hahn, M.D.

Today, we are providing an update on the status of U.S. Food and Drug Administration inspections outside of the U.S. in response to the COVID-19 outbreak. After careful consideration, the FDA is postponing most foreign inspections through April, effective immediately. Inspections outside the U.S. deemed mission-critical will still be considered on a case-by-case basis.

The FDA based this decision on a number of factors, including State Department Level 4 travel advisories in which travel is prohibited for U.S. government employees, Centers for Disease Control and Prevention travel recommendations, access restrictions being imposed on foreign visitors by certain countries, guidance from the Office of Personnel Management, and the importance of the health and safety of our employees. Another critical factor in taking this action is the confidence we have in our ability to maintain oversight over international manufacturers and imported products using alternative tools and methods.

We are aware of how this action may impact other FDA responsibilities, including product application reviews. We will be vigilant and monitoring the situation very closely and will try to mitigate potential impacts from this outbreak in lockstep with the whole of the federal government. We stand ready to resume foreign inspections as soon as feasible.

When we are temporarily not able to physically inspect foreign produced FDA-regulated products or manufacturers, as an interim measure we employ additional tools to ensure the safety of products imported to the U.S., which have proved effective in the past. These include denying entry of unsafe products into the U.S., physical examinations and/or product sampling at our borders, reviewing a firm's previous compliance history, using information sharing from foreign governments as part of mutual recognition and confidentiality agreements, and requesting records "in advance of or in lieu of" on-site drug inspections. For example, we began exercising this authority when we postponed on-the-ground inspections of manufacturers of FDA-regulated products in China earlier in the outbreak. This is all part of the FDA's multi-pronged and risk-based approach to ensuring quality, as well as compliance, with applicable federal laws and regulations.

As this remains a dynamic situation, we will continue to assess and calibrate our approach as needed to help advance federal response efforts in the fight against this outbreak.

From: Caccomo, Stephanie
Sent: Friday, March 06, 2020 5:10 PM
To: Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; Devin M. O'Malley - Department of Treasury (Devin.M.O'Malley@ovp.eop.gov) <Devin.M.O'Malley@ovp.eop.gov>; Katie Miller (Katie.R.Miller@ovp.eop.gov) <Katie.R.Miller@ovp.eop.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Subject: RE: [CLOSE HOLD] FDA update on inspections

Update on timing here. We are delaying this til Monday so we can do some additional internal communications.

Stephanie Caccomo

Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: 301.348.1956
Cell: (b)(6)
stephanie.caccomo@fda.hhs.gov

From: Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>
Sent: Friday, March 6, 2020 4:15 PM
To: Devin M. O'Malley - Department of Treasury (b)(6) <(b)(6)>
Katie Miller (b)(6) @ (b)(6) <(b)(6) @ (b)(6)>
Cc: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Subject: RE: [CLOSE HOLD] FDA update on inspections

Hey Katie and Devin – just confirming you saw this.
- Ryan

From: Murphy, Ryan (OS/ASPA)
Sent: Friday, March 6, 2020 2:16 PM
To: Devin M. O'Malley - Department of Treasury (Devin.M.O'Malley@ovp.eop.gov) <Devin.M.O'Malley@ovp.eop.gov>; Katie Miller (Katie.R.Miller@ovp.eop.gov) <Katie.R.Miller@ovp.eop.gov>
Cc: Caccomo, Stephanie (FDA/OC) <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura (FDA/OC) <Laura.Caliguiri@fda.hhs.gov>
Subject: [CLOSE HOLD] FDA update on inspections

Hey Devin and Katie – (b) (5)

[REDACTED]

- Ryan

FOR IMMEDIATE RELEASE

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OVERSIGHT

FDA-OC-2020-1977/2020-4765-001120

MULTI-HHS-FDA-20-0400, 20-0415-C-000128

(b) (5)

Additional Resources:

- [Novel Coronavirus](#)

#

From: Fetalvo, Ninio J. EOP/OVP [(b)(6)]
Sent: 3/9/2020 5:38:27 PM
To: Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]
CC: Hall, Bill (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e56218361cd4ffbaccdd06ac2d7b809d-HHS-bill.ha]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]
Subject: RE: FDA Commissioner All Hands update on COVID

Ok thanks

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Sent: Monday, March 9, 2020 4:06 PM
To: Fetalvo, Ninio J. EOP/OVP <[(b)(6)]>
Cc: Hall, Bill (OS) <bill.hall@hhs.gov>; Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>
Subject: FDA Commissioner All Hands update on COVID

FYSA Attached is the Commissioner All-Hands mail to the FDA staff. It has cleared our process and ASPA. We plan to send today. Please let me know if you have any questions.

From: Fetalvo, Ninio J. EOP/OVP (b)(6)
Sent: 3/7/2020 11:42:59 AM
To: Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]
Subject: RE: Coronavirus Comms Calls this weekend

Great thank you

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Sent: Saturday, March 7, 2020 11:42 AM
To: Fetalvo, Ninio J. EOP/OVP <(b)(6)>
Subject: RE: Coronavirus Comms Calls this weekend

Thanks so much. We have a draft ready and then it goes to through a few clearances internally and then given to him. Given today's activities, I think it is not realistic to send to you tonight but could possible tomorrow. If we did that, it would be fantastic to send first thing Mon am if doable. Will let you know and appreciate the quick response.

From: Fetalvo, Ninio J. EOP/OVP <(b)(6)>
Sent: Saturday, March 7, 2020 11:39 AM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Subject: Re: Coronavirus Comms Calls this weekend

Yes we are available.

—
Ninio J.H. Fetalvo
Office of the Vice President
(b)(6)

On Mar 7, 2020, at 11:38 AM, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov> wrote:

Are you all doing clearance of internal staff comms this weekend?
Flagging we have a draft all-hands message from the Commissioner that is going through our process now. It is helpful to know for our planning and prioritizing of everyone's very full plates over the weekend. Thanks!

From: Fetalvo, Ninio J. EOP/OVP (b)(6)
Sent: Saturday, March 7, 2020 8:59 AM
To: Fetalvo, Ninio J. EOP/OVP (b)(6) >
Cc: Miller, Katie R. EOP/OVP <Katie.R.Miller@ovp.eop.gov>; O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>; Frattaroli, Caroline E. EOP/OVP (b)(6)
Subject: Coronavirus Comms Calls this weekend

Hi all -

We do not plan on having our daily Coronavirus Comms calls this weekend as we are traveling with the VP today. If one needs to be added this weekend, we will let everyone know.

Thanks,

Ninio

—

Ninio J.H. Fetalvo

Office of the Vice President

(b)(6)

From: Fetalvo, Ninio J. EOP/OVP (b)(6)
Sent: 3/7/2020 12:37:04 PM
To: Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]
Subject: Re: Coronavirus Comms Calls this weekend

Sounds good thank you

—
Ninio J.H. Fetalvo
Office of the Vice President
(b)(6)

On Mar 7, 2020, at 11:42 AM, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov> wrote:

Thanks so much. We have a draft ready and then it goes to through a few clearances internally and then given to him. Given today's activities, I think it is not realistic to send to you tonight but could possible tomorrow. If we did that, it would be fantastic to send first thing Mon am if doable. Will let you know and appreciate the quick response.

From: Fetalvo, Ninio J. EOP/OVP (b)(6)
Sent: Saturday, March 7, 2020 11:39 AM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Subject: Re: Coronavirus Comms Calls this weekend

Yes we are available.

—
Ninio J.H. Fetalvo
Office of the Vice President
(b)(6)

On Mar 7, 2020, at 11:38 AM, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov> wrote:

Are you all doing clearance of internal staff comms this weekend?
Flagging we have a draft all-hands message from the Commissioner that is going through our process now. It is helpful to know for our planning and prioritizing of everyone's very full plates over the weekend. Thanks!

From: Fetalvo, Ninio J. EOP/OVP (b)(6)
Sent: Saturday, March 7, 2020 8:59 AM
To: Fetalvo, Ninio J. EOP/OVP (b)(6)
Cc: Miller, Katie R. EOP/OVP <Katie.R.Miller@ovp.eop.gov>; O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>; Frattaroli, Caroline E. EOP/OVP (b)(6)
Subject: Coronavirus Comms Calls this weekend

Hi all -

We do not plan on having our daily Coronavirus Comms calls this weekend as we are traveling with the VP today. If one needs to be added this weekend, we will let everyone know.

Thanks,
Ninio

—
Ninio J.H. Fetalvo
Office of the Vice President
(b)(6)

From: Fetalvo, Ninio (CMS/OC) [(b)(6)]
Sent: 3/2/2020 7:27:18 PM
To: Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]
CC: [(b)(6)]; Devin.O'Malley@treasury.gov; Frattaroli, Caroline E. EOP/OVP
Subject: RE: 3/2/20 PM Notes from Daily Coronavirus Comms Sync

Thank you!

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Sent: Monday, March 2, 2020 7:20 PM
To: Fetalvo, Ninio (CMS/OC) <Ninio.Fetalvo@cms.hhs.gov>; Fetalvo, Ninio (CMS/OC) <Ninio.Fetalvo@cms.hhs.gov>
Cc: katie.r.miller@ovp.eop.gov; Devin.O'Malley@treasury.gov; Frattaroli, Caroline E. EOP/OVP
(b)(6)
Subject: RE: 3/2/20 PM Notes from Daily Coronavirus Comms Sync

HHS/FDA/CDC Today, 7pm Secretary Azar announced on Lou Dobbs that FDA and CDC are taking action to increase access to respirators, including N95s, by granting an emergency use authorization (EUA) to allow health care personnel to use certain industrial respirators during the COVID-19 outbreak in health care settings. Press Release going now, not yet posted.

From: Fetalvo, Ninio (CMS/OC) <Ninio.Fetalvo@cms.hhs.gov>
Sent: Monday, March 2, 2020 7:10 PM
To: Fetalvo, Ninio (CMS) <Ninio.Fetalvo@cms.hhs.gov>
Cc: (b)(6) Devin.O'Malley@treasury.gov; Frattaroli, Caroline E. EOP/OVP
<(b)(6)>
Subject: RE: 3/2/20 PM Notes from Daily Coronavirus Comms Sync
Importance: High

Hi everyone—

We wanted to clarify the types of examples we are looking for.

- On Friday, FDA issued a new policy to help expedite the availability of diagnostics.

<https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-new-policy-help-expedite-availability-diagnostics>

We need this no later than 9pm.

Thanks,

Ninio

From: Fetalvo, Ninio (CMS/OC)
Sent: Monday, March 2, 2020 7:04 PM

To: Fetalvo, Ninio (CMS/OC) <ninio.fetalvo@cms.hhs.gov>

Cc: (b)(6) Devin.O'Malley@treasury.gov; Frattaroli, Caroline E. EOP/OVP

<(b)(6)>

Subject: 3/2/20 PM Notes from Daily Coronavirus Comms Sync

Hi all—

Thanks for hopping on the call. As a reminder, please send accomplishments to us ASAP.

Thanks,
Ninio

Notes from Daily Coronavirus Comms Sync

6:30 PM Monday, March 2, 2020

(b) (5)

(b) (5)

(b) (5)

From: O'Malley, Devin M. EOP/OVP [Devin.M.O'Malley@ovp.eop.gov]
Sent: 4/10/2020 10:56:20 PM
To: Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]
CC: DL OVP Comms COVID (b)(6); Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Hall, Bill (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e56218361cd4ffbaccdd06ac2d7b809d-HHS-bill.ha]; Robinson, Michael J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4118fde5239947c6bccbdbd4cb7488fa-HHS-michael]; Oakley, Caitlin B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8feed045e954557aa1e0052f925865f-HHS-Caitlin]; McKeogh, Katherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3facab3fd03480f8553892121fd2009-HHS-Katheri]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Block, Molly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e32ca68078848889751e7ec26910142-Molly.Block]
Subject: Re: Inquiry from NBC on Blood Donations

(b) (5)

Besides that this is fine

Sent from my iPhone

On Apr 10, 2020, at 8:08 PM, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov> wrote:

Checking in on this inquiry/response.

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Date: April 10, 2020 at 6:37:52 PM EDT
To: 'DL OVP Comms COVID' <(b)(6)>
Cc: Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>, Hall, Bill (OS) <bill.hall@hhs.gov>, Robinson, Michael J (OS) <michael.robinson@hhs.gov>, Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>, McKeogh, Katherine (OS) <Katherine.McKeogh@hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Block, Molly <Molly.Block@fda.hhs.gov>
Subject: RE: Inquiry from NBC on Blood Donations

Reupping this plus another follow-up response to a Q about whether blood banks can implement immediately (some say they can't because they are waiting for the FDA, but that isn't true):

(b) (5)

From: Felberbaum, Michael

Sent: Friday, April 10, 2020 4:30 PM

To: DL OVP Comms COVID <(b)(6)>

Cc: Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>; Hall, Bill (OS) <bill.hall@hhs.gov>; Robinson, Michael J (OS) <michael.robinson@hhs.gov>; Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>; McKeogh, Katherine (OS) <Katherine.McKeogh@hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Block, Molly <Molly.Block@fda.hhs.gov>

Subject: Inquiry from NBC on Blood Donations

Hi,

NBC News is doing a story for its website regarding blood donations and recent changes by FDA. Local and national blood donation organization told them that the implementation process of the new guidance would take approximately three months. All said they have been experiencing outrage from newly eligible donors who attempt to donate, believing the new FDA guidance would immediately go into effect. Some blood centers say that the FDA guidance has put them in a difficult position by creating public expectation of immediate effectiveness and that there are additional steps that require FDA involvement in order to implement these changes.

- Can the FDA provide comment in response to the blood donation centers and why the agency has not emphasized that newly eligible donors would not be able to donate immediately?
- Additionally, we've been told that the implementation involves updating the FDA-controlled computer system which is used to screen donors who were previously deferred under the old guidelines. Is it true that the FDA controls the approvals and rejections of donors at blood centers? If so, has the FDA updated this software? If not, when do they plan on updating this software?
- Lastly, can the agency comment on its use of "immediate implementation" in the April 2nd press release? Does this language infer that the new guidelines should immediately be put in practice? Is there anything that can be done to expedite the process of implementation?

The below has been cleared by FDA and we are past the reporter's 4pm deadline – please let us know if we are OK to send..

(b) (5)

Michael

Michael Felberbaum

Senior Advisor

Office of Media Affairs

Office of External Affairs

U.S. Food and Drug Administration

Tel: 240-402-9548 / Cell: (b)(6)

michael.felberbaum@fda.hhs.gov

<image007.png>

<image009.jpg>

<image011.jpg>

<image013.jpg>

<image015.jpg>

<image017.jpg>

From: Caliguiri, Laura [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AA086F2D6C0346C49E996932D86AC62E-LAURA.CALIG]
Sent: 4/3/2020 12:12:37 PM
To: Block, Molly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e32ca68078848889751e7ec26910142-Molly.Block]; Stephanie Caccamo (Stephanie.Caccamo@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
Subject: FW: DRAFT comms sitrep - please send input by 2:45 p.m.

From: Finnen, April <April.Finnen@fda.hhs.gov>
Sent: Friday, April 3, 2020 11:55 AM
To: 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>
Cc: 2019-nCoV FDA IMG JIC Leadership <2019-nCoV-FDA-IMG-JIC-Leadership@fda.hhs.gov>
Subject: DRAFT comms sitrep - please send input by 2:45 p.m.

Note that late input may not make it into today's report. Please continue to send late additions/updates and weekend sitrep input to 2019-nCoV-FDA-IMG-JIC-Leadership@fda.hhs.gov. Input is due **7 days/week at 2:45 p.m.** Thanks.

Gray highlighted items are for JIC reference, and will not go into the sitrep.

(b) (5)

(b) (5)

(b) (5)

Released yesterday, April 2

- Press statements - Coronavirus (COVID-19) Updates:
 - [Daily roundup](#) – topics include 3 new warning letters, a public service announcement on food safety/supply, and a diagnostics update, including the first serology test under EUA
 - [FDA Provides Updated Guidance to Address the Urgent Need for Blood During the Pandemic](#)
- Media briefings:
 - FDA Offers Assurance About Food Safety and Supply for People and Animals During COVID-19 (Frank Yiannas) 10:15 am
 - Blood guidance (Dr. Marks w/SG VADM Adams) 12:30 p.m.
- Web updates:
 - [FDA Voices](#): FDA Commissioned Corps Officers on the Front Line of COVID-19 Response
 - CDRH: [FAQ updates](#) for swabs has posted on the FAQ page on diagnostic tests for SARS-CoV-2.
- Video:
 - New PSA: [What You Need to Know: Food and COVID-19 PSA with Frank Yiannas](#)
- Consumer & patient updates:
 - Coronavirus Q&As for Consumers - New weekly email for consumers sent to 115K subscribers (Consumer Update list), featuring top 3 Q&A this week (on testing and hydroxychloroquine/chloroquine)
- Stakeholders:
 - Dr. Hahn and Dr. Shah talked with pharma CEOs at 12:30 p.m. to discuss therapeutics
 - CBER: Stakeholder call on blood donor guidance, 1:00 p.m.
 - CFSAN: Virtual Town Hall for the Produce Marketing Association, Frank Yiannas remarks
 - CDER: Listserv messages (Drug Info/CDER SBIA) - Coronavirus Treatment Acceleration Program (CTAP) launch press release
 - CDRH: Updates to [Appendix B: Authorized Ventilators, Ventilator Tubing Connectors, and Ventilator Accessories](#)
 - CDRH: Updates to [FAQs on Diagnostic Testing for SARS-CoV-2](#)
 - CDRH guidance: [Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease \(COVID-19\) Public Health Emergency \(Revised\)](#)

Pending release, April 4-April 10 [all internal confidential]

(b) (5)

(b) (5)

April Finnen

IMG JIC Section Chief

2019 Novel Coronavirus (COVID-19) Incident Management Group (IMG)

U.S. Food and Drug Administration

Cell: (b)(6) ← Call this # or IM/Skype to reach me

Email: april.finnen@fda.hhs.gov

JIC (Joint Information Center) leads email: 2019-nCoV-FDA-IMG-JIC-Leadership@fda.hhs.gov



For your review please.

Agency/Office: OFPR/CFSAN/CVM

Subject (or headline): FDA Offers Assurance About Food Safety and Supply for People and Animals During COVID-19

Materials: Media advisory

Deadline for comments: 3/31 COB

Planned release date: April 1.

Driving event: Significant interest from reporters in food issues in relation to COVID-19. Deputy Commissioner Yiannas will use this opportunity to amplify our food messaging: <https://www.fda.gov/news-events/fda-voices-perspectives-fda-leadership-and-experts/fda-offers-assurance-about-food-safety-and-supply-people-and-animals-during-covid-19>.

Thanks!

Peter Cassell

Press Officer

Office of Media Affairs

Office of External Affairs

U.S. Food and Drug Administration

Tel: 240-402-6537

Cell: 202-906-0043

Peter.Cassell@fda.hhs.gov



FDA MEDIA ADVISORY

For Immediate Release: April 1, 2020

**** FOR CREDENTIALLED MEDIA ONLY ****

Media Briefing: FDA Offers Assurance About Food Safety and Supply for People and Animals During COVID-19

WHAT:

A media briefing to discuss the American food supply during the pandemic and other food issues from the U.S. Food and Drug Administration.

WHO:

Frank Yiannas, Deputy Commissioner for Food Policy and Response

WHEN:

Wed., Apr. 1, at 10:15 a.m. ET

HOW:

Callers in the United States or Canada may call 888-603-7036. International callers will need to dial 517-308-9392. The passcode for all callers is "FDA." A replay will be available beginning one hour after the briefing until Apr. X, 2020. To listen to the replay, call 866-396-4184. International callers dial 203-369-0510.

#

Media Contact: Peter Cassell, 240-402-6537

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

From: Caliguiri, Laura [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AA086F2D6C0346C49E996932D86AC62E-LAURA.CALIG]
Sent: 4/1/2020 10:02:10 AM
To: Johnston, Darcie (HHS/IEA) [Darcie.Johnston@hhs.gov]
CC: Stevens, Lee R (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=183b49fc951b40d1bab6fbee680803d5-HHS-Lee.Ste]
Subject: RE: [EXTERNAL] Emergency PPE Supplies for COVID19

I can put it through IMG. BTW answers forthcoming on the KN95 and need to call you on serology and NY.

From: Johnston, Darcie (HHS/IEA) <Darcie.Johnston@hhs.gov>
Sent: Wednesday, April 1, 2020 9:59 AM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Cc: Stevens, Lee R (OS) <Lee.Stevens@hhs.gov>
Subject: FW: [EXTERNAL] Emergency PPE Supplies for COVID19

Hi Laura-
Who at FDA can we refer this to? Thanks, Darcie

Darcie L. Johnston
Director, Intergovernmental Affairs
U.S. Department of Health and Human Services
Office of the Secretary
202-690-1058 (office)
(b)(6) (cell)

From: Behnke, Matthew (b)(6) >
Sent: Wednesday, April 1, 2020 9:52 AM
To: Johnston, Darcie (HHS/IEA) <Darcie.Johnston@hhs.gov>
Subject: FW: [EXTERNAL] Emergency PPE Supplies for COVID19

Do you have a POC at FDA that I can refer this person to?

This person (designer/manufacturer) referred by WH is seeking a POC at FDA. See email traffic below for context.

Matthew Behnke
Federal Emergency Management Agency
(b)(6)
(b)(6)

This communication, along with any attachments, is covered by federal and state law governing electronic communications and may contain confidential and legally privileged information. If the reader of this message is not the intended recipient, you are hereby notified that any dissemination, distribution, use or copying of this message is strictly prohibited. If you have received this in error, please reply immediately to the sender and delete this message.

From: Behnke, Matthew
Sent: Monday, March 30, 2020 3:30 PM
To: Misha Nonoo <misha@mishanonoo.com>; Lindsey Saletta <lindsey@mishanonoo.com>
Cc: Duffey, Michael P. EOP/OMB <(b)(6)>; Rader, John N. EOP/NSC

(b)(6)

Subject: RE: [EXTERNAL] Emergency PPE Supplies for COVID19

Ms. Nonoo and Ms. Saletta,

Attached are the testing requirements for manufacturers from the American National Standards Institute (ANSI) and International Safety Equipment Association (ISEA). These have researchable standards that should be able to guide you all.

Still working on the FDA portion of the ask.

Regards,
-Matt

Matthew Behnke
Federal Emergency Management Agency
(b)(6)
matthew.behnke@fema.dhs.gov

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From: Misha Nonoo <misha@mishanonoo.com>

Sent: Monday, March 30, 2020 11:52 AM

To: Rader, John N. EOP/NSC <(b)(6)>

Cc: Behnke, Matthew <(b)(6)>; Duffey, Michael P. EOP/OMB

<(b)(6)>; Lindsey Saletta <lindsey@mishanonoo.com>

Subject: Re: [EXTERNAL] Emergency PPE Supplies for COVID19

Thank you so much John! I really appreciate it. I am cc'ing our COO, Lindsey, here too so that she can follow up with questions as she is spearheading this project for us.

Thank you again for all your help,
Misha

Sent from my iPhone

On Mar 30, 2020, at 11:31 AM, Rader, John N. EOP/NSC (b)(6) wrote:

Hi Misha:

I just spoke with my colleague Mike Duffey, copied here. He said he'd be able to connect you with someone who can provide the specs in order to begin making products.

If this doesn't get you pointed in the right direction, please let me know!

John

On Mar 30, 2020, at 9:51 AM, Misha Nonoo <misha@mishanonoo.com> wrote:

Thanks John! Calling you now.

On Mon, Mar 30, 2020 at 9:34 AM Rader, John N. EOP/NSC (b)(6) > wrote:

Hi Misha:

If you would like to call my cell, I can walk you through all the spec information that I think would be helpful. I can be reached at (b)(6)

Sincerely,

John

On Mar 30, 2020, at 9:28 AM, Misha Nonoo <misha@mishanonoo.com> wrote:

Thank you so much again for the intro Ivanka!

Just following up John to see if you had a POC I could connect with directly.

Thank you both so much in advance.

All my best,
Misha

On Wed, Mar 25, 2020 at 6:53 PM imt@who.eop.gov <imt@who.eop.gov> wrote:

Thanks Misha! I am looping in John Rader who can connect you with the right POC!
We appreciate your efforts!

Sent from my iPhone

On Mar 25, 2020, at 5:47 PM, Misha Nonoo <misha@mishanonoo.com> wrote:

Dear Ivanka,

As we discussed, I understand there is a shortage of hospital supplies in the United States that is urgently needed and I want to help however we can. We have a network of apparel manufacturers based in China that are already back at work and have capacity and interest in producing emergency PPE supplies such as surgical masks, hospital gowns, scrubs, aprons, blankets, etc for hospitals throughout the USA.

We have been able to gather technical specifications for surgical masks from the AHA, but we need additional specs and requested quantities for any other soft goods in short supply. We also need to know the FDA requirements for such goods to be acceptable to US hospitals during this crisis.

We are looking for the correct contact in emergency medical supplies procurement at the White House or the relevant agency who can answer these questions and get us set up as an approved supplier with a contract to deliver goods.

We are ready to help and look forward to pitching in as best as we can!

Thank you in advance for your help with this and looking forward to hearing from you.

All my best in the meantime,
Misha

--

MISHA NONOO
CEO & CREATIVE DIRECTOR

PLEASE NOTE OUR NEW ADDRESS:
27 West 24th Street
Suite 900A
New York, NY 10010

--

MISHA NONOO
CEO & CREATIVE DIRECTOR

PLEASE NOTE OUR NEW ADDRESS:
27 West 24th Street
Suite 900A
New York, NY 10010

--

By clicking "I agree", you acknowledge that you have read and understand the Terms of Service and that you agree to be bound by them.

MISHA NONOO
CEO & CREATIVE DIRECTOR

PLEASE NOTE OUR NEW ADDRESS:
27 West 24th Street
Suite 900A
New York, NY 10010

From: Caliguiri, Laura [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AA086F2D6C0346C49E996932D86AC62E-LAURA.CALIG]
Sent: 4/1/2020 11:31:32 AM
To: Johnston, Darcie (HHS/IEA) [Darcie.Johnston@hhs.gov]; Beck, Gary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9eaf3460f2f04ef9a80298a7acd61e64-HHS-Gary.Be]; Stevens, Lee R (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=183b49fc951b40d1bab6fbee680803d5-HHS-Lee.Ste]
Subject: RE: Blood Shortage

Received Lee can you put in your response queue.

From: Johnston, Darcie (HHS/IEA) <Darcie.Johnston@hhs.gov>
Sent: Wednesday, April 1, 2020 11:18 AM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Beck, Gary (OS) <Gary.Beck@hhs.gov>; Stevens, Lee R (OS) <Lee.Stevens@hhs.gov>
Subject: FW: Blood Shortage

FYI

Darcie L. Johnston
Director, Intergovernmental Affairs
U.S. Department of Health and Human Services
Office of the Secretary
202-690-1058 (office)
(b)(6) (cell)

From: Caleb Merendino (b)(6)
Sent: Wednesday, April 1, 2020 8:45 AM
To: Leadership@fda.hhs.gov
Subject: Re: Blood Shortage

Good morning: As someone that has served our community as a volunteer first responder for several years, I am writing to ask for your assistance. COVID-19 and other medical emergencies are causing an endless amount of concerns, but we know we need more blood donors. Please lift the ban on gays and lesbians immediately. Your administration has sufficient science to know that healthy members of the LGBT community can donate safe blood. In practicality, if you are already accepting blood from a straight prostitute with no concerns, there is absolutely no reason it cannot be accepted from a healthy donor -- regardless of their sexual orientation. We need your action. Our healthcare system and patients are counting on you. It's not about a progressive statement; it's about helping Americans and knowing enough science exists to detect pathogens with current screening measures. Thank you for your time and all you do!

Stay safe,

Caleb

From: Caliguiri, Laura [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AA086F2D6C0346C49E996932D86AC62E-LAURA.CALIG]
Sent: 3/31/2020 8:53:03 PM
To: Brad Kimberly (Brad.Kimberly@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08bc909ed76d49868a5ff92c3c70fb72-Bradley.Kim]; Sarah Lynch (Sarah.Lynch@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d24ee4a4fc6241f48110d6b35e6704ed-Sarah.Lynch]; Capobianco, Abigail [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=660b8e4204f74d4b912265b9c85613bd-Abigail.Cap]
Subject: FW: What You Need To Know | President Trump's Coronavirus Response Efforts

From: Mitchell, Austin A. EOP/WHO (b)(6)
Sent: Tuesday, March 31, 2020 8:51 PM
Subject: What You Need To Know | President Trump's Coronavirus Response Efforts

What You Need To Know | President Trump's Coronavirus Response Efforts

President Trump and his Administration are working every day to protect the health and wellbeing of Americans and respond to the coronavirus.

WHOLE-OF-GOVERNMENT APPROACH

- The President signed the CARES Act, providing unprecedented and immediate relief to American families, workers, and businesses.
- President Trump declared a national emergency, inviting States, territories, and tribes to access over \$42 billion in existing funding.
- President Trump signed initial legislation securing \$8.3 billion for coronavirus response.
- President Trump signed the Families First Coronavirus Response Act, ensuring that American families and businesses impacted by the virus receive the strong support they need.
- To leverage the resources of the entire government, the President created a White House Coronavirus Task Force to coordinate response.
- The Vice President named Dr. Deborah Birx to serve as the White House Coronavirus Response Coordinator.
- At the request of President Trump, FEMA is leading federal operations on behalf of the White House Coronavirus Task Force.
- FEMA's National Response Coordination Center has been activated to its highest level in support of coronavirus response.

- The President held a teleconference with other G20 leaders to coordinate coronavirus response.
- President Trump signed an executive order giving the DoD and DHS the authority to activate the ready reserve components of the armed forces to assist with coronavirus response.

SUPPORTING STATE AND LOCAL EFFORTS

- President Trump issued a letter informing our nation's governors that the Administration is developing new guidelines for state and local policy makers.
- Through the CARES Act, we more than doubled the funds available through the President's Emergency and Disaster Declarations to help State, local, and tribal leaders effectively respond.
- The President has approved major disaster declarations for heavily impacted states.
- The Administration is covering costs of deploying National Guard units to assist with response efforts in hard hit states, while ensuring governors remain in command.
- The President has held multiple teleconferences with our nation's governors to coordinate response efforts and offer his full support.

TRAVEL RESTRICTIONS

- In January, President Trump reacted quickly to implement travel restrictions on travel from China, buying us valuable time to respond to the virus.
- The President has announced further travel restrictions on global hotspots, including Europe, the United Kingdom and Ireland, and Iran.
- American citizens returning from travel-restricted countries are being routed to specific airports, where they can be screened and isolated as needed.
- The United States reached mutual agreements with Mexico and Canada to restrict non-essential travel across our northern and southern borders.
- The Administration announced it will expeditiously return aliens who cross between ports of entry or are otherwise not allowed to enter the country, as the facilities in which these aliens would be held cannot support quarantine for the time needed to assess potential cases.
- The Administration raised travel warnings to their highest level for other hot spot locations, like Japan and South Korea.
- The President has expanded airport screenings to identify travelers showing symptoms and instituted mandatory quarantines.
- The State Department issued a global level 4 travel advisory, urging Americans to avoid all international travel due to the coronavirus outbreak worldwide.
- The State Department has worked to safely repatriate thousands of Americans from around the world.

EXPANDING TESTING ACCESS

- The FDA has issued emergency approval for multiple new commercial coronavirus tests, including some that deliver results to healthcare providers within minutes.

- The President secured legislation that will ensure Americans are able to be tested for free.
- The Administration is working with state and local partners and the private sector to open up drive-through testing sites.
- The Administration worked with Apple to launch an app and website to help Americans determine if they should seek care for coronavirus, and provide them guidance on next steps.
- HHS is providing funding to help accelerate the development of rapid diagnostic tests for the coronavirus.
- The FDA cut red tape to expand testing availability.
- Admiral Brett Giroir – the Assistant Secretary for Health and head of the Public Health Service – has been appointed to coordinate coronavirus testing efforts.
- The FDA is empowering states to authorize tests developed and used by laboratories in their states.
- The Department of Defense has set up 15 coronavirus testing sites worldwide.
- The President signed legislation requiring more reporting from state and private labs to ensure our public health officials have the data they need to respond to this outbreak.
- DoD and HHS worked to airlift hundreds of thousands of swabs and sample test kits from Italy to the United States.

HELPING FAMILIES AND WORKING AMERICANS

- President Trump signed historic legislation to provide direct payments to Americans, significantly expand unemployment benefits, and more.
- The Administration negotiated legislation which will provide tax credits for eligible businesses that give paid leave to Americans affected by the virus.
- The Department of Labor issued guidance to help inform Americans about the paid family and medical leave available to them.
- The Administration took action to provide more flexibility in unemployment insurance programs for workers impacted by the coronavirus.
- The Treasury Department moved tax day from April 15 to July 15.
- President Trump signed legislation providing funding and flexibility for emergency nutritional aid for senior citizens, women, children, and low-income families.
- USDA announced new flexibilities to allow meal service during school closures.
- USDA announced a new collaboration with the private sector to deliver nearly 1,000,000 meals a week to students in rural schools closed due to the coronavirus.
- USDA launched a partnership with Panera Bread and the Children’s Hunger Alliance to provide meals to children across Ohio, with more states to come.
- HHS has announced \$250 million in grants to help communities provide meals for seniors.

- The Administration is halting foreclosures and evictions for families with FHA-insured mortgages.
- The Department of Labor announced up to \$100 million in dislocated worker grants in response to the coronavirus national health emergency.
- The White House worked with the private sector to launch a central website where families, students, and educators can access online education technologies.
- President Trump signed legislation to provide continuity in educational benefits for veterans and their families who attend schools that have had to switch to online learning.
- The Department of Education has given broad approval to colleges and universities to allow them to more easily move their classes online.
- The Department of Education set interest rates on all federally-held student loans to 0% for at least 60 days.
- The Department of Education announced borrowers will have the option to suspend their payments on federally-held student loans for at least two months.
- The Department of Education is providing waivers for federal testing requirements to states that have had to close schools.

SUPPORTING IMPACTED BUSINESSES

- President Trump signed legislation providing almost \$350 billion in loans for small businesses and much needed payroll tax relief.
- The President secured legislation giving the Treasury and Federal Reserve \$500 billion to provide liquidity and purchase business, municipal, and State debt.
- Thanks to legislation signed by President Trump, the Federal Reserve can leverage more than \$4 trillion in funds if needed during this crisis.
- The Small Business Administration has announced disaster loans which provide impacted businesses with up to \$2 million.
- SBA relaxed criteria for disaster assistance loans – expanding small businesses’ access to economic assistance.
- The President directed the Energy Department to purchase large quantities of crude oil for the strategic reserve.
- President Trump has held calls and meetings with business leaders from the pharmaceutical industry, airlines, health insurers, grocery stores, retail stores, banks, and more.
- The Treasury Department approved the establishment of the Money Market Mutual Fund Liquidity Facility to provide liquidity to the financial system.
- The Export-Import Bank announced four new temporary relief programs to provide maximum financing flexibility and inject liquidity into the market.

INFORMING THE PUBLIC

- The Administration launched a website – coronavirus.gov – to keep the public informed about the outbreak.
- The President announced he is extending CDC guidelines for 30 days to slow the spread of the virus.
- The President launched a partnership with the Ad Council, media networks, and digital platforms to communicate public services announcements about the coronavirus.
- The President announced guidelines for Americans to follow and do their part to stem the spread of the virus.
- The Task Force is holding nearly daily press conferences to provide the American people with the latest information.
- The Task Force recommended mitigation strategies to heavily impacted communities, like those in New York, Washington, and California.
- CMS announced guidance to protect vulnerable elderly Americans and limit medically unnecessary visits to nursing homes.
- President Trump's PREVENTS initiative started a new public awareness campaign to promote emotional wellbeing for veterans during the coronavirus pandemic.

SUPPORTING PATIENTS AND HEALTHCARE PROVIDERS

- The President worked with Congress to secure \$100 billion for out healthcare providers.
- In January, the Administration declared the coronavirus to be a public health emergency.
- The President donated his fourth-quarter 2019 salary to the Department of Health and Human Services for coronavirus response efforts.
- The Army Corps of Engineers and FEMA are helping to build temporary hospitals and medical facilities in hard hit areas.
- The Vice President penned a letter to hospital administrators asking hospitals to report testing data to HHS to help inform policies.
- The President took action to give HHS authority to waive rules and regulations so that healthcare providers have maximum flexibility to respond to this outbreak.
- CMS issued sweeping regulatory changes to increase hospital capacity, rapidly expand the healthcare workforce, and cut paperwork so doctors can put patients first.
- HHS is providing funding to help healthcare systems across the country quickly prepare for a surge in coronavirus patients.
- CMS is giving flexibility to Medicare Advantage and Part D plans to waive cost-sharing for coronavirus tests and treatment.
- The President announced that Humana and Cigna will waive co-pays, coinsurance, and deductibles for coronavirus treatments.
- CMS created new billing codes for coronavirus tests to promote better tracking of the public health response.

- The White House Office of Science and Technology Policy coordinated with the NIH, the tech industry, and non-profits to release a machine readable collection of 29,000 coronavirus-related research articles, which will help scientists discover insights to virus' genetics, incubation, treatment, symptoms, and prevention.
- The White House launched a new public-private consortium to help provide coronavirus research projects access to powerful supercomputer resources.
- The Administration announced that health plans with health savings accounts will be able to cover coronavirus testing and treatment without co-payments.
- CMS dramatically expanded telehealth for Medicare beneficiaries, ensuring more patients can access their doctors remotely while avoiding exposure.
- HHS lifted HIPAA penalties to enable healthcare providers to expand telehealth access for patients.
- The FDA took action to allow expanded use of devices to monitor patients' vital signs remotely, reducing hospital visits and minimizing risks of exposure.
- The VA established 19 emergency operations centers across the country and put in place visitation restrictions to limit patients' exposure.
- Thanks to a waiver from the Office of Personnel Management, the VA is working to rehire retired medical personnel during the coronavirus outbreak.
- CMS and the VA are working to limit nonessential, elective medical procedures to free up healthcare resources.
- The Department of Defense issued guidance to delay elective medical procedures at military facilities in order to preserve healthcare resources.
- The Navy deployed two medical ships to help support impacted areas.
- The President announced Carnival Cruise Lines will be making ships available for hospitals to use for non-coronavirus patients.

STRENGTHENING ESSENTIAL MEDICAL SUPPLIES

- The Administration mobilized a Supply Chain Stabilization Task Force led by Rear Admiral John Polowczyk.
- FEMA is working to distribute ventilators and other critical supplies to hard hit states.
- FEMA launched Project Airbridge to help quickly airlift critical supplies across the country.
- The President invoked the Defense Production Act, providing a number of authorities that can be used as needed.
- The President took action under the Defense Production Act to compel General Motors to accept, perform, and prioritize Federal contracts for ventilators.
- President Trump signed an executive order providing HHS and DHS with the full authorities available under the Defense Production Act to respond to this outbreak.

- The President urged the private sector to bolster response efforts, leading companies across the country to produce more critical supplies like masks, ventilators, and hand sanitizer.
- The President signed a memorandum directing his Administration to make general-use face masks available to healthcare workers.
- HHS announced it will be purchasing 500 million N95 respirators for the Strategic National Stockpile.
- The Department of Defense announced it will be providing 5 million respirator masks and 2,000 specialized ventilators to assist.
- The Department of Defense is procuring 8,000 ventilators worth an estimated \$84.4 million
- The President signed legislation removing restrictions that prevented manufacturers from selling industrial masks – which can readily protect healthcare workers – directly to hospitals.
- The FDA gave emergency approval to a new system to sterilize N95 masks, helping hospitals get the most use out of their masks.
- The President signed an executive order to prevent hoarding and price-gouging of critical medical supplies.
- The Department of Justice has taken action to combat coronavirus related fraud.

DEVELOPING VACCINES AND THERAPEUTICS

- The Administration is working to help accelerate the development of therapeutics and a vaccine to combat the coronavirus.
- The FDA is evaluating existing drugs that could serve as potential therapeutics for coronavirus patients.
- The FDA approved emergency use of convalescent plasma treatments for seriously ill coronavirus patients.
- HHS accepted 30 million doses of hydroxychloroquine sulfate donated by pharmaceutical companies.
- The Trump Administration is actively working with drug manufacturers to monitor any potential drug supply chain issues.
- The Administration is expanding research and consulting with experts to better understand the transmission of coronavirus.
- The National Institutes of Health has announced the beginning of a clinical trial for a coronavirus vaccine candidate.

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From: Caliguiri, Laura [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AA086F2D6C0346C49E996932D86AC62E-LAURA.CALIG]
Sent: 3/26/2020 8:08:22 PM
To: Sarah Lynch (Sarah.Lynch@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d24ee4a4fc6241f48110d6b35e6704ed-Sarah.Lynch]; Brad Kimberly (Brad.Kimberly@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08bc909ed76d49868a5ff92c3c70fb72-Bradley.Kim]; Capobianco, Abigail [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=660b8e4204f74d4b912265b9c85613bd-Abigail.Cap]
Subject: FW: What You Need To Know | President Trump's Coronavirus Response Efforts

From: Mitchell, Austin A. EOP/WHO <(b)(6)>
Sent: Thursday, March 26, 2020 7:56 PM
Subject: What You Need To Know | President Trump's Coronavirus Response Efforts

What You Need To Know | President Trump's Coronavirus Response Efforts

President Trump and his Administration are working every day to protect the health and wellbeing of Americans and respond to the coronavirus.

WHOLE-OF-GOVERNMENT APPROACH

- President Trump declared a national emergency, inviting States, territories, and tribes to access over \$42 billion in existing funding.
- President Trump signed legislation securing \$8.3 billion for coronavirus response.
- President Trump signed the Families First Coronavirus Response Act, ensuring that American families and businesses impacted by the virus receive the strong support they need.
- To leverage the resources of the entire government, the President created a White House Coronavirus Task Force to coordinate response.
- The Vice President named Dr. Deborah Birx to serve as the White House Coronavirus Response Coordinator.
- At the request of President Trump, FEMA is leading federal operations on behalf of the White House Coronavirus Task Force.
- FEMA's National Response Coordination Center has been activated to its highest level in support of coronavirus response.
- The President held a teleconference with other G20 leaders to coordinate coronavirus response.

SUPPORTING STATE AND LOCAL EFFORTS

- President Trump issued a letter informing our nation's governors that the Administration is developing new guidelines for state and local policy makers.
- The President has approved major disaster declarations for heavily impacted states.
- The Administration is covering costs of deploying National Guard units to assist with response efforts in hard hit states, while ensuring governors remain in command.
- The President has held multiple teleconferences with our nation's governors to coordinate response efforts and offer his full support.

TRAVEL RESTRICTIONS

- In January, President Trump reacted quickly to implement travel restrictions on travel from China, buying us valuable time to respond to the virus.
- The President has announced further travel restrictions on global hotspots, including Europe, the United Kingdom and Ireland, and Iran.
- American citizens returning from travel-restricted countries are being routed to specific airports, where they can be screened and isolated as needed.
- The United States reached mutual agreements with Mexico and Canada to restrict non-essential travel across our northern and southern borders.
- The Administration announced it will expeditiously return aliens who cross between ports of entry or are otherwise not allowed to enter the country, as the facilities in which these aliens would be held cannot support quarantine for the time needed to assess potential cases.
- The Administration raised travel warnings to their highest level for other hot spot locations, like Japan and South Korea.
- The President has expanded airport screenings to identify travelers showing symptoms and instituted mandatory quarantines.
- The State Department issued a global level 4 travel advisory, urging Americans to avoid all international travel due to the coronavirus outbreak worldwide.
- The State Department has worked to safely repatriate 9,000 Americans from 28 countries around the world.

EXPANDING TESTING ACCESS

- The FDA has issued emergency approval for multiple new commercial coronavirus tests to significantly expand testing across the country.
- The President secured legislation that will ensure Americans are able to be tested for free.
- The Administration is working with state and local partners and the private sector to open up drive-through testing sites.
- The Administration is working with the private sector to develop a website that Americans can utilize to determine whether they need a test and, if so, where to get it.

- HHS is providing funding to help accelerate the development of rapid diagnostic tests for the coronavirus.
- The FDA cut red tape to expand testing availability.
- Admiral Brett Giroir – the Assistant Secretary for Health and head of the Public Health Service – has been appointed to coordinate coronavirus testing efforts.
- The FDA is empowering states to authorize tests developed and used by laboratories in their states.
- The Department of Defense has set up 15 coronavirus testing sites worldwide.
- The President signed legislation requiring more reporting from state and private labs to ensure our public health officials have the data they need to respond to this outbreak.
- DoD and HHS worked to airlift hundreds of thousands of swabs and sample test kits from Italy to the United States.

HELPING FAMILIES AND WORKING AMERICANS

- The Administration negotiated legislation which will provide tax credits for eligible businesses that give paid leave to Americans affected by the virus.
- The Department of Labor issued guidance to help inform Americans about the paid family and medical leave available to them.
- The Administration took action to provide more flexibility in unemployment insurance programs for workers impacted by the coronavirus.
- The Treasury Department moved tax day from April 15 to July 15.
- President Trump signed legislation providing funding and flexibility for emergency nutritional aid for senior citizens, women, children, and low-income families.
- USDA announced new flexibilities to allow meal service during school closures.
- USDA announced a new collaboration with the private sector to deliver nearly 1,000,000 meals a week to students in rural schools closed due to the coronavirus.
- HHS has announced \$250 million in grants to help communities provide meals for seniors.
- The Administration is halting foreclosures and evictions for families with FHA-insured mortgages.
- The Department of Labor announced up to \$100 million in dislocated worker grants in response to the coronavirus national health emergency.
- The White House worked with the private sector to launch a central website where families, students, and educators can access online education technologies.
- President Trump signed legislation to provide continuity in educational benefits for veterans and their families who attend schools that have had to switch to online learning.
- The Department of Education has given broad approval to colleges and universities to allow them to more easily move their classes online.

- The Department of Education set interest rates on all federally-held student loans to 0% for at least 60 days.
- The Department of Education announced borrowers will have the option to suspend their payments on federally-held student loans for at least two months.
- The Department of Education is providing waivers for federal testing requirements to states that have had to close schools.

SUPPORTING IMPACTED BUSINESSES

- The Small Business Administration has announced disaster loans which provide impacted businesses with up to \$2 million.
- SBA relaxed criteria for disaster assistance loans – expanding small businesses’ access to economic assistance.
- The President directed the Energy Department to purchase large quantities of crude oil for the strategic reserve.
- President Trump has held calls and meetings with business leaders from the pharmaceutical industry, airlines, health insurers, grocery stores, retail stores, banks, and more.
- The Treasury Department approved the establishment of the Money Market Mutual Fund Liquidity Facility to provide liquidity to the financial system.
- The Export-Import Bank announced four new temporary relief programs to provide maximum financing flexibility and inject liquidity into the market.

INFORMING THE PUBLIC

- The Administration launched a website – coronavirus.gov – to keep the public informed about the outbreak.
- The President launched a partnership with the Ad Council, media networks, and digital platforms to communicate public services announcements about the coronavirus.
- The President announced guidelines for Americans to follow and do their part to stem the spread of the virus.
- The Task Force is holding nearly daily press conferences to provide the American people with the latest information.
- The Task Force has recommended mitigation strategies to heavily impacted communities, like those in New York, Washington, and California.
- CMS announced guidance to protect vulnerable elderly Americans and limit medically unnecessary visits to nursing homes.

SUPPORTING PATIENTS AND HEALTHCARE PROVIDERS

- In January, the Administration declared the coronavirus to be a public health emergency.
- The President donated his fourth-quarter 2019 salary to the Department of Health and Human Services for coronavirus response efforts.

- The President took action to give HHS authority to waive rules and regulations so that healthcare providers have maximum flexibility to respond to this outbreak.
- HHS is providing funding to help healthcare systems across the country quickly prepare for a surge in coronavirus patients.
- CMS is giving flexibility to Medicare Advantage and Part D plans to waive cost-sharing for coronavirus tests and treatment.
- CMS created new billing codes for coronavirus tests to promote better tracking of the public health response.
- The White House Office of Science and Technology Policy coordinated with the NIH, the tech industry, and non-profits to release a machine readable collection of 29,000 coronavirus-related research articles, which will help scientists discover insights to virus' genetics, incubation, treatment, symptoms, and prevention.
- The White House launched a new public-private consortium to help provide coronavirus research projects access to powerful supercomputer resources.
- The Administration announced that health plans with health savings accounts will be able to cover coronavirus testing and treatment without co-payments.
- CMS dramatically expanded telehealth for Medicare beneficiaries, ensuring more patients can access their doctors remotely while avoiding exposure.
- HHS lifted HIPAA penalties to enable healthcare providers to expand telehealth access for patients.
- The FDA took action to allow expanded use of devices to monitor patients' vital signs remotely, reducing hospital visits and minimizing risks of exposure.
- The VA established 19 emergency operations centers across the country and put in place visitation restrictions to limit patients' exposure.
- Thanks to a waiver from the Office of Personnel Management, the VA is working to rehire retired medical personnel during the coronavirus outbreak.
- CMS and the VA are working to limit nonessential, elective medical procedures to free up healthcare resources.
- The Department of Defense issued guidance to delay elective medical procedures at military facilities in order to preserve healthcare resources.
- The Navy will be deploying two medical ships to help support impacted areas.
- The President announced Carnival Cruise Lines will be making ships available for hospitals to use for non-coronavirus patients.
- The Army Corps of Engineers is helping to build temporary hospitals and medical facilities in states like New York and Washington.

STRENGTHENING ESSENTIAL MEDICAL SUPPLIES

- The Administration mobilized a Supply Chain Stabilization Task Force led by Rear Admiral John Polowczyk.

- FEMA is working to distribute ventilators and other critical supplies to hard hit states like New York.
- The President invoked the Defense Production Act, providing a number of authorities that can be used if needed.
- The President urged the private sector to bolster response efforts, leading companies across the country to produce more critical supplies like masks, ventilators, and hand sanitizer.
- The President signed a memorandum directing his Administration to make general-use face masks available to healthcare workers.
- HHS announced it will be purchasing 500 million N95 respirators for the Strategic National Stockpile.
- The Department of Defense announced it will be providing 5 million respirator masks and 2,000 specialized ventilators to assist.
- The President signed legislation removing restrictions that prevented manufacturers from selling industrial masks – which can readily protect healthcare workers – directly to hospitals.
- The President signed an executive order to prevent hoarding and price-gouging of critical medical supplies.
- The Department of Justice has taken action to combat coronavirus related fraud.

DEVELOPING VACCINES AND THERAPEUTICS

- The Administration is working to help accelerate the development of therapeutics and a vaccine to combat the coronavirus.
- The FDA is evaluating existing drugs that could serve as potential therapeutics for coronavirus patients.
- The Trump Administration is actively working with drug manufacturers to monitor any potential drug supply chain issues.
- The Administration is expanding research and consulting with experts to better understand the transmission of coronavirus.
- The National Institutes of Health has announced the beginning of a clinical trial for a coronavirus vaccine candidate.

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From: Caliguiri, Laura [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AA086F2D6C0346C49E996932D86AC62E-LAURA.CALIG]
Sent: 3/24/2020 8:36:14 PM
To: Sarah Lynch (Sarah.Lynch@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d24ee4a4fc6241f48110d6b35e6704ed-Sarah.Lynch]; Capobianco, Abigail [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=660b8e4204f74d4b912265b9c85613bd-Abigail.Cap]; Brad Kimberly (Brad.Kimberly@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08bc909ed76d49868a5ff92c3c70fb72-Bradley.Kim]
Subject: FW: What You Need To Know | President Trump's Coronavirus Response Efforts

From: Mitchell, Austin A. EOP/WHO (b)(6)
Sent: Tuesday, March 24, 2020 8:35 PM
Subject: What You Need To Know | President Trump's Coronavirus Response Efforts

What You Need To Know | President Trump's Coronavirus Response Efforts

President Trump and his Administration are working every day to protect the health and wellbeing of Americans and respond to the coronavirus.

WHOLE-OF-GOVERNMENT APPROACH

- President Trump declared a national emergency, inviting States, territories, and tribes to access over \$42 billion in existing funding.
- President Trump signed legislation securing \$8.3 billion for coronavirus response.
- President Trump signed the Families First Coronavirus Response Act, ensuring that American families and businesses impacted by the virus receive the strong support they need.
- To leverage the resources of the entire government, the President created a White House Coronavirus Task Force to coordinate response.
- The Vice President named Dr. Deborah Birx to serve as the White House Coronavirus Response Coordinator.
- At the request of President Trump, FEMA is leading federal operations on behalf of the White House Coronavirus Task Force.
- FEMA's National Response Coordination Center has been activated to its highest level in support of coronavirus response.

SUPPORTING STATE AND LOCAL EFFORTS

- The President has approved major disaster declarations for impacted states like New York, Washington, and California.
- The Administration is covering costs of deploying National Guard units to assist with response efforts in hard hit states, while ensuring governors remain in command.
- The President has held multiple teleconferences with our nation's governors to coordinate response efforts and offer his full support.

TRAVEL RESTRICTIONS

- In January, President Trump reacted quickly to implement travel restrictions on travel from China, buying us valuable time to respond to the virus.
- The President has announced further travel restrictions on global hotspots, including Europe, the United Kingdom and Ireland, and Iran.
- American citizens returning from travel-restricted countries are being routed to specific airports, where they can be screened and isolated as needed.
- The United States reached mutual agreements with Mexico and Canada to restrict non-essential travel across our northern and southern borders.
- The Administration announced it will expeditiously return aliens who cross between ports of entry or are otherwise not allowed to enter the country, as the facilities in which these aliens would be held cannot support quarantine for the time needed to assess potential cases.
- The Administration raised travel warnings to their highest level for other hot spot locations, like Japan and South Korea.
- The President has expanded airport screenings to identify travelers showing symptoms and instituted mandatory quarantines.
- The State Department issued a global level 4 travel advisory, urging Americans to avoid all international travel due to the coronavirus outbreak worldwide.
- The State Department has worked to safely repatriate 9,000 Americans from 28 countries around the world.

EXPANDING TESTING ACCESS

- The FDA has issued emergency approval for multiple new commercial coronavirus tests to significantly expand testing across the country.
- The President secured legislation that will ensure Americans are able to be tested for free.
- The Administration is working with state and local partners and the private sector to open up drive-through testing sites.
- The Administration is working with the private sector to develop a website that Americans can utilize to determine whether they need a test and, if so, where to get it.
- HHS is providing funding to help accelerate the development of rapid diagnostic tests for the coronavirus.
- The FDA cut red tape to expand testing availability.

- Admiral Brett Giroir – the Assistant Secretary for Health and head of the Public Health Service – has been appointed to coordinate coronavirus testing efforts.
- The FDA is empowering states to authorize tests developed and used by laboratories in their states.
- The Department of Defense has set up 15 coronavirus testing sites worldwide.
- The President signed legislation requiring more reporting from state and private labs to ensure our public health officials have the data they need to respond to this outbreak.
- DoD and HHS worked to airlift hundreds of thousands of swabs and sample test kits from Italy to the United States.

SUPPORTING IMPACTED BUSINESSES

- The Small Business Administration has announced disaster loans which provide impacted businesses with up to \$2 million.
- SBA relaxed criteria for disaster assistance loans – expanding small businesses’ access to economic assistance.
- The President directed the Energy Department to purchase large quantities of crude oil for the strategic reserve.
- President Trump has held calls and meetings with business leaders from the pharmaceutical industry, airlines, health insurers, grocery stores, retail stores, banks, and more.
- The Treasury Department approved the establishment of the Money Market Mutual Fund Liquidity Facility to provide liquidity to the financial system.

HELPING FAMILIES AND WORKING AMERICANS

- The Administration negotiated legislation which will provide tax credits for eligible businesses that give paid leave to Americans affected by the virus.
- The Administration took action to provide more flexibility in unemployment insurance programs for workers impacted by the coronavirus.
- The Treasury Department moved tax day from April 15 to July 15.
- President Trump signed legislation providing funding and flexibility for emergency nutritional aid for senior citizens, women, children, and low-income families.
- USDA announced new flexibilities to allow meal service during school closures.
- USDA announced a new collaboration with the private sector to deliver nearly 1,000,000 meals a week to students in rural schools closed due to the coronavirus.
- HHS has announced \$250 million in grants to help communities provide meals for seniors.
- The Administration is halting foreclosures and evictions for families with FHA-insured mortgages.
- The Department of Labor announced up to \$100 million in dislocated worker grants in response to the coronavirus national health emergency.

- The White House worked with the private sector to launch a central website where families, students, and educators can access online education technologies.
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INFORMING THE PUBLIC

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- The President donated his fourth-quarter 2019 salary to the Department of Health and Human Services for coronavirus response efforts.
- The President took action to give HHS authority to waive rules and regulations so that healthcare providers have maximum flexibility to respond to this outbreak.
- HHS is providing funding to help healthcare systems across the country quickly prepare for a surge in coronavirus patients.
- CMS is giving flexibility to Medicare Advantage and Part D plans to waive cost-sharing for coronavirus tests and treatment.
- CMS created new billing codes for coronavirus tests to promote better tracking of the public health response.

- The White House Office of Science and Technology Policy coordinated with the NIH, the tech industry, and non-profits to release a machine readable collection of 29,000 coronavirus-related research articles, which will help scientists discover insights to virus' genetics, incubation, treatment, symptoms, and prevention.
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From: Caliguiri, Laura [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AA086F2D6C0346C49E996932D86AC62E-LAURA.CALIG]
Sent: 3/22/2020 6:08:05 PM
To: Finnen, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; 2019-nCoV FDA IMG Planning [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8aa3f7699ef4e84b4b1a9541592d0cf-2019-nCoV F]
CC: Lynch, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d24ee4a4fc6241f48110d6b35e6704ed-Sarah.Lynch]; Choe, Lena [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87ea73b7c30d4023b19ad798cc1c1896-CHOELE]; Rawlings, Kimberly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae46d13993dc46e190ae70b61e1d4871-KRawling]
Subject: RE: Concern about medications for coronavirus

Given CDC has posted, let's refer to them. Thank you!

From: Finnen, April <April.Finnen@fda.hhs.gov>
Sent: Sunday, March 22, 2020 4:53 PM
To: Mair, Michael <Michael.Mair@fda.hhs.gov>; 2019-nCoV FDA IMG Planning <2019-nCoVFDAIMGPlanning@fda.hhs.gov>
Cc: Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>; Choe, Lena <Lena.Choe@fda.hhs.gov>; Rawlings, Kimberly <Kimberly.Rawlings@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Subject: RE: Concern about medications for coronavirus

SJ – (b) (5) Yes, we need to know when routing these inquiries who is expected to respond, if not the IMG team to which it is routed. Thanks.

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Sunday, March 22, 2020 4:41 PM
To: Finnen, April <April.Finnen@fda.hhs.gov>; 2019-nCoV FDA IMG Planning <2019-nCoVFDAIMGPlanning@fda.hhs.gov>
Cc: Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>; Choe, Lena <Lena.Choe@fda.hhs.gov>; Rawlings, Kimberly <Kimberly.Rawlings@fda.hhs.gov>
Subject: RE: Concern about medications for coronavirus

Hi. I think this may be more of a CDC question.

They just released "Information for Clinicians on Therapeutic Options for COVID-19 Patients"

<https://www.cdc.gov/coronavirus/2019-ncov/hcp/therapeutic-options.html>

From: Finnen, April <April.Finnen@fda.hhs.gov>
Sent: Sunday, March 22, 2020 4:36 PM
To: 2019-nCoV FDA IMG Planning <2019-nCoVFDAIMGPlanning@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>; Choe, Lena <Lena.Choe@fda.hhs.gov>; Rawlings, Kimberly <Kimberly.Rawlings@fda.hhs.gov>
Subject: FW: Concern about medications for coronavirus

Planning – can you please log/route this inquiry appropriately within IMG? Seems like a CDER question. Thank you.

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Sent: Sunday, March 22, 2020 11:51 AM
To: Mair, Michael <Michael.Mair@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>
Cc: Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>
Subject: FW: Concern about medications for coronavirus

Can you all process for response?

From: Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>
Sent: Sunday, March 22, 2020 11:49 AM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: Fw: Concern about medications for coronavirus

(b) (5)

From: Robert Ledbetter (b)(6) >
Sent: Sunday, March 22, 2020 11:14 AM
To: Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>
Subject: Concern about medications for coronavirus

Good morning,

My name is Robert W Ledbetter. I am a cardiologist in Tampa, Florida. I am glad they are testing treatments but I have a concern no one has addressed. One of my family members is a pharmacist and people are giving the Hydroxychloroquine and Azithromycin already... My concern is that if a person has Long QT syndrome 1:2500 people in reading or if you are on antiarrhythmic drugs ie Sotalol, Amiodarone, or Tikosyn which is millions of people could induce life threatening arrhythmia and with our atrial fibrillation population there is a lot of patients on these meds. People giving these meds could induce life threatening QT prolongation not realizing what they are doing. There needs to be protocols with EKG's for these patients... we are talking millions of patients on meds for atrial fibrillation. Ie Sotalol on 4\$ list at Walmart. Several years ago major warning for these meds with Biaxin, azithromycin etc. Now you going to give 2 drugs that could be life threatening if mixed.... I would appreciate a response.

Sincerely

Robert W Ledbetter, DO, FACC

From: Caliguiri, Laura [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AA086F2D6C0346C49E996932D86AC62E-LAURA.CALIG]
Sent: 3/23/2020 8:44:16 PM
To: Sarah Lynch (Sarah.Lynch@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d24ee4a4fc6241f48110d6b35e6704ed-Sarah.Lynch]; Brad Kimberly (Brad.Kimberly@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08bc909ed76d49868a5ff92c3c70fb72-Bradley.Kim]; Capobianco, Abigail [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=660b8e4204f74d4b912265b9c85613bd-Abigail.Cap]
Subject: FW: President Trump's Coronavirus Response Efforts

From: Mitchell, Austin A. EOP/WHO <(b)(6)>
Sent: Monday, March 23, 2020 8:43 PM
Subject: President Trump's Coronavirus Response Efforts

All – see below for some of the new actions announced by President Trump and his administration in recent days to respond to the coronavirus.

- The President announced new action to support governors' use of the national guard in response to the coronavirus.
- President Trump approved multiple major disaster declarations for heavily impacted states.
- President Trump signed an executive order to prohibit hoarding and price-gouging of critical supplies.
- President Trump signed legislation to provide continuity in educational benefits for veterans and their families who have had to switch to online learning.
- The Administration launched a new public-private consortium to help provide coronavirus research projects access to powerful supercomputer resources.

What You Need To Know | President Trump's Coronavirus Response Efforts

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Sent: 3/21/2020 5:50:09 PM
To: Brad Kimberly (Brad.Kimberly@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08bc909ed76d49868a5ff92c3c70fb72-Bradley.Kim]; Ruberry, Erin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6eb9830932304426936396d5f70b4c04-Erin.Ruberr]; Sarah Lynch (Sarah.Lynch@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d24ee4a4fc6241f48110d6b35e6704ed-Sarah.Lynch]
CC: Stephanie Caccamo (Stephanie.Caccamo@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
Subject: FW: What You Need To Know | President Trump is Leveraging the Resources and Innovation of the Private Sector to Help Combat the Coronavirus

From: Mitchell, Austin A. EOP/WHO <(b)(6)>
Sent: Saturday, March 21, 2020 5:45 PM
Subject: What You Need To Know | President Trump is Leveraging the Resources and Innovation of the Private Sector to Help Combat the Coronavirus

What You Need To Know | President Trump is Leveraging the Resources and Innovation of the Private Sector to Help Combat the Coronavirus

President Trump is working with business leaders from across the country to bolster coronavirus response efforts.

The President announced that Hanes has agreed to use its manufacturing facilities to help produce medical masks.

- PRESIDENT TRUMP: “Hanes – everybody knows Hanes, great company, great consumer cotton products – is retrofitting its manufacturing capabilities in large sections of their plants to produce masks. And they are in that process right now. At my direction the FDA has taken rapid steps to make these items available for medical use right now.”

- HANES: “At Team Hanes, we are working to help by retrofitting some of our facilities to produce medical masks urgently needed in the U.S. to fight the spread of the virus.”

After speaking with the White House, Walmart agreed to allow their parking lots to be used as drive through coronavirus testing locations.

- WALMART CEO DOUG MCMILLON: “When we got the call yesterday from the White House, we were eager to do our part to help serve the country. And given what we’re facing, that’s certainly important to do. We should all be doing that. So we’ve been asked to make portions of our parking lot available in select locations in the beginning, and scaling over time as supply increases, so that people can experience the drive-thru experience that the President described.”

After the President spoke with the Chairman of Carnival Corporation, the company offered to make ships available to help burdened hospitals.

- PRESIDENT TRUMP: “One of the things that happened this morning: I spoke with Micky Arison of Carnival Cruise Lines, and he’s going to make ships available.”
- CARNIVAL CORPORATION: “Carnival Corporation & plc the world's largest leisure travel company, today announced that select cruise ships from the company's global cruise line brands, including Carnival Cruise Line, Holland America Line, Princess Cruises and P&O Cruises Australia, will be made available to communities for use as temporary hospitals to help address the escalating impacts of the COVID-19 pandemic on healthcare systems around the world.”

Honeywell and 3M have assisted in efforts to build up needed medical supplies by increasing their production of industrial respiratory masks.

- VICE PRESIDENT PENCE: “We’re encouraged to see companies like Honeywell and 3M, that I visited a few short weeks ago, take advantage of the changes in the law last night that allow the sale of industrial masks directly to hospitals. Those companies have now greatly increased, by the tens of millions, their production of so-called N-95 masks that will give our healthcare workers the protection that they need to minister to those that are dealing with the symptoms or the disease of coronavirus.”

General Motors have agreed to assist in increasing production of ventilators.

- GM CHAIRMAN AND CEO MARY BARRA: “We are working closely with Ventec to rapidly scale up production of their critically important respiratory products to support our country's fight against the COVID-19 pandemic.”

Diagnostic test providers like LabCorp and Quest Pharmaceuticals stepped up to rapidly expand testing.

- LAB CORP CEO ADAM SCHECHTER: “Thank you, Mr. President. At LabCorp, we’re working every second of every day to increase the number of tests that we can run.”
- QUEST DIAGNOSTICS CEO STEPHEN RUSCKOWSKI: “We were called, with the leadership of the Vice President, last week to come together as an industry. And we took advantage of that opportunity to work with the FDA, to work with the Center for Disease Control. And we are up and running with tests in a number of our facilities.”

After speaking with the President, Target and Walgreens agreed to do their part to keep stores open and serve American consumers.

- WALGREENS PRESIDENT RICHARD ASHWORTH: “We’re happy to stand in here and help in communities all across America. Because a lot of times, when we have natural disasters, our stores are a beacon in the community, and this situation is no different.”
- TARGET CEO BRIAN CORNELL: “In the near term, we’re all committed to making sure we’re keeping our stores open to serve the American consumer who is rapidly stocking up on household essentials, key food and beverage items that they need during this time; making sure we run safe stores; and creating an environment that’s safe for our team members, making sure that they feel supported during this very critical time.”

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From: Caliguiri, Laura [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AA086F2D6C0346C49E996932D86AC62E-LAURA.CALIG]
Sent: 3/23/2020 11:52:40 AM
To: Foster, Timothy (OS/ASPA) [Timothy.Foster@hhs.gov]; Caccamo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
Subject: RE: For review: Deputy Secretary Hargan blood donation video script
Attachments: 5 Things Donating Blood_V1 3.22.20 (003) CBER.docx



5 Things Donating
Blood_V1 3.22.20...

With suggested edits.

From: Foster, Timothy (OS/ASPA) <Timothy.Foster@hhs.gov>
Sent: Monday, March 23, 2020 11:50 AM
To: Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Subject: RE: For review: Deputy Secretary Hargan blood donation video script

Laura & Stephanie – (b) (5)

Thanks!

From: Foster, Timothy (OS/ASPA)
Sent: Sunday, March 22, 2020 10:51 PM
To: Caccamo, Stephanie (FDA/OC) <Stephanie.Caccamo@fda.hhs.gov>; Caliguiri, Laura (FDA/OC) <Laura.Caliguiri@fda.hhs.gov>
Subject: For review: Deputy Secretary Hargan blood donation video script

Hey Laura & Stephanie

Attached is a video script for Deputy Secretary Hargan on blood donation. (b) (5)

Requesting clearance by noon tomorrow – please let me know if you have any edits or comments.

Thank you!

<< File (b) (5) >>

Timothy Foster
Advisor, Strategic Communications
Office of the Assistant Secretary for Public Affairs
U.S. Department of Health and Human Services
Timothy.Foster@HHS.Gov

AMERICAN
OVERSIGHT

FDA-OC-2020-1977/2020-4765-001176

MULTI-HHS-FDA-20-0400, 20-0415-C-000184

(b)(6)

Predecisional/deliberative communication

From: Caliguiri, Laura [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AA086F2D6C0346C49E996932D86AC62E-LAURA.CALIG]
Sent: 3/17/2020 8:16:02 PM
To: Sarah Lynch (Sarah.Lynch@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d24ee4a4fc6241f48110d6b35e6704ed-Sarah.Lynch]; Capobianco, Abigail [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=660b8e4204f74d4b912265b9c85613bd-Abigail.Cap]; Brad Kimberly (Brad.Kimberly@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08bc909ed76d49868a5ff92c3c70fb72-Bradley.Kim]
CC: Stephanie Caccamo (Stephanie.Caccamo@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Michael Felberbaum (Michael.Felberbaum@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Carly McWilliams (Carly.McWilliams@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]
Subject: FW: What You Need To Know | President Trump's Coronavirus Response Efforts

fysa

From: Mitchell, Austin A. EOP/WHO (b)(6)
Sent: Tuesday, March 17, 2020 8:13 PM
Subject: What You Need To Know | President Trump's Coronavirus Response Efforts

What You Need To Know | President Trump's Coronavirus Response Efforts

President Trump and his Administration are working every day to protect the health and wellbeing of Americans and respond to the coronavirus.

WHOLE-OF-GOVERNMENT RESPONSE

- President Trump signed legislation securing \$8.3 billion for coronavirus response.
- President Trump declared a national emergency, inviting States, territories, and tribes to access over \$42 billion in existing funding.
- To leverage the resources of the entire government, the President created a White House Coronavirus Task Force to coordinate response.
- The Vice President named Dr. Deborah Birx to serve as the White House Coronavirus Response Coordinator.

TRAVEL RESTRICTIONS

- In January, President Trump reacted quickly to implement travel restrictions on travel from China, buying us valuable time to respond to the virus.
- The President has announced further travel restrictions on global hotspots, including Europe, the United Kingdom and Ireland, and Iran.

- American citizens returning from travel-restricted countries are being routed to specific airports, where they can be screened and isolated as needed.
- The Administration raised travel warnings to their highest level for other hot spot locations, like Japan and South Korea.
- The President has expanded airport screenings to identify travelers showing symptoms and instituted mandatory quarantines.

EXPANDING TESTING ACCESSIBILITY

- The FDA issued emergency approval for new commercial coronavirus tests to significantly expand testing across the country.
- The President secured legislation that will ensure Americans are able to be tested for free.
- The Administration is working with state and local partners and the private sector to open up drive-through testing sites.
- The Administration is working with the private sector to develop a website that Americans can utilize to determine whether they need a test and, if so, where to get it.
- HHS is providing funding to help accelerate the development of rapid diagnostic tests for the coronavirus.
- The FDA cut red tape to expand testing availability.
- The Administration is working to provide states with flexibility to approve coronavirus testing laboratories.
- Admiral Brett Giroir – the Assistant Secretary for Health and head of the Public Health Service – has been appointed to coordinate coronavirus testing efforts.
- The FDA is empowering states to authorize tests developed and used by laboratories in their states.

RELIEF FOR IMPACTED BUSINESSES

- The Small Business Administration has announced disaster loans which provide impacted businesses with up to \$2 million.
- The President has met with bank executives, insurers, pharmaceutical executives, and other industry leaders.
- The President directed the Energy Department to purchase large quantities of crude oil for the strategic reserve.
- President Trump has held numerous calls and meetings with business leaders from the pharmaceutical industry, health insurers, grocery stores, retail stores, banks, and more.

HELPING FAMILIES AND WORKING AMERICANS

- The Administration negotiated legislation which will provide tax credits for eligible businesses that give paid leave to Americans affected by the virus.

- The Administration took action to provide more flexibility in unemployment insurance programs for workers impacted by the coronavirus.
- The President has directed the Education Department to waive interest on student loans held by the federal government.
- The President has directed the Treasury Department to defer tax payments for certain impacted individuals and businesses.
- President Trump has called on Congress to pass a payroll tax cut.
- USDA announced new flexibilities to allow meal service during school closures.
- USDA announced a new collaboration with the private sector to deliver nearly 1,000,000 meals a week to students in rural schools closed due to the coronavirus.

INFORMING THE PUBLIC

- The Administration launched a website – coronavirus.gov – to keep the public informed about the outbreak.
- The President announced guidelines for Americans to follow and do their part to stem the spread of the virus.
- The Task Force is holding nearly daily press conferences to provide the American people with the latest information.
- The Task Force has recommended mitigation strategies to heavily impacted communities, like those in New York, Washington, and California.
- CMS announced guidance to protect vulnerable elderly Americans and limit medically unnecessary visits to nursing homes.

SUPPORTING PATIENTS AND HEALTHCARE PROVIDERS

- In January, the Administration declared the coronavirus to be a public health emergency.
- The President donated his fourth-quarter 2019 salary to the Department of Health and Human Services for coronavirus response efforts.
- The President signed a memorandum directing his Administration to make general-use face masks available to healthcare workers.
- HHS announced it will be purchasing 500 million N95 respirators for the Strategic National Stockpile.
- The Department of Defense announced it will be providing 5 million respirator masks and 2,000 specialized ventilators to assist.
- The President took action to give HHS authority to waive rules and regulations so that healthcare providers have maximum flexibility to respond to this outbreak.
- CMS is giving flexibility to Medicare Advantage and Part D plans to waive cost-sharing for coronavirus tests and treatment.

- CMS created new billing codes for coronavirus tests to promote better tracking of the public health response.
- The Administration announced that health plans with health savings accounts will be able to cover coronavirus testing and treatment without co-payments.
- CMS dramatically expanded telehealth for Medicare beneficiaries, ensuring more patients can access their doctors remotely while avoiding exposure.

DEVELOPING VACCINES AND THERAPEUTICS

- The Administration is working to help accelerate the development of therapeutics and a vaccine to combat the disease.
- The Trump Administration is actively working with drug manufacturers to monitor any potential drug supply chain issues.
- The Administration is expanding research and consulting with experts to better understand the transmission of coronavirus.
- The National Institutes of Health has announced the beginning of a clinical trial for a coronavirus vaccine candidate.

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From: Caliguiri, Laura [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AA086F2D6C0346C49E996932D86AC62E-LAURA.CALIG]
Sent: 3/19/2020 5:20:13 PM
To: Brad Kimberly (Brad.Kimberly@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08bc909ed76d49868a5ff92c3c70fb72-Bradley.Kim]; Capobianco, Abigail [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=660b8e4204f74d4b912265b9c85613bd-Abigail.Cap]
CC: Sarah Lynch (Sarah.Lynch@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d24ee4a4fc6241f48110d6b35e6704ed-Sarah.Lynch]
Subject: FW: President Trump is Cutting Red Tape and Empowering Coronavirus Response Efforts

From: Mitchell, Austin A. EOP/WHO <(b)(6)>
Sent: Thursday, March 19, 2020 5:17 PM
Subject: President Trump is Cutting Red Tape and Empowering Coronavirus Response Efforts

What You Need To Know | President Trump is Cutting Red Tape and Empowering Coronavirus Response Efforts

President Trump is cutting red tape to empower federal, state, local, and private sector response efforts.

PROVIDING FLEXIBILITY FOR HEALTHCARE PROVIDERS

- President Trump took action to give HHS the authority to waive certain rules and regulations to provide flexibility to healthcare providers in response to the coronavirus emergency.
- The President signed legislation removing restrictions preventing manufacturers from selling industrial masks – which can readily protect healthcare workers – directly to hospitals.

EXPEDITING AND EXPANDING TESTING

- FDA empowered certain qualified laboratories to use validated coronavirus tests while their Emergency Use Authorization requests were under review.
- The FDA took action to empower states to authorize tests developed and used within their borders.

ENABLING MORE TELEHEALTH

- CMS removed restrictions on telehealth for Medicare patients, dramatically expanding access across the country.
- HHS lifted HIPAA penalties to enable healthcare providers to expand telehealth for their patients.

EMPOWERING EDUCATORS

- The Department of Education has given broad approval to colleges and universities to allow them to more easily move their classes online.
- USDA waived certain requirements to allow children to continue receiving meals during school closures.

SUPPORTING SMALL BUSINESSES

- SBA relaxed criteria for disaster assistance loans – greatly expanding small businesses' access to economic assistance.

###

From: Caliguiri, Laura [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AA086F2D6C0346C49E996932D86AC62E-LAURA.CALIG]
Sent: 3/15/2020 4:03:48 PM
To: Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Capobianco, Abigail [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=660b8e4204f74d4b912265b9c85613bd-Abigail.Cap]; Dennis, Claire [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2f0121bf65bf48adb8077a2c49324223-Claire.Denn]; Busch, Marcy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec4ef9f06a684cafbe4307486233609e-Marcy.Busch]; Kumar, Dinesh [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=508e6d982bff426cab84531e12cfdd46-Dinesh.Kuma]; Kennelly, Mary [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3b122be759324e868c4dbf10295af981-Mary.Kennel]
CC: Lynch, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d24ee4a4fc6241f48110d6b35e6704ed-Sarah.Lynch]; Kimberly, Brad [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08bc909ed76d49868a5ff92c3c70fb72-Bradley.Kim]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
Subject: RE: FOR URGENT OCC CLERANCE: URGENT Clearance Diagnostics Tweets

Understood and removing. TY.

From: Raza, Mark <Mark.Raza@fda.hhs.gov>
Sent: Sunday, March 15, 2020 3:59 PM
To: Capobianco, Abigail <Abigail.Capobianco@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; Kennelly, Mary <Mary.Kennelly@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: RE: FOR URGENT OCC CLERANCE: URGENT Clearance Diagnostics Tweets

Hi – from OCC – (b) (5)

Thanks.

Mark

Mark Raza
Principal Deputy Chief Counsel
OCC

From: Capobianco, Abigail <Abigail.Capobianco@fda.hhs.gov>
Sent: Sunday, March 15, 2020 3:42 PM
To: Raza, Mark <Mark.Raza@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; Kennelly, Mary <Mary.Kennelly@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: FOR URGENT OCC CLERANCE: URGENT Clearance Diagnostics Tweets

Hi All,

I took the tweets on the chain below and formatted them into more social-friendly statements. Please review for urgent OCC clearance.

Thanks!

Abby

(b) (5)

From: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>
Sent: Sunday, March 15, 2020 2:57 PM
To: Capobianco, Abigail <Abigail.Capobianco@fda.hhs.gov>
Subject: FW: URGENT Clearance Diagnostics Tweets

Brad Kimberly

Director, Social Media

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-1002 | Cell: 240-750-9302
brad.kimberly@fda.hhs.gov



From: Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>
Sent: Sunday, March 15, 2020 2:53 PM

AMERICAN
OVERSIGHT

FDA-OC-2020-1977/2020-4765-001185

MULTI-HHS-FDA-20-0400, 20-0415-C-000193

To: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>
Subject: FW: URGENT Clearance Diagnostics Tweets

Happy to discuss in a moment if you need (AEG finishing soon, but extended re: internal/employee comms), yet can you/Abby clean up and put through JIC for showstoppers only as he wants to do ASAP? Sounds like to cc: OCC. TY.

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Sent: Sunday, March 15, 2020 2:50 PM
To: Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>
Subject: RE: URGENT Clearance Diagnostics Tweets

We can and PLEASE note this is not for copy editing show stoppers only. He wants to tweet asap.

From: Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>
Sent: Sunday, March 15, 2020 2:48 PM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Subject: RE: URGENT Clearance Diagnostics Tweets

Laura, can Brad/Abby now route through JIC process?

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Sent: Sunday, March 15, 2020 2:37 PM
To: Raza, Mark <Mark.Raza@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>
Cc: Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: RE: URGENT Clearance Diagnostics Tweets

(b) (5)

(b) (5)

From: Raza, Mark <Mark.Raza@fda.hhs.gov>
Sent: Sunday, March 15, 2020 2:22 PM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>
Cc: Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: RE: URGENT Clearance Diagnostics Tweets

Ok, please send us the revised version. Standing by.

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Sent: Sunday, March 15, 2020 2:21 PM
To: Raza, Mark <Mark.Raza@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>
Cc: Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>
Subject: RE: URGENT Clearance Diagnostics Tweets

Hold on he is making new edits. Thank you and appreciate it!

From: Caliguiri, Laura
Sent: Sunday, March 15, 2020 2:10 PM
To: Raza, Mark <Mark.Raza@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>
Cc: Sarah Lynch (Sarah.Lynch@fda.hhs.gov) <Sarah.Lynch@fda.hhs.gov>
Subject: URGENT Clearance Diagnostics Tweets

Mark and Dinesh
Could you please review ASAP for posting this afternoon. TY.
Laura

TWEETS ON COVID DIAGNOSTICS

(b) (5)

(b) (5)

Laura Caliguiri

Associate Commissioner for External Affairs

Office of External Affairs
U.S. Food and Drug Administration
Tel: 301 796-8546
Laura.Caliguiri@fda.hhs.gov

<image001.png>

<image002.jpg>

<image003.jpg>

<image004.jpg>

<image005.jpg>

<image006.jpg>

From: Caliguiri, Laura [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AA086F2D6C0346C49E996932D86AC62E-LAURA.CALIG]
Sent: 3/15/2020 3:46:39 PM
To: Michael Felberbaum (Michael.Felberbaum@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]
Subject: FW: FOR URGENT OCC CLERANCE: URGENT Clearance Diagnostics Tweets

Heading to the jic now

From: Capobianco, Abigail <Abigail.Capobianco@fda.hhs.gov>
Sent: Sunday, March 15, 2020 3:42 PM
To: Raza, Mark <Mark.Raza@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; Kennelly, Mary <Mary.Kennelly@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>
Subject: FOR URGENT OCC CLERANCE: URGENT Clearance Diagnostics Tweets

Hi All,

I took the tweets on the chain below and formatted them into more social-friendly statements. Please review for urgent OCC clearance.

Thanks!
Abby

Consult to EOP

to the needs of labs & #COVID19 diagnostic developers.

From: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>
Sent: Sunday, March 15, 2020 2:57 PM

AMERICAN
OVERSIGHT

FDA-OC-2020-1977/2020-4765-001189

MULTI-HHS-FDA-20-0400, 20-0415-C-000197

To: Capobianco, Abigail <Abigail.Capobianco@fda.hhs.gov>

Subject: FW: URGENT Clearance Diagnostics Tweets

Brad Kimberly

Director, Social Media

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-1002 | Cell: 240-750-9302
brad.kimberly@fda.hhs.gov



From: Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>

Sent: Sunday, March 15, 2020 2:53 PM

To: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>

Subject: FW: URGENT Clearance Diagnostics Tweets

Happy to discuss in a moment if you need (AEG finishing soon, but extended re: internal/employee comms), yet can you/Abby clean up and put through JIC for showstoppers only as he wants to do ASAP? Sounds like to cc: OCC. TY.

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>

Sent: Sunday, March 15, 2020 2:50 PM

To: Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>

Subject: RE: URGENT Clearance Diagnostics Tweets

We can and PLEASE note this is not for copy editing show stoppers only. He wants to tweet asap.

From: Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>

Sent: Sunday, March 15, 2020 2:48 PM

To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>

Subject: RE: URGENT Clearance Diagnostics Tweets

Laura, can Brad/Abby now route through JIC process?

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>

Sent: Sunday, March 15, 2020 2:37 PM

To: Raza, Mark <Mark.Raza@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>

Cc: Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>

Subject: RE: URGENT Clearance Diagnostics Tweets

Revised

First tweet: here is role of FDA

(b) (5)

From: Raza, Mark <Mark.Raza@fda.hhs.gov>
Sent: Sunday, March 15, 2020 2:22 PM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>
Cc: Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: RE: URGENT Clearance Diagnostics Tweets

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Cc: Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>
Subject: RE: URGENT Clearance Diagnostics Tweets

Hold on he is making new edits. Thank you and appreciate it!

From: Caliguiri, Laura
Sent: Sunday, March 15, 2020 2:10 PM
To: Raza, Mark <Mark.Raza@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>
Cc: Sarah Lynch (Sarah.Lynch@fda.hhs.gov) <Sarah.Lynch@fda.hhs.gov>
Subject: URGENT Clearance Diagnostics Tweets

Mark and Dinesh
Could you please review ASAP for posting this afternoon. TY.

Laura

(b) (5)

Laura Caliguiri
Associate Commissioner for External Affairs

Office of External Affairs
U.S. Food and Drug Administration
Tel: 301 796-8546
Laura.Caliguiri@fda.hhs.gov

AMERICAN
OVERSIGHT

FDA-OC-2020-1977/2020-4765-001192

MULTI-HHS-FDA-20-0400, 20-0415-C-000200

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<image006.jpg>

From: Caliguiri, Laura [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AA086F2D6C0346C49E996932D86AC62E-LAURA.CALIG]
Sent: 3/15/2020 6:01:26 PM
To: Dr. Hahn (sh1@fda.hhs.gov) [sh1@fda.hhs.gov]
CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Colin Rom (Colin.Rom@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
Subject: FW: Tonight's 7pm Call on Testing
Attachments: Information for Stakeholder Call on Testing.docx

Sir

1. Please make sure earlier number match this

Host Dial-In: (b) (6)

Code: (b)(6)

2. Here are questions being asked of you. I think you are covered w/ talker but lmk if you would like something else.

Azar: I'd like to turn to FDA Commissioner Hahn. The FDA has taken several steps to expand testing capacity that open up avenues for both public and private labs. Can you describe the new pathways to increase capacity?

(b)(6)

Azar: Commissioner, there has also been some supply challenges in getting one of the components needed to complete testing – the re-agents. FDA has provided some alternative means to meet that need. For the lab directors listening, could you describe what FDA has done and where they can get more information?

Hahn responds



Information for
Stakeholder Call ...

Here is what you need to know:

Location: White House, Roosevelt Room

Time: Pre-Gathering: 6:45 PM
Call: 7:00 PM – 8:00 PM

Audience:

Private: Major Health Systems, FAH, AHA, America's Essential Hospitals Association, Physician Hospitals of America, Catholic Health Association, Public and Private Lab Associations (ACLA and APhL), National Rural Health Association, College of American Pathologists, Range of individual hospitals

Public: Governors (COS, Policy Director, State Federal Affairs Reps); State Health Officers, County Health Officers

Format:

We are going to use a interactive format. After openers from Birx and Azar, Azar will act as a moderator of sorts, asking questions to the key participants. These questions represent the queries that IEA and others are receiving the most often.

If you feel that we have crafted the wrong question for you, please send back a note and we will revise.

(b) (5)

(b) (5)

Laura C. Trueman
Director, Office of Intergovernmental and External Affairs
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington D.C. 20201
Laura.Trueman@hhs.gov

(b) (6)

From: Caliguiri, Laura [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AA086F2D6C0346C49E996932D86AC62E-LAURA.CALIG]
Sent: 3/15/2020 2:12:03 PM
To: Lynch, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d24ee4a4fc6241f48110d6b35e6704ed-Sarah.Lynch]
Subject: RE: URGENT Clearance Diagnostics Tweets

When we spoke this am but heads up would be helpful ty

From: Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>
Sent: Sunday, March 15, 2020 2:11 PM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Subject: RE: URGENT Clearance Diagnostics Tweets

Let me know if you want me to connect to Brad on this or if you have already.

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Sent: Sunday, March 15, 2020 2:10 PM
To: Raza, Mark <Mark.Raza@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>
Cc: Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>
Subject: URGENT Clearance Diagnostics Tweets

Mark and Dinesh
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Laura

TWEETS ON COVID DIAGNOSTICS

(b) (5)

(b) (5)

Laura Caliguiri
Associate Commissioner for External Affairs

Office of External Affairs
U.S. Food and Drug Administration
Tel: 301 796-8546
Laura.Caliguiri@fda.hhs.gov

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From: Caliguiri, Laura [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AA086F2D6C0346C49E996932D86AC62E-LAURA.CALIG]
Sent: 3/15/2020 2:49:33 PM
To: Lynch, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d24ee4a4fc6241f48110d6b35e6704ed-Sarah.Lynch]
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Then

(b)(6)

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Cc: Sarah Lynch <Sarah.Lynch@fda.hhs.gov> <Sarah.Lynch@fda.hhs.gov>
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TWEETS ON COVID DIAGNOSTICS

(b) (5)

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Associate Commissioner for External Affairs

Office of External Affairs
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Sent: 3/15/2020 2:08:01 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]
Subject: RE: Diagnostics Tweets

Copy

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Sunday, March 15, 2020 2:00 PM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Cc: Hahn, Stephen <SH1@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: Re: Diagnostics Tweets

Send to OCC now to pls.

Sent from my iPhone

On Mar 15, 2020, at 1:57 PM, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov> wrote:

Sir

Below please find tweetorial style message on diagnostics. It has not gone through the broader review or OCC clearance process KL and Heidi have both responded in the positive. Please let me know if you would like to proceed. Laura

TWEETS ON COVID DIAGNOSTICS

(b) (5)

(b) (5)

Laura Caliguiri
Associate Commissioner for External Affairs

Office of External Affairs
U.S. Food and Drug Administration
Tel: 301 796-8546
Laura.Caliguiri@fda.hhs.gov

<image001.png>

<image002.jpg>

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From: Caliguiri, Laura [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AA086F2D6C0346C49E996932D86AC62E-LAURA.CALIG]
Sent: 3/8/2020 9:43:27 AM
To: Lynch, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d24ee4a4fc6241f48110d6b35e6704ed-Sarah.Lynch]
Subject: RE: Trump's mismanagement helped fuel coronavirus crisis

Am ok, see them let's focus on our other priorities. TY

From: Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>
Sent: Sunday, March 8, 2020 9:31 AM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Subject: FW: Trump's mismanagement helped fuel coronavirus crisis

You get these, I am sure, yet do you like/is it helpful to have some of the stronger ones flagged? Just checking for awareness/preference.

From: POLITICO Pro Health Care <politicoemail@politicopro.com>
Sent: Sunday, March 8, 2020 9:16 AM
To: Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>
Subject: Trump's mismanagement helped fuel coronavirus crisis

Trump's mismanagement helped fuel coronavirus crisis

By Dan Diamond

03/08/2020 09:13 AM EDT

On Friday, as coronavirus infections rapidly multiplied aboard a cruise ship marooned off the coast of California, health department officials and Vice President Mike Pence came up with a plan to evacuate thousands of passengers, avoiding the fate of a similar cruise ship, the Diamond Princess, which became a petri dish of coronavirus infections. Quickly removing passengers was the safest outcome, health officials and Pence reasoned.

But President Donald Trump had a different idea: Leave the infected passengers on board — which would help keep the number of U.S. coronavirus cases as low as possible.

“Do I want to bring all those people off? People would like me to do it,” Trump admitted at a press conference at the CDC later on Friday. “I would rather have them stay on, personally.”

“I don't need to have the numbers double because of one ship that wasn't our fault,” Trump added, saying that he ultimately empowered Pence to decide whether to evacuate the passengers.

For six weeks behind the scenes, and now increasingly in public, Trump has undermined his administration's own efforts to fight the coronavirus outbreak — resisting attempts to plan for worst-case scenarios, overturning a public-health plan upon request from political allies and repeating only the warnings that he chose to hear. Members of Congress have grilled top officials like Health and Human Services Secretary Alex Azar and Centers for Disease Control Director Robert Redfield over the government's biggest mistake: failing to secure enough testing to head off a coronavirus outbreak in the United States. But many current and former Trump administration officials say the true management failure was Trump's.

“It always ladders to the top,” said one person helping advise the administration's response, who noted that Trump's aides discouraged Azar from briefing the president about the coronavirus threat back in January. “Trump's created an atmosphere where the judgment of his staff is that he shouldn't need to know these things.”

Interviews with 13 current and former officials, as well as individuals close to the White House, painted a picture of a president who rewards those underlings who tell him what he wants to hear while shunning those who deliver bad news. For instance, aides heaped praise on Trump for his efforts to lock down travel from China — appealing to the president’s comfort zone of border security — but failed to convey the importance of doing simultaneous community testing, which could have uncovered a potential U.S. outbreak. Government officials and independent scientists now fear that the coronavirus has been silently spreading in the United States for weeks, as unexplained cases have popped up in more than 25 states.

“It’s a clearly difficult situation when the top wants to hear certain answers,” said one former official who’s briefed the White House. “That can make it difficult for folks to express their true assessment — even the most experienced and independent minds.”

While Trump last week allowed hospitals and labs to start developing their own coronavirus tests, wrongly blaming Obama administration regulations for a delay, the same move could have been made weeks ago had the president and his advisers felt it was necessary, said two officials.

The White House press office declined to comment on the record, referring questions to HHS.

The health department said that Trump had been responsive to the department's concerns and understood the seriousness of the coronavirus threat from the first day he was briefed.

"The President took early and decisive actions like instituting travel restrictions and utilizing the quarantine authority" to protect Americans from the outbreak, an HHS spokesperson said.

HHS also stressed that Azar and Trump had a good working relationship.

"The Secretary always offers the President his honest assessment, and always insists when briefing the President on public health issues that the relevant experts participate," the spokesperson said.

Trump-inspired disorganization plagues early response

As the outbreak has grown, Trump has become attached to the daily count of coronavirus cases and how the United States compares to other nations, reiterating that he wants the U.S. numbers kept as low as possible. Health officials have found explicit ways to oblige him by highlighting the most optimistic outcomes in briefings, and their agencies have tamped down on promised transparency. The CDC has stopped detailing how many people in the country have been tested for the virus, and its online dashboard is running well behind the number of U.S. cases tracked by Johns Hopkins and even lags the European Union’s own estimate of U.S. cases.

After senior CDC official Nancy Messonnier correctly warned on Feb. 25 that a U.S. coronavirus outbreak was inevitable, a statement that spooked the stock market and broke from the president’s own message that the situation was under control, Trump himself grew angry and administration officials discussed muzzling Messonnier for the duration of the coronavirus crisis, said two individuals close to the administration. However, Azar defended her role, and Messonnier ultimately was allowed to continue making public appearances, although her tone grew less dire in subsequent briefings.

Trump’s defenders can point to many coronavirus crises that, so far, have been failures of bureaucracy and disorganization. The president didn’t lock out a government scientist from CDC. He didn’t know that officials decided to fly back coronavirus-infected Americans aboard planes with hundreds of others who had tested negative, with Trump bursting in anger when he learned the news.

But Trump has added to that disorganization through his own decisions. Rather than empower a sole leader to fight the outbreak, as President Barack Obama did with Ebola in 2014, he set up a system where at least three different people — Azar, Vice President Mike Pence and coronavirus task force coordinator Debbie Birx — can claim responsibility. Three people who have dealt with the task force said it’s not clear what Birx’s role is, and that coronavirus-related questions sent to her have been rerouted to the vice president’s office.

In response, Pence's office said it has positioned Birx as the vice president's "right arm," advising him on the response, while Azar continues to oversee the health department's numerous coronavirus operations.

Trump on Friday night also shook up White House operations, replacing acting Chief of Staff Mick Mulvaney with Rep. Mark Meadows, a longtime ally. The long-expected ouster of Mulvaney was welcomed in corners like the health department, given that Mulvaney had been one of Azar's top critics. But the abrupt staff shuffle in the middle of the coronavirus outbreak injects further uncertainty into the government's response, said a current official and two former officials. It's not yet clear what Mulvaney's departure will mean for his key lieutenants involved in fighting the outbreak, like Domestic Policy Council chief Joe Grogan, for instance.

"Every office has office politics — even the Oval Office," said one individual. "You'd hope we could wait to work it out until after a public health emergency."

Health officials compete for Trump's approval

The pressure to earn Trump's approval can be a distraction at best and an obsession at worst: Azar, having just survived a bruising clash with a deputy and sensing that his job was on the line, spent part of January making appearances on conservative TV outlets and taking other steps to shore up his anti-abortion bona fides and win approval from the president, even as the global coronavirus outbreak grew stronger.

"We have in President Trump the greatest protector of religious liberty who has ever sat in the Oval Office," Azar said on Fox News on Jan. 16, hours after working to rally global health leaders to fight the United Nations' stance on abortion rights. Trump also had lashed out at Azar over bad health-care polling that day.

Around the same time, Azar had concluded that the new coronavirus posed a public health risk and tried to share an urgent message with the president: The potential outbreak could leave tens of thousands of Americans sickened and many dead.

But Trump's aides mocked and belittled Azar as alarmist, as he warned the president of a major threat to public health and his own economic agenda, said three people briefed on the conversations. Some officials argued that the virus would be no worse than the flu.

Azar, meanwhile, had his own worries: A clash with Medicare chief Seema Verma had weakened his standing in the White House, which in December had considered replacements for both Azar and Verma.

"Because he feels pretty insecure, about the feuds within his department and the desire to please the president, I don't know if he was in the position to deliver the message that the president didn't want to hear," said one former official who's worked with Azar.

The jockeying for Trump's favor was part of the cause of Azar's destructive feud with Verma, as the two tried to box each other out of events touting Trump initiatives. Now, officials including Azar, Verma and other senior leaders are forced to spend time shoring up their positions with the president and his deputies at a moment when they should be focused on a shared goal: stopping a potential pandemic.

"The boss has made it clear, he likes to see his people fight, and he wants the news to be good," said one adviser to a senior health official involved in the coronavirus response. "This is the world he's made."

President swayed by flattery, personal appeals

Trump's unpredictable demands and attention to public statements — and his own susceptibility to flattery — have created an administration where top officials feel constantly at siege, worried that the next presidential tweet will decide their professional future, and panicked that they need to regularly impress him.

The most obvious practitioner of this strategy is Azar, who became Trump's second health secretary after the first, Tom Price, failed to bond with Trump and was ousted over a charter-jet scandal. Azar decided early in his tenure to have "zero daylight" with the president, said three individuals close to him, and the health secretary routinely fawns over the president in his TV appearances on Fox News. "No other president has had the guts,

the courage to take on these special interests,” Azar told Fox News host Tucker Carlson in December after Trump pushed new price transparency on the health care industry.

Azar’s team also has insisted upon using background photos for his Twitter account that always show him with the president — sometimes silently standing behind Trump while he speaks. Azar is alone among Cabinet members in this practice; secretaries like HUD’s Ben Carson, Transportation’s Elaine Chao and Treasury’s Steven Mnuchin opted for bland Twitter backgrounds that show their headquarters.

"The Secretary respects the President and values their strong relationship," said an HHS spokesperson, when asked about Azar’s approach to working with Trump and use of Twitter photos.

Other health officials have modeled similar behavior as Azar. Asked by Trump if he wanted to make a “little statement” on Friday, CDC Director Redfield responded by praising the president’s “decisive leadership” and visit to CDC headquarters amid the outbreak. “I think that’s the most important thing I want to say,” Redfield said.

At least one health official has offered a more subtle reminder of her loyalties. Verma wore an Ivanka Trump-brand pendant to some meetings and events with the president, before it was stolen in 2018.

Health officials also have to guard their words and predictions, worried that the president will fixate on the wrong data point or blurt out damaging information in public. Trump on Friday told reporters that he’d initially scrapped a trip to the CDC because of a possible coronavirus case at the agency. The announcement came as a surprise to CDC staff, including those preparing for Trump’s visit, because they hadn’t been briefed on the potential coronavirus case, POLITICO first reported.

Meanwhile, Trump’s political allies have tried to circumvent the policy process, causing further headaches for the overwhelmed health department. Alabama Republicans prevailed upon Trump to scrap an HHS contingency plan to potentially quarantine some coronavirus-infected Americans at a facility in their state last month.

“I just got off the phone with the President,” Sen. Richard Shelby tweeted on Feb. 23. “He told me that his administration will not be sending any victims of the Coronavirus from the Diamond Princess cruise ship to Anniston, Alabama.”

But Democrats in a California city facing a similar situation failed to get a similar guarantee, leading them to file a lawsuit that accused the administration of political favoritism.

“California must not have the pull to get taken off the list,” attorney Jennifer Keller, representing Costa Mesa, Calif., reportedly said during a court hearing last month. “Alabama does.” A federal judge later halted plans to transfer coronavirus-stricken patients to a facility in the city.

Meanwhile, the president has allowed feuds to fester and spill into public view. Azar, for instance, has battled with White House officials and Verma for months over policies, personnel and even seats aboard the presidential airplane. Those fights have been reignited amid the coronavirus crisis, when Azar clashed with longtime rivals like Grogan over funding the response and whether enough coronavirus tests were being performed.

They’ve also cast a long shadow over strategy, like Azar’s decision not to push for Verma to be added to the coronavirus task force that he oversaw for nearly a month. Verma instead was added to the task force on March 2, several days after Pence took over leading the effort. While Azar said he asked for Verma to join the task force, and an HHS spokesperson pointed to the secretary’s public statement, two people with knowledge of task force operations said that the White House officials had raised questions about her omission.

Officials call the original decision to exclude Verma from the task force short-sighted at best, given the virus’ potential threat to the elderly patients covered by the Medicare program and residents living in nursing homes that are regulated by Verma’s agency.

With Trump unwilling — or unable — to put a stop to the health department’s fights, they’ve occupied and gripped Washington during relative peacetime. When at war against a potential pandemic, there’s no room for these distractions, officials say.

“If this sort of dysfunction exists as part of the everyday operations — then, yes, during a true crisis the problems are magnified and exacerbated,” said a former Trump HHS official. “And with extremely detrimental consequences.”

To view online:

<https://subscriber.politicopro.com/health-care/article/2020/03/trumps-mismanagement-helped-fuel-coronavirus-crisis-1888975>

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From: Caliguiri, Laura [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AA086F2D6C0346C49E996932D86AC62E-LAURA.CALIG]
Sent: 3/10/2020 3:48:31 PM
To: Finnen, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]
CC: Lynch, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d24ee4a4fc6241f48110d6b35e6704ed-Sarah.Lynch]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]
Subject: RE: AEG & getting links placed on CDC response page

I asked Chris and Brad to reach out to the JIC to make sure everyone is connected. I had told him there was a lot of web work being done and the Dept workgroup and JIC need to be connected. I asked him to reach to Brooke and make sure this connection is made.

From: Finnen, April <April.Finnen@fda.hhs.gov>
Sent: Tuesday, March 10, 2020 3:25 PM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Cc: Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: FW: AEG & getting links placed on CDC response page
Importance: High

Laura – Hi. I checked with the web team supporting JIC, and they are not aware of this request/process. Can you please let me know who you talked to, so we can circle back and make sure this happens? Thanks.

From: Finnen, April
Sent: Tuesday, March 10, 2020 1:20 PM
To: Mulieri, Chris <Charles.Mulieri@fda.hhs.gov>; Elicker, Janet (<Janet.Elicker@fda.hhs.gov> <Janet.Elicker@fda.hhs.gov>)
Cc: Leggin, Brooke <Brooke.Leggin@fda.hhs.gov>; Choe, Lena <Lena.Choe@fda.hhs.gov>; MacLennan, Lori <Lori.MacLennan@fda.hhs.gov>
Subject: AEG & getting links placed on CDC response page
Importance: High

Hi – at noon AEG today, Laura mentioned that she is working with the web team to send links from our COVID-19 content to be populated at coronavirus.gov (which redirects to CDC's landing page). Who is working on this? What is the process? What are you sending / what have you sent? Need to know for both awareness, and daily sitrep. Keagan and Commissioner Hahn both very insistent that this happen ASAP, particularly for diagnostic test info...

Apologies if this is news to you... just trying to ensure that it is actually getting done, and that we are reporting it as such to the AEG. (If you are not aware, let me know and will try to get more info from Laura...)

Thanks,
April

p.s. Lori – Suzanne Schwartz was involved in this conversation, and potentially tasked CDRH w/this...

April Finnen
IMG JIC Lead
2019 Novel Coronavirus (COVID-19) Incident Management Group (IMG)

U.S. Food and Drug Administration

Desk: 240-402-0470

EOC: 301-796-8281 (hours at EOC: Mon. & Thurs. 9:00 a.m. – 11:30 a.m., 1:00 – 3:00 p.m.)

Cell: (b)(6)

Email: april.finnen@fda.hhs.gov

JIC (Joint Information Center) email: 2019-nCoVFDAIMGJIC@fda.hhs.gov



From: Caliguiri, Laura [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AA086F2D6C0346C49E996932D86AC62E-LAURA.CALIG]
Sent: 3/5/2020 3:58:58 PM
To: Walsh, Sandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c61503c4e7884fc28b9ef6cb8f2514ec-Sandy.Walsh]
CC: Lynch, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d24ee4a4fc6241f48110d6b35e6704ed-Sarah.Lynch]
Subject: RE: Reupping - LAURA - for review: SMH all hands email COVID update
Attachments: SMH all hands update on COVID 3.5.2020_.docx

Really nicely done. Only a comment on getting OO preference.

From: Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>
Sent: Thursday, March 5, 2020 3:52 PM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Cc: Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>
Subject: Reupping - LAURA - for review: SMH all hands email COVID update
Importance: High

Sandy Walsh
Acting Director
Office of Editorial and Creative Services
Office of External Affairs
U.S. Food and Drug Administration
Tel: 301-796-4669
Sandy.Walsh@fda.hhs.gov



From: Walsh, Sandy
Sent: Thursday, March 5, 2020 12:47 PM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Cc: Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>; Leggin, Brooke <Brooke.Leggin@fda.hhs.gov>
Subject: LAURA - for review: SMH all hands email COVID update
Importance: High

Hi Laura,

SJ has reviewed and I incorporated her edits. Please let me know your thoughts. Once you have reviewed I'll put into JIC clearance.

Also pasted the text below:

DRAFT – ALL HANDS MESSAGE FROM DR. HAHN TO STAFF

SUBJECT: Update on FDA's efforts around COVID-19

DATE: Target Friday March 6

(b) (5)

(b) (5)

Sincerely,

Stephen M. Hahn
Commissioner of Food and Drugs

Draft, SWalsh, OECS, 3/5/2020
Edited/Reviewed, SJLynch, OEA, 3/5/2020

Sandy Walsh
Acting Director
Office of Editorial and Creative Services
Office of External Affairs
U.S. Food and Drug Administration
Tel: 301-796-4669
Sandy.Walsh@fda.hhs.gov



From: Caliguiri, Laura [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AA086F2D6C0346C49E996932D86AC62E-LAURA.CALIG]
Sent: 3/3/2020 7:25:35 AM
To: Stephanie Cacco (Stephanie.Cacco@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
Subject: FW: Coronavirus Talking Points 3.3
Attachments: Press Briefing by Vice President Pence and Members of the Coronavirus Task Force; What They Are Saying | Support for the White House Coronavirus Response ; Coronavirus 3.3.docx; Coronavirus Response Accomplishments FINAL.docx

From: Miller, Katie R. EOP/OVP <Katie.R.Miller@ovp.eop.gov>
Sent: Tuesday, March 3, 2020 7:24 AM
To: Miller, Katie R. EOP/OVP <Katie.R.Miller@ovp.eop.gov>
Cc: Devin.O'Malley@treasury.gov; Fetalvo, Ninio (CMS) <Ninio.Fetalvo@cms.hhs.gov>
Subject: Coronavirus Talking Points 3.3

Hi all – please find today's talking points labeled "Coronavirus 3.3" attached.

Also attached is:

- An ICYMI with a round-up of the coverage from the call with over 50 Governors, the Pharmaceutical Meeting at the White House and the Press Briefing.
- The Accomplishments document of this Administration's work to combat the Coronavirus that will be distributed to press this morning at **8AM ET**.
- The transcript of yesterday's press briefing with the VP, Secretary Azar, CDC Director Dr. Redfield, FDA Commissioner Dr. Hahn, NIAID Director Dr. Fauci.

As a look ahead for today:

- The President and VP will visit NIH to hear about the drug trials and therapeutics discussed in yesterday's meeting.
- The Vice President will meet with both Republican and Democrat Senate Caucus – a readout will be forthcoming from the Vice President's office.
- Members of the Task Force will hold a briefing in the White House press briefing room immediately following today's task force meeting at **5:30PM ET**.
- Dr. Fauci is on Good Morning America in the **7AM** hour.
- Seema Verma will be on TBC Fox News this evening.

Lastly, please welcome Ninio Fetalvo to the OVP Team, who has been detailed over from CMS for the duration of the Coronavirus. He should have a working OVP email within the next couple days.

As a reminder we will have a communicators call this morning at 10:30AM.

Thanks,

—
Katie Miller
Press Secretary
Vice President Mike Pence
Cell: (b)(6)

From: Caliguiri, Laura [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AA086F2D6C0346C49E996932D86AC62E-LAURA.CALIG]
Sent: 2/19/2020 7:41:34 PM
To: Capobianco, Abigail [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=660b8e4204f74d4b912265b9c85613bd-Abigail.Cap]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]
CC: Leggin, Brooke [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c876a439c57d4d0abaa3c8898c803db3-Brooke.Leggin]; Ruberry, Erin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6eb9830932304426936396d5f70b4c04-Erin.Ruberry]; Humbert, Jason [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7e25fbc271284103869c8e8df8247417-Humbert]; Taube, Anthony C [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c91a978a6ae543b196fd4c189dcc762c-ATaube]; Montemurro, Ann M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7cd8f2a06ae04c2cbb1b432ade3a9b8d-ASCHOFIE]; Windt, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c120697b3879498d8bf3469fe8975fbb-DSW]; Walsh, Sandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c61503c4e7884fc28b9ef6cb8f2514ec-Sandy.Walsh]; Stephanie Caccomo (Stephanie.Caccomo@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
Subject: RE: OCC- CLEARED COVID-19 TWEETS FOR TODAY

Circling back, circled by LT and sent to Brad. Noting only one minor edit to include reference to Coronavirus in addition to COVID. Thank you all so much.

From: Capobianco, Abigail <Abigail.Capobianco@fda.hhs.gov>
Sent: Wednesday, February 19, 2020 6:09 PM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Cc: Leggin, Brooke <Brooke.Leggin@fda.hhs.gov>; Ruberry, Erin <Erin.Ruberry@fda.hhs.gov>; Humbert, Jason <Jason.Humbert@fda.hhs.gov>; Taube, Anthony C <Anthony.Taube@fda.hhs.gov>; Montemurro, Ann M <Ann.Montemurro@fda.hhs.gov>; Windt, David <David.Windt@fda.hhs.gov>; Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>
Subject: RE: OCC- CLEARED COVID-19 TWEETS FOR TODAY

Great, thank you!

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Sent: Wednesday, February 19, 2020 6:07 PM
To: Capobianco, Abigail <Abigail.Capobianco@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Cc: Leggin, Brooke <Brooke.Leggin@fda.hhs.gov>; Ruberry, Erin <Erin.Ruberry@fda.hhs.gov>; Humbert, Jason <Jason.Humbert@fda.hhs.gov>; Taube, Anthony C <Anthony.Taube@fda.hhs.gov>; Montemurro, Ann M <Ann.Montemurro@fda.hhs.gov>; Windt, David <David.Windt@fda.hhs.gov>; Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>
Subject: RE: OCC- CLEARED COVID-19 TWEETS FOR TODAY

Hi there
Thank you so we will send forward to Anna/KL next. Thank you. Laura

From: Caliguiri, Laura [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AA086F2D6C0346C49E996932D86AC62E-LAURA.CALIG]
Sent: 4/8/2020 11:24:34 AM
To: Brad Kimberly (Brad.Kimberly@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08bc909ed76d49868a5ff92c3c70fb72-Bradley.Kim]; Abigail Capobianco (Abigail.Capobianco@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=660b8e4204f74d4b912265b9c85613bd-Abigail.Cap]; Sarah Lynch (Sarah.Lynch@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d24ee4a4fc6241f48110d6b35e6704ed-Sarah.Lynch]
Subject: FW: President Trump is Supporting America's Patients and Heroic Healthcare Workers

From: Mitchell, Austin A. EOP/WHO (b)(6) >
Sent: Wednesday, April 8, 2020 10:41 AM
Subject: President Trump is Supporting America's Patients and Heroic Healthcare Workers

What You Need To Know | President Trump is Supporting America's Patients and Heroic Healthcare Workers

President Trump is providing support to the healthcare providers on the frontlines of this outbreak.

- The President signed bipartisan legislation that provides \$100 billion to hospitals and other healthcare providers on the front lines of the coronavirus response.
- \$30 billion is being distributed immediately to healthcare providers.
 - Many providers could obtain these critical funds as early as this week.
- The Trump Administration has made it a priority to ensure this relief is going where needed most, including in hotspots and rural communities across the country that need support.

President Trump is working to ensure that American patients impacted by the virus have the support they deserve.

- The President has prioritized our nation's most vulnerable citizens by reimbursing hospitals for treating uninsured coronavirus patients.
- The Trump Administration is committed to ensuring Americans are not hit by surprise billing from the testing and treatment they need for COVID-19.
 - SECRETARY AZAR: "As a condition of receiving funds under this program, providers will be forbidden from balance billing the uninsured for the cost of their care. Providers will be reimbursed at Medicare rates."
- President Trump signed legislation to provide Americans with access to coronavirus tests for free.
- The President has secured agreements from major healthcare insurers like Humana, Cigna, and Blue Cross Blue Shield to waive out of pocket costs for coronavirus testing and treatment.

###

From: Caliguiri, Laura [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AA086F2D6C0346C49E996932D86AC62E-LAURA.CALIG]
Sent: 5/29/2020 4:25:35 PM
To: Frank Olivarria (Frank.Olivarria@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]
CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Colin Rom (Colin.Rom@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Dayle Cristinzio (Dayle.Cristinzio@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b5a8dc4e587946fa938714a962df4246-Dayle.Crist]
Subject: for H/W Monday Alliance speech/meeting
Attachments: Hahn FDA covid speech AW WP.1docx.docx

Here is Dr. Hahn's speech for Monday's Alliance for the Stronger FDA meeting. Below is the invitee list with approx. 80 rsvps, *including media*. The show flow is as follows:

Agenda

Via telecon only - 9:30 am Start

I Introduction by Ladd Wiley

II. Dr. Hahn will

-**Thank** the group for their time and hard work, especially during the pandemic and overall support for the Agency

-**Note** the intention of time together – to share insight about his role, priorities and how he is working during the Covid-19 Pandemic -- Finding Solutions, Applying Lessons Learned

-**Read** prepared speech

II. Once completed, he will hand back to Ladd. No q and a.

Name	Email	Organization	Notes
Steven Grossman	(b)(6)	Alliance for a Stronger FDA	
Reed Diskey		Alliance for a Stronger FDA	
Ladd Wiley		Alliance for a Stronger FDA	
Sue Peschin		Alliance for Aging Research	
Amanda Grimm			
Wiegrefe		American College of Rheumatology	
Donna Garren		American Frozen Food Institute	
Kimberly Walker		American Society for Microbiology	
Betsy Foss-		American Society of Gene & Cell	
Campbell		Therapy	
Jessica Skerritt		American Spice Trade Association	
Ron Phillips		Animal Health Institute	
		Association for Accessible	
David Gaugh		Medicines	
Kristin Palmer		Association for Clinical Oncology	
		Association of Clinical Research	
Elyssa Clauson		Organizations	
Matt Raymond		Astellas	
Susie Bergman		Audentes Therapeutics, Inc	
		Biotechnology Innovation	
John Murphy		Organization	
		Biotechnology Innovation	
Danielle Friend		Organization	

Camelia
Thompson

Victoria Dohnal
Jerry Phillips
Hermann Spicker
Nakos Balamotis
Scott Piergrossi
Cristina Milesi

Jon Bigelow
John Martin
Victoria Gemme
Betty Carillo
Laura Weidner
Molly McDonnell

Brigid Brennan
Deborah Walter
Jerry K Hagstrom
John Lewis
Miriam
Goldstein
Jordan Chapman

Beth Wang
Kelly Lienhard
Danielle Doheny
Carla Cartwright
Patricia Villani
Darrel Jodrey

Campbell Hutton
Brian Oscherwitz
Jason Harris
Travis Smith
Diane Gross
Joyce Frieden
Andrew Sperling

Rachel Sher
Lori Shogren
Andrew Rosen

(b)(6)

Biotechnology Innovation
Organization
Biotechnology Innovation
Organization
Brand Institute
Brand Institute
Brand Institute
Brand Institute
Brand Institute
Coalition for Healthcare
Communication
CRISPR Therapeutics
Cystic Fibrosis Foundation
E.C.G., Inc.
Epilepsy Foundation
Fight Colorectal Cancer
Friedreich's Ataxia Research
Alliance
Greenwich Biosciences
Hagstrom Report
Heart Valve Voice US

Media

Hemophilia Federation of America
Horizon Therapeutics
Individual

Individual
Individual
Individual
Individual
Individual

Inside Health Policy
Inside Health Policy
Media
Media

International Myeloma Foundation
Johnson & Johnson
Johnson & Johnson
Johnson & Johnson
Juvenile Diabetes Research
Foundation
Kinexum

Lupus Foundation of America
Lupus Foundation of America
Lupus Research Alliance

MedPage Today
Media

National Alliance on Mental Illness
National Association for Rare
Disorders

National Ataxia Foundation
National Ataxia Foundation

Lisa Weddig
Robert DeHaan

Kurt Vorndran
Cynthia Bens
Christopher Wells
Morgan Beach
Peter Tabor
Andrew Emmet
Erin Greene
Lucy
Vereshchagina
Mary Kosinski
David Lim
Michael
McCaughan

Michael Mezher
Mitzi Baum
Eva Hurt
Cathy Cochran
Jill Yersak
Sandra Eskin
Derrick Gingery
Sarah Karlin-
Smith
Kate Rawson
Sohail
Mosaddegh
Jennifer Devine

(b)(6)

National Fisheries Institute
National Fisheries Institute
National Treasury Employees
Union
Personalized Medicine Coalition

Personalized Medicine Coalition
Pet Food Institute
Pet Food Institute
Pfizer
Pfizer,

PhRMA
PhRMA
Politico Media

Prevision Policy Media
Regulatory Affairs Professional
Society Media

Stop Foodborne Illness
Sustainable Food Policy Alliance
Sustainable Food Policy Alliance
The ALS Association

The Pew Charitable Trusts
The Pink Sheet Media

The Pink Sheet Media
The RPM Report Media

United States Pharmacopeia
United States Pharmacopeia

Laura Caliguiri
Associate Commissioner for External Affairs

Office of External Affairs
U.S. Food and Drug Administration
Tel: 301 796-8546
Laura.Caliguiri@fda.hhs.gov



From: Caliguiri, Laura [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AA086F2D6C0346C49E996932D86AC62E-LAURA.CALIG]
Sent: 5/29/2020 2:00:52 PM
To: Sandy Walsh (Sandy.Walsh@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c61503c4e7884fc28b9ef6cb8f2514ec-Sandy.Walsh]; Cooper, Mildred [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa838567ff8147ffb5933a8a698133b0-Mildred.Coo]; Henriques, Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc46749df13d4d62addf0b0c02f6e6e0-Maria.Henri]
CC: Stephanie Caccamo (Stephanie.Caccamo@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Michael Felberbaum (Michael.Felberbaum@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]
Subject: FW: Clean CU and Voices
Attachments: Revised CU Treatments and Terms 05292020_144pm.docx; Revised HCQ voices_5.29.20_142pm.docx

OECS Team

Thanks for moving this forward. Sandy, appreciate you sending to Social. Would you ask them to send drafts back to me, Michael and Stephanie before moving forward to post? Can you give an ETA of post time closer to when it is going? TY.
Laura

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Sent: Friday, May 29, 2020 1:51 PM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Cc: Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>
Subject: Clean CU and Voices

Michael Felberbaum
Senior Advisor

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-9548 / Cell: (b)(6)
michael.felberbaum@fda.hhs.gov



From: Caliguiri, Laura [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AA086F2D6C0346C49E996932D86AC62E-LAURA.CALIG]
Sent: 5/29/2020 11:46:22 AM
To: Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]; Sipes, Grail [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ccee8d18ee1f4a36885078f780c2f2f8-SIPESG]; Beers, Donald [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d079bf15a01744bd94687d6718ca4c42-Donald.Beer]; Stacy Amin (Stacy.Amin@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Anand Shah (Anand.Shah@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
CC: Sandy Walsh (Sandy.Walsh@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c61503c4e7884fc28b9ef6cb8f2514ec-Sandy.Walsh]; Michael Felberbaum (Michael.Felberbaum@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Colin Rom (Colin.Rom@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: for urgent CDER/OCC review 1:30pm today
Attachments: Revised HCQ voices_5.29.20_1056am.docx; Revised528cr as hcq statement 5.28.20_1133am.docx; Revised CU Treatments and Terms 05282020.docx

Colleagues

Attached for your review/clearance is the Commissioner's revised Voices, the Consumer Update and Reactive Only Statement. He has cleared all and would like us to post today. Can you please provide any feedback by 1:45pm. If you cannot make that timeline, please let me know your timeframe and/or defer to a colleague. I appreciate it and thank you in advance.

Laura

Laura Caliguiri
Associate Commissioner for External Affairs

Office of External Affairs
U.S. Food and Drug Administration
Tel: 301 796-8546
Laura.Caliguiri@fda.hhs.gov



From: Caliguiri, Laura [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AA086F2D6C0346C49E996932D86AC62E-LAURA.CALIG]
Sent: 5/28/2020 6:22:08 PM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Pines, Wayne [WPines@apcoworldwide.com]; Anand Shah (Anand.Shah@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Colin Rom (Colin.Rom@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Molly Block (Molly.Block@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e32ca68078848889751e7ec26910142-Molly.Block]
CC: Michael Felberbaum (Michael.Felberbaum@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Stephanie Caccamo (Stephanie.Caccamo@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
Subject: RE: follow up Voice/CU/Statement
Attachments: Revised CU Treatments and Terms 05282020.docx; Revised HCQ voices_5.28.20_525pm.docx; Revised528cr as hcq statement 5.26.20_1140am (003).docx

Resending attachments

From: Caliguiri, Laura
Sent: Thursday, May 28, 2020 6:18 PM
To: Hahn, Stephen <sh1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Pines, Wayne <wpines@apcoworldwide.com>; Anand Shah (Anand.Shah@fda.hhs.gov) <Anand.Shah@fda.hhs.gov>; Colin Rom (Colin.Rom@fda.hhs.gov) <Colin.Rom@fda.hhs.gov>; Molly Block (Molly.Block@fda.hhs.gov) <Molly.Block@fda.hhs.gov>
Cc: Michael Felberbaum (Michael.Felberbaum@fda.hhs.gov) <Michael.Felberbaum@fda.hhs.gov>; Stephanie Caccamo (Stephanie.Caccamo@fda.hhs.gov) <Stephanie.Caccamo@fda.hhs.gov>
Subject: follow up Voice/CU/Statement

Attached are 3 documents for your review:

- 1) Revised Voices
- 2) Revised Consumer Update
- 3) Revised Reactive Statement

Once this group reviews and clears, we can move to agency clearance noting that we ought to anticipate feedback. Depending on our turnaround, we can put into clearance for tomorrow with a short suspense clearance window. We can courtesy notice ASPA and then post.

In the meantime, we are prepared to push the Voices and Consumer Update through the following channels:

- Stakeholder Newsletter (Published Fridays, subscription-based of 75,000 heavily healthcare professionals)
- Office of Patient Affairs Distro (companion list to our health care providers with a patient focus)
- Medscape (100,000s of 1000s subscription based with MOU relationship)

Additionally,

- Include overarching narrative in media interview/responses
- Pitch Interview (Written/Pre-taped) to Medscape for distribution (longer lead)
- Survey Targeted Patient Groups to measure their member feedback and provide Voices/Consumer Update for distribution

- Academy of Rheumatology
Arthritis Foundation
- Lupus Foundation of America
- National Consumer League
- NORD

On behalf of Stephanie, Michael and myself,
Laura

Laura Caliguiri
Associate Commissioner for External Affairs

Office of External Affairs
U.S. Food and Drug Administration
Tel: 301 796-8546
Laura.Caliguiri@fda.hhs.gov



From: Caliguiri, Laura [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AA086F2D6C0346C49E996932D86AC62E-LAURA.CALIG]
Sent: 5/28/2020 6:18:17 PM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Pines, Wayne [WPines@apcoworldwide.com]; Anand Shah (Anand.Shah@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Colin Rom (Colin.Rom@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Molly Block (Molly.Block@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e32ca68078848889751e7ec26910142-Molly.Block]
CC: Michael Felberbaum (Michael.Felberbaum@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Stephanie Caccamo (Stephanie.Caccamo@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
Subject: follow up Voice/CU/Statement
Attachments: Revised CU Treatments and Terms 05282020.docx; Revised HCQ voices_5.28.20_525pm.docx; Revised HCQ voices_5.28.20_525pm.docx

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- Survey Targeted Patient Groups to measure their member feedback and provide Voices/Consumer Update for distribution

- Academy of Rheumatology

Arthritis Foundation

- Lupus Foundation of America

- National Consumer League

- NORD

On behalf of Stephanie, Michael and myself,
Laura

Laura Caliguiri
Associate Commissioner for External Affairs

Office of External Affairs
U.S. Food and Drug Administration
Tel: 301 796-8546
Laura.Caliguiri@fda.hhs.gov

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FDA-OC-2020-1977/2020-4765-001225

MULTI-HHS-FDA-20-0400, 20-0415-C-000233



From: Caliguiri, Laura [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AA086F2D6C0346C49E996932D86AC62E-LAURA.CALIG]
Sent: 5/28/2020 11:03:38 AM
To: Michael Felberbaum (Michael.Felberbaum@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]
Subject: speech
Attachments: Hahn FDA covid speech AW WP.1docx.docx

Laura Caliguiri
Associate Commissioner for External Affairs

Office of External Affairs
U.S. Food and Drug Administration
Tel: 301 796-8546
Laura.Caliguiri@fda.hhs.gov



From: Caliguiri, Laura [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AA086F2D6C0346C49E996932D86AC62E-LAURA.CALIG]
Sent: 5/26/2020 6:20:28 PM
To: Wilker, Michael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b44146bfe276479087e58001593976b0-HHS-Michael]; Foster, Timothy (OS/ASPA) [Timothy.Foster@hhs.gov]; Morgan Courbois [mcourbois@hhs.tv]
CC: Molly Block (Molly.Block@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e32ca68078848889751e7ec26910142-Molly.Block]
Subject: studio time tomorrow
Attachments: Hahn FDA covid speech AW WP.1docx.docx

Hi there

During Dr. Hahn's time tomorrow, we'd like to try to record the attached for teleprompter if he (and you) have time after the other two pieces.

Would that work for you all and we appreciate everything.

Laura

Laura Caliguiri
Associate Commissioner for External Affairs

Office of External Affairs
U.S. Food and Drug Administration
Tel: 301 796-8546
Laura.Caliguiri@fda.hhs.gov



From: Fetalvo, Ninio J. EOP/OVP (b)(6)
Sent: 4/16/2020 4:59:15 PM
To: Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; DL OVP Comms COVID (b)(6)
CC: Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Oakley, Caitlin B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8feed045e954557aa1e0052f925865f-HHS-Caitlin]; McKeogh, Katherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3facab3fd03480f8553892121fd2009-HHS-Katheri]; Block, Molly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e32ca68078848889751e7ec26910142-Molly.Block]; Peddicord, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=225d83cc787341deb87d23ac33b6fb6c-Sarah.Peddi]; Spaulding, Emma [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33e041de6759414a8de9511bec153a0c-Emma.Spauld]
Subject: RE: FDA Interview Request - WSJ - COVID Plasma Expanded Protocol

Sounds fine

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Sent: Thursday, April 16, 2020 4:54 PM
To: Fetalvo, Ninio J. EOP/OVP (b)(6) DL OVP Comms COVID (b)(6)
Cc: Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>; Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>; McKeogh, Katherine (OS) <Katherine.McKeogh@hhs.gov>; Block, Molly <Molly.Block@fda.hhs.gov>; Peddicord, Sarah <Sarah.Peddicord@fda.hhs.gov>; Spaulding, Emma <Emma.Spaulding@fda.hhs.gov>
Subject: RE: FDA Interview Request - WSJ - COVID Plasma Expanded Protocol

On the record. A little more technical than what's in the statement.

From: Fetalvo, Ninio J. EOP/OVP (b)(6)
Sent: Thursday, April 16, 2020 4:48 PM
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; DL OVP Comms COVID (b)(6)
Cc: Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>; Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>; McKeogh, Katherine (OS) <Katherine.McKeogh@hhs.gov>; Block, Molly <Molly.Block@fda.hhs.gov>; Peddicord, Sarah <Sarah.Peddicord@fda.hhs.gov>; Spaulding, Emma <Emma.Spaulding@fda.hhs.gov>
Subject: RE: FDA Interview Request - WSJ - COVID Plasma Expanded Protocol

On background?

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Sent: Thursday, April 16, 2020 3:19 PM
To: DL OVP Comms COVID <(b)(6)@ovp.eop.gov>
Cc: Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>; Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>; McKeogh, Katherine (OS) <Katherine.McKeogh@hhs.gov>; Block, Molly <Molly.Block@fda.hhs.gov>; Peddicord, Sarah <Sarah.Peddicord@fda.hhs.gov>; Spaulding, Emma <Emma.Spaulding@fda.hhs.gov>
Subject: FDA Interview Request - WSJ - COVID Plasma Expanded Protocol

Please see below phone interview request from WSJ to speak with Dr. Peter Marks, director, FDA Center for Biologics Evaluation and Research regarding the COVID convalescent plasma expanded access protocol. We would like to schedule the interview for tomorrow.

Reporter: Amy Marcus

Organization: The Wall Street Journal

Phone #(s): N/A

Subject: COVID Convalescent Plasma

Deadline: 10am, Friday, April 17

Spokesperson: Dr. Peter Marks, director, FDA Center for Biologics Evaluation and Research, in telephone interview

Additional information: From the reporter: "I'm working on a deadline story for WSJ about the expanded access convalescent plasma program. I am interested in speaking with him about the wider issue of using real world data as a way of learning about new products/therapies outside of a randomized controlled trial. In what ways might the protocol devised for the expanded access convalescent therapy program fit into this larger landscape of mining data from real world use?" Dr. Marks will discuss using talking points from the following announcement: >>[>>https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-coordinates-national-effort-develop-blood-related-therapies-covid-19](https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-coordinates-national-effort-develop-blood-related-therapies-covid-19)<<.

Thanks!

Michael

Michael Felberbaum
Senior Advisor

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-9548 / Cell: (b)(6)
michael.felberbaum@fda.hhs.gov



From: O'Malley, Devin M. EOP/OVP [Devin.M.O'Malley@ovp.eop.gov]
Sent: 4/8/2020 2:52:33 AM
To: Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]
CC: DL OVP Comms COVID (b)(6); Oakley, Caitlin B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8feed045e954557aa1e0052f925865f-HHS-Caitlin]; McKeogh, Katherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3facab3fd03480f8553892121fd2009-HHS-Katheri]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Hall, Bill (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e56218361cd4ffbaccdd06ac2d7b809d-HHS-bill.ha]; Robinson, Michael J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4118fde5239947c6bccbdbd4cb7488fa-HHS-michael]
Subject: Re: Newsweek Inquiry on Hydroxychloroquine

Ok

Sent from my iPhone

On Apr 7, 2020, at 10:53 PM, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov> wrote:

Hi all,

Newsweek just reached out for a story the reporter is planning to submit within the next hour. The reporter says the story is about President Trump's statements that hydroxychloroquine could be an excellent treatment for COVID-19 and is asking if the FDA working towards approving hydroxychloroquine for that purpose?

Suggest sharing the following information both on the record and on background.

(b) (5)

(b) (5)

Thank you,

Michael

Michael Felberbaum
Senior Advisor

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-9548 / Cell: (b)(6)
michael.felberbaum@fda.hhs.gov

<image013.png>

<image014.jpg>

<image015.jpg>

<image016.jpg>

<image017.jpg>

<image018.jpg>

From: Fetalvo, Ninio J. EOP/OVP (b)(6)
Sent: 4/3/2020 6:34:41 PM
To: Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; DL OVP Comms COVID [DL.OVP.CommsCOVID@ovp.eop.gov]
CC: Oakley, Caitlin B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8feed045e954557aa1e0052f925865f-HHS-Caitlin]; McKeogh, Katherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3facab3fd03480f8553892121fd2009-HHS-Katheri]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Hall, Bill (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e56218361cd4ffbaccdd06ac2d7b809d-HHS-bill.ha]; Robinson, Michael J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4118fde5239947c6bccbdbd4cb7488fa-HHS-michael]
Subject: RE: FDA Interview Request - Reuters - (Hydroxy)chloroquine EUA

ok

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Sent: Friday, April 3, 2020 5:24 PM
To: DL OVP Comms COVID (b)(6)
Cc: Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>; McKeogh, Katherine (OS) <Katherine.McKeogh@hhs.gov>; Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>; Hall, Bill (OS) <bill.hall@hhs.gov>; Robinson, Michael J (OS) <michael.robinson@hhs.gov>
Subject: RE: FDA Interview Request - Reuters - (Hydroxy)chloroquine EUA

Bumping.

From: Felberbaum, Michael
Sent: Friday, April 03, 2020 2:35 PM
To: DL OVP Comms COVID (b)(6)
Cc: Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>; McKeogh, Katherine (OS) <Katherine.McKeogh@hhs.gov>; Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>; Hall, Bill (OS) <bill.hall@hhs.gov>; Robinson, Michael J (OS) <michael.robinson@hhs.gov>
Subject: RE: FDA Interview Request - Reuters - (Hydroxy)chloroquine EUA

Re-upping – looking to get back to the reporter ASAP.

From: Felberbaum, Michael
Sent: Friday, April 03, 2020 1:47 PM
To: DL OVP Comms COVID (b)(6)
Cc: Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>; McKeogh, Katherine (OS) <Katherine.McKeogh@hhs.gov>; Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>; Hall, Bill (OS) <bill.hall@hhs.gov>; Robinson, Michael J (OS) <michael.robinson@hhs.gov>
Subject: RE: FDA Interview Request - Reuters - (Hydroxy)chloroquine EUA

Hi all –

Flagging the below written responses related to the same Reuters story that HHS sent up content on yesterday.

Michael

Michael Felberbaum
Senior Advisor

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-9548 / Cell: (b)(6)
michael.felberbaum@fda.hhs.gov



From: Robinson, Michael J (HHS/ASPA) <michael.robinson@hhs.gov>

Sent: Friday, April 03, 2020 12:29 PM

To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; OS - Interviews <interviews@hhs.gov>; ODOCPL Interviews (NIH/OD OCPL) (b)(6) <(b)(6)>; ASPRMEDIA (OS/ASPR/COO) <ASPRMEDIA@hhs.gov>; Bialek, Stephanie M (CDC) <ilq8@cdc.gov>; CDC OADC Media Review <OADCMediaReview@cdc.gov>

Cc: OC OEA OMA-Press <OCOEAOAOMA-Press@fda.hhs.gov>; Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>; McKeogh, Katherine (OS) <Katherine.McKeogh@hhs.gov>; Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>

Subject: RE: FDA Interview Request - Reuters - (Hydroxy)chloroquine EUA

Ok

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>

Sent: Friday, April 3, 2020 12:25 PM

To: OS - Interviews <interviews@hhs.gov>

Cc: OCOEAOMA-Press (FDA) <OCOEAOAOMA-Press@fda.hhs.gov>; Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>; McKeogh, Katherine (OS/ASPA) <Katherine.McKeogh@hhs.gov>; Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>

Subject: FDA Interview Request - Reuters - (Hydroxy)chloroquine EUA

ASPA Media Interview Request

Reporter: Aram Roston/Marisa Taylor

Organization: Reuters

Phone #(s): N/A

Subject: (Hydroxy)chloroquine EUA

Deadline: ASAP, Friday, April 3

Spokesperson: FDA Office of Media Affairs, in written response

Additional information: From what we understand, the story is focusing – similar to other stories from other outlets – that there’s been pressure to allow for the use of these drugs for unapproved use and taking a deeper look at the development of the EUA. We are providing a general response (previously cleared for NYT) and then answers to specific questions. Reporter has also been working with ASPA/ASPR/BARDA on additional responses to specific questions in their lane.

Proposed Response:

(b) (5)

1. On what date did ASPR file a request for the EUA that the FDA issued on March 28?

(b) (5)

2. What countries are being referred to here: “Based upon limited in-vitro and anecdotal clinical data in case series, chloroquine phosphate and hydroxychloroquine sulfate are currently recommended for treatment of hospitalized COVID-19 patients in several countries, and a number of national guidelines report incorporating recommendations regarding use of chloroquine phosphate or hydroxychloroquine sulfate in the setting of COVID-19.”?

(b) (5)

3. Does the mention of “national guidelines” in the EUA letter include the CDC information for clinicians?

(b) (5)

Michael Felberbaum
Senior Advisor

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-9548 / Cell: (b)(6)
michael.felberbaum@fda.hhs.gov

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FDA-OC-2020-1977/2020-4765-001235

MULTI-HHS-FDA-20-0400, 20-0415-C-000243

From: Fetalvo, Ninio J. EOP/OVP (b)(6)
Sent: 4/3/2020 6:17:20 PM
To: Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; DL OVP Comms COVID (b)(6)
Subject: RE: FDA Interview Request - WIRED - COVID Plasma Therapy

Ok

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Sent: Friday, April 3, 2020 5:24 PM
To: Fetalvo, Ninio J. EOP/OVP <(b)(6)>; DL OVP Comms COVID (b)(6)
Subject: RE: FDA Interview Request - WIRED - COVID Plasma Therapy

Backgrounder went well – reporter asking to move the following quote to on the record from Dr. Marks:

"If there's anything that can come out of a catastrophe like COVID-19 is that you had government, industry, and academics all working together to make something really good happen. This is really something I think we can be quite proud of."

Please advise.

From: Fetalvo, Ninio J. EOP/OVP (b)(6)
Sent: Friday, April 03, 2020 3:15 PM
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; DL OVP Comms COVID (b)(6)
Subject: RE: FDA Interview Request - WIRED - COVID Plasma Therapy

Good

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Sent: Friday, April 3, 2020 2:33 PM
To: Fetalvo, Ninio J. EOP/OVP <(b)(6)> DL OVP Comms COVID (b)(6)
Subject: RE: FDA Interview Request - WIRED - COVID Plasma Therapy

(b) (5)

From: Felberbaum, Michael
Sent: Friday, April 03, 2020 2:07 PM
To: 'Fetalvo, Ninio J. EOP/OVP' <(b)(6)>; DL OVP Comms COVID
<(b)(6)>
Subject: RE: FDA Interview Request - WIRED - COVID Plasma Therapy

Will circle back with high level responses – standby.

From: Fetalvo, Ninio J. EOP/OVP <(b)(6)>
Sent: Friday, April 03, 2020 1:47 PM
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; DL OVP Comms COVID
(b)(6)
Subject: RE: FDA Interview Request - WIRED - COVID Plasma Therapy

What will be said in response to these?

I'd prefer (b) (5)

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Sent: Friday, April 3, 2020 1:44 PM
To: Fetalvo, Ninio J. EOP/OVP <(b)(6)> DL OVP Comms COVID
(b)(6)
Subject: RE: FDA Interview Request - WIRED - COVID Plasma Therapy

He's interested in how this work all came together, what the organizing has been like, and how your team thought about the protocols FDA needed to see so the trials would be safe and effective, and produce usable results.

Can be on background if preferred – please advise.

From: Fetalvo, Ninio J. EOP/OVP (b)(6)
Sent: Friday, April 03, 2020 1:37 PM
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; DL OVP Comms COVID
<(b)(6)>
Subject: RE: FDA Interview Request - WIRED - COVID Plasma Therapy

Is this on background? Are they looking for anything specific not outlined in the release?

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Sent: Friday, April 3, 2020 1:18 PM
To: DL OVP Comms COVID <(b)(6)>
Subject: FW: FDA Interview Request - WIRED - COVID Plasma Therapy

FYI

Michael Felberbaum
Senior Advisor

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-9548 / Cell: (b)(6)
michael.felberbaum@fda.hhs.gov



From: Robinson, Michael J (HHS/ASPA) <michael.robinson@hhs.gov>
Sent: Friday, April 03, 2020 1:16 PM
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; OS - Interviews (b)(6)
Cc: OC OEA OMA-Press (b)(6) >
Subject: RE: FDA Interview Request - WIRED - COVID Plasma Therapy

Ok

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Sent: Friday, April 3, 2020 1:09 PM
To: OS - Interviews (b)(6)
Cc: OCOEAOMA-Press (FDA) <(b)(6)>
Subject: FDA Interview Request - WIRED - COVID Plasma Therapy

ASPA Media Interview Request

Reporter: Adam Rogers

Organization: WIRED

Phone #(s): N/A

Subject: COVID Plasma Therapies

Deadline: 2 p.m. Friday, April 3

Spokesperson: Dr. Peter Marks, director of FDA's Center for Biologics Evaluation and Research, in telephone interview.

Additional information: Dr. Marks will discuss contents of today's press release:

>>>>[<<<<https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-coordinates-national-effort-develop-blood-related-therapies-covid-19](https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-coordinates-national-effort-develop-blood-related-therapies-covid-19)<<<<;;

Michael Felberbaum
Senior Advisor

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-9548 / Cell: (b)(6)
michael.felberbaum@fda.hhs.gov



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FDA-OC-2020-1977/2020-4765-001239

MULTI-HHS-FDA-20-0400, 20-0415-C-000247

From: Fetalvo, Ninio J. EOP/OVP (b)(6)
Sent: 3/27/2020 7:40:36 PM
To: Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]
CC: DL OVP Comms COVID (b)(6); Hall, Bill (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e56218361cd4ffbacdd06ac2d7b809d-HHS-bill.ha]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Oakley, Caitlin B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8feed045e954557aa1e0052f925865f-HHS-Caitlin]; McKeogh, Katherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3facab3fd03480f8553892121fd2009-HHS-Katheri]; Robinson, Michael J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4118fde5239947c6bccbdbd4cb7488fa-HHS-michael]
Subject: Re: URGENT Inquiry from Politico re: hydroxychloroquine/chloroquine

Good

—
Ninio J.H. Fetalvo
Office of the Vice President
(b)(6)

On Mar 27, 2020, at 7:32 PM, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov> wrote:

Hi all –

We have an inquiry from Politico reaching out regarding hydroxychloroquine/chloroquine – both on POTUS remarks at presser and sources saying that WH is directing FDA to issue emergency use authorization for the drugs for COVID patients.

We do not have any specifics to share on any potential EUAs on this topic, but have shared the response below for other inquiries on hydroxychloroquine/chloroquine broadly.

The FDA remains actively engaged with partners across the U.S. government, academia and regulated industry to expedite the development and availability of critical medical products to prevent and treat this novel virus – including collecting data in a variety of ways to both evaluate the safety and efficacy of potential therapies and facilitate emergency access for patients, as appropriate. This includes work to investigate the use of the drugs hydroxychloroquine and chloroquine, which are already approved for treating malaria, lupus and rheumatoid arthritis, to determine whether they can be used to treat patients with mild-to-moderate COVID-19 and potentially reduce the duration of symptoms, as well as viral shedding, which can help prevent the spread of disease.

The reporter is on immediate deadline – please advise if OVP is OK with this response or if we should refer to OVP or WH. I can also share reporter contact info if you'd like to reach out directly.

Thanks,

Michael
Michael Felberbaum
Senior Advisor

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-9548 / Cell: (b)(6)
michael.felberbaum@fda.hhs.gov

<image013.png>

<image014.jpg>

<image015.jpg>

<image016.jpg>

<image017.jpg>

<image018.jpg>

From: O'Malley, Devin M. EOP/OVP [Devin.M.O'Malley@ovp.eop.gov]
Sent: 3/21/2020 2:43:47 PM
To: McGowan, Robert K (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e6175b088b1d49a4bfa2de3862800d4a-HHS-omc2-cd]; McGuffee, Tyler A. EOP/OVP (b)(6) Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Miller, Katie R. EOP/OVP [Katie.R.Miller@ovp.eop.gov]
CC: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Lane, Henry C (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d904337536cf41719032a9359a1ec2ab-HHS-CLANE-n]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: RE: NEEDS FINAL AFFIRMATIVE CLEARANCE RE: Treatment Document

My understanding is that our approval was the final outstanding approval, so if that's correct then yes.

From: McGowan, Robert (Kyle) (CDC/OD/OCS) <omc2@cdc.gov>
Sent: Saturday, March 21, 2020 2:42 PM
To: O'Malley, Devin M. EOP/OVP (b)(6); McGuffee, Tyler A. EOP/OVP (b)(6); Hahn, Stephen <SH1@fda.hhs.gov>; Birx, Deborah L. EOP/NSC (b)(6); Fauci, Anthony (NIH/NIAID) [E] (b)(6); Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>; Miller, Katie R. EOP/OVP (b)(6)
Cc: Rom, Colin (FDA/OC) <Colin.Rom@fda.hhs.gov>; Lane, Cliff (NIH/NIAID) [E] (b)(6); Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>
Subject: Re: NEEDS FINAL AFFIRMATIVE CLEARANCE RE: Treatment Document

Is the CDC cleared to post this on our website?

Get Outlook for iOS

From: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>
Sent: Saturday, March 21, 2020 2:38:18 PM
To: McGuffee, Tyler A. EOP/OVP (b)(6); Hahn, Stephen <SH1@fda.hhs.gov>; Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>; Fauci, Anthony (NIH/NIAID) [E] (b)(6); Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>; Miller, Katie R. EOP/OVP <Katie.R.Miller@ovp.eop.gov>
Cc: Rom, Colin (FDA/OC) <Colin.Rom@fda.hhs.gov>; McGowan, Robert (Kyle) (CDC/OD/OCS) <omc2@cdc.gov>; Lane, Cliff (NIH/NIAID) [E] (b)(6); Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: NEEDS FINAL AFFIRMATIVE CLEARANCE RE: Treatment Document

Good. Just want to make sure that the appropriate comms teams know that we want to see the content that promotes this before it goes out. Thanks!

From: McGuffee, Tyler A. EOP/OVP (b)(6)
Sent: Saturday, March 21, 2020 2:26 PM
To: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>; Fauci, Anthony S (NIH) (b)(6); Redfield, Robert R (CDC) <olx1@cdc.gov>; Miller, Katie R. EOP/OVP <Katie.R.Miller@ovp.eop.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; McGowan, Robert K (CDC) <omc2@cdc.gov>; Lane, Henry C (NIH)

<(b)(6)>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Subject: RE: NEEDS FINAL AFFIRMATIVE CLEARANCE RE: Treatment Document

Message from Dr. Stephen Hahn to all:

Attached is the FINAL v9. Dr. Hahn and Devin O'Malley just met in person and made the following changes:

(b) (5)

Pushing this back to OVP Comms for final affirmative clearance. Please advise when approved by OVP Comms we are ready for OVP comms to coordinate with Dr. Redfield, CDC communications and others on publication.

Sincerely,
TAM

Tyler Ann McGuffee
Assistant to Ambassador Birx, M.D.
Office of the White House Coronavirus Response Coordinator
Associate Advisor to the Office of the Vice President
C: (b)(6)

From: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>

Sent: Saturday, March 21, 2020 1:59 PM

To: McGuffee, Tyler A. EOP/OVP <(b)(6)>; Hahn, Stephen <SH1@fda.hhs.gov>; Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>; Fauci, Anthony S (NIH) <(b)(6)>; Redfield, Robert R (CDC) <olx1@cdc.gov>; Miller, Katie R. EOP/OVP <Katie.R.Miller@ovp.eop.gov>

Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; McGowan, Robert K (CDC) <omc2@cdc.gov>; Lane, Henry C (NIH)

<(b)(6)>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Subject: RE: NEEDS FINAL AFFIRMATIVE CLEARANCE RE: Treatment Document

Some thoughts attached. I don't know if there's an established format for such a doc, so I didn't want to mess with it too much.

From: McGuffee, Tyler A. EOP/OVP <(b)(6)>

Sent: Saturday, March 21, 2020 1:14 PM

To: Hahn, Stephen <SH1@fda.hhs.gov>; Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>; Fauci, Anthony S (NIH) <(b)(6)>; Redfield, Robert R (CDC) <olx1@cdc.gov>; Miller, Katie R. EOP/OVP <Katie.R.Miller@ovp.eop.gov>; O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>

Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; McGowan, Robert K (CDC) <omc2@cdc.gov>; Lane, Henry C (NIH)

<(b)(6)>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Subject: RE: NEEDS FINAL AFFIRMATIVE CLEARANCE RE: Treatment Document

Message from Dr. Stephen Hahn to OVP Comms:

Attached is the FINAL information for clinicians regarding treatment of COVID-19 patients. This has been reviewed and approved by the principals in the "To:" line.

When approved by OVP Comms we are ready for you to coordinate with Dr. Redfield, CDC communications and others on publication.

Sincerely,
TAM

Tyler Ann McGuffee
Assistant to Ambassador Birx, M.D.
Office of the White House Coronavirus Response Coordinator
Associate Advisor to the Office of the Vice President
C: (b)(6)

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Saturday, March 21, 2020 12:48 PM
To: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@ (b)(6)> Lane, Henry C (NIH) <(b)(6)> McGuffee, Tyler A. EOP/OVP (b)(6); Fauci, Anthony S (NIH) (b)(6); Redfield, Robert R (CDC) <olx1@cdc.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; McGowan, Robert K (CDC) <omc2@cdc.gov>
Subject: Re: NEEDS FINAL AFFIRMATIVE CLEARANCE RE: Treatment Document

(b) (5)

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Date: March 21, 2020 at 12:40:16 PM EDT
To: Lane, Henry C (NIH) (b)(6), McGuffee, Tyler A. EOP/OVP <(b)(6)>, Fauci, Anthony S (NIH) (b)(6), Hahn, Stephen <SH1@fda.hhs.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>, McGowan, Robert K (CDC) <omc2@cdc.gov>
Subject: Re: NEEDS FINAL AFFIRMATIVE CLEARANCE RE: Treatment Document

(b) (5)

deb

From: "Lane, Cliff (NIH/NIAID) [E]" (b)(6)
Date: Saturday, March 21, 2020 at 12:31 PM
To: "McGuffee, Tyler A. EOP/OVP" <(b)(6)>, "Fauci, Anthony (NIH/NIAID) [E]" <(b)(6)>, "Hahn, Stephen" <SH1@fda.hhs.gov>, "Birx, Deborah L. EOP/NSC" <(b)(6)>, "Redfield, Robert R. (CDC/OD)" <olx1@cdc.gov>
Cc: "Rom, Colin (FDA/OC)" <Colin.Rom@fda.hhs.gov>, "McGowan, Robert (Kyle) (CDC/OD/OCS)" <omc2@cdc.gov>
Subject: Re: NEEDS FINAL AFFIRMATIVE CLEARANCE RE: Treatment Document

I realize I am on the cc line, however I have three comments and have tracked suggestions:

(b) (5)
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FDA-OC-2020-1977/2020-4765-001244

MULTI-HHS-FDA-20-0400, 20-0415-C-000252

(b) (5)

Cliff Lane

From: "McGuffee, Tyler A. EOP/OVP" (b)(6)
Date: Saturday, March 21, 2020 at 11:33 AM
To: Anthony Fauci (b)(6), "Hahn, Stephen" <SH1@fda.hhs.gov>, "Birx, Deborah L. EOP/NSC" <Deborah.L.Birx@nsc.eop.gov>, "Redfield, Robert R. (CDC/OD)" <olx1@cdc.gov>
Cc: "Lane, Cliff (NIH/NIAID) [E]" <(b)(6)> "Rom, Colin (FDA/OC)" <Colin.Rom@fda.hhs.gov>, "McGowan, Robert (Kyle) (CDC/OD/OCS)" <omc2@cdc.gov>
Subject: NEEDS FINAL AFFIRMATIVE CLEARANCE RE: Treatment Document

Per Dr. Hahn, V6 attached for FINAL approval. Please REPLY ALL with affirmative clearance.

Sincerely,
TAM

Tyler Ann McGuffee
Assistant to Ambassador Birx, M.D.
Office of the White House Coronavirus Response Coordinator
Associate Advisor to the Office of the Vice President
C: (b)(6) [no text]

From: Fauci, Anthony (NIH/NIAID) [E] (b)(6)
Sent: Friday, March 20, 2020 7:47 PM
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>; Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>; Lane, Cliff (NIH/NIAID) [E] <(b)(6)>; McGuffee, Tyler A. EOP/OVP <Tyler.A.McGuffee2@ovp.eop.gov>; Rom, Colin (FDA/OC) <Colin.Rom@fda.hhs.gov>
Subject: RE: Treatment Document

Sounds good to me.
Thanks,
Tony

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Friday, March 20, 2020 7:36 PM
To: Fauci, Anthony (NIH/NIAID) [E] (b)(6)
Cc: Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>; Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>; Lane, Cliff (NIH/NIAID) [E] <(b)(6)> tyler.a.mcgufee2@ovp.eop.gov; Rom, Colin (FDA/OC) <Colin.Rom@fda.hhs.gov>
Subject: Re: Treatment Document

Tony,

(b) (5)

We would like to meet up prior to or after the task force meeting tomorrow. Sound OK?
Steve

Sent from my iPad

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FDA-OC-2020-1977/2020-4765-001245

MULTI-HHS-FDA-20-0400, 20-0415-C-000253

On Mar 20, 2020, at 7:06 PM, Hahn, Stephen <SH1@fda.hhs.gov> wrote:

(b) (5)

Thanks
Steve

Sent from my iPad

On Mar 20, 2020, at 6:45 PM, Fauci, Anthony (NIH/NIAID) [E] (b)(6) wrote:

Team:

As per my discussion with Steve a few minutes ago (b) (5)

Please take a look and Steve said that he would like to set up a quick call to discuss after you have had a look. I am very sorry to come in with these changes at this late point, but I really did not get a chance to have a good look at the document as I was in a car.

Thanks,
Tony

Anthony S. Fauci, MD
Director
National Institute of Allergy and Infectious Diseases

(b) (6)

National Institutes of Health
Bethesda, MD 20892-2520
Phone: (b) (6)
FAX: (301) 496-4409
E-mail: (b) (6)

The information in this e-mail and any of its attachments is confidential and may contain sensitive information. It should not be used by anyone who is not the original intended recipient. If you have received this e-mail in error please inform the sender and delete it from your mailbox or any other storage devices. The National Institute of Allergy and Infectious Diseases (NIAID) shall not accept liability for any statements made that are the sender's own and not expressly made on behalf of the NIAID by one of its representatives.

<dbInformation for Clinicians on COVID-19 Therapies31hcl - with Fauci and Lane tracked changes showing.docx>
<dbInformation for Clinicians on COVID-19 Therapies31hcl - with Fauci and Lane tracked Clean copy.docx>

From: O'Malley, Devin M. EOP/OVP [Devin.M.O'Malley@ovp.eop.gov]
Sent: 3/21/2020 3:22:05 PM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: McGuffee, Tyler A. EOP/OVP (b)(6)
Subject: Fwd: For WH Clearance: COVID-19: HHS funds Phase 2/3 clinical trial for potential treatment for COVID-19
Attachments: ASPR News Release nCoV plus up on Regeneron clinical trial_finalfinal.docx; ATT00001.htm

Sent from my iPhone

Begin forwarded message:

From: "Lemar, Naweed (OS/ASPA)" <Naweed.Lemar@hhs.gov>
Date: March 20, 2020 at 7:05:09 PM EDT
To: "Fetalvo, Ninio J. EOP/OVP" <(b)(6)>, "O'Malley, Devin M. EOP/OVP" <(b)(6)>
Cc: "Hall, Bill (HHS/ASPA)" <bill.hall@hhs.gov>, "Murphy, Ryan (OS/ASPA)" <Ryan.Murphy1@hhs.gov>, "Weber, Mark (HHS/ASPA)" <Mark.Weber@hhs.gov>, "Myrie, Simone (OS/ASPA)" <Simone.Myrie@hhs.gov>, "Robinson, Michael J (HHS/ASPA)" <michael.robinson@hhs.gov>, "Daniels, Carla (HHS/ASPA)" <Carla.Daniels@hhs.gov>, "Formoso, Paula (HHS/ASPA)" <Paula.Formoso@hhs.gov>, "Bradley, Tasha (OS/ASPA)" <Tasha.Bradley@hhs.gov>, "McKeogh, Katherine (OS/ASPA)" <Katherine.McKeogh@hhs.gov>, "Oakley, Caitlin B. (OS/ASPA)" <Caitlin.Oakley@HHS.GOV>
Subject: For WH Clearance: COVID-19: HHS funds Phase 2/3 clinical trial for potential treatment for COVID-19

Hello OVP folks,

This news release has been HHS cleared. (b) (5)

Thank you,

From: O'Malley, Devin M. EOP/OVP [Devin.M.O'Malley@ovp.eop.gov]
Sent: 5/8/2020 6:52:47 AM
To: John P Polowczyk (b)(6); Redd, John T (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d7be3c75e1c4375b5d6d2a315c581c5-HHS-John.Re]; Bix, Deborah L. EOP/NSC (b)(6); Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; (b)(6); Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; (b)(6); Ueland, Eric M. EOP/WHO [Eric.M.Ueland@who.eop.gov]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffb9dd983419fcd-HHS-olx1-cd]; (b)(6)
CC: Troye, Olivia EOP/NSC (b)(6)
Subject: Fwd: ADMIN FLAG: Scoop: Trump officials' dysfunction harms delivery of remdesivir

Sent from my iPhone

Begin forwarded message:

From: News Alerts <NewsAlerts@WHO.eop.gov>
Date: May 8, 2020 at 6:07:44 AM EDT
Subject: ADMIN FLAG: Scoop: Trump officials' dysfunction harms delivery of remdesivir

Scoop: Trump officials' dysfunction harms delivery of coronavirus drug

Axios

Jonathan Swan

May 7, 2020

<https://www.axios.com/trump-coronavirus-drug-remdesivir-hospitals-pharmacies-86ad5bd0-d1ba-47dc-97f2-b19cc97603f4.html>

A complete breakdown in communication and coordination within the Trump administration has undermined the distribution of a promising treatment, according to senior officials with direct knowledge of the discussions.

Why it matters: The drug, remdesivir, hasn't made it to some of the high-priority hospitals where it's most needed, and administration officials have responded by shifting blame and avoiding responsibility, sources said.

Where it stands: Gilead Sciences, the company that makes remdesivir, donated hundreds of thousands of doses to the federal government after the Food and Drug Administration authorized it as an emergency treatment for coronavirus patients.

- More than 32,000 doses of remdesivir were shipped and delivered on Tuesday to Indiana, Massachusetts, New Jersey, New York, Rhode Island, Tennessee and Virginia.
- But many of these doses went to "less impacted counties," an administration official said.

"Some went to the wrong places, some went to the right places," said one senior official. "We don't know who gave the order. And no-one is claiming responsibility."

Yes, but: That's only about 5% of the total doses that will be distributed.

Behind the scenes: Senior Trump administration officials, including Vice President Mike Pence and Coronavirus Response Coordinator Deborah Birx, were angered about what has transpired here.

- At Wednesday's meeting of the White House Coronavirus Task Force, Pence personally directed Health and Human Services Secretary Alex Azar to take more ownership for getting remdesivir to the places where it's needed, according to a source familiar with the meeting.
- In subsequent conversations with colleagues, Azar said he had not known about the arrangements that led to mass confusion and misaligned shipments the day before.
- Azar distanced himself from the debacle despite the fact that one of his top officials, assistant secretary for preparedness and response Robert Kadlec, was intimately involved in the distribution plan.

Between the lines: HHS was supposed to work with FEMA to allocate and distribute remdesivir to coronavirus hotspots around the U.S., but as the problems became apparent to the wider team on Wednesday, neither agency took responsibility.

- HHS was supposed to be the brains of the operation, using clinical expertise to allocate the drug to the places and hospitals around the country most in need, according a senior administration official, while FEMA was supposed to be the "arms and legs" putting that plan into action.
- But somewhere along the way, communication broke down. Thousands of doses were maldistributed, but as of Thursday, nobody was willing to put their name on this situation.

How it happened: The official said the criteria that determined where the drug was distributed was based off of outdated data, though it was nonetheless the best data the federal government had available

- The official added that this failure of distribution highlights the need for better data. "But it more importantly highlights the reason why the administration continues to push a locally-executed response effort, because they [the local jurisdictions] know the data and the distribution better than the federal government."
- The administration will use more stringent criteria to target the remaining doses to the patients most in need, a source familiar with the planning said.

This dysfunction and blame-shifting inside the Trump administration was vividly highlighted in a CNN [story](#) Thursday about how doctors and pharmacists have been struggling to understand the administration's process for distributing the drug, as the two agencies placed the ultimate responsibility for the plan on each other.

- As [CNN](#) and the [Wall Street Journal](#) have reported, health care leaders have been sounding the alarm over the Trump administration's lack of transparency in distributing remdesivir.

The backstory: This isn't the first time the Trump administration has descended into dysfunction over its handling of remdesivir.

- As Axios first reported, federal officials were slow to act on Gilead's request, in January, to send doses of the drug to China to begin clinical trials.

- The drug has shown promising initial results, at least at the margins, in some clinical trials. It appears to shorten some patients' hospital stays by about four days. Although the FDA hasn't yet fully approved the drug, it signed off last week on emergency use to treat coronavirus.
- Gilead then offered to donate more than 600,000 doses of remdesivir for the federal government to distributed to where it's most needed around the country.

What they're saying: "An initial allocation of the drug remdesivir was made to seven states on Tuesday, and—after consultation with health experts—HHS will be managing distribution of the next tranche of the treatment to 16 states tonight and tomorrow, based on urgent need," Devin O'Malley, a spokesman for the White House Coronavirus Task Force, told Axios.

- Trump administration officials worked throughout the day on Thursday on the distribution plan for its next batch of remdesivir.

From: "Polowczyk, John P RADM USN JS J4 (USA)" <(b)(6)>
Date: Wednesday, May 6, 2020 at 8:46 PM
To: "Kadlec, Robert (OS/ASPR/IO)" <Robert.Kadlec@hhs.gov>, "Birx, Deborah L. EOP/NSC" <(b)(6)>, "O'Malley, Devin M. EOP/OVP" <(b)(6)>
Cc: "Fauci, Anthony (NIH/NIAID) [E]" <(b)(6)>, "McGuffee, Tyler Ann A. EOP/OVP" <(b)(6)>, "Troye, Nsc" <(b)(6)>, "Amerau, Colin C LT USN JS J4 (USA)" <(b)(6)>, "Shuy, Bryan (OS/ASPR/IO)" <Bryan.Shuy@hhs.gov>, "Harrison, Brian (HHS/IOS)" <Brian.Harrison@hhs.gov>, "Mango, Paul (HHS/IOS)" <Paul.Mango@hhs.gov>, "Redd, John (OS/ASPR/SPPR)" <John.Redd@hhs.gov>, "Callahan, Victoria (OS/ASPR/IO) (CTR)" <Victoria.Callahan@hhs.gov>
Subject: Re: [Non-DoD Source] RE: remdesivir Distro Plan

Roger. Will dial in
Vr John

From: "Kadlec, Robert (OS/ASPR/IO)" <Robert.Kadlec@hhs.gov>
Date: Wednesday, May 6, 2020 at 8:35:54 PM
To: "Birx, Deborah L. EOP/NSC" <(b)(6)>, "O'Malley, Devin M. EOP/OVP" <(b)(6)>
Cc: "Fauci, Anthony (NIH/NIAID) [E]" <(b)(6)>, "Polowczyk, John P RADM USN JS J4 (USA)" <(b)(6)>, "McGuffee, Tyler Ann A. EOP/OVP" <(b)(6)>, "Troye, Olivia (nsc.eop.gov)" <(b)(6)>, "Amerau, Colin C LT USN JS J4 (USA)" <(b)(6)>, "Shuy, Bryan (OS/ASPR/IO)" <Bryan.Shuy@hhs.gov>, "Harrison, Brian (HHS/IOS)" <Brian.Harrison@hhs.gov>, "Mango, Paul (HHS/IOS)" <Paul.Mango@hhs.gov>, "Redd, John (OS/ASPR/SPPR)" <John.Redd@hhs.gov>, "Callahan, Victoria (OS/ASPR/IO) (CTR)" <Victoria.Callahan@hhs.gov>
Subject: [Non-DoD Source] RE: remdesivir Distro Plan

All active links contained in this email were disabled. Please verify the identity of the sender, and confirm the authenticity of all links contained within the message prior to copying and pasting the address to a Web browser.

As follow up in a telecom with Devin who suggested at 930 pm teleconference call tonight. Call n information to be sent shortly.

From: Kadlec, Robert (OS/ASPR/IO)
Sent: Wednesday, May 6, 2020 8:33 PM
To: Birx, Deborah L. EOP/NSC <(b)(6)>; O'Malley, Devin M. EOP/OVP <(b)(6)>
Cc: Fauci, Anthony (NIH/NIAID) [E] <(b)(6)>; Polowczyk, John P (MIL) <(b)(6)>; McGuffee, Tyler Ann A. EOP/OVP <(b)(6)>; Troye, Olivia (nsc.eop.gov) <(b)(6)>; Amerau, Colin C (MIL) <(b)(6)>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov> <Bryan.Shuy@hhs.gov>; Harrison, Brian (HHS/IOS) <Brian.Harrison@hhs.gov>; Mango, Paul (HHS/IOS) <Paul.Mango@hhs.gov>
Subject: RE: remdesivir Distro Plan
Importance: High

(b) (5)

From: Birx, Deborah L. EOP/NSC [REDACTED]@nsc.eop.gov <Caution-mailto:Deborah.L.Birx@nsc.eop.gov> >
Sent: Wednesday, May 6, 2020 8:03 PM
To: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov <Caution-mailto:Robert.Kadlec@hhs.gov>>; O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>
Cc: Fauci, Anthony (NIH/NIAID) [E] (b)(6); Polowczyk, John P (MIL) (b)(6); McGuffee, Tyler Ann A. EOP/OVP <Tyler.A.McGuffee2@ovp.eop.gov <Caution-mailto:Tyler.A.McGuffee2@ovp.eop.gov>>; Troye, Olivia (nsc.eop.gov) [REDACTED] <Caution-mailto:[REDACTED]>>; Amerau, Colin C (MIL) <(b)(6)> >
Subject: Re: remdesivir Distro Plan

Do we have a sense when the plan will be available?

From: "Kadlec, Robert (OS/ASPR/IO)" <Robert.Kadlec@hhs.gov <Caution-mailto:Robert.Kadlec@hhs.gov>>
Date: Wednesday, May 6, 2020 at 7:03 PM
To: "O'Malley, Devin M. EOP/OVP" <Devin.M.O'Malley@ovp.eop.gov>
Cc: "Birx, Deborah L. EOP/NSC" <Deborah.L.Birx@nsc.eop.gov <Caution-mailto:Deborah.L.Birx@nsc.eop.gov>>, "Fauci, Anthony (NIH/NIAID) [E]" <afauci@niaid.nih.gov <Caution-mailto:afauci@niaid.nih.gov>>, "Polowczyk, John P (MIL)" <john.p.polowczyk.mil@mail.mil <Caution-mailto:john.p.polowczyk.mil@mail.mil>>, "McGuffee, Tyler Ann A. EOP/OVP" <Tyler.A.McGuffee2@ovp.eop.gov <Caution-mailto:Tyler.A.McGuffee2@ovp.eop.gov>>, "Troye, Nsc" <Olivia.Troye@nsc.eop.gov <Caution-mailto:Olivia.Troye@nsc.eop.gov>>, "Amerau, Colin C (MIL)" <colin.c.amerau.mil@mail.mil <Caution-mailto:colin.c.amerau.mil@mail.mil>>
Subject: Re: remdesivir Distro Plan

Can do Devin what's your number ?

Sent from my iPhone

On May 6, 2020, at 7:02 PM, O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov> wrote:

Hi all-

Marc Short has asked that I handle the remdesivir rollout once we get a distribution plan set. Can you please include me on any call/meeting invites to discuss the distribution plan on the remaining doses?

Dr. Kadlec- Can you please connect me with someone who can walk me through what has been done already?

Thanks!

Devin

From: O'Malley, Devin M. EOP/OVP [Devin.M.O'Malley@ovp.eop.gov]
Sent: 4/20/2020 5:17:08 PM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
Subject: FW: Serological Test TPs 4.20 CFR_SC V2
Attachments: Serological Test TPs 4.20 CFR_SC V2.docx

Here is a framework of sorts that Colin and I came up with. Here's to hoping you get the opportunity to use it soon!

From: O'Malley, Devin M. EOP/OVP
Sent: Monday, April 20, 2020 5:11 PM
To: 'Rom, Colin' <Colin.Rom@fda.hhs.gov>
Subject: Serological Test TPs 4.20 CFR_SC V2

From: O'Malley, Devin M. EOP/OVP [Devin.M.O'Malley@ovp.eop.gov]
Sent: 3/25/2020 9:32:39 PM
To: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: FW: CLEARANCE_0326: FDA "Coronavirus (COVID-19) Update: Development of Antibody Products Derived from Human Plasma to Prevent or Treat COVID-19"
Attachments: DRAFT_PR_Plasma and Hyperimmune Globulin 03252020 754pm.docx

Hey guys-

(b) (5)

Feel free to call if easier.

Devin

From: Robinson, Michael J (HHS/ASPA) <michael.robinson@hhs.gov>
Sent: Wednesday, March 25, 2020 9:29 PM
To: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>; Fetalvo, Ninio J. EOP/OVP <Ninio.J.Fetalvo@ovp.eop.gov>
Cc: Weber, Mark (HHS/ASPA) <Mark.Weber@hhs.gov>; Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>; McKeogh, Katherine (OS/ASPA) <Katherine.McKeogh@hhs.gov>; Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>; Myrie, Simone (OS/ASPA) <Simone.Myrie@hhs.gov>; Lemar, Naweed (OS/ASPA) <Naweed.Lemar@hhs.gov>; Daniels, Carla (HHS/ASPA) <Carla.Daniels@hhs.gov>; Formoso, Paula (HHS/ASPA) <Paula.Formoso@hhs.gov>; Bradley, Tasha (OS/ASPA) <Tasha.Bradley@hhs.gov>; OS HHSPress (HHS/ASPA) <(b)(6)@hhs.gov>; Pratt, Michael (OS/ASPA) <Michael.Pratt@hhs.gov>
Subject: RE: CLEARANCE_0326: FDA "Coronavirus (COVID-19) Update: Development of Antibody Products Derived from Human Plasma to Prevent or Treat COVID-19"

Ninio and Devin –Good evening!

(b) (5)

V/r,

From: Robinson, Michael J (HHS/ASPA)
Sent: Wednesday, March 25, 2020 9:23 PM
To: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>; Fetalvo, Ninio J. EOP/OVP <Ninio.J.Fetalvo@ovp.eop.gov>

Subject: RE: CLEARANCE_0326: FDA "Coronavirus (COVID-19) Update: Development of Antibody Products Derived from Human Plasma to Prevent or Treat COVID-19"

Hi

(b) (5)

Mike

From: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>

Sent: Wednesday, March 25, 2020 7:38 PM

To: Robinson, Michael J (HHS/ASPA) <michael.robinson@hhs.gov>; Fetalvo, Ninio J. EOP/OVP

(b)(6)

Subject: RE: CLEARANCE_0326: FDA "Coronavirus (COVID-19) Update: Development of Antibody Products Derived from Human Plasma to Prevent or Treat COVID-19"

(b) (5)

From: Robinson, Michael J (HHS/ASPA) <michael.robinson@hhs.gov>

Sent: Wednesday, March 25, 2020 6:35 PM

To: Fetalvo, Ninio J. EOP/OVP <(b)(6)> O'Malley, Devin M. EOP/OVP

(b)(6)

Subject: FW: CLEARANCE_0326: FDA "Coronavirus (COVID-19) Update: Development of Antibody Products Derived from Human Plasma to Prevent or Treat COVID-19"

Hi!

For awareness

(b) (5)

V/r,

From: OS HHSPress (HHS/ASPA) (b)(6)

Sent: Wednesday, March 25, 2020 6:32 PM

Subject: CLEARANCE_0326: FDA "Coronavirus (COVID-19) Update: Development of Antibody Products Derived from Human Plasma to Prevent or Treat COVID-19"

URGENT

Agency/Office: FDA

Subject: *Coronavirus (COVID-19) Update: Development of Antibody Products Derived from Human Plasma to Prevent or Treat COVID-19*

(b) (5)

V/r,

Mike Robinson
Strategic Planning, ASPA

202-690-6885 –desk
(b)(6) –mobile

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BY LAW:***

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From: O'Malley, Devin M. EOP/OVP [Devin.M.O'Malley@ovp.eop.gov]
Sent: 3/21/2020 1:49:35 PM
To: McGuffee, Tyler A. EOP/OVP [Tyler.A.McGuffee2@ovp.eop.gov]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: RE: FINAL-- Information for Clinicians on COVID-19 Therapies

I just got off a 30-minute call with Dr. Birx. I will review now.

From: McGuffee, Tyler A. EOP/OVP <Tyler.A.McGuffee2@ovp.eop.gov>
Sent: Saturday, March 21, 2020 1:40 PM
To: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: FINAL-- Information for Clinicians on COVID-19 Therapies

Devin, It's in your inbox. (b) (5)

Sincerely,
TAM

Tyler Ann McGuffee
Assistant to Ambassador Birx, M.D.
Office of the White House Coronavirus Response Coordinator
Associate Advisor to the Office of the Vice President
C: (b)(6)

From: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>
Sent: Saturday, March 21, 2020 1:10 PM
To: McGuffee, Tyler A. EOP/OVP <Tyler.A.McGuffee2@ovp.eop.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: FINAL-- Information for Clinicians on COVID-19 Therapies

That's fine.

From: McGuffee, Tyler A. EOP/OVP <Tyler.A.McGuffee2@ovp.eop.gov>
Sent: Saturday, March 21, 2020 1:09 PM
To: Rom, Colin <Colin.Rom@fda.hhs.gov>; O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>
Subject: RE: FINAL-- Information for Clinicians on COVID-19 Therapies

Coming to OVP Comms for approval within 5-10 minutes. Please standby.
Devin, should I include you and Katie Miller? Any one else?

Sincerely,
TAM

Tyler Ann McGuffee
Assistant to Ambassador Birx, M.D.
Office of the White House Coronavirus Response Coordinator
Associate Advisor to the Office of the Vice President
C: (202) 881-8195 [no text]

From: Rom, Colin <Colin.Rom@fda.hhs.gov>
Sent: Saturday, March 21, 2020 1:08 PM
To: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>
Cc: McGuffee, Tyler A. EOP/OVP <Tyler.A.McGuffee2@ovp.eop.gov>
Subject: RE: FINAL-- Information for Clinicians on COVID-19 Therapies

+ Tyler Ann

From: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>
Date: March 21, 2020 at 12:50:48 PM EDT
To: Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: FINAL-- Information for Clinicians on COVID-19 Therapies

What's the status of this?

From: Rom, Colin <Colin.Rom@fda.hhs.gov>
Sent: Friday, March 20, 2020 6:12 PM
To: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; McGuffee, Tyler A. EOP/OVP <Tyler.A.McGuffee2@ovp.eop.gov>; Fauci, Anthony S (NIH) (b)(6); Redfield, Robert R (CDC) <olx1@cdc.gov>; Birx, Deborah L <BirxDL@state.gov>; Hahn, Stephen <(b)(6)@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Miller, Katie R. EOP/OVP <Katie.R.Miller@ovp.eop.gov>; O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>; Troye, Olivia EOP/NSC (b)(6)>
Subject: RE: FINAL-- Information for Clinicians on COVID-19 Therapies

Thanks, Patrizia!

Dr. Redfield and Dr. Fauci, are you both ok with the version as attached? If so, please clear so that Katie Miller and Devin O'Malley can review for task force comms.

Thanks!

From: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Sent: Friday, March 20, 2020 4:35 PM
To: McGuffee, Tyler A. EOP/OVP <Tyler.A.McGuffee2@ovp.eop.gov>; Fauci, Anthony S (NIH) (b)(6); Redfield, Robert R (CDC) <olx1@cdc.gov>; Birx, Deborah L <BirxDL@state.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: FINAL-- Information for Clinicians on COVID-19 Therapies

Cleared by FDA-CDER
Patrizia Cavazzoni

From: McGuffee, Tyler A. EOP/OVP <Tyler.A.McGuffee2@ovp.eop.gov>
Sent: Friday, March 20, 2020 4:17 PM
To: Fauci, Anthony S (NIH) (b)(6); Redfield, Robert R (CDC) <olx1@cdc.gov>; Birx, Deborah L <BirxDL@state.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>

Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>

Subject: FINAL-- Information for Clinicians on COVID-19 Therapies

FINAL – Per Dr. Hahn, please review and REPLY ALL with affirmative clearance.

Sincerely,
TAM

Tyler Ann McGuffee
Assistant to Ambassador Birx, M.D.
Office of the White House Coronavirus Response Coordinator
Associate Advisor to the Office of the Vice President
C: (b)(6)

From: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Sent: Friday, March 20, 2020 4:15 PM
To: McGuffee, Tyler A. EOP/OVP <Tyler.A.McGuffee2@ovp.eop.gov>; Farley, John <John.Farley@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>
Subject: RE: [WARNING: UNSCANNABLE EXTRACTION FAILED]Fwd: Information for Clinicians on COVID-19 Therapies

Revised version, for final distribution

From: McGuffee, Tyler A. EOP/OVP <Tyler.A.McGuffee2@ovp.eop.gov>
Sent: Friday, March 20, 2020 4:10 PM
To: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>
Subject: FW: [WARNING: UNSCANNABLE EXTRACTION FAILED]Fwd: Information for Clinicians on COVID-19 Therapies

Please see attached

Sincerely,
TAM

Tyler Ann McGuffee
Assistant to Ambassador Birx, M.D.
Office of the White House Coronavirus Response Coordinator
Associate Advisor to the Office of the Vice President
C: (b)(6)

From: Birx, Deborah L. EOP/NSC <(b)(6)>
Sent: Friday, March 20, 2020 4:10 PM
To: McGuffee, Tyler A. EOP/OVP <Tyler.A.McGuffee2@ovp.eop.gov>
Subject: FW: [WARNING: UNSCANNABLE EXTRACTION FAILED]Fwd: Information for Clinicians on COVID-19 Therapies

From: "Birx, Deborah L. EOP/NSC" <(b)(6)>
Date: Friday, March 20, 2020 at 4:03 PM
To: "Redfield, Robert R. (CDC/OD)" <olx1@cdc.gov>, "Stephen Hahn (SH1@fda.hhs.gov)" <SH1@fda.hhs.gov>, "Fauci, Anthony (NIH/NIAID) [E]" <(b)(6)>, "Uyeki, Timothy M. (CDC/DDID/NCIRD/ID)" <tmu0@cdc.gov>

Subject: Re: [WARNING: UNSCANNABLE EXTRACTION FAILED]Fwd: Information for Clinicians on COVID-19 Therapies

From: "Birx, Deborah L. EOP/NSC" <Deborah.L.Birx@nsc.eop.gov>

Date: Friday, March 20, 2020 at 3:58 PM

To: "Redfield, Robert R. (CDC/OD)" <olx1@cdc.gov>, "Stephen Hahn (SH1@fda.hhs.gov)" <SH1@fda.hhs.gov>, "Fauci, Anthony (NIH/NIAID) [E]" <(b)(6)>, "Uyeki, Timothy M. (CDC/DDID/NCIRD/ID)" <tmu0@cdc.gov>

Subject: Re: [WARNING: UNSCANNABLE EXTRACTION FAILED]Fwd: Information for Clinicians on COVID-19 Therapies

From: "Redfield, Robert R. (CDC/OD)" <olx1@cdc.gov>

Date: Wednesday, March 18, 2020 at 10:34 PM

To: "Stephen Hahn (SH1@fda.hhs.gov)" <SH1@fda.hhs.gov>, "Fauci, Anthony (NIH/NIAID) [E]" <(b)(6)>, "Birx, Deborah L. EOP/NSC" <(b)(6)>, "Redfield, Robert R. (CDC/OD)" <olx1@cdc.gov>, "Uyeki, Timothy M. (CDC/DDID/NCIRD/ID)" <tmu0@cdc.gov>

Subject: [WARNING: UNSCANNABLE EXTRACTION FAILED]Fwd: Information for Clinicians on COVID-19 Therapies

Please forward suggested edits. Thanks peace God bless r3
Get [Outlook for iOS](#)

From: Uyeki, Timothy M. (CDC/DDID/NCIRD/ID) <tmu0@cdc.gov>

Sent: Wednesday, March 18, 2020 9:04 PM

To: Redfield, Robert R. (CDC/OD)

Subject: Information for Clinicians on COVID-19 Therapies

Dear Dr. Redfield,

I attached a summary of the document requested "Information for Clinicians on COVID-19 Therapies." I also attached a summary of applicable clinical trials compiled by my team this evening (includes information on trials worldwide) for background in case this information might be useful. Let me know if you have any questions.

Thanks,
Tim

Tim Uyeki MD, MPH, MPP
CDC 2019 Novel Coronavirus Response
Clinical Team Lead
Chief Medical Officer, Influenza Division
National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention
Mailstop H24-7
1600 Clifton Road, N.E.
Atlanta, GA 30329
Email: tmu0@cdc.gov
Office phone: 404-639-0277
CDC Cell phone: (b)(6)

From: O'Malley, Devin M. EOP/OVP [Devin.M.O'Malley@ovp.eop.gov]
Sent: 4/10/2020 11:23:19 PM
To: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: Fwd: murder board Qs
Attachments: murder board questions.docx; ATT00001.htm

Sent from my iPhone

Begin forwarded message:

From: "Caccommo, Stephanie" <Stephanie.Caccommo@fda.hhs.gov>
Date: April 10, 2020 at 11:18:04 PM EDT
To: "O'Malley, Devin M. EOP/OVP" <Devin.M.O'Malley@ovp.eop.gov>, "Caliguiri, Laura" <Laura.Caliguiri@fda.hhs.gov>, "Block, Molly" <Molly.Block@fda.hhs.gov>, "Felberbaum, Michael" <Michael.Felberbaum@fda.hhs.gov>, "Rebello, Heidi" <Heidi.Rebello@fda.hhs.gov>
Subject: murder board Qs

Hi folks!

Sorry for late Qs! Devin from VP office is joining us for Dr. Hahn's prep.

I'm attaching 3 subject area of questions. I'd recommend Michael and I lead treatment/testing like last time, and then others feel free to chime in along the way with other questions along the way. These are just proposed Qs, so feel free to deviate and do what works best.

I'd also recommend we go through the whole prep this time and provide feedback at the end.

Talk in the morning!

Stephanie Caccommo
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: 301.348.1956
Cell: (b)(6)
stephanie.caccommo@fda.hhs.gov

From: O'Malley, Devin M. EOP/OVP [Devin.M.O'Malley@ovp.eop.gov]
Sent: 4/3/2020 10:43:33 AM
To: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: Fwd: [EXTERNAL] ExxonMobil/GCMI Partnership for Reusable Masks and Face Shield
Attachments: image003.png; ATT00001.htm; ExxonMobil GCMI PR.pdf; ATT00002.htm

Sent from my iPhone

Begin forwarded message:

From: Laine Striegel <lstriegel@guidepost-strategy.com>
Date: April 3, 2020 at 10:41:01 AM EDT
To: "Pinkos, Stephen M. EOP/OVP" <(b)(6)> "O'Malley, Devin M. EOP/OVP" <Devin.M.O'Malley@ovp.eop.gov>
Subject: [EXTERNAL] ExxonMobil/GCMI Partnership for Reusable Masks and Face Shield

Morning Steve and Devin –

Hope you're both doing well and staying healthy.

Wanted to make sure your team saw the attached press release from Exxon that went out this morning at 8:00AM CST on their partnership with the Global Center for Medical Innovation (GCMI) to make reusable masks and face shields.

Production will commence immediately once they receive FDA approval. Once approved, manufacturers indicate they will be able to produce as many as 40,000 ready-to-use masks and filter cartridges per hour.

Let me know if you have any questions. Keep fighting the good fight!

Laine

Laine Evans Striegel | VP Operations & Client Relations
GuidePost Strategies, LLC
1401 H Street NW, 5th Floor | Washington, DC 20005
T: 615.828.0484 | lstriegel@guidepost-strategy.com
>www.guidepost-strategy.com<

From: Fetalvo, Ninio J. EOP/OVP (b)(6)
Sent: 3/23/2020 5:37:51 PM
To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Caliguirri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Conrad, Patricia L (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e30cd6224aeb49c795844f43fd78a049-HHS-conradp]

Subject: Principal Media Prep: Primetime/Morning/Daytime Shows
Location: Dial-In: (202) 395-6392 | Code: (b)(6)

Start: 3/23/2020 8:00:00 PM
End: 3/23/2020 8:30:00 PM
Show Time As: Tentative

Recurrence: (none)

Hi all—

This will be a media prep for any principals doing primetime/morning/daytime shows. Please forward this invite to your respective principal's scheduler.

Dr. Hahn

- Tucker Carlson Tonight
- Topics: Therapeutics—vaccines, drugs for treatment Recent press release, CDC just posted information for clinicians treating coronavirus patients, Regulatory flexibility—we've been reducing red tape on a number of actions: Allowing N95s intended for industrial/construction use to be used in health care, Ventilators—allowing hospitals to repurpose other types of breathing machines (like CPAPs), plus allowing non-traditional manufacturers, like auto manufacturers, to make parts, Conservations strategies for gloves and surgical gowns

Dr. Fauci

- Hannity
- Topics:

Dr. Birx

- NBC TODAY
- Topics: latest government guidelines and social distancing, update on where things stand in combating the virus, any new discoveries about the virus/possible treatments going forward, supplies and working with states
- FBN Mornings w/ Maria
- Topics: the latest on COVID-19, message to millennials

Administrator Gaynor

- ABC Good Morning America
- Topics:
- FNC Fox & Friends
- Topics:

Larry Kudlow

- Varney & Co.
- Topics: Economy, stimulus package, Hill negotiations

If you have any conflicts, please let us know asap.

Thank you,
Ninio

From: Fetalvo, Ninio J. EOP/OVP (b)(6)
Sent: 3/23/2020 7:54:17 PM
To: Henning, Alexa A. EOP/WHO [Katherine.A.Henning@who.eop.gov]; Love, Kelly A. EOP/OVP (b)(6); Hahn, Julia A. EOP/WHO [Julia.A.Hahn@who.eop.gov]; Miller, Katie R. EOP/OVP [Katie.R.Miller@ovp.eop.gov]; Daravi, Roma S. EOP/WHO [Roma.S.Daravi2@who.eop.gov]; O'Malley, Devin M. EOP/OVP [Devin.M.O'Malley@ovp.eop.gov]; Gidley, Hogan H. EOP/WHO [Hogan.Gidley@who.eop.gov]; McGuffee, Tyler A. EOP/OVP (b)(6); Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Montesi, Janet [janet.montesi@fema.dhs.gov]; Litzow, Elizabeth [elizabeth.litzow@fema.dhs.gov]; Baker, Brittany G. EOP/WHO [Brittany.G.Baker@who.eop.gov]; Caccamo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Caliguri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Conrad, Patricia L (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e30cd6224aeb49c795844f43fd78a049-HHS-conradp]; Sherman, Jennifer (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=96ea669491654aba8d4ea6816279e040-HHS-Jennife]
Subject: Principal Media Prep: Primetime/Morning/Daytime Shows
Location: Dial-In: (202) 395-6392 | Code: (b)(6)
Start: 3/23/2020 8:15:00 PM
End: 3/23/2020 8:45:00 PM
Show Time As: Tentative

Recurrence: (none)

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- Varney & Co.
 - Topics: Economy, stimulus package, Hill negotiations

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From: Fetalvo, Ninio J. EOP/OVP (b)(6)
Sent: 3/23/2020 5:38:12 PM
To: Fetalvo, Ninio J. EOP/OVP (b)(6); Henning, Alexa A. EOP/WHO [Katherine.A.Henning@who.eop.gov]; Love, Kelly A. EOP/OVP (b)(6); Hahn, Julia A. EOP/WHO [Julia.A.Hahn@who.eop.gov]; Miller, Katie R. EOP/OVP [Katie.R.Miller@ovp.eop.gov]; Daravi, Roma S. EOP/WHO [Roma.S.Daravi2@who.eop.gov]; O'Malley, Devin M. EOP/OVP [Devin.M.O'Malley@ovp.eop.gov]; Gidley, Hogan H. EOP/WHO [Hogan.Gidley@who.eop.gov]; McGuffee, Tyler A. EOP/OVP [Tyler.A.McGuffee2@ovp.eop.gov]; Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Montesi, Janet [janet.montesi@fema.dhs.gov]; Litzow, Elizabeth [elizabeth.litzow@fema.dhs.gov]; Baker, Brittany G. EOP/WHO [Brittany.G.Baker@who.eop.gov]; Caccamo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Caligui, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Conrad, Patricia L (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e30cd6224aeb49c795844f43fd78a049-HHS-conradp]; Sherman, Jennifer (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=96ea669491654aba8d4ea6816279e040-HHS-Jennife]

Subject: Principal Media Prep: Primetime/Morning/Daytime Shows
Location: Dial-In: (202) 395-6392 | Code (b)(6)

Start: 3/23/2020 8:15:00 PM
End: 3/23/2020 8:45:00 PM
Show Time As: Busy

Recurrence: (none)

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- FNC Fox & Friends
- Topics:

Larry Kudlow

- Varney & Co.
- Topics: Economy, stimulus package, Hill negotiations

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From: Fetalvo, Ninio J. EOP/OVP (b)(6)
Sent: 3/23/2020 5:38:12 PM
To: Fetalvo, Ninio J. EOP/OVP (b)(6); Caccamo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Conrad, Patricia L (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e30cd6224aeb49c795844f43fd78a049-HHS-conradp]

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Sent: 3/23/2020 5:38:12 PM
To: Fetalvo, Ninio J. EOP/OVP (b)(6); Caccamo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Caligui, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Conrad, Patricia L (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e30cd6224aeb49c795844f43fd78a049-HHS-conradp]

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Thank you,
Ninio

From: O'Malley, Devin M. EOP/OVP [Devin.M.O'Malley@ovp.eop.gov]
Sent: 4/20/2020 5:10:40 PM
To: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: Serological Test TPs 4.20 CFR_SC V2
Attachments: Serological Test TPs 4.20 CFR_SC V2.docx

From: O'Malley, Devin M. EOP/OVP [Devin.M.O'Malley@ovp.eop.gov]
Sent: 5/14/2020 1:56:25 PM
To: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: FW: FOR OVP APPROVAL -- FW: CLEARANCE_0608: FDA "Coronavirus (COVID-19) Update: FDA informs public about accuracy concerns with Abbott ID NOW, point of care test"
Attachments: 20200514_PR_Abbott ID Now_120pm.docx

Are you involved in the drafting of these statements?

From: Robinson, Michael J (HHS/ASPA) <michael.robinson@hhs.gov>
Sent: Thursday, May 14, 2020 1:33 PM
To: O'Malley, Devin M. EOP/OVP <(b)(6)>; Miller, Katie R. EOP/OVP <(b)(6)>; MacInnis, Hannah F. EOP/OVP <(b)(6)>; Burris, Meghan K. EOP/WHO <Meghan.K.Burris@who.eop.gov>; Yanick, Brittany M. EOP/WHO <Brittany.M.Yanick@who.eop.gov>; Syrek, Tori Q. EOP/WHO <Tori.Q.Syrek@who.eop.gov>; Deere, Judd P. EOP/WHO <(b)(6)>
Cc: Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>; McKeogh, Katherine (OS/ASPA) <Katherine.McKeogh@hhs.gov>; Robinson, Michael J (HHS/ASPA) <michael.robinson@hhs.gov>; Formoso, Paula (HHS/ASPA) <Paula.Formoso@hhs.gov>; Daniels, Carla (HHS/ASPA) <Carla.Daniels@hhs.gov>; Bradley, Tasha (OS/ASPA) <Tasha.Bradley@hhs.gov>; Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>; Myrie, Simone (OS/ASPA) <Simone.Myrie@hhs.gov>; Weber, Mark (HHS/ASPA) <Mark.Weber@hhs.gov>
Subject: FOR OVP APPROVAL -- FW: CLEARANCE_0608: FDA "Coronavirus (COVID-19) Update: FDA informs public about accuracy concerns with Abbott ID NOW, point of care test"

Hello

(b) (5)

Respectfully,

From: OS HHSPress (HHS/ASPA)
Sent: Thursday, May 14, 2020 12:20 PM
Subject: CLEARANCE_0608: FDA "Coronavirus (COVID-19) Update: FDA informs public about accuracy concerns with Abbott ID NOW, point of care test"

URGENT

Agency/Office: FDA

Subject: *Coronavirus (COVID-19) Update: FDA informs public about accuracy concerns with Abbott ID NOW, point of care test*

(b) (5)

V/r,

Mike Robinson
Strategic Planning, ASPA

202-690-6885 –desk
(b)(6) –mobile

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From: O'Malley, Devin M. EOP/OVP [Devin.M.O'Malley@ovp.eop.gov]
Sent: 7/8/2020 3:11:05 PM
To: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: FW: Press Briefing by Vice President Pence and Members of the Coronavirus Task Force | July 8, 2020

From: Dansky Bari, Dominique A. EOP/WHO (b) (6)
Sent: Wednesday, July 8, 2020 3:08 PM
Subject: Press Briefing by Vice President Pence and Members of the Coronavirus Task Force | July 8, 2020

THE WHITE HOUSE

Office of the Vice President

For Immediate Release

July 8, 2020

PRESS BRIEFING
BY VICE PRESIDENT PENCE
AND MEMBERS OF THE CORONAVIRUS TASK FORCE

Department of Education
Washington, D.C.

11:41 A.M. EDT

THE VICE PRESIDENT: Well, good morning all. The White House Coronavirus Task Force met today, here at the Department of Education, as part of our ongoing effort to focus on a mission to save lives, meet the needs of our states and our healthcare workers, to protect the vulnerable, and to safely reopen America and reopen America's schools.

As you will hear today from Admiral Brett Giroir, at this point, we have tested more than 39 million Americans. Among those, more than 3 million Americans have tested positive and more than 1.3 million Americans have recovered. Sadly, more than 133,000 Americans have lost their lives, and our sympathies are with all of the impacted families.

And while we mourn with those who mourn, because of what the American people have done, because of the extraordinary work of our healthcare workers around the country, we are encouraged that the average fatality rate continues to be low and steady. And at days earlier this week, it was actually 90 percent lower than at the height of this pandemic.

Again, it's a credit to the sacrifices the American people have made, to the extraordinary work that our healthcare workers are doing. And we pledge that this task force, working in partnership with governors all

across the country, is going to continue to work our hearts out 24 hours a day to continue to keep our losses low.

In just a few moments, Dr. Deborah Birx will outline the data that we're seeing around the country. We're tracking literally state by state, county by county. But as she will describe in a moment, we're actually seeing early indications of a percent of positive testing flattening in Arizona and Florida and Texas. Governors in each of those states have taken strong steps to flatten the curve. And again, as Dr. Birx will describe, we're beginning to see early indications that positivity is flattening, and in Arizona and Florida, we're beginning to see declining numbers of emergency room visits as well.

We believe the takeaway from this for every American, particularly in those states that are impacted, is: Keep doing what you're doing, because we're starting to see the first indications that as we were able to do in the Northeast, as we were able to do in New Orleans and Louisiana and Michigan and other places around the country, we're putting into practice those mitigation efforts and we're beginning to see indications that they are having a good effect.

We are focused on the states where more than half of the new cases have arisen -- Texas, Arizona, Florida, and California -- and have received encouraging reports even through this morning: strong supplies of PPE in hospitals; hospital capacity remains strong.

The one need that we did hear from governors across the region is for personnel. And over the last week, working through FEMA, the Department of Defense, and HHS, we've been processing requests to deploy over 1,070 doctors and nurses and medical personnel. At this point, roughly 525 doctors and nurses are on the ground in Arizona, California, and Texas, and we're processing a request from Florida for an additional amount.

We've made it very clear as we -- if you'll recall, we deployed, at the President's direction, active-duty military medical personnel to New York, to New Jersey, to Connecticut, to Michigan, to Louisiana, and we're in the process of doing that again just to make sure that those dedicated doctors and nurses and healthcare workers have the relief that they need as we see cases rising in various communities across the Sun Belt. And we'll continue to work that.

We had a conference call yesterday with the nation's governors. We are in the process of continuing to send, every week, detailed county-by-county summaries, analysis, and recommendations to governors that are being -- that are being implemented and well received.

We also are issuing renewed guidance on preservation and reuse of PPE. Again, what we're hearing, in not just speaking to governors but talking directly to hospitals, is that, frankly, because of the historic effort that President Trump implemented to spin up hundreds of millions of supplies of gloves and masks and face shields and -- as well as the construction of ventilators -- we now have 59,000 ventilators in our

supplies -- PPE, we hear, remains very strong, but we're encouraging healthcare workers to begin now to use some of the best practices that we learned in other parts of the country to preserve and to reuse the PPE supplies.

So our focus is to make sure our states have everything they need, when they need it. And we're working closely with all the governors to make that a reality. But what brings us to the Department of Education is, as we --- as we see to the needs of our states and we focus on the healthcare of the American people, we're working to reopen America and to reopen America's schools.

And yesterday, President Trump convened a summit of education leaders and health officials at the White House. And as the President made clear yesterday: It's time. It's time for us to get our kids back to school. And the summit yesterday gave us an opportunity to outline and to learn what we might be able to do then.

In just a few moments, I'm going to ask Secretary DeVos to talk about the approach the Department of Education is taking to assisting local communities and states in bringing their schools back online. And also, we'll hear from Dr. Bob Redfield, who has been literally, since early in this pandemic, providing guidance to schools and will be issuing additional guidance next week.

I wouldn't want to pass the opportunity, though, not just as Vice President but as someone who's been married to a school teacher now for 35 years, just to say -- to say thank you to all the teachers out there. From early in this pandemic, teachers learned how to do the distance teaching and did a remarkable job, oftentimes having to care for their own families and make sure their own children's studies were happening. So to all of our -- America's teachers, we say thank you.

We also want to say thank you to the parents -- the parents who had to step in and become educators for all of their kids. It's really been remarkable when you see what our kids have been able to accomplish during this difficult time.

But what we heard again yesterday from education officials and what we heard from the American Academy of Pediatrics: It's absolutely essential that we get our kids back into a classroom for in-person learning. We can't let our kids fall behind academically, but it's important that the American people remember that for children that have mental health issues, for special needs children, for nutrition for children in communities facing persistent poverty, the school is the place where they receive all those services.

And so this is not just simply about making sure our kids are learning and they're advancing academically, but for their mental health, for their wellbeing, for their physical health, for nutrition. We got to get our kids back to school.

And as you heard the President yesterday and even again this morning, we're absolutely determined to work in partnership with our states to give the guidance for states and communities to be able to safely reopen our schools. The CDC will be issuing new guidance next week -- part of a five-part series of recommendations that will give all-new tools to our schools.

But what Dr. Redfield made clear yesterday I'm sure he'll make clear again today, is: We're here to help. We don't want federal guidance to be a substitute for state and local laws and rules and guidance. We're here to assist with the shared objective that I think is shared by every parent in America, which is we want to get our kids back. We want to get them back in the classroom. We want to get our teachers back in the front of those classrooms. We got to get our kids learning, in person, once again.

As Congress is still in recess but will gather again soon, we already are in discussions about additional potential support, although we were able to remind governors that \$13.3 billion is available in the CARES Act for states, to be able to assist them as they roll out and restart schools across the country.

At the present moment, we learned yesterday that only 1.5 percent of those funds has been drawn down by states, and we encouraged the governors to take advantage of that.

Our objectives, as I said, are to save lives, meet the needs of our states and their healthcare workers, protect the most vulnerable, and safely reopen America, and safely reopen our schools.

And the good news is we are -- we are reopening America. The jobs report last Thursday spoke for itself: Nearly 5 million jobs created. And I can tell you, evidence all around the country is that the American people are finding a way to do their part to put the health of their neighbors first, even while we all find a way to get back to work, to worship, and to school.

And we all have a role to play to slow the spread, to protect the most vulnerable, and to safely reopen our country and our schools. And so I would just -- I would just close, before I turn the podium over to Dr. Birx for her report, just simply to say thank you to the American people. Thank you for what you've done so far. Thank you for the way you've put the health and wellbeing of not just family members and friends, but strangers -- people you didn't even know -- first.

And we just encourage you to keep doing what you're doing: Keep heeding the guidance of state and local authorities. Practice good hygiene. Wash your hands. Wear a mask wherever state and local authorities determine it's indicated, or wear a mask where you can't engage in social distancing.

This is the role each of us can continue to play, and we're seeing some early indications in some of the most impacted states that Americans are doing just that. So we want to encourage you on and tell you that we're going to continue to do our part.

And I'm just absolutely confident -- just as we proved when this pandemic was striking so deeply in the Northeast, when it was striking in Louisiana and in Michigan -- the American people know what needs to be done, and we know we can do it.

And we flattened -- we flattened the curve before, we slowed the spread before, and we can do it again. But we've got to all do our part, and we'll do it together.

With that, Dr. Deborah Birx. And then we'll get a report from Admiral Giroir before we move on to other reports.

Dr. Birx?

DR. BIRX: Thank you, Mr. Vice President. If I could have the first slide, please. And I know some of you do watch what I wear, so I'm wearing this specially today. This came from the Salt River tribe. I just want to -- masks can be a fashion statement.

And I want to thank the Salt River tribe. It was a real pleasure to be out and speaking to individuals around the United States about the issues that they're facing with COVID-19, to be able to meet with communities, hospital personnel, African American communities, Hispanic communities, and our (inaudible) tribal nations. That was a privilege last week.

I want to start with Arizona, just to pick up where the Vice President left off. That orange line is the number of tests performed, and the blue line is the test positivity. Now, this is at the level of the state. And Arizona does have three counties that we're tracking very closely, obviously you know that the largest one being Phoenix and Maricopa County. But this does show that the blue line, which is a five-day -- a seven-day average -- and thank you to the data team for these wonderful slides -- the five -- the seven-day average is showing some flattening, and we find that encouraging.

Also equally encouraging at this point -- because we know that the test-positivity rate is the first thing to increase, and we're hoping that it heralds a stability in Arizona of at least reaching a plateau in their curve.

The red line represents the emergency room visits for any of the COVID-like symptoms. And this is also an early indicator, and we find that encouraging.

The next slide does show the counties that we're tracking. Obviously, the largest county being Maricopa County with the largest number of infections, but clearly there's issues in Yuma and Pima.

The Vice President mentioned the weekly reports that go to governors. This is what the report looks like. It (inaudible) their full-side pages.

This is Alaska's. On the front page is our interpretation of what we're seeing, relevant to their epidemic, with specific recommendations related to where we see them, as far as being in a danger zone. They are coded by yellow and red. And it follows that they see everything you're seeing on that first report in boxes -- warning boxes -- and then each of the counties are represented so that they have, in one place, five pages from the White House and task force that summarizes what we're seeing. And that goes out weekly.

Next slide, please.

This looks at Florida, and you can see, in the same way, the red line -- early suggestions of decreasing emergency room visits for the symptoms of COVID and some stability starting in that blue line. Hoping that heralds stability in the number of daily reported cases.

We also understand that we went through a holiday weekend, and holiday weekends can impact datas on both ends: underreporting through the weekend and then catch-up reporting on Monday, Tuesday, and Wednesday after a holiday weekend.

Next slide.

This shows the counties of Florida that we're tracking. These are the top 10 counties in Florida, and you can see each of them have a different profile.

I want to call your attention to the counties that are across the bottom there that are more difficult to see. Some of those represent Jacksonville and other large metros, including Tampa. When the governor talks about how they were "steady and low" for a long period of time after reopening, this is where that is reflected for almost five weeks after reopening. Clearly, there was something that happened though. And those that we're looking into across the board -- because whatever happened in Florida happened across the Sun Belt, and that all of the curves and all of the findings are mirrored.

If you remember early on in March and April, we were talking about, first, the New York metro, followed by Boston, followed by Philadelphia, then Chicago -- and New Orleans was with the New York metro. And so it was a series of individual curves.

In this case, whatever occurred occurred almost simultaneously across the South. And so we're investigating that very closely to really see the etiology behind that because that can help us as an early warning signal, but also help us in guidance to the American people of what we're asking them to do.

Next slide.

Texas. And you can see Texas is in a similar situation with their blue line. And we're watching this very closely across Texas.

Next slide.

But I think all of you know that there is a series of major metros in Texas with significant increase in cases from Houston to Dallas to San Antonio to El Paso and McAllen area. And so the governors get this type of report with specific recommendations.

And then, finally, California, where you can see -- next slide, thank you -- again, a long time of stability, but then this increase in the number of test positives and rapid increase in cases.

Next slide.

And you can see the majority of the issue is in the Los Angeles area, although we see this through Riverside, Imperial, Sacramento, and now San Francisco with increased number of cases.

So I want to finish with where the Vice President started: about the sacrifices of the American people. Because in that recommendations are very clear recommendations that when you have a county with these types of cases, we are recommending everyone using a face covering. And I think the studies now that have been done, showing that cotton face coverings work, that does open up the ability for us all to have individualized face coverings that express our personality.

But in addition, I think the work that these governors have done to -- and ask the American people is it's stop going to bars, to close the bars, to move to outdoor dining, to decrease indoor -- any kind of indoor gatherings again. To all of the Americans out there that are in these four states and the states that have -- in the report, were in the red zone -- because there's a series of other states that we have in that zone -- is really asking the American people in those counties and in those states -- in those states to not only use the face coverings -- not going to bars, not going to indoor dining -- but really not gathering in homes either and decreasing those gatherings back down to our phase one recommendation, which was 10 or less.

So, thank you. Thank you, Mr. Vice President.

THE VICE PRESIDENT: Admiral, report on testing.

ADMIRAL GIROIR: Thank you, Mr. Vice President. Since we're bragging on our face coverings, this was made by a small religious community in Pennsylvania, who were helped by the Public Health Service, and they hand sewed these for a lot of our officers to match our operational dress -- those blue uniforms. So, I wear this proudly, and I think of that community every single day -- everybody pitching in across America to help us all.

So, in terms of testing, I want to cover three quick topics. First one is just where we are numerically. The Vice President has already said, we are now topping 39 million tests across the country. The states really crushed their goal in June. The state goals was about 12.9 million in June; CDC numbers have finalized that at about 16 and a half million tests for June. So, congratulations to almost all of the states who made their goal and exceeded their goal.

We're doing very well right now, between 6- and 700,000 tests per day. We did top the 700,000 mark last week, and we're averaging about 620-630,000 tests per day. We continue to ship. We are ripe with swabs and media. So the states tell us what they need. We work with them to set those goals, based on their state testing plans.

After technical assistance by the CDC and my office, FEMA ships those every week. Now that's along with ASPR -- the Assistant Secretary for Preparedness and Response -- at HHS. So that's sort of the overall general view.

We announced, yesterday, what we talked about a little bit last week, and that is federal surge sites. We opened these in three communities. There was a list of communities identified by Dr. Birx and her team that had certain characteristics of their infection trend, but also met certain characteristics of numerical numbers in isolation that surge testing might have an impact over a short period of time.

So our goal, in those communities, is to do at least 5,000 tests per day. And those are in Baton Rouge, Jacksonville, and McAllen -- the McAllen in Texas. And we have many other sites that we're working with. Again, this is a partnership with the state and local governments to make that happen. They're up and running and testing in all three sites. Baton Rouge started yesterday, the other two sites start today, and we already have almost 6,500 appointments already made this morning. So that's going very, very well.

The last thing I wanted to talk about is Phoenix. And I don't know if we have the slides for this. I get just a little bit concerned when I hear things in the news, like "we're doing nothing for Phoenix" and "the federal government hasn't been doing anything with Phoenix." Because that really is not correct, and it undermines a lot of the things that we're doing.

I'm going to show you some slides. I didn't make these slides up. My team -- this was part of a 55-slide deck -- 55-slides slide deck just on

Phoenix, where we understand the demographics, the health disparities, the income levels, the racial and ethnicity backgrounds, where the tests are done, where the resources are. This is how we really work the issues.

So, first of all, we're in constant contact with Governor Ducey and his team. His state health officials are outstanding. We not only talk on the calls, but we have frequent calls. And I know Dr. Redfield does this as well, and Ambassador Birx does this as well.

Number two, we provide support according to the state plans. Just in the last two months, we've shipped over 500,000 swabs and media to the state to fulfill their plans.

In terms of Phoenix -- if I can get the first slide back, please -- I just want to say that, yes, we have lots of support in Phoenix. This is the community-based testing locations. I didn't decode this because it's right out of my slide deck. Phoenix has three federally funded retail sites. This is paid on a per-capita basis. You come up and get a test. These sites -- not these three sites, but this overall program has tested just under a million individuals, and they're located specifically in communities of high social vulnerability. We have three there.

We also have 13 -- what we call "3.0 sites." These are retail pharmacies that, because of our regulatory flexibility, they can do that without a federal stipend or grant. They do this just through the insurance Medicare and Medicaid billing system. So, those are 16 federal sites we have in Phoenix.

Next slide.

I don't know if there's a map to go with that, but under the leadership of Secretary Azar, we've really surged into FQHCs -- Federally Qualified Health Centers. This is where you really want testing to happen because these are medical homes for those who are indigent and underserved. We have 28 FQHCs sites performing testing just in the Phoenix area right now.

Next slide.

We don't have that slide, but let me talk about -- we've also identified every single testing machine in Phoenix. So there are testing machines to do tens of thousands of tests per day. And we're sending at least 100,000 --- okay, maybe it'll come up, maybe it won't, but at least 100,000 assays to the Phoenix area every week.

So these are all the things we're doing in the background, that happen on a regular basis, that we do community by community by community.

Now, two days ago, I heard that Mayor Gallego was unhappy because there was no federal support. I heard that on Monday -- on Monday morning. I was on the phone with the FEMA representative in the afternoon. It was clear to me that Phoenix was not in tune with all the things that the

state were doing. We convened a call last night, where we had Governor Ducey's people on the phone, where we had the mayor's people on the phone, where we had various health officials on the phone. We got everybody together, understood where the gaps are. There's a surge from Arizona State. There are a surge in testing sites that are state testing sites in Phoenix that are up there.

And this morning, Governor Ducey looked at everything, thought a surge site would be helpful in west Phoenix. He requested that, and we're contracting that right now.

So I just wanted to give you that example because it really pains me when somebody says the federal government isn't doing anything, when we have 41 federal sites there. We're sending supplies, we're sending tests. And we work with the governor every day. And if there's an appropriate request and it's on the list for Dr. Birx, which it was, we will send a surge site. And that's what we're doing; we're contracting that this afternoon.

Thank you.

THE VICE PRESIDENT: Good job, Brett. Thank you, Admiral Giroir.

As we said, the focus today is on safely reopening our schools. And as we discussed yesterday at the White House summit, from very early in this process, the Centers for Disease Control has been issuing guidance for schools and for childcare services, in early March -- March the 12th, to be specific. And when we first published the "15 Days to Slow the Spread" and encouraged people to engage in schooling from home, wherever possible, from that point forward, CDC has published decision trees about how schools can begin to develop reopening plans, and just last week, published new guidance for K-12 schools.

But next week, as Dr. Redfield can elaborate in a few moments, they'll be issuing five new documents that'll range from preparing communities to return to school safely, to decision-making tools for parents and caregivers, and to create symptom screening considerations as children and teachers return to school.

But as we made clear yesterday, we'll make clear again today: We're here to help. And none of the CDC's recommendations are intended to replace state and local rules and guidance; that what we've made clear to governors and to state and local health officials is CDC stands ready to work with local officials as they tailor their plan for reopening their schools. But we're all committed to getting our kids back in the classroom and getting them back in the classroom this fall.

With that, I want the Secretary of Education to reflect on the efforts she's making here at the Department of Education, then we'll hear from Dr. Redfield, and then a few wrap-up comments from Secretary of HHS before we go to questions.

Madam Secretary?

SECRETARY DEVOS: Thanks, Mr. Vice President. Thank you so much, Mr. Vice President. Thanks for hosting the task force here today. We are so grateful to the President and to you for your leadership on doing what's right for students.

Yesterday we had a really good and important conversation at the White House with local leaders and great teachers and parents. It was insightful and inspiring. And as Mrs. Pence noted, these past few months, parents have worn multiple hats. They really are our unsung heroes, and I might add, as the Vice President noted, as are the teachers who were often playing dual roles as parents themselves and continuing to help their students learn.

She also said -- Mrs. Pence also said that as we reopen businesses, restaurants, theaters in our country, we simply can't leave out our schools, and that is so correct. Students can and must continue to learn full-time.

I've been really inspired by the innovative teachers, schools, and their communities that have kept learning going through this past few months, and they're getting ready to do it again this fall.

A couple of great examples in Harlem and the surrounding boroughs in New York: Success Academy moved to distance learning in one week, using multiple technology platforms. Teachers there insisted on learning new materials, right along with their students. The students were still graded. They made sure all the students had the needed tech that they did not maybe have at home, initially.

Miami-Dade County used its existing instructional continuity plans to make a seamless transition to distance learning. They added interventions for students who were struggling already before the pandemic.

The International Leadership Academy in Texas started from the mindset that not learning wasn't an option for any student. They delivered multilingual and special education curriculum to all of their students. There were a number of schools and districts across the country that did an awesome job of transitioning this spring. And there were a lot in which I and state school leaders were disappointed in that they didn't figure out how to continue to serve their students. Too many of them just gave up.

The Center for Reinventing Public Education said that only 10 percent across the board provided any kind of real curriculum and instruction program.

And, as I said, I've talked to all of the state school chiefs at least once, most of them more than once, and they've told me that while many of their districts in their states have done well through the past several

months, a number of them, they were very disappointed in, in doing next to nothing.

And then we see as we talk about reopening schools, there are some creating false paradigms for the fall. And here, right in our neighborhood, the D.C. area, Fairfax County, which is one of the most well-funded -- I would call it an elite public school system in America -- offered families a so-called "choice" for this fall: either zero days in school for their students or two days. And their springtime attempt at distance learning was a disaster. I have to -- I give this as an example because things like this cannot happen again in the fall. It would fail America's students, and it would fail taxpayers who pay high taxes for their education.

Ultimately, it's not a matter of "if" schools should reopen, it's simply a matter of "how." They must fully open, and they must be fully operational. And how that happens is best left to education and community leaders.

I really appreciate something that Secretary Azar reiterated yesterday at the White House. It's the Surgeon General's prescription for healthcare, and I'm going to repeat it again because it bears repeating:

First, ask yourself what's your individual circumstance. Are you or is someone in your home vulnerable? Second, what's going on in your community? Is the virus widespread or is it isolated? And third, think about the kind of school activity that you're talking -- that you're thinking about how to -- how to accommodate and deal with.

What needs to be in place for things to be successful: Education leaders need to examine real data for their own states and communities and weigh the risks. Local leaders in every community need to ask these questions and consider all the risks. Physical health and safety are factors -- so is mental health; so is social emotional development; and importantly, very importantly, so are lost opportunities for students, particularly the most vulnerable among us and students with disabilities.

The American Academy of Pediatrics noted: Keeping schools closed "places children and adolescents at considerable risk of morbidity and, in some cases, mortality." The Pediatrics guidance concluded that everyone "should start with a goal of having students physically present in school." "Fully open" and "fully operational" means that students need a full school year or more, and it's expected it will look different depending on where you are.

What's clear is that students and their families need more options. I've talked a long time about the need to rethink education and the -- to expand education options for all students. This moment really demands action, and America always was, and is, and always will be a country of doers.

We are confident that with grit and determination and a measure of grace, we can and will do what's right for all the students in our nation. Thanks very much.

THE VICE PRESIDENT: Dr. Redfield.

DR. REDFIELD: Thank you very much, Mr. Vice President. First and foremost, I want to make it very, very clear that the guidance that CDC continues to put out for schools K-12 and higher learning is intentional for reopening and keeping our schools open. That's its purpose. We recognize that there's a variety of unique circumstances for different schools and different school districts, and so we've outlined a number of strategies that those schools, those administrators can use to accomplish this goal safely.

But I want to make it very clear that what is not the intent of CDC's guidelines is to be used as a rationale to keep schools closed. We're prepared to work with each school, each jurisdiction to help them use the different strategies that we propose that help do this safely so they come up with the optimal strategy for those schools.

I think it's critical -- and it would be, personally, very disappointing to me and, I know, my agency -- if we saw that individuals were using these guidelines as a rationale for not reopening our schools.

I think there's a series of different additional guidelines that we are about to put out to help, really, with the K-12 community, particularly at the community level, to help open safely. Guidelines also that come out were consideration documents for parents and caregivers; guidelines for schools to help them understand how best to do symptom surveillance and characterize symptoms in the schools as a tool; and guidelines to really work out how -- and the ins and outs of using face mask in the school setting; as well as, finally, some guidance and to help the schools have systems which they can monitor their programs.

But I want to close by just reiterating again: The purpose of CDC's guidance is -- remember, it's guidance; it's not requirements -- and its purpose is to facilitate the reopening and the keeping open the schools in this country. Because as the Vice President said, it is critical that we get these schools open and do it safely. We're prepared to work with all the school districts and schools to help them facilitate their development of their own unique plan to accomplish that.

Thank you.

THE VICE PRESIDENT: Thanks, Dr. Redfield. Opening up schools is the right thing to do for our kids so they don't fall behind academically and also so that children that are in need of services -- special-needs children, children with mental health issues, nutrition needs -- have the support that they receive at the schools.

It's important, though, for parents and for working families. And we -- I asked Secretary Scalia to be here from the Department of Labor to speak about the impact on -- as we put America back to work, making it possible for us to have single parents back in the workforce, it's essential that we get our schools open as well.

And so I wanted Secretary Scalia, and then of course Secretary of HHS, to finish our remarks before we go to questions.

Mr. Secretary.

SECRETARY SCALIA: Thank you, Mr. Vice President. It's good to be with you all today. For reasons that Secretary DeVos has mentioned and that the Vice President mentioned, of course, having our schools open is so important to our children's education. But as the Vice President has said, it's very important as well to working men and women across the country who need to be able to structure their workdays in a predictable manner. And the expectation that schools will be open and their children will be able to be in school so that the parents, in turn, can have a predictable schedule that they bring to the workplace, of course, that's important to our business places as well. And in that sense, it's really critically important to our national reopening.

One study has suggested that if we closed all our schools and daycare for just a month -- just, hypothetically, if we did that -- the impact on U.S. productivity would be in the order of \$50 billion. That gives you some sense of the impact having our schools closed can have on our national recovery.

I did want to mention a couple of groups in particular to whom this is very important. First: lower-wage workers. One of the great triumphs of the economy that we enjoyed until the virus came was how well lower-income men and women were doing in the workplace. We, as you know, had unemployment that tied a 50-year low. We had record low unemployment for African Americans, Hispanic Americans, and others. And we had rising wages; wages actually rose about 15 percent for lower-income men and women during the first three years of this administration.

Unfortunately -- and a number of people have observed this -- it's the lower-income workers who've been particularly adversely affected by some of the shutdowns that we've had in response to the coronavirus.

Unemployment among the lower-income workers has been higher than for other populations. And therefore, for them, having schools reopen so that they can themselves have predictable schedules, be able to return to the workplace, is going to be very important. They hold jobs that are less likely be jobs by which you can telecommute. I think many of us know that, even telecommuting, there are burdens being placed on mothers, fathers who are getting up a little bit earlier or staying up a lot later to get work done, to plan around caring for their children in the interim. But for lower-income men and women, that option often is not even available.

And then, second, let me comment briefly on working women, who -- studies show and I think the experience of many of us reflects that it's women in the household who quite often bear the larger burden when it comes to caring for children. Studies show this. And again, prior to COVID, another great success of the economy we were enjoying was the employment rate for women. The unemployment rate for women was actually lower than for men, right before the virus came. But unfortunately -- and this is a statistic we've been tracking -- we see that the unemployment rate for women now is higher than it is for men.

Now, we made great progress in June. The Vice President mentioned the extraordinary jobs report. We've put seven and a half million Americans back to work in just two months, and the unemployment rate for women dropped nearly 3 percent in June.

But still, we have important work to do, and we know that working women will have a harder time getting back to the workplace. They continue to cite childcare at a much higher rate than men do as a reason that they're not able to work. And so for them, too, reopening our schools will be very important.

Look, just to wrap up -- and it's such an important sense the pace and structure of our national life is built around the expectation that our young people will be in school, in person, during the school year. That's so important for them, but it's also vitally important for their parents, and in that sense, so critical to this reopening that is proceeding very well, economically. But to keep going, we need our schools open in the fall.

Thank you very much.

THE VICE PRESIDENT: Great. Thank you, Gene.

Mr. Secretary.

SECRETARY AZAR: Well, thank you very much, Mr. Vice President, for your leadership of the President's all-of-America approach to combatting the virus and for the focus that you're now putting on getting our kids safely back to school.

From HHS's perspective, reopening schools safely may be the single-most important thing that we can do to support healthy families during this pandemic. All decisions about undertaking activities during COVID-19 have to look at risk as a continuum, not a binary question. States and school districts can think about the same things that we urge individuals to think about.

As Secretary DeVos noted, our Surgeon General has come out with his "prescription for health." Ask yourself three critical questions: Where are you? Is there significant community transmission of the virus in your area? Whom are we talking about? Children are much less susceptible to

severe outcomes from the virus than adults. And what activities are we looking at?

There are more and less risky activities for schools, like keeping kids in the same classroom versus changing classes, avoiding large gatherings, and doing activities outside whenever possible. Reopening schools comes with some risk, but there are risks to keeping kids at home too.

At home, kids aren't benefitting from social stimulation. They may be falling behind with learning. They may be more vulnerable to abuse that goes unreported by the mandatory reporters in our school system. They may not be getting special services they may need. They may not be getting the nutrition that they get at school. And it may be difficult for parents to get back to work, as Secretary Scalia noted.

This issue, like so many considerations around safely reopening, isn't about health versus the economy, but about health versus health. All of this is why the American Academy of Pediatrics has strongly recommended beginning with the goal of having students physically present in school. This goal is the right way to use the extensive guidance that CDC has put out to help each state and school district think through a safe reopening.

Last week, we put out guidance around testing for K-through-12 schools. This guidance, like our guidance for colleges and universities, offers recommendations for how and when students, teachers, and staff should be tested.

While CDC does not make a recommendation in favor of universal testing, it's a perfectly appropriate surveillance technique where the capacity exists, and capacity is growing all the time. We've talked with colleges and universities that are able to use their research lab capacity with pooling of multiple samples to test their whole student bodies and staff frequently, thanks to regulatory flexibility that CMS and the FDA have provided.

Many of the leaders we heard from yesterday at the White House School Reopening Summit are doing testing before returning to school, and then sentinel surveillance.

On top of that, the measures we recommend universally -- like keeping a distance, wearing a face covering, and frequent hand washing -- are effective and can be applied in the college or the K-through-12 setting.

We put out the CDC guidance to enable and support states and school districts in reopening safely. We want them to use the tools available to reduce risk, and we'll be putting out more guidance on how schools can use each of these tools, such as face coverings.

On top of that, I will reiterate that our set of tools is expanding all of the time. Just yesterday, we signed a new agreement with Regeneron to provide nearly half a billion dollars in support for a promising

therapeutic, all the way to manufacturing hundreds of thousands of doses for the American people. The initial doses, pending approval, would be available as soon as the end of this summer or early fall. That is the first of a number of therapeutic agreements that we will do under the President's Operation Warp Speed initiative.

Promising therapeutics are already being administered every day by our heroic healthcare workers. I want to thank these heroes who continue to put themselves at risk, caring for those suffering from the virus. We know many frontline workers have gotten sick, and we know some have given their lives, including some of my employees in the Indian Health Service, and America is deeply grateful.

It is because we are making progress against the virus and learning more about it every day that we can talk about how to bring America's kids and teachers back to school safely. We have the tools to do it, and it has to be a top priority.

So thank you to President Trump and the Vice President for putting such a focus on this very important aspect of our road to recovery. Thank you.

THE VICE PRESIDENT: Great job. Thank you.

Right here. Please.

Q Mr. Vice President, in the President's call to reopen schools, is there a situation in some states, if the health situation doesn't allow for this, where you would be supportive of some states continuing distance learning?

And we now see the President threatening to cut off funding for schools. Is that a serious threat? And what would that look like?

THE VICE PRESIDENT: Well, the principle behind our approach to this coronavirus pandemic has been to provide federal support as states manage their own response. And what I can tell you is, in the weekly reports that we provide governors, we're down to the county level in terms of where the new cases are, where the positivity lies.

And I think we would account for the fact that while we hope -- we hope every school in America is able to open this fall, there may be some states and local communities that, given cases or positivity in that community, may adjust to either a certain set of days or certain limitations. And we'll be very respectful of that.

What the President has made clear, though, is that we think it's absolutely imperative that every state and territory in this country make -- make steps and -- takes steps, rather, to get kids back in the classroom to the fullest extent possible.

We really believe that every state has the ability to do that. But for those individual communities that may be seeing outbreaks, we'll work with

them, give them the guidance and the support to be able to implement the policies that they deem are most appropriate.

Our mission here is to safely reopen our schools. And as you've heard from all of these members of our task force, it's -- it's not just about kids learning and not falling behind academically; it's about all the vital services that children receive at our schools, it's about working families, it's about opening up America again. And so we'll continue to drive on that.

On your second point, I would tell you that, at this point, I think 90 percent of education funding comes from the states; roughly 10 percent, depending on states' budgets, come from the federal government. And as we work with Congress on the next round of state support, we're going to be looking for ways to give states a strong incentive and an encouragement to get kids back to school.

Please, go ahead.

Q Thank you, Mr. Vice President. The President tweeted this morning that he disagrees with the CDC's very tough and expansive guidelines for reopening schools. Do you also disagree with those guidelines? And are you concerned that you may be putting the health of students and teachers at risk by trying to meet the President's demand to reopen?

THE VICE PRESIDENT: Well, the President and I spoke about that this morning. And I think what you will see in the coming days, what you heard from Dr. Redfield yesterday at the summit and again today, is very consistent with the President's objective and the concerns that he's raised.

We don't want the guidance from CDC to be a reason why schools don't open. We want to partner with states, with local education officials, with governors, with local health officials to find a way to meet their needs to open up. And I think the President's statement this morning was simply reflective of that desire.

And -- but we remain very confident that as we continue to provide resources, we're seeing not just -- not just K-through-12 education; I mean, all 47 states and two territories have already published plans and guidance for reopening their schools. And we reiterated to the governors earlier this week, and again at the summit yesterday, that we're really here to partner with them to achieve that.

I think what the President was saying this morning is that if there are aspects of the CDC's recommendations that are prescriptive or that serve as a barrier to kids getting back to school, we want -- we want governors and local officials and education leaders to know that we're here to work with them to support the measures they're putting into place.

But I think that every American -- every American knows that we can safely reopen our schools. And we just want we want -- we want -- we want, as

the President said this morning, to make sure that what we're doing doesn't stand in the way of doing that.

Q Can I just follow up on that, sir?

THE VICE PRESIDENT: Go ahead.

Q Just to follow up, when we're talking about the health of children though, shouldn't the guidance be tough and should no expense be spared?

THE VICE PRESIDENT: Well, I'm going to ask Bob Redfield to speak to that. And one of the things that we have seen -- and I tell you as a parent as much as your Vice President and the head of this task force, I've been -- I've been grateful for it, is that apart from having an underlying health condition, children do not appear to be susceptible to serious illness from the coronavirus. Dr. Birx can speak to that statistically on a global basis, and that's been a blessing for Americans and American families.

And so, as Secretary Azar just said, we know that the risk of serious illness to children is very low. And there are measures we can put into place to make sure that we don't -- we don't see the spread of a virus or outbreaks in individual schools by having children learn in a single classroom or learn outside as often as possible and not go into larger settings. And this is all the kind of guidance that the CDC is putting forward.

But I'm going to let Bob Redfield speak to that because we really do believe that we can open these schools safely, given the -- what we've seen in terms of outcomes among children, and also the kind of measures that we think we can put into effect to prevent the spread.

DR. REDFIELD: Thank you, Mr. Vice President. I think it's really important to be clear that our recommendations to open these schools are really based on the sound public health and safety and health of children.

I think you heard already from some of the speakers, there's substantial health consequences that we've seen as a consequence of schools being closed, whether it's access to mental health services or it's access to nutrition. Clearly, we know a lot, and I think it's important that we don't react emotionally, but we act based on data.

Clearly, the ability of this virus to cause significant illness in children is very, very -- very limited. We know of the host immune inflammatory disease that you've heard about, but it's very rare. But in general, this virus does not cause significant illness in children.

Secondly, and I think it's important, unlike influenza -- where one of our biggest concerns -- is we've been able to show that it's really schools and children that become the instrument of transmission throughout our

community with influenza. We really don't have evidence that children are driving the transmission cycle of this.

The most important thing, as we reopen schools -- and as I mentioned before, we're prepared to work with every school and every school district to help them find the right mixture of strategies for them to do this safely. Our recommendations are not requirements, and they're not meant to be prescriptive. We have lots of different options on how the schools can put it together.

But what we do want to reiterate, as we reopen schools, is to remember the importance of protecting the vulnerable. That, we will be strong on. It's important to limit the ability of individuals with significant comorbidities, individuals that happen to be elderly with comorbidities. We want to limit those individuals, their interactions in general and in society, independent of the schools.

THE VICE PRESIDENT: Thanks, Bob.

Now, let me say, just also in response to your question: I would recommend that every American review this statement issued by the American Academy of Pediatrics that released an important report, indicating that there are real physical and mental cause for children to be deprived of an in-classroom setting. It ranges from nutrition to children that have special needs.

We heard from Dr. McCance-Katz that some 7 million children in America deal with mental health issues, and the services and the counseling they receive, they receive at their schools.

And so we want to put the health and wellbeing of our kids first. And given the fact that children, as Dr. Redfield said again, do not appear to be susceptible to serious outcomes from the coronavirus, we want to put their -- the totality of their health and their wellbeing forward. And that all tells us, it tells the President, it tells this task force, that means we need to get our kids back to school.

Please.

Q Mr. Vice President, thank you. So you've articulated the problem -- the myriad risks that students face if they stay out of school come the fall. But what's the plan? What's the administration's specific plan in terms of increased testing, contact tracing, increased PPE, if it's needed, to support these schools?

As you well know, schools weren't built for students to socially distance. They were built to pack in as many kids as humanly possible, which is one of the reasons why school districts -- like Fairfax, Virginia; the school district in New York; Texas -- they have moved to this hybrid approach: some virtual learning, some in-person learning. So what's the plan?

And then, I have a question for Dr. Birx about kids and COVID, if I may.

THE VICE PRESIDENT: Well, the plan is to continue to do what we have done from the very beginning. As you heard again this morning, we're -- we're at, I believe, 39 million tests that have been performed all across this country. You heard Admiral Giroir describe the extraordinary commitment in just one community alone. And what we've conveyed to governors is: Whatever support they need to get kids back to school, we're going to make sure that they have. We're going to make sure that they have the testing resources.

We're currently educating states on the possibility -- and working with commercial labs -- on the possibility of what's called pooling, so that, literally, there could be one test run on, say, 10 samples. And there are -- there are particularly universities that already have built into their plans the idea of testing all of their students at the beginning of the academic year, and then doing surveillance testing.

But we made it very clear -- whether it's testing, whether it's personal protective equipment or other resources -- that we stand ready to provide those resources to the states. And we reiterated that once again to the governors.

But the good news is, because of the historic mobilization that President Trump initiated, we literally have hundreds of millions of supplies of personal protective equipment, 59,000 ventilators in the Strategic National Stockpile. Testing is scaling all across America. And we know that come the school year, we'll be ready to meet those needs.

But -- question?

Q Yes. Thank you. Dr. Birx, what's the infection rate among children? And what's the very latest in terms of -- that you know -- in terms of how the virus presents in children; how children transmit the virus to older adults? Nearly a third of teachers across this country are age 50 and older. And what's the best practice in terms of testing children? I've never heard of a case where a school child is tested for COVID-19.

DR. BIRX: Those are all good questions, and I think it really comes to the evidence base of what do we have as far as testing and children. So if you look across all of the tests that we've done, and whether -- when we have the age, the portion that has been the lowest-tested portion is the under-10- year-olds. So we're putting into place other ways to get testing results from them and looking at antibody in that discarded samples, and try to really figure this out, because parents have really done an amazing job of protecting their children.

I think Americans have done a great job in keeping infection rates low in children, and in the sheltering time, and keeping infection rates, right now, in this new cases. Originally, I think we saw great protection of people with comorbidities.

We are worried now that as cases spread, that it's getting to the older parents and the grandparents. And I call on, again, every multi-generational household: Get tested and protect those in the household.

And we do know that there are children with vulnerabilities, and certainly within the CDC plan and Department of Education, it's protecting those children also from getting exposed to the virus, because we do know there are children with comorbidities. We know that there are children in America with cancer and getting -- undergoing chemotherapy.

But when you ask that question, the parents have so protected their children. And remember early on, we said: Test if you have symptoms. And now we know that if you're under 18, the majority of you don't have symptoms. And so, really figuring out -- and there's universities working around the country on a saliva test, so it'd be easy -- easier for children to put saliva in a tube. Just, basically, what we call spitting in a tube or spitting through a straw into a tube. And looking at that kind of innovation and testing.

And what Admiral Giroir has been working on very hard is this antigen-based testing and getting that equipment into the vulnerable areas like nursing homes, assisted living, and other places, but also considering how a school district could use that would make it much easier to test and to use saliva.

So all of those are being worked on, and it's why we've been pushing on the antigen test. I know you've heard me talk about that in April. We're pushing on that because we think it is important for testing of students and testing in universities.

But we have the -- our data is skewed originally to people with symptoms, and then skewed to adults over 18. And so we are looking very closely into that category by using our antibody tests.

THE VICE PRESIDENT: Did you want to talk about the risk to children (inaudible)?

DR. BIRX: I think the Vice President covered that incredibly well. We know the mortality rate in under 25 from the CDC data is less than 0.1 percent. And so that has been holding.

But until we know how many have been infected, we have no evidence that there is significant mortality in children without coexisting diseases. And that's what we're looking for right now, is to really make sure we've unturn- -- overturned every rock and understand that in deep detail.

THE VICE PRESIDENT: Thanks, Deborah. Right here, and then there.

Q Mr. Vice President, we all know the CDC guidelines are not requirements, they're advice.

THE VICE PRESIDENT: Right.

Q And is the President, when he calls it "too tough" or "impractical," making it easier for Americans and for school officials to ignore that advice?

THE VICE PRESIDENT: Well, I have every confidence that governors and state education officials and local health officials are going to implement the policies that they think are in the best interest of children and families.

And I think the President's sentiment this morning, I think, is shared widely by the American people and certainly by members of this task force. We want to make it very clear that -- that -- excuse me -- the guidance that we're issuing is not to supplant the laws, the rules, the regulation of the decisions at the state level; it's meant to create essentially a range of options.

And what we made clear to governors on the governors' call this week, specifically, was that we are prepared at the CDC to sit down with state officials and to work through their plan and be able to advise and dialogue with them about the best way forward.

But I must tell you that, in this role over the last four months, I've been impressed by governors in both political parties and health officials in all of our states and our territories with the way they've put the health of their people first.

And -- but I must also say that I have a great sense, talking to governors -- and a great sense that this is something the American people want to see happen. And governors are hearing that, they know that, and that's why you have 47 states that have already issued plans or guidelines. And we're going to work with them to make those a reality.

AIDE: Last question, guys.

THE VICE PRESIDENT: Okay.

Q Thank you, Mr. Vice President. I have two questions: one for you and then one for Dr. Redfield. Can you explain why the President is threatening to cut funding from schools at a time when educators are saying they need more so they can safely reopen?

THE VICE PRESIDENT: Kaitlan, first and foremost, it's -- what you heard from the President is just a determination to provide the kind of leadership from the federal level that says that we're going to get our kids back school because that's where they belong. And we know, based upon what our best health officials tell us, that we can do that in a safe and in a responsible way.

But to be clear: The current CARES Act provided \$13.3 billion to support education efforts in states in the midst of the pandemic. We're going to work with Congress; we expect there'll be additional support there.

But the President is just very serious. For all the reasons that we discussed today, he believes and we believe it's absolutely essential for our children's academic development and -- and for their social and emotional and health and nutrition needs to be back in the classroom. And we're going to provide the leadership from the federal level to do that.

But that being said, I -- I will tell you, I sense a great desire among governors around the country to find a way forward. And we've made it very clear to them that we're going to partner with them, providing them with the resources to impact that and also the supplies.

Q But you've said -- you're saying it's a -- describing it as a local decision. So shouldn't it be up to them to decide if they can safely reopen and not the President saying he's going to pressure them to do so?

THE VICE PRESIDENT: Well, I've -- look, we're going to respect those unique communities that may have challenges -- that have rising cases or rising positivity. And -- but I think you look at the nation as a whole. I think what the President of the United States has made clear is: He thinks, as we reopen America, we need to reopen America's schools.

It's just as the President said early in this pandemic: that he wanted to get our places of worship back open again. I think what you're seeing the President provide is leadership. And what we're providing from the White House Coronavirus Task Force is partnership with the governors and with state health officials because we just got to get -- we got to get our kids back.

I have to tell you, the best expert I know on this topic is my wife Karen. And she's spoken at the summit yesterday very compellingly about how a lot of our kids are hurting out there. They're struggling with loneliness, with social isolation. The American Academy of Pediatrics spoke about that -- a very forceful statement from pediatricians across the country that said we got to get our kids back into school.

Q But do you think (inaudible)?

THE VICE PRESIDENT: So, what you're -- what you're going to see, Kaitlan, is the President is going to continue to provide leadership. I expect the -- as the debate in Congress goes forward about additional resources, we're going to look to build in incentives for states to go forward.

But President has made it clear -- and I think most parents in America would agree with him -- that we got to get our kids back to school, and we got to get them back into the classroom, and we can do it in a safe in a responsible way.

Q My question for Dr. Redfield --

AIDE: Thanks guys.

Q I have a question for Dr. Redfield.

THE VICE PRESIDENT: That's okay.

Q I have a question for Dr. Redfield.

THE VICE PRESIDENT: Bob, a question.

Q My second question: Dr. Redfield, you're talking about the guidance that the CDC has put out. It sounds like you think it is in the best interest of students and ways to safely reopen schools so far. So are you going to change that guidance because the President said that he does not like it?

DR. REDFIELD: Well, I think I just want to reiterate: We're going to continue to work with local states and jurisdictions. I think the guidance that we've put out gives a series of different strategies for them to consider what is the most appropriate in their unique situation to adopt. Again -- and I want to come back to the goal, and the goal of this is to get schools reopened.

I did mention and I want to reiterate: That goal is just not a goal to reopen schools. That's the goal because we believe that's in the best public health interest of the students for the reasons you've heard.

Q (Inaudible) why did you change that guidance?

DR. REDFIELD: We will continue to develop and evolve our guidance to meet the needs of the schools in the states that we continue to provide that assistance to.

AIDE: Thanks, guys. Thanks, guy.

Q (Inaudible.)

THE VICE PRESIDENT: I'm sorry. I can't hear your question.

Q Mr. Vice President --

THE VICE PRESIDENT: Go ahead.

Q For the guidance -- the guidance recommends that schools have social distancing of students, six feet apart. And that's why these schools are adopting these hybrid models is because they don't feel they can keep students six feet apart within their -- within their building.

So I'm just wondering if that particular part of the guidance is something you're rethinking? Or do you support that social distancing inside schools? Because that's where schools, I think, are having trouble.

THE VICE PRESIDENT: Well, the President said today we just don't want the guidance to be too tough. And that's the reason why, next week, CDC is going to be issuing a new set of tools: five different documents that will be giving even more clarity on the guidance going forward. But we know each school system, you know, has unique capabilities, different facilities.

And what parents around the country should know is that we're here to help. We're here to work with their governors, with their local education officials to get our kids back to school.

I mean, the truth of the matter is that, as we -- as we reopen America, we've got to -- we got to reopen our schools for the wellbeing of our kids, for their academic advancement, for working families. But also, as you've heard again today, for -- to continue the momentum that we see in this economy that we saw last week with nearly 5 million jobs created.

I want to promise the American people: We're going to stay focused at this task force on saving lives, meeting the needs of our state and our healthcare workers, on protecting the vulnerable, and reopening America's economy, schools, work, and worship.

So thank you all very much. We'll talk to you in a few days.

END

12:52 P.M. EDT

From: O'Malley, Devin M. EOP/OVP [Devin.M.O'Malley@ovp.eop.gov]
Sent: 7/14/2020 9:27:53 PM
To: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: Fwd: Trump Administration Announces Initiative for More and Faster COVID-19 Testing in Nursing Homes

Sent from my iPhone

Begin forwarded message:

From: HHS Office of Public Affairs <hhsopa@hhs.gov>
Date: July 14, 2020 at 8:35:21 PM EDT
To: "O'Malley, Devin M. EOP/OVP" <Devin.M.O'Malley@ovp.eop.gov>
Subject: Trump Administration Announces Initiative for More and Faster COVID-19 Testing in Nursing Homes
Reply-To: hhsopa@hhs.gov



News Release

U.S. Department of Health and Human Services

202-205-0143
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FOR IMMEDIATE RELEASE

Tuesday, July 14, 2020

Trump Administration Announces Initiative for More and Faster COVID-19 Testing in Nursing Homes

Today, under the leadership of President Trump, the U.S. Department of Health and Human Services (HHS) is announcing a large-scale procurement of U.S. Food and Drug Administration (FDA) -authorized rapid point-of-care diagnostic test instruments and tests to be distributed to nursing homes in COVID-19 hotspot geographic areas with the United States. This initiative is a one-time procurement of devices and tests targeted to facilitate on-site testing among nursing home residents and staff. Through this crucial action, nursing homes will be able to augment their current capacity for coronavirus testing, bolstering their response and helping to prevent the spread of SARS-CoV-2, the virus that causes COVID-19.

“Access to rapid point-of-care testing in nursing homes will further protect our Nation’s most vulnerable patients,” said Assistant Secretary for Health ADM Brett P. Giroir, M.D. “With the recent FDA Emergency Use Authorization of the BD Veritor system, combined with the earlier authorization of the Quidel Sofia and Sofia 2 systems, we now have the ability to provide more testing faster. This could not have been possible without the scientific investments made by these companies, advanced regulatory science from the FDA and other investments by the Federal government.”

Distribution will begin next week with nursing homes prioritized by Centers for Medicare & Medicaid Services (CMS) in their

FDA-OC-2020-1977/2020-4765-001303

MULTI-HHS-FDA-20-0400, 20-0415-C-000311

continuing effort to protect older adults. Each nursing home will receive one diagnostic test instrument and associated tests. Following initial distribution, nursing homes can procure additional tests directly from the respective manufacturers. Nursing homes must have the capability to screen and test residents, and test staff on a weekly basis or according to specific guidance by the state and local health departments. This procurement will also enable testing of visitors if appropriate for that facility.

“This new testing initiative is critical for keeping vulnerable older adults safe while delivering the quality of life they deserve,” said CMS Administrator Seema Verma. “It gives nursing homes the ability to swiftly identify residents that need to be isolated and mitigate the spread of the virus. As one more tool in the toolbox, it represents an important step toward the long-awaited reunion of residents with their loved ones.”

Both the Quidel Sofia and Sofia 2 Instruments and BD Veritor Plus Systems use antigen tests that can quickly detect fragments of proteins found on or within the virus by testing samples collected from the nasal cavity using swabs, providing results in minutes. Antigen tests will play a critical role in the fight against COVID-19 and will be essential to reach the Nation’s goal of testing millions of Americans each day.

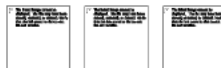
Additional Background

The FDA has granted Emergency Use Authorization to two antigen detection tests: (1) the Sofia SARS Antigen FIA manufactured by Quidel Corporation (Quidel) and (2) the Veritor System for Rapid Detection of SARS-CoV-2 manufactured by Becton, Dickinson and Company. These tests may be slightly more likely to have a false negative result than molecular PCR COVID tests. See [FDA](#) for more details. These assays are approved for detection of the nucleocapsid protein antigen from SARS-CoV-2 in nasal (both devices) and nasopharyngeal (Sofia SARS Antigen FIA only) swab specimens, and authorized for use by laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, which meet the requirements to perform waived, moderate, or high complexity tests. These tests are authorized for use at the point of care, e.g., in patient care settings such as nursing homes operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

According to CMS, there are more than 200,000 confirmed or suspected cases of COVID-19 and more than 35,000 COVID-19 deaths among nursing home residents as of July 9, 2020. Additionally, the [Centers for Disease Control and Prevention](#) recommends that nursing homes perform baseline testing of all residents and staff, followed by regular screening and surveillance through routine testing to detect potential outbreak situations early and reduce morbidity and mortality.

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Sent: 3/10/2020 8:03:32 PM
To: Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: FW: Exclusive: U.S. coronavirus testing threatened by shortage of critical lab materials

Can we please chat about this tonight?

-

Exclusive: U.S. coronavirus testing threatened by shortage of critical lab materials

By David Lim, Brianna Ehley

03/10/2020 06:46 PM EDT

A looming shortage in lab materials is threatening to delay coronavirus test results and cause officials to undercount the number of Americans with the virus.

The slow pace of coronavirus testing has created a major gap in the U.S. public health response. The latest problem involves an inability to prepare samples for testing, creating uncertainties in how long it will take to get results.

CDC Director Robert Redfield told POLITICO on Tuesday that he is not confident that U.S. labs have an adequate stock of the supplies used to extract genetic material from any virus in a patient's sample — a critical step in coronavirus testing.

"The availability of those reagents is obviously being looked at," he said, referring to the chemicals used for preparing samples. "I'm confident of the actual test that we have, but as people begin to operationalize the test, they realize there's other things they need to do the test."

The coronavirus task force convened by the White House is also aware of the shortages, and one official said members are working on it.

The growing scarcity of these "RNA extraction" kits is the latest trouble for U.S. labs, which have struggled to implement widespread coronavirus testing in the seven weeks since the country diagnosed its first case. Epidemiologists and public health officials say that the delayed rollout, caused in part by a botched CDC test, has masked the scope of the U.S. outbreak and hobbled efforts to limit it.

If enough processing kits aren't available, the risk that testing will be disrupted is "huge," said Michael Mina, associate medical director of molecular diagnostics at Brigham and Women's Hospital in Boston.

"RNA extraction is the first step in being able to perform" a coronavirus test, he said. "If we cannot perform this step, the [coronavirus] test cannot be performed."

Qiagen, a major supplier of the kits, confirmed that its product is backordered due to "the extraordinary pace" at which the world has increased coronavirus testing over the last few weeks.

Public health labs across the U.S. have tested more than 5,000 people, according to the Trump administration. HHS Secretary Alex Azar told lawmakers on Tuesday that U.S. labs' capacity could grow to 10,000-20,000 people per day by the end of the week.

"Increased demand for testing has the potential to exhaust supplies needed to perform the test itself," said Robin Patel, president of the American Society for Microbiology. That would limit the testing capacity of public health, hospital and commercial labs alike, she added.

Complicating the situation, most labs have been running at least two tests per patient — although that could soon change. The [CDC issued interim guidelines on Monday](#) that minimize the number of tests required for a diagnosis. The agency says labs can combine a patient's nose and throat samples into one test, a move experts say will cut in half the amount of supplies used to test each person.

But Redfield said he doesn't know how the agency would deal with any scarcity of RNA extraction kits and reagents that arise. "I don't know the answer to that question," he said when asked how the CDC would handle such a situation — adding that he is hopeful "there will be mechanisms between multiple manufacturers to correct" it.

Mandy Cohen, North Carolina's secretary of health, said that a shortage of extraction kits and other chemicals had hampered testing in her state. "Folks were saying, 'We are sending you the [test] kits,' and I don't think they understood at first what exact part of the supply chain we needed," she said. "We needed extraction kits."

An FDA spokesperson said that the agency is contacting labs that are testing for the coronavirus "to understand their supply issues and assist where we can."

The FDA has also approved a change to the CDC diagnostic test that allows labs to switch from Qiagen's RNA extraction method to another manufactured by Roche, says Denny Russell, who leads the coronavirus response at Washington state's public health lab. But getting his lab ready to use the Roche method could take a week in part because technicians will need training to use it.

Commercial labs, which have recently started running coronavirus tests, have not experienced any supply shortages, according to a spokesperson for the American Clinical Laboratory Association.

In the meantime, Qiagen has told customers that it may not be able to fill large standing orders, because it is trying to provide smaller numbers of kits to as many labs as possible, said spokesperson Robert Reitze. The company is ramping up production of RNA extraction kits at manufacturing sites in Hilden, Germany; Barcelona, Spain; and Germantown, Md.

Nancy Cook and Dan Goldberg contributed to this report.

From: O'Malley, Devin M. EOP/OVP [Devin.M.O'Malley@ovp.eop.gov]
Sent: 3/10/2020 9:29:11 PM
To: Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Caccamo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
Subject: FW: Exclusive: U.S. coronavirus testing threatened by shortage of critical lab materials

Hi team FDA-

Sorry for the late email. From my conversations with FDA officials, it seems [REDACTED]

Thanks for all your hard work!!

Devin

-

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By David Lim, Brianna Ehley

03/10/2020 06:46 PM EDT

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If enough processing kits aren't available, the risk that testing will be disrupted is "huge," said Michael Mina, associate medical director of molecular diagnostics at Brigham and Women's Hospital in Boston.

"RNA extraction is the first step in being able to perform" a coronavirus test, he said. "If we cannot perform this step, the [coronavirus] test cannot be performed."

Qiagen, a major supplier of the kits, confirmed that its product is backordered due to "the extraordinary pace" at which the world has increased coronavirus testing over the last few weeks.

Public health labs across the U.S. have tested more than 5,000 people, according to the Trump administration. HHS Secretary Alex Azar told lawmakers on Tuesday that U.S. labs' capacity could grow to 10,000-20,000 people per day by the end of the week.

"Increased demand for testing has the potential to exhaust supplies needed to perform the test itself," said Robin Patel, president of the American Society for Microbiology. That would limit the testing capacity of public health, hospital and commercial labs alike, she added.

Complicating the situation, most labs have been running at least two tests per patient — although that could soon change. The CDC issued interim guidelines on Monday that minimize the number of tests required for a diagnosis. The agency says labs can combine a patient's nose and throat samples into one test, a move experts say will cut in half the amount of supplies used to test each person.

But Redfield said he doesn't know how the agency would deal with any scarcity of RNA extraction kits and reagents that arise. "I don't know the answer to that question," he said when asked how the CDC would handle such a situation — adding that he is hopeful "there will be mechanisms between multiple manufacturers to correct" it.

Mandy Cohen, North Carolina's secretary of health, said that a shortage of extraction kits and other chemicals had hampered testing in her state. "Folks were saying, 'We are sending you the [test] kits,' and I don't think they understood at first what exact part of the supply chain we needed," she said. "We needed extraction kits."

An FDA spokesperson said that the agency is contacting labs that are testing for the coronavirus "to understand their supply issues and assist where we can."

The FDA has also approved a change to the CDC diagnostic test that allows labs to switch from Qiagen's RNA extraction method to another manufactured by Roche, says Denny Russell, who leads the coronavirus response at Washington state's public health lab. But getting his lab ready to use the Roche method could take a week in part because technicians will need training to use it.

Commercial labs, which have recently started running coronavirus tests, have not experienced any supply shortages, according to a spokesperson for the American Clinical Laboratory Association.

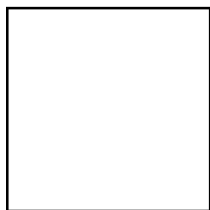
In the meantime, Qiagen has told customers that it may not be able to fill large standing orders, because it is trying to provide smaller numbers of kits to as many labs as possible, said spokesperson Robert Reitze. The company is ramping up production of RNA extraction kits at manufacturing sites in Hilden, Germany; Barcelona, Spain; and Germantown, Md.

Nancy Cook and Dan Goldberg contributed to this report.

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Sent: 5/24/2020 10:31:00 PM
To: Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Guram, Jeet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ef73bea97e2b477b847ea302c4730ccf-Gurjeet.Gur]; Block, Molly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e32ca68078848889751e7ec26910142-Molly.Block]
Subject: FW: FOR REVIEW: Draft Factsheet - Lowering Medicare Insulin Prices and Improving Healthcare for our Nation's Seniors
Attachments: Factsheet - Lowering Medicare Insulin Prices V.1_HHS.docx

Hi all - (b) (5) [REDACTED] ? If so, it would be good to add to this fact sheet.

Thanks,
Ninio

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From: Boyse, Natalie (OS/IOS) <Natalie.Boyse@hhs.gov>
Sent: Sunday, May 24, 2020 7:26 PM
To: Moughalian, Jen (HHS/ASFR) <Jen.Moughalian@hhs.gov>; Hayes, Jonathan (OS/ASPR/IO) <Jonathan.Hayes@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Waters, Cicely (OS/ASPR/OEA) <Cicely.Waters@hhs.gov>; block.molly@epa.gov; Michael, Gretchen (OS/ASPR/OEA) <Gretchen.Michael@hhs.gov>; Arbes, Sarah (HHS/ASL) <Sarah.Arbes@hhs.gov>; Morse, Sara (HHS/ASL) <Sara.Morse@hhs.gov>; Pence, Laura (HHS/ASL) <Laura.Pence@hhs.gov>; Galatas, Kate (CDC/OD/OADC) <kkg2@cdc.gov>; CDC IMS JIC OADC LNO -2 <eocevent202@cdc.gov>; Bonds, Michelle E. (CDC/OD/OADC) <meb0@cdc.gov>; Heldman, Amy B. (CDC/OD/OADC) <evd4@cdc.gov>; McGowan, Robert (Kyle) (CDC/OD/OCS) <omc2@cdc.gov>; Oury, Rachael (CDC/OD) <QKC3@cdc.gov>; Brandt, Kimberly (CMS/OA) <Kimberly.Brandt1@cms.hhs.gov>; Brookes, Brady (CMS/OA) <Brady.Brookes@cms.hhs.gov>; Corry, Thomas (CMS/OA) <Thomas.Corry@cms.hhs.gov>; Bell, Damian (CMS/OC) <Damian.Bell@cms.hhs.gov>; Brady, Will (HHS/IOS) <William.Brady@hhs.gov>; Callahan, Kenneth (HHS/IOS) <Kenneth.Callahan@hhs.gov>; Caliguiri, Laura (FDA/OC) <Laura.Caliguiri@fda.hhs.gov>; Felberbaum, Michael (FDA/OC) <Michael.Felberbaum@fda.hhs.gov>; Caccamo, Stephanie (FDA/OC) <Stephanie.Caccamo@fda.hhs.gov>; Trueman, Laura (HHS/IEA) <Laura.Trueman@hhs.gov>; Johnston, Darcie (HHS/IEA) <Darcie.Johnston@hhs.gov>; Stannard, Paula (HHS/IOS) <Paula.Stannard@hhs.gov>; Conrad, Patricia (NIH/NIAID) [E] <(b)(6)>; Stover, Kathy (NIH/NIAID) [E] <(b)(6)>; Routh, Jennifer (NIH/NIAID) [E] <(b)(6)>; Sherman, Jennifer (HHS/OASH) <Jennifer.Sherman@hhs.gov>; Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Kellogg, Rachel (HHS/OASH) <Rachel.Kellogg@hhs.gov>; Grigsby, Garrett (HHS/OS/OGA) <Garrett.Grigsby@hhs.gov>; Stimson, Brian (HHS/OGC) <Brian.Stimson@hhs.gov>; Charrow, Robert (HHS/OGC) <Robert.Charrow@hhs.gov>; Thomas, Gloria (HHS/OS/OGA) <Gloria.Thomas@hhs.gov>; Fulmer, Brendan (HHS/IOS) <Brendan.Fulmer@hhs.gov>; Ezernack, Paige (OS/ASPR/SPPR) <Paige.Ezernack@hhs.gov>; Myles, Renate (NIH/OD) [E] <(b)(6)>; Burklow, John (NIH/OD) [E] <(b)(6)>; Fine, Amanda (NIH/OD) [E] <(b)(6)>; Fritz, Craig (NIH/OD) [E] <(b)(6)>; Wojtowicz, Emma (NIH/OD) [E] <(b)(6)>; Akinso, Woleola (NIH/OD) [E] <(b)(6)>; Beckham, Tammy (HHS/OASH) <Tammy.Beckham@hhs.gov>; Monroe, Johnathan (CMS/OC) <Johnathan.Monroe1@cms.hhs.gov>; Overstreet, Elizabeth (OS/ASFR) <Elizabeth.Overstreet@hhs.gov>; Amin, John (HHS/ASFR) (CTR) <John.Amin@hhs.gov>; Parker, Jim (HHS/IOS) <Jim.Parker@hhs.gov>; Fetalvo, Ninio (CMS/OC) <Ninio.Fetalvo@cms.hhs.gov>; Keveney, Sean (HHS/OGC) <Sean.Keveney@hhs.gov>; Schwartz, Erica (HHS/OASH) <Erica.Schwartz@hhs.gov>; Uehlecke, Nick (HHS/IOS) <Nicholas.Uehlecke@hhs.gov>; Brooks, John (CMS/OA) <John.Brooks@cms.hhs.gov>; Nicholls, Richard (ACL) <Richard.Nicholls@acl.hhs.gov>
Cc: ASPA-Deputies <ASPA-Deputies@hhs.gov>; Bird, Catherine (OS/IOS) <Catherine.Bird@hhs.gov>; Agnew, Ann

(HHS/IOS) <Ann.Agnew@hhs.gov>; Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov>; Mango, Paul (HHS/IOS) <Paul.Mango@hhs.gov>

Subject: FOR REVIEW: Draft Factsheet - Lowering Medicare Insulin Prices and Improving Healthcare for our Nation's Seniors

Hi Everyone -

Attached via Staff Sec is a draft factsheet about the Administration's efforts to reduce the cost of insulin and improve healthcare for our Nation's seniors. This factsheet is intended to accompany the event on Tuesday on protecting Americans with diabetes.

Please let me know if you have any feedback on the factsheet **by 2pm tomorrow (Monday)**. Affirmative clearance is requested from **ACL, CMS and NIH**. All others are, of course, welcome to provide feedback as well.

Thanks,
Natalie

Natalie Boyse
Special Assistant, Immediate Office of the Secretary
U.S. Department of Health & Human Services
M: (b)(6)

From: O'Malley, Devin M. EOP/OVP [Devin.M.O'Malley@ovp.eop.gov]
Sent: 5/12/2020 1:05:28 PM
To: Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
Subject: FW: [EXTERNAL] (b) (4)
Attachments: Coagulo - FDA - Letter and Proposal for (b) (4) - w_App'x 2 - 2022604201-4 - 2022804201-2.pdf

Just passing this along.

From: Jarrod Niebloom <j.niebloom@coagulomed.com>
Sent: Tuesday, May 12, 2020 1:02 PM
To: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>
Subject: [EXTERNAL] (b) (4)

Dear Mr. O'Malley,

My name is Jarrod Niebloom and I am the CEO of Coagulo Medical Technologies, Inc. (b) (4)

[REDACTED]

(b) (4)

(b) (4)

Best regards,
Jarrod
Jarrod B. Niebloom
Chairman & CEO
main: +1.617.340.3103
direct: +(b)(6)
j.niebloom@coagulomed.com

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