



Case No. 2020-00717-FOIA-OS
American Oversight v. HHS, Civil No. 20-1169

January 7, 2022

Austin Evers
Executive Director
American Oversight
Sent via email: foia@americanoversight.org

Dear Mr. Evers:

This letter is the eighth interim response to your March 18, 2020, Freedom of Information Act (FOIA) request.

American Oversight requests that HHS produce the following records as soon as practicable, and at least within twenty business days:

All email communications (including email messages, complete email chains, email attachments, calendar invitations) sent by the government officials specified below containing any of the following key terms:

1. Coronavirus
2. Corona
3. Virus
4. Disease
5. Pandemic
6. Epidemic
7. Outbreak
8. containment
9. "public health emergency"
10. "COVID-19"
11. "COVID 19"
12. COVID19
13. SARS
14. "2019-nCoV"
15. POTUS
16. Test
17. Tests
18. Testing
19. EUA
20. Emergency
21. Wuhan
22. Hoax
23. Hubei
24. Princess
25. Cruise
26. Kirkland
27. Seattle
28. "New Rochelle"
29. "BioGen Conference"
30. CPAC
31. AIPAC
32. RNA
33. "Extraction kits"

34. Roche
35. Vaccine
36. Antiviral
37. Antiretroviral
38. Quarantine
39. Distancing
40. Isolation
41. N95
42. Mask
43. Respirator

Government Officials

1. Alex Azar, Secretary
2. Brian Harrison, Chief of Staff
3. Eric Hargan, Deputy Secretary
4. Jerome Adams, Surgeon General
5. Robert Kadlec, Assistant Secretary for Preparedness and Response
6. John Brooks, Senior Advisor to the Secretary for Drug Pricing Reform

On February 10, 2021, you narrowed your request per the following:

Eliminate attachments, documents regarding “Red Dawn” and obvious marketing and news bulletins

- a. Limit the date range of the following key terms as stand-alone search terms from January 15, 2020 through February 29, 2020. ~~[[Limit responsive records to those that also include: (Test OR Tests OR Vaccine OR EUA OR “Emergency Use” OR Shortage OR Shortages OR Supplies OR “the WHO” OR States OR Governor OR Governors OR PPE OR Ventilators OR Respirators OR Swabs OR DPA OR “Defense Production Act” OR Trump OR Pence OR Jared OR Kushner OR “White House” OR “the WH”)]]~~

- i. Coronavirus
- ii. Corona
- iii. “COVID-19”
- iv. “COVID 19”
- v. COVID19
- vi. “2019-nCoV”

~~vii. SARS~~

~~viii. Epidemic~~

~~ix. Pandemic~~

~~x. Outbreak~~

~~xi. “Public Health Emergency”~~

-

- b. After March 1, 2020, for the key terms listed in Column A below (the same search terms as identified above), limit responsive records to those that also include one or more of the terms from Column B:

Column A	Column B
• Coronavirus • Corona • “COVID-19” • “COVID 19” • COVID19 • “2019-nCoV” • SARS • Epidemic • Pandemic • Outbreak • “Public Health Emergency”	• Test • Tests • Vaccine • Antiviral • Antiretroviral • EUA • “Emergency Use” • Shortage • Shortages • Supplies • “Emergency Use” • EUA • “the WHO” • “W.H.O.” • “World Health Organization” • States • Governor • Governors • PPE • Ventilators • Respirators • Swabs • DPA • “Defense Production Act”

- c. For the key terms that are in Column A below, limit responsive records to those that also include one or more of the terms from Column B, for the full time period of the search.

Column A	Column B
• Test • Tests • “Extraction Kits”	• CV19 • “CV-19” • C19 • “C-19” • Roche • RNA • Shortage • Shortages • Supplies • “Emergency Use” • “EUA” • “the WHO” • “W.H.O.” • “World Health Organization” • States • Governor • Governors • Kit • Kits • DPA • “Defense Production Act”

- d. ~~[~500 records] For the key terms that are in Column A below, limit responsive records to those that also include one or more of the terms from Column B, for the full time period of the search.~~

Column A	Column B
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• Vaccine • Antiviral • Antiretroviral	• CV19 • “CV-19” • C19 • “C-19” • “EUA” • “Emergency Use” • “DPA” • “Defense Production Act” • “the WHO” • “W.H.O.” • “World Health Organization”
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c. ~~[<50 records] For the key term “Emergency” limit responsive records to those that also include “DPA” or “Defense Production Act,” for the full time period of the search.~~

f. For the following key terms, please limit the time period as indicated:

i. Princess - February 1, 2020, through March 1, 2020 ~~[[Limit responsive records to those that also include: Trump OR Pence OR Jared OR Kushner OR “White House” OR “the WH”]]~~

~~ii. [~~150 records~~] Kirkland February 24, 2020, through March 24, 2020~~

~~iii. [~~750 records~~] Seattle February 24, 2020, through March 24, 2020~~

~~iv. [~~200 records~~] “New Rochelle” March 1, 2020, through March 31, 2020~~

~~v. [~~<50 records~~] “BioGen Conference” March 1, 2020, through March 31, 2020~~

~~vi. [~~50 records~~] CPAC February 21, 2020, through March 21, 2020~~

~~vii. [~~<50 records~~] AIPAC February 21, 2020, through March 21, 2020~~

g. For the following key terms, please run the search without any modifiers and using the full date range (i.e., no changes from original search)

i. Wuhan ~~[[Limit responsive records to those that also include: Trump OR Pence OR Jared OR Kushner OR “White House” OR “the WH”]]~~

ii. Hoax ~~[[no changes]]~~

iii. Hubei ~~[[Limit responsive records to those that also include: Trump OR Pence OR Jared OR Kushner OR “White House” OR “the WH”]]~~

iv. POTUS ~~[[no changes]]~~

v. Cruise ~~[[Limit responsive records to those that also include: Trump OR Pence OR Jared OR Kushner OR “White House” OR “the WH”]]~~

vi. Quarantine ~~[[Limit responsive records to those that also include: Trump OR Pence OR Jared OR Kushner OR “White House” OR “the WH”]]~~

vii. Distancing ~~[[Limit responsive records to those that also include: Trump OR Pence OR Jared OR Kushner OR “White House” OR “the WH”]]~~

~~viii. Isolation~~

ix. N95 ~~[[Limit responsive records to those that also include: (CV19 OR “CV-19” OR C19 OR “C-19” OR Shortage OR Shortages OR Supplies OR “Emergency Use” OR “EUA” OR “the WHO” OR States OR Governor OR Governors OR DPA OR “Defense Production Act” OR Trump OR Pence OR Jared OR Kushner OR “White House” OR “the WH”]]~~

x. Mask ~~[[Limit responsive records to those that also include: (CV19 OR “CV-19” OR C19 OR “C-19” OR Shortage OR Shortages OR Supplies OR “Emergency Use” OR “EUA” OR “the WHO” OR States OR Governor OR Governors OR DPA OR “Defense Production Act” OR Trump OR Pence OR Jared OR Kushner OR “White House” OR “the WH”]]~~

xi. Respirator ~~[[Limit responsive records to those that also include: (CV19 OR “CV-19” OR C19 OR “C-19” OR Shortage OR Shortages OR Supplies OR “Emergency Use” OR “EUA” OR “the WHO” OR States OR Governor OR Governors OR DPA OR “Defense Production Act” OR Trump OR Pence OR Jared OR Kushner OR “White House” OR “the WH”]]~~

xii. Testing ~~[[Limit responsive records to those that also include: (CV19 OR “CV-19” OR C19 OR “C-19” OR Shortage OR Shortages OR Supplies OR “Emergency Use” OR “EUA” OR “the WHO” OR States OR Governor OR Governors OR DPA OR “Defense Production Act” OR Trump OR Pence OR Jared OR Kushner OR “White House” OR “the WH”]]~~

~~xiii. Containment~~

h. Cut the following key terms completely: [[no changes]]

- i. Disease
- ii. Virus

The Department processed **400 pages** of potentially responsive records captured in the agency's search for FOIA request 2020-00717-FOIA-OS. After a careful review of these pages, I have determined to release **197 pages** to you in their entirety and I am further releasing **64 pages** in part, with portions redacted, pursuant to Exemptions (b)(5), and (b)(6) of the FOIA (5 U.S.C. §552 (b)(5) and (b)(6)). Furthermore, I have determined that **139 pages** should be sent for consultation to others and returned to this Department for final disposition.

FOIA exemption (b)(5) protects inter-agency or intra-agency memoranda or letters which would not be available by law to a party other than an agency in litigation with the agency. This exemption protects documents that would be covered by any privilege an agency could assert in a civil proceeding. These privileges include, among others, the deliberative process privilege, the attorney-client privilege, the attorney work-product privilege and the presidential communications privilege.

FOIA exemption (b)(6) permits a Federal agency to withhold information and records about individuals in "personnel and medical files and similar files, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy." The definition of "similar files" has historically been broadly interpreted to include a wide variety of files, and the United States Supreme Court has held that Congress intended the term "similar files" to be interpreted broadly, rather than narrowly. I have analyzed these records and find they meet the threshold requirement of this exemption. Additionally, I have reviewed and weighed the public interest in disclosure of this information against the privacy interest in nondisclosure, and found that the privacy interest outweighs the public's interest in disclosure.

We will continue to review the remaining records as efficiently and expeditiously as possible, consistent with our available resources. Should you have questions or concerns regarding the Department's response and/or the processing of your request, any such issues should be communicated to your legal counsel and Department of Justice Attorney representing the Department in this matter.

Sincerely yours,



Alesia Y. Williams
Director, FOIA Appeals and Litigations
FOI/Privacy Act Division

Enclosure(s)

From:	CARL TUTTLE (b)(6)@comcast.net>
To:	Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd.inistrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bda3a527cbc247e7b2b52b192f68b92d-Tick-Borne>; Dixon, Dennis M. (NIH/NIAID) [E] </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9125b98ed0f34b839d3d253d40d3982b-dennis.dixo>
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Subject:	Re: An open letter to CDC attorney Heather Huntley
Date:	2020/03/05 07:48:22
Priority:	Normal
Type:	Note

To the Tick-Borne Disease Working Group:

Please see the latest letter below from Dr. Sin Lee of Milford Molecular Diagnostics. It would appear that the CDC could use

some lessons for the direct detection of the coronavirus..... but then again, Dr. Lee is blacklisted because of his ability to

identify chronic Lyme disease.

Carl Tuttle

----- Original Message -----

From: Sin Lee <shlee01@snet.net>

To: "hhh1@cdc.gov" <hhh1@cdc.gov>

Cc: CARL TUTTLE <runagain@comcast.net>

Date: March 4, 2020 at 3:22 PM

Subject: COVID-19 molecular diagnosis

Dear Attorney Huntley:

Since you are my official CDC contact, this letter is addressed to you.

We have learned that the CDC RT-qPCR test kit for COVID-19 assay is generating false positive results.

To raise the sensitivity and specificity of the test, you may select a pair of PCR primers defining an ~355 b.p. amplicon from the following sequence for an initial RT-PCR, including the sequence underlined

CTGCTAAAGCTTACAAAGATTATCTAGCTAGTGGGGGACAACCAATCACTAATTGT
GTTAAGATGTTGTGTACACACACTGGTACTGGTCAGGCAATAACAGTTACACCGGAA
GCCAATATGGATCAAGAATCCTTTGGTGGTGCATCGTGTGTCTGTACTGCCGTTGC
CACATAGATCATCCAAATCCTAAAGGATTTTGTGACTTAAAAGGTAAGTATGTACAA
ATACCTACAACCTTGTGCTAATGACCCCTGTGGGTTTTACACTTAAAAACACAGTCT
GTACCGTCTGCGGTATGTGGAAAGGTTATGGCTGTAGTTGTGATCAACTCCGC
GAACCCATGCTTCAGTCAGCTGATGCACAATCGTTTTAAACGGGTTTGCGGTGT
AAGTGCAGCCCGTCTTACACCGTGCGGCACAGGCACTAGTACTGATGTCGTATACAG
GGCTTTTGACATCTACAATGATAAAGTAGCTGGTTTTGCTAAATTCCTAAAAACTAA
TTGTTGTCGCTTCCAAGAAAAGGACGAAGATGACAATTTAATTGATTCTTACTTTGT
AGTTAAGAGACACACTTTCTCTAACTACCAACATGAAGAAACAATTTATAATTTACT
T

Then perform a heminested PCR to generate an amplicon of about 300 b.p. in size to be used as the template for Sanger sequencing. As you know, you will have no false positives with this protocol.

Thank you for designing a more accurate molecular diagnostic test for an emerging infectious disease.

Sincerely,

Sin Hang Lee, MD

On March 1, 2020 at 1:08 PM CARL TUTTLE <runagain@comcast.net>wrote:

To the Tick-Borne Disease Working Group:

Please see the correspondence below from Dr. Sin Lee of Milford Molecular Diagnostics.

----- Original Message -----

From: Sin Lee <shlee01@snet.net>
To: "hhh1@cdc.gov" <hhh1@cdc.gov>
Cc: CARL TUTTLE <(b)(6)@comcast.net>
Date: March 1, 2020 at 11:14 AM
Subject: An open letter to CDC attorney Heather Huntley

Dear Attorney Huntley:

I am the Plaintiff-Appellant in the United States Court of Appeals FOR THE FEDERAL CIRCUIT case No. 19-2060-JL.

But this letter does not concern the lawsuit. So I did not go through my lawyers involved in this case.

Per your previous advice, I am sending all letters addressed to the CDC through you.

So, please answer the question posed in the attached letter.

Thank you.

Sincerely,

Sin Hang Lee, MD

Carl Tuttle's response sent to Attorney Huntley:

----- Original Message -----

From: CARL TUTTLE <(b)(6)@comcast.net>
To: Sin Lee <shlee01@snet.net>, hhh1@cdc.gov
Date: March 1, 2020 at 11:27 AM
Subject: Re: An open letter to CDC attorney Heather Huntley

Thank you Dr. Lee!

To: Attorney Huntley,

Dr. Lee's letter will be posted to social media for the world to see as what has been deceitfully established by the CDC here in America is wreaking havoc globally. This antibiotic resistant/tolerant superbug has been well hidden from the public through avoidance of direct detection methods.

Direct detection methods have recently identified chronic Lyme disease in France:

PETITION UPDATE

Chronic Lyme disease in France

<https://www.change.org/p/the-us-senate-calling-for-a-congressional-investigation-of-the-cdc-idsa-and-aldf/u/25825323>

Sincerely,

Carl Tuttle

Lyme Endemic Hudson, NH

Dr. Lee's open letter to CDC attorney Heather Huntley:
(Attached)

Attorney Heather Huntley

Centers for Disease Control and Prevention

1600 Clifton Road NE M/S D-53

Atlanta, GA 30329

Open Letter via email: hhh1@cdc.gov

March 1, 2020

Re: Lyme Disease and COVID-19 infection

Dear Attorney Huntley:

I am the Plaintiff-Appellant in the United States Court of Appeals FOR THE FEDERAL CIRCUIT case No. 19-2060-JL. This case is against the Centers for Disease Control and Prevention (CDC) about breach of a contract to continue evaluation of polymerase chain reaction (PCR)/DNA sequencing against the two-tier serology test in the diagnosis of Lyme disease infections for better patient care.

You are the CDC lawyer who is blocking a public hearing in court through a series of legal maneuvers.

This letter requests that you on behalf of the CDC answer an extremely relevant question in view of the current COVID-19 outbreak:

Why is the CDC not using a two-tier serology test for the diagnosis of COVID-19 infection, as for Lyme disease infection?

I think both the Lyme disease patients and potential COVID-19 patients would like to know the answers.

Thank you in advance.

Sincerely,

Sin Hang Lee, MD

Sender:	CARL TUTTLE (b)(6)@comcast.net>
Recipient:	Tick-Borne Disease Working Group (OS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bda3a527cbc247e7b2b52b192f68b92d-Tick-Borne>; Dixon, Dennis M. (NIH/NIAID) [E] </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9125b98ed0f34b839d3d253d40d3982b-dennis.dixo>; (b)(6)@aol.com>; <jgs@jacquessimon.com>; <liawl@mmc.org>; (b)(6)@hotmail.com>; <hanp@mmc.org>; <gskall@wcsr.com>; <sgreen@hardball-law.com>; (b)(6)@ucdavis.edu>; (b)(6)@ucsd.edu>;

(b)(6)@mc.duke.edu>;
 <lda@lymediseaseassociation.org>;
 (b)(6)@gmu.edu>;
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 <chris.smith@mail.house.gov>;
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 (b)(6)@gmail.com>;
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 <andrew.dillon@nice.org.uk>;
 <nice@nice.org.uk>;
 <phil.fontanarosa@jamanetwork.org>;
 <howard.bauchner@jamanetwork.org>;
 <leah.colton@us.af.mil>;
 (b)(6)@usuhs.edu>;
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 (b)(6)@gmail.com>;
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Subject:	Re: An open letter to CDC attorney Heather Huntley
Date:	2020/03/05 07:47:52
Priority:	Normal
Type:	Note

To the Tick-Borne Disease Working Group:

Please see the latest letter below from Dr. Sin Lee of Milford Molecular Diagnostics. It would appear that the CDC could use

some lessons for the direct detection of the coronavirus..... but then again, Dr. Lee is blacklisted because of his ability to

identify chronic Lyme disease.

Carl Tuttle

----- Original Message -----

From: Sin Lee <shlee01@snet.net>

To: "hhh1@cdc.gov" <hhh1@cdc.gov>

Cc: CARL TUTTLE <(b)(6)@comcast.net>

Date: March 4, 2020 at 3:22 PM

Subject: COVID-19 molecular diagnosis

Dear Attorney Huntley:

Since you are my official CDC contact, this letter is addressed to you.

We have learned that the CDC RT-qPCR test kit for COVID-19 assay is generating false positive results.

To raise the sensitivity and specificity of the test, you may select a pair of PCR primers defining an ~355 b.p. amplicon from the following sequence for an initial RT-PCR, including the sequence underlined

CTGCTAAAGCTTACAAAGATTATCTAGCTAGTGGGGGACAACCAATCACTAATTGT
GTTAAGATGTTGTGTACACACACTGGTACTGGTCAGGCAATAACAGTTACACCGGAA
GCCAATATGGATCAAGAATCCTTTGGTGGTGCATCGTGTGTCTGTACTGCCGTTGC
CACATAGATCATCCAAATCCTAAAGGATTTTGTGACTTAAAAGGTAAGTATGTACAA
ATACCTACAACCTTGTGCTAATGACCCCTGTGGGTTTTACACTTAAAAACACAGTCT
GTACCGTCTGCGGTATGTGGAAAGGTTATGGCTGTAGTTGTGATCAACTCCGC
GAACCCATGCTTCAGTCAGCTGATGCACAATCGTTTTAAACGGGTTTGCGGTGT
AAGTGCAGCCCGTCTTACACCGTGCGGCACAGGCACTAGTACTGATGTCGTATACAG
GGCTTTTGACATCTACAATGATAAAGTAGCTGGTTTTGCTAAATTCCTAAAAACTAA
TTGTTGTCGCTTCCAAGAAAAGGACGAAGATGACAATTTAATTGATTCTTACTTTGT
AGTTAAGAGACACACTTTCTCTAACTACCAACATGAAGAAACAATTTATAATTTACT
T

Then perform a heminested PCR to generate an amplicon of about 300 b.p. in size to be used as the template for Sanger sequencing. As you know, you will have no false positives with this protocol.

Thank you for designing a more accurate molecular diagnostic test for an emerging infectious disease.

Sincerely,

Sin Hang Lee, MD

On March 1, 2020 at 1:08 PM CARL TUTTLE (b)(6)@comcast.net wrote:

To the Tick-Borne Disease Working Group:

Please see the correspondence below from Dr. Sin Lee of Milford Molecular Diagnostics.

----- Original Message -----

From: Sin Lee <shlee01@snet.net>
To: "hhh1@cdc.gov" <hhh1@cdc.gov>
Cc: CARL TUTTLE (b)(6)@comcast.net>
Date: March 1, 2020 at 11:14 AM
Subject: An open letter to CDC attorney Heather Huntley

Dear Attorney Huntley:

I am the Plaintiff-Appellant in the United States Court of Appeals FOR THE FEDERAL CIRCUIT case No. 19-2060-JL.

But this letter does not concern the lawsuit. So I did not go through my lawyers involved in this case.

Per your previous advice, I am sending all letters addressed to the CDC through you.

So, please answer the question posed in the attached letter.

Thank you.

Sincerely,

Sin Hang Lee, MD

Carl Tuttle's response sent to Attorney Huntley:

----- Original Message -----

From: CARL TUTTLE (b)(6)@comcast.net>
To: Sin Lee <shlee01@snet.net>, hhh1@cdc.gov
Date: March 1, 2020 at 11:27 AM
Subject: Re: An open letter to CDC attorney Heather Huntley

Thank you Dr. Lee!

To: Attorney Huntley,

Dr. Lee's letter will be posted to social media for the world to see as what has been deceitfully established by the CDC here in America is wreaking havoc globally. This antibiotic resistant/tolerant superbug has been well hidden from the public through avoidance of direct detection methods.

Direct detection methods have recently identified chronic Lyme disease in France:

PETITION UPDATE

Chronic Lyme disease in France

<https://www.change.org/p/the-us-senate-calling-for-a-congressional-investigation-of-the-cdc-idsa-and-aldf/u/25825323>

Sincerely,

Carl Tuttle

Lyme Endemic Hudson, NH

Dr. Lee's open letter to CDC attorney Heather Huntley:
(Attached)

Attorney Heather Huntley

Centers for Disease Control and Prevention

1600 Clifton Road NE M/S D-53

Atlanta, GA 30329

Open Letter via email: hhh1@cdc.gov

March 1, 2020

Re: Lyme Disease and COVID-19 infection

Dear Attorney Huntley:

I am the Plaintiff-Appellant in the United States Court of Appeals FOR THE FEDERAL CIRCUIT case No. 19-2060-JL. This case is against the Centers for Disease Control and Prevention (CDC) about breach of a contract to continue evaluation of polymerase chain reaction (PCR)/DNA sequencing against the two-tier serology test in the diagnosis of Lyme disease infections for better patient care.

You are the CDC lawyer who is blocking a public hearing in court through a series of legal maneuvers.

This letter requests that you on behalf of the CDC answer an extremely relevant question in view of the current COVID-19 outbreak:

Why is the CDC not using a two-tier serology test for the diagnosis of COVID-19 infection, as for Lyme disease infection?

I think both the Lyme disease patients and potential COVID-19 patients would like to know the answers.

Thank you in advance.

Sincerely,

Sin Hang Lee, MD

Sender:	CARL TUTTLE (b)(6)@comcast.net>
Recipient:	Tick-Borne Disease Working Group (OS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bda3a527cbc247e7b2b52b192f68b92d-Tick-Borne>; Dixon, Dennis M. (NIH/NIAID) [E] </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9125b98ed0f34b839d3d253d40d3982b-dennis.dixo>; (b)(6)@aol.com>; <jgs@jacquessimon.com>; <liawl@mmc.org>; (b)(6)@hotmail.com>; <hanp@mmc.org>; <gskall@wcsr.com>; <sgreen@hardball-law.com>; (b)(6)@ucdavis.edu>; (b)(6)@ucsd.edu>;

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Subject:	COVID-19 Morning CDC Update 05Mar20
Date:	2020/03/05 09:18:39
Priority:	Normal
Type:	Note

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COVID-19 Response update Mar 5, 2020

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Daily Report Summary

Where feasible, changes in numbers will be show in red. For the US case counts (below), all counts will be shown in black, since very few are changing daily.

- # of confirmed and presumptive US cases of COVID-19: **149** including:
 - 100 confirmed or presumptive (i.e., positive by CDC test performed in state lab, pending confirmation at CDC) US cases presenting in the US**, locations of detection include Arizona (2), California (37), Florida (2), Georgia (2), Illinois (4), Massachusetts (2), North Carolina, New Hampshire (2), NYC, New York State, Oregon (3), Rhode Island (3), Washington (39), Wisconsin
 - 3 among evacuees from Hubei Province**
 - 46 among evacuees from Diamond Princess**, including:
 - 29 diagnosed in Japan
 - 17 diagnosed after arrival in US
- # of total confirmed cases in China: **80,422**
- # of total confirmed deaths in China: **2,984**

Domestic Updates

1. US COVID-19 Cases

- 14 jurisdictions (13 states) reporting 33 US confirmed cases and 67 presumptive cases
- 3 cases among evacuees from Hubei repatriation cohort
- 46 cases among evacuees from Diamond Princess repatriation cohort (29 diagnosed in Japan, 17 diagnosed after arrival in US)

International Updates

Countries or territories with reported laboratory-confirmed COVID-19 cases and deaths.

Source: WHO Sit Rep 42. Data as of 04 March 2020

Global Summary – Total and new cases in the last 24 hours. Data as of 04:00 EST 4 Mar 2020 [Source: WHO SitRep]

Globally	China	Outside of	
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		China			
Confirmed Cases	Confirmed Cases	Deaths	Confirmed Cases	Deaths	Countries
93,090 (2,223 new)	80,422 (120 new)	2,984 (38 new)	12,668 (2,103 new)	214 (48 new)	76 (4 new)

Countries, territories or areas outside China with reported laboratory-confirmed COVID-19 cases and deaths. Data as of 04:00 EST 4 Mar 2020 [Source: [WHO SitRep](#)]

Country	Total confirmed* cases	Total confirmed new cases	Total deaths	Total new deaths	Transmission classification†	Days since last reported case**
Western Pacific Region						
Republic of Korea	5328	516	32	4	Local transmission	0
Japan	284	16	6	0	Local transmission	0
Singapore	110	2	0	0	Local transmission	0
Malaysia	50	21	0	0	Local transmission	0
Australia	43	10	1	0	Local transmission	0
Viet Nam	16	0	0	0	Local transmission	20
Philippines	3	0	1	0	Imported cases only	28
New Zealand	2	0	0	0	Imported cases only	1
Cambodia	1	0	0	0	Imported cases only	36
European Region						
Italy	2502	466	80	28	Local transmission	0
France	212	21	4	1	Local transmission	0
Germany	196	39	0	0	Local transmission	0
Spain	151	37	0	0	Local transmission	0

the United Kingdom¶	51	12	0	0	Local transmission	0
Switzerland	37	7	0	0	Local transmission	0
Norway	32	7	0	0	Local transmission	0
Netherlands	28	10	0	0	Local transmission	0
Austria	24	6	0	0	Imported cases only	0
Sweden	24	9	0	0	Local transmission	0
Iceland	16	7	0	0	Imported cases only	0
Israel	12	2	0	0	Local transmission	0
Croatia	9	1	0	0	Local transmission	0
Belgium	8	0	0	0	Imported cases only	1
Denmark	8	3	0	0	Local transmission	0
San Marino	8	0	0	0	Local transmission	1
Finland	7	0	0	0	Local transmission	1
Greece	7	0	0	0	Local transmission	2
Czechia	5	2	0	0	Imported cases only	1
Romania	4	1	0	0	Local transmission	0
Azerbaijan	3	0	0	0	Imported cases only	3
Georgia	3	0	0	0	Imported cases only	3
Russian Federation	3	0	0	0	Imported cases only	1
Estonia	2	1	0	0	Imported cases only	0
Ireland	2	1	0	0	Imported	0

					cases only		
Portugal	2	0	0	0	Imported cases only	1	
Andorra	1	0	0	0	Imported cases only	1	
Armenia	1	0	0	0	Imported cases only	2	
Belarus	1	0	0	0	Imported cases only	5	
Latvia	1	0	0	0	Imported cases only	1	
Lithuania	1	0	0	0	Imported cases only	5	
Luxembourg	1	0	0	0	Imported cases only	2	
Monaco	1	0	0	0	Under investigation	3	
North Macedonia	1	0	0	0	Imported cases only	6	
Poland	1	1	0	0	Imported cases only	0	
Ukraine	1	1	0	0	Imported cases only	0	
South-East Asia Region							
Thailand	43	0	1	0	Local transmission	1	
India	6	1	0	0	Imported cases only	0	
Indonesia	2	0	0	0	Local transmission	2	
Nepal	1	0	0	0	Imported cases only	40	
Sri Lanka	1	0	0	0	Imported cases only	37	
Eastern Mediterranean Region							
Iran (Islamic Republic of)	2336	835	77	11	Local transmission	0	
Kuwait	56	0	0	0	Imported cases only	2	

Bahrain	49	0	0	0	Imported cases only	1
Iraq	31	5	0	0	Imported cases only	0
United Arab Emirates	27	6	0	0	Local transmission	0
Lebanon	13	0	0	0	Local transmission	1
Oman	12	6	0	0	Imported cases only	0
Qatar	8	1	0	0	Imported cases only	0
Pakistan	5	0	0	0	Imported cases only	1
Egypt	2	0	0	0	Imported cases only	2
Afghanistan	1	0	0	0	Imported cases only	8
Jordan	1	0	0	0	Imported cases only	1
Morocco	1	0	0	0	Imported cases only	1
Saudi Arabia	1	0	0	0	Imported cases only	1
Tunisia	1	0	0	0	Imported cases only	1
Region of the Americas						
the United States ^{§§}	108	44	6	4	Local transmission	0
Canada	30	3	0	0	Local transmission	0
Ecuador	7	1	0	0	Local transmission	0
Mexico	5	0	0	0	Imported cases only	2
Brazil	2	0	0	0	Imported cases only	3
Argentina	1	1	0	0	Imported cases only	0
Chile	1	1	0	0	Imported	0

					cases only	
Dominican Republic	1	0	0	0	Imported cases only	2
African Region						
Algeria	5	0	0	0	Local transmission	1
Nigeria	1	0	0	0	Imported cases only	5
Senegal	1	0	0	0	Imported cases only	1
Subtotal for all regions	11962	2103	208	48		
International conveyance (Diamond Princess) ‡	706	0	6	0	Local transmission	2
Grand totals§	12668	2103	214	48		

^ Numbers include both domestic and repatriated cases

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†Transmission classification is based on WHO analysis of available official data and may be subject to reclassification as additional data become available. Countries/territories/areas experiencing multiple types of transmission are classified in the highest category for which there is evidence; they may be removed from a given category if interruption of transmission can be demonstrated. It should be noted that even within categories, different countries/territories/areas may have differing degrees of transmission as indicated by the differing numbers of cases and other factors. Not all locations within a given country/territory/area are equally affected.

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¶ Includes cases from Gibraltar

‡Cases identified on a cruise ship currently in Japanese territorial waters.

** Days since last report have been adjusted to reflect 10AM-10AM epidemiologic days rather than calendar days

§343 female/469 male/11 856 unknown. 38 healthcare workers (10 female/13 male/ 15 unknown).

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Very Respectfully,

Secretary's Operations Center

U.S. Department of Health and Human Services (HHS)
Assistant Secretary for Preparedness and Response (ASPR)
200 Independence Ave. S.W.

Washington D.C. 20201
Office (202) 619-7800
Fax: 800-514-4256
Email: hhs.soc@hhs.gov

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Subject:	COVID-19 Morning CDC Update 05Mar20
Date:	2020/03/05 09:18:38
Priority:	Normal
Type:	Note

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COVID-19 Response update Mar 5, 2020

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Daily Report Summary

Where feasible, changes in numbers will be show in red. For the US case counts (below), all counts will be shown in black, since very few are changing daily.

- # of confirmed and presumptive US cases of COVID-19: **149** including:
 - 100 confirmed or presumptive (i.e., positive by CDC test performed in state lab, pending confirmation at CDC) US cases presenting in the US**, locations of detection include Arizona (2), California (37), Florida (2), Georgia (2), Illinois (4), Massachusetts (2), North Carolina, New Hampshire (2), NYC, New York State, Oregon (3), Rhode Island (3), Washington (39), Wisconsin
 - 3 among evacuees from Hubei Province**
 - 46 among evacuees from Diamond Princess**, including:
 - 29 diagnosed in Japan
 - 17 diagnosed after arrival in US
- # of total confirmed cases in China: **80,422**
- # of total confirmed deaths in China: **2,984**

Domestic Updates

1. US COVID-19 Cases

- 14 jurisdictions (13 states) reporting 33 US confirmed cases and 67 presumptive cases
- 3 cases among evacuees from Hubei repatriation cohort
- 46 cases among evacuees from Diamond Princess repatriation cohort (29 diagnosed in Japan, 17 diagnosed after arrival in US)

International Updates

Countries or territories with reported laboratory-confirmed COVID-19 cases and deaths.

Source: WHO Sit Rep 42. Data as of 04 March 2020

Global Summary – Total and new cases in the last 24 hours. Data as of 04:00 EST 4 Mar 2020 [Source: WHO SitRep]

Globally	China	Outside of	
----------	-------	------------	--

		China			
Confirmed Cases	Confirmed Cases	Deaths	Confirmed Cases	Deaths	Countries
93,090 (2,223 new)	80,422 (120 new)	2,984 (38 new)	12,668 (2,103 new)	214 (48 new)	76 (4 new)

Countries, territories or areas outside China with reported laboratory-confirmed COVID-19 cases and deaths. Data as of 04:00 EST 4 Mar 2020 [Source: [WHO SitRep](#)]

Country	Total confirmed* cases	Total confirmed new cases	Total deaths	Total new deaths	Transmission classification†	Days since last reported case**
Western Pacific Region						
Republic of Korea	5328	516	32	4	Local transmission	0
Japan	284	16	6	0	Local transmission	0
Singapore	110	2	0	0	Local transmission	0
Malaysia	50	21	0	0	Local transmission	0
Australia	43	10	1	0	Local transmission	0
Viet Nam	16	0	0	0	Local transmission	20
Philippines	3	0	1	0	Imported cases only	28
New Zealand	2	0	0	0	Imported cases only	1
Cambodia	1	0	0	0	Imported cases only	36
European Region						
Italy	2502	466	80	28	Local transmission	0
France	212	21	4	1	Local transmission	0
Germany	196	39	0	0	Local transmission	0
Spain	151	37	0	0	Local transmission	0

the United Kingdom¶	51	12	0	0	Local transmission	0
Switzerland	37	7	0	0	Local transmission	0
Norway	32	7	0	0	Local transmission	0
Netherlands	28	10	0	0	Local transmission	0
Austria	24	6	0	0	Imported cases only	0
Sweden	24	9	0	0	Local transmission	0
Iceland	16	7	0	0	Imported cases only	0
Israel	12	2	0	0	Local transmission	0
Croatia	9	1	0	0	Local transmission	0
Belgium	8	0	0	0	Imported cases only	1
Denmark	8	3	0	0	Local transmission	0
San Marino	8	0	0	0	Local transmission	1
Finland	7	0	0	0	Local transmission	1
Greece	7	0	0	0	Local transmission	2
Czechia	5	2	0	0	Imported cases only	1
Romania	4	1	0	0	Local transmission	0
Azerbaijan	3	0	0	0	Imported cases only	3
Georgia	3	0	0	0	Imported cases only	3
Russian Federation	3	0	0	0	Imported cases only	1
Estonia	2	1	0	0	Imported cases only	0
Ireland	2	1	0	0	Imported	0

					cases only		
Portugal	2	0	0	0	Imported cases only	1	
Andorra	1	0	0	0	Imported cases only	1	
Armenia	1	0	0	0	Imported cases only	2	
Belarus	1	0	0	0	Imported cases only	5	
Latvia	1	0	0	0	Imported cases only	1	
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Chile	1	1	0	0	Imported	0

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Assistant Secretary for Preparedness and Response (ASPR)
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Washington D.C. 20201
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CC:	Heck, Mia (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70dbe2065d644b8dadbf56c5d63553d-Heck, Mia>; Anderson-Villaluz, Dennis (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=61dfc265c6ce45f686ad00f9dfd27901-Anderson-Vi>
Subject:	RE: DeWine script DRAFT
Date:	2020/03/05 09:29:44
Priority:	Normal
Type:	Note

(b)(5)

From: Adams, Jerome (HHS/OASH) <Jerome.Adams@hhs.gov>
Sent: Thursday, March 5, 2020 9:17 AM
To: Wright, Janet (HHS/OASH) <Janet.Wright@HHS.GOV>
Cc: Heck, Mia (HHS/OASH) <Mia.Heck@hhs.gov>; Anderson-Villaluz, Dennis (HHS/OASH) <Dennis.Anderson-villaluz@hhs.gov>
Subject: Re: DeWine script DRAFT

(b)(5)

VADM Jerome Adams
20th US Surgeon General

On Mar 5, 2020, at 9:09 AM, Wright, Janet (HHS/OASH) <Janet.Wright@hhs.gov>wrote:

(b)(5)

(b)(5)

Janet S. Wright, MD, FACC

Director of Science and Policy (Acting), Office of the Surgeon General

U.S. Department of Health and Human Services, 200 Independence Ave SW, Suite 701H, Washington, DC 20201

Office Phone: 202-690-5157

Email: janet.wright@hhs.gov

<DeWine summit draft.docx>

<Agenda -- Governor's Summit on COVID-19 Preparedness.pdf>

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Subject:	VPOTUS pool report #1 (leaving JBA)
Date:	2020/03/05 09:53:30
Priority:	Normal
Type:	Note

-->

From: Alex Leary <alex.leary@wsj.com>
Date: March 5, 2020 at 9:46:30 AM EST
Subject: [EXTERNAL] VPOTUS pool report #1 (leaving JBA)

Hello from Joint Base Andrews, where Vice President Mike Pence will depart for a two-state trip focused on coronavirus. VP boarded AF2 at 9:45 a.m. and we will be rolling soon.

VP will travel first to Minnesota to meet with Mike Roman, CEO of 3M, which is ramping up mask production. Gov. Tim Walz will join.

Making the trip on AF2 will be Dr. Deborah Birx and FDA Commissioner Stephen Hahn.

(*See below for delegation that will link up in Washington State, with some members of that group flying separately from JBA.)

VP will then fly to Washington to meet with Gov. Jay Inslee, tour the state's emergency operations center and hold a press briefing. Of the 11 deaths in the U.S. tied to coronavirus, 10 are in Washington State, which has more than 40 confirmed cases.

During the flight to Tacoma, VP will hold a conference call with the White House coronavirus task force, according to his schedule.

He will return to JBA early Friday.

*Washington State delegation:

The Honorable Jay Inslee, Governor of the State of Washington

Congressman Rick Larsen, U.S. Representative for Washington's 2nd Congressional District

Congresswoman Cathy McMorris Rodgers, U.S. Representative for Washington's 5th Congressional District

Congresswoman Jaime Herrera Beutler, U.S. Representative for Washington's 3rd Congressional District

Congresswoman Suzan DelBene, U.S. Representative for Washington's 1st Congressional District

Congressman Derek Kilmer, U.S. Representative for Washington's 6th Congressional District

Congressman Dan Newhouse, U.S. Representative for Washington's 4th Congressional District

Congresswoman Pramila Jayapal, U.S. Representative for Washington's 7th Congressional District

Congresswoman Kim Schrier, U.S. Representative for Washington's 8th Congressional District

Administrator Seema Verma, Centers for Medicare and Medicaid Services

Dr. Robert R. Redfield, Director, Center for Disease Control

Dr. John Wiesman, DrPH, MPH, Secretary of Health, State of Washington

Mr. Dow Constantine, Executive of King County, State of Washington

Mayor Penny Sweet, Mayor of Kirkland County, State of Washington

Mayor Jenny Durkan, Mayor of City of Seattle, State of Washington

Major General Bret D. Daugherty, The Adjutant General, State of Washington

Dr. Jeff Duchin, Health Commissioner, King County, State of Washington

Alex Leary
Wall Street Journal
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Delivered Date:	2020/03/05 09:53:30

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Subject:	AMA Video Call with Member States of the Association of Southeast Asian Nations (ASEAN).
Date:	2020/03/04 13:10:25
Start Date:	2020/03/18 08:00:00
End Date:	2020/03/18 09:00:00
Priority:	Normal
Type:	Appointment
Location:	615-F
Attendees:	AMA2 (OS/IOS); Apple, Matthew (HHS/IOS); Callaghan-Arguelles, Christine (HHS/IOS); Harrison, Brian (HHS/IOS); Paul Mango ; Puesan, Cesar (HHS/OS/IOS); Stecker, Judy (OS/IOS); Tignor, Beth (HHS/IOS); Garrett Grigsby (HHS/OS/OGA) (Garrett.Grigsby@hhs.gov); Kyle Zebley (HHS/OS/OGA) (Kyle.Zebley@hhs.gov); Schaeffer, Alison (HHS/OS/OGA); Smith, Christopher (HHS/ASPA) (Christopher.Smith@HHS.GOV); Schmoyer, Michael (OS/ONS); Wolfe, Mitchell (CDC/OD); Blandford, John (CDC/DDPHSIS/CGH/DGHT); MacArthur, John R. (CDC/DDPHSIS/CGH/DGHP); Fauci, Anthony (NIH/NIAID) [E]; Kadlec, Robert (OS/ASPR/IO) (Robert.Kadlec@hhs.gov); Elvander, Erika (OS/OGA)

Topic: Video teleconference with health ministers and senior health representatives of Member States of the Association of Southeast Asian Nations (ASEAN).

Objectives: Introductory meeting with ASEAN Member States (AMS); share US domestic and global positions on COVID-19 preparation and response; enquire how HHS can support AMS COVID-19 efforts

AMA's Role: To talk to AMS health ministers and senior representatives; co-chair discussion between AMS senior health representatives and HHS senior health representatives with AMS co-chair (TBD: Vietnam, Laos, or Cambodia)

Project Lead (IOS Senior Staff): Brian Harrison

Working Project Lead (Name, Cell and email): Kyle Zebley, (b)(6) Kyle.Zebley@hhs.gov

Is Conference Call Line needed? Yes

Who will initiate the conference call? Erika Elvander

Who will provide Briefing materials? Office of Global Affairs

HHS Staff Attendees: Garrett Grigsby, Kyle Zebley, Erika Elvander

Schedule Request Justification:

AMS are regionally at the center of the COVID-19 global outbreak. They have met with China and the EU to solicit and share information on outbreak preparedness and response. Engagement with ASEAN on COVID-19 is a priority of the NSC as well as HHS.

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Sent Date:	2020/03/05 09:55:57
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(Robert.Kadlec@hhs.gov); Elvander, Erika (OS/OGA); Ford-Barnes, Arwenithia (OS/ASPR/IO); Marston, Hilary (NIH/NIAID) [E]

Passcodes:

Leader: (b)(6)

Participant: (b)(6)

Dial in numbers*:

Country

Local/Toll Number

Freephone/Toll Free Number

USA

(b)(6)

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Project Lead (IOS Senior Staff): Brian Harrison

Working Project Lead (Name, Cell and email): Kyle Zebley, (b)(6) Kyle.Zebley@hhs.gov<mailto:Kyle.Zebley@hhs.gov>

Is Conference Call Line needed? Yes

Who will initiate the conference call? Erika Elvander

Who will provide Briefing materials? Office of Global Affairs

HHS Staff Attendees: Garrett Grigsby, Kyle Zebley, Erika Elvander

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Sent Date: 2020/03/05 09:55:57

Delivered Date: 2020/03/04 13:10:25

From:	Hussey, Kendall <khussey@akingump.com>
To:	Kadlec, Robert (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a182eda693d040d3832bae6efcf7a255-Kadlec, Rob>; Shuy, Bryan (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdeb5ca04b6b4ed19fec2209b5f571e7-Shuy, Bryan>
CC:	Bajnrauh, Heide <hbajnrauh@akingump.com>
Subject:	Meeting request - Honeywell re: COVID19
Date:	2020/03/05 10:35:54
Priority:	Normal
Type:	Note

Dr. Bob! and Bryan,

I hope you both are well – thank you for all you are doing, I can imagine it’s incredibly overwhelming, but I greatly appreciate your hard work to keep everyone healthy and safe. Bryan, Dr. Bob was my direct boss on the HELP Committee’s Bioterrorism and Public Health Preparedness Subcmte years ago, when Sen. Richard Burr was the Chairman of the Subcommittee. Governor Tommy Thompson, our Akin Gump colleague, recommended that we reach out to you.

I am submitting a meeting request on behalf of our client – Honeywell, a leading manufacturer and supplier of personal protective equipment (PPE), including respirators. We understand that the federal government and Congress is doing all it can to ensure it is prepared in light of the coronavirus epidemic. To be helpful, we would appreciate the opportunity to meet with you to discuss how Honeywell can be a front line resource to support the public health response.

As this is a timely issue, we are available to meet **tomorrow, Friday, March 6th** if this works for your schedules. You will be meeting with the following individuals:

- Will Lang, President, Honeywell PPE
- Brian Hovey, Chief Marketing Officer, Honeywell PPE
- Romina Khananisho, VP Global Government Relations
- Ben Nicholson, VP Global Government Relations
- Romina Khananisho, Vice President, Global Government Relations

Thank you for your consideration of this request. Please let me know if you have any questions!

Best,
Kendall

Kendall B. Hussey | Policy Advisor

AKIN GUMP STRAUSS HAUER & FELD LLP

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Sender:	Hussey, Kendall <khussey@akingump.com>
Recipient:	Kadlec, Robert (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a182eda693d040d3832bae6efcf7a255-Kadlec, Rob>; Shuy, Bryan (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdeb5ca04b6b4ed19fec2209b5f571e7-Shuy, Bryan>; Bajnrauh, Heide <hbajnrauh@akingump.com>
Sent Date:	2020/03/05 10:35:17
Delivered Date:	2020/03/05 10:35:54

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Subject:	VPOTUS pool report #2 (Minn arrival)
Date:	2020/03/05 12:35:05
Priority:	Normal
Type:	Note

-->

From: Alex Leary <alex.leary@wsj.com>
Date: March 5, 2020 at 11:17:44 AM CST
Subject: [EXTERNAL] VPOTUS pool report #2 (Minn arrival)

AF2 landed at Minneapolis-St. Paul International Airport at 11:15 a.m. local time.

We will motorcade to 3M Innovation Center, in Maplewood, where VP will meet with CEO Mike Roman and Gov. Tim Walz. (Full list below)

During the flight, VP met with Dr. Birx and had phone calls with Sec. Azar and Acting Sec. Wolf. VP also came back and visited with pool for an OTR conversation.

--
 *

The Honorable Tim Walz, Governor of Minnesota

Mike Roman, Chairman and CEO, 3M

Stephen Hahn, Commissioner for the Food and Drug Administration

Dr. Deborah Birx, White House Coronavirus Coordinator

Janet Malcolm, Health Commissioner of Minnesota

Mojdeh Poul, Executive Vice President – Health Care Business Group, 3M

Michael Vale, Executive Vice President – Safety and Industrial
Business Group, 3M

Denise Rutherford, Senior Vice President – Corporate Affairs, 3M

Omar Vargas, Vice President – Global Government Affairs, 3M

Alex Leary
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Recipient:	Harrison, Brian (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>
Sent Date:	2020/03/05 12:32:22
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Message Flags:	Unread

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CC:	Harrison, Brian (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>; Parker, Jim (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f7ac2e66aa043a6b7cb2eaaf967ffa3-Parker, Jam>
Subject:	RE: Requesting HHS Assistance ASAP
Date:	2020/03/05 13:12:11
Priority:	Normal
Type:	Note

Hi Judy,

Thanks for the follow up! Since yesterday morning CMS has now been looped into a lot more discussions within the Department so I really appreciate the quick action from the HHS team to make that happen. (b)(5)

(b)(5)

Thanks!
Brady

Confidential and deliberative, pre-decisional communication

From: Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov>
Sent: Thursday, March 5, 2020 12:34 PM
To: Mango, Paul (HHS/IOS) <Paul.Mango@hhs.gov>
Cc: Brookes, Brady (CMS/OA) <Brady.Brookes@cms.hhs.gov>; Harrison, Brian (HHS/IOS) <Brian.Harrison@hhs.gov>; Parker, Jim (HHS/IOS) <Jim.Parker@hhs.gov>
Subject: Re: Requesting HHS Assistance ASAP

Hey Brady,

As you know, Jim is your immediate resource to resolve any concerns you have at HHS. The processes remain the same, you work through Jim to get communications and actions handled. And of course ASV can reach out to Brian or the Secretary any time.

On the clearance coordination... that too remains the same. Clearing policy via Exec Sec and comms via ASPA. That's how the two actions CMS has already taken got cleared quickly through HHS.

Coordination internally was also done according to already established protocols, other operating divisions central to the COVID-19 response all activated their incident response teams and appointed incident response coordinators in early January and these coordinators worked closely with their senior advisors And the front office using the normal processes to get things done.

I'm not aware of any other issues that CMS has raised or meeting requests that went unanswered please let me know if that's not the case.

I do want to raise some issues I've heard from other staff divisions about CMS communications internally. ASL for example let me know that they were completely unaware of a 4pm hill briefing yesterday via phone and had asked CMS OL earlier bc they were getting pinged from staff about comments VP made on nursing home action.

Understand we are all moving at a breakneck pace, just want to be sure we are communicating and coordinating inside and outside of HHS.

Thanks!

Please let me know how I can help.

Sent from my iPhone

On Mar 4, 2020, at 10:36 AM, Mango, Paul (HHS/IOS) <Paul.Mango@hhs.gov>wrote:

Looking forward to seeing you.

Sent from my iPhone

On Mar 4, 2020, at 10:34 AM, Brookes, Brady (CMS/OA) <Brady.Brookes@cms.hhs.gov>wrote:

(b)(5)

Confidential and deliberative, pre-decisional communication

From: Mango, Paul (HHS/IOS) <Paul.Mango@hhs.gov>
Sent: Wednesday, March 4, 2020 10:23 AM
To: Brookes, Brady (CMS/OA) <Brady.Brookes@cms.hhs.gov>
Cc: Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov>; Harrison, Brian (HHS/IOS) <Brian.Harrison@hhs.gov>; Parker, Jim (HHS/IOS) <Jim.Parker@hhs.gov>
Subject: Re: Requesting HHS Assistance ASAP

Brady- we have a daily HHS PMO meeting to which CMS has been invited. It occurs at 1100am daily. This is the established channel, initiated at Secretary's request, for dealing with any intra-HHS coordination issues. I know Demetrios, and I believe others from CMS have been invited, but heard the Administrator wanted to limit CMS participation to a couple of emergency response folks. You are welcome to join us daily. It involves general updates, progress on modeling, adjudicating quick decisions, and determining real time implications for the health system participants. We usually conduct it in 610F. Please send whomever you'd like.

Sent from my iPhone

On Mar 4, 2020, at 10:11 AM, Brookes, Brady (CMS/OA) <Brady.Brookes@cms.hhs.gov> wrote:

All,

(b)(5)

(b)(5)

Some of the issues we have requested to discuss with others are listed below. We appreciate your help on this matter.

Thank you,
Brady

(b)(5)

(b)(5)

Confidential and deliberative, pre-decisional communication

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Sent Date:	2020/03/05 13:12:10
Delivered Date:	2020/03/05 13:12:11

From:	POLITICO Pro <politicoemail@politicopro.com>
To:	Brooks, John (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=646c7a34da9148189df0d76a885388b9-Brooks, Joh>
Subject:	PRO PHARMACEUTICAL REPORT: Thursday, March 5, 2020
Date:	2020/03/05 14:22:54
Priority:	Normal
Type:	Note

TOP NEWS

Squabble over mask shortage erupts as coronavirus spreads

By Dan Diamond and David Lim

The mask supply is a growing concern for the administration as more outbreaks of coronavirus are being reported in multiple states.

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Squabble over mask shortage erupts as coronavirus spreads [\(back\)](#)

By Dan Diamond and David Lim

A squabble is breaking out over whether respirator mask manufacturers need more protection from legal liability as the Trump administration presses them to ramp up production amid a major shortage during the coronavirus crisis.

With officials estimating the U.S. has only 1 percent of the masks needed for health workers in a full pandemic, Trump administration and mask makers wanted a provision added to the emergency coronavirus spending bill to protect manufacturers if wearers get sick. But House Democrats, including Speaker Nancy Pelosi, viewed the effort as an expansive legal waiver and blocked it from being added to the final version.

The \$8.3 billion spending bill will come up for a vote in the Senate Thursday after passing the House on Wednesday. It won't be changed now, but manufacturers and White House officials are warning that the omission could lead to hoarding of masks and not enough supply for nurses and doctors.

The fight echoes the post-9/11 debate over whether the government should accept liability for anti-terrorism technologies that fail to prevent future attacks or antidotes to anthrax that were produced on a large scale.

Under the 2005 PREP Act, the government assumes the cost of liability claims when it asks companies to provide products in response to a public emergency. But the protection doesn't apply to items like industrial masks because they're not regulated by the FDA, according to Charles Johnson, president of the International Safety Equipment Association.

The mask supply is a growing concern for the administration as more outbreaks of coronavirus are being reported in multiple states. The CDC is trying to speed masks to health care workers under an emergency use authorization granted Monday that allows more types of respirators, like industrial masks, to be used in health care settings. The FDA already allows a subset of respirators to be used in health care settings.

HHS this week said the U.S. has about 1 percent of the required respirator masks needed to equip health workers in a full-blown pandemic, estimating the medical system would need as many as 3.5 billion N95 respirator masks in a year.

Administration officials say the lack of liability protections means manufacturers including 3M, Dräger and Moldex could potentially face a wave of individual lawsuits, even for circumstances like someone wrongly wearing the mask and contracting the virus. Vice President Mike Pence and other members of the White House Coronavirus Task Force are set to meet with 3M CEO Mike Roman Thursday afternoon to talk about supply chain matters.

"This liability issue makes it harder for the industry to step up and do the right thing when the government asks them to do so," said Johnson, who supports expanding the PREP Act's protections. "The masks may be slower to market and into the hands of the people who need them."

"I have worked alongside manufacturers like 3M, who have a plant in Nebraska, who are working around the clock manufacturing protection devices," added Rep. Don Bacon (R-Neb.), the lead sponsor of the provision. "Manufacturers must be willing and able to respond in the event of an outbreak — this legislation would have done just that."

3M officials have said Congress' failure to include the language in the spending package could lead to hoarding of masks.

The health department has warned that the provision was an important step to enlist the industry to fight coronavirus, said two individuals with knowledge of the deliberations. A White House official confirmed that the administration supported the provision.

"We can't expect companies to go above and beyond to meet the needs of the American people when they have the looming threat of litigation hanging over their heads," said one individual with knowledge of the talks.

But Democrats balked at adding the measure. "The committees raised early objections to including an expansive liability waiver in the supplemental and the Speaker agreed," said a senior Democratic aide.

Congressional aides familiar also say the industry needs to demonstrate evidence that a blanket liability shield is needed in order to make enough masks to fight the coronavirus outbreak. They also said the administration hadn't actively pushed for the provision, which introduces complications around who's going to pay to cover liability — and could leave Congress on the hook to come up with the funding.

To view online [click here](#).

A few months? Trump's vaccine hyperbole complicates coronavirus message ([back](#))

By Arthur Allen and Meridith McGraw

Nearly every time President Donald Trump has talked about a coronavirus vaccine, he has gotten a real-time fact check from a health expert sitting nearby.

"So you're talking over the next few months, you think you could have a vaccine?" Trump asked during a meeting with top health officials on Monday.

"You won't have a vaccine," corrected Health and Human Services Secretary Alex Azar after some cross talk. "You'll have a vaccine to go into testing."

"All right, so you're talking within a year," Trump said moments later.

"A year to a year and a half," interjected Anthony Fauci, a government veteran of disease outbreaks under six presidents.

At a time when the federal government is trying to carefully control messaging about the possibility of a cure for a disease that has already claimed the lives of 11 Americans, the president's penchant for on-camera hyperbole has been a constant challenge.

Trump has long claimed to know more than the authorities on a long list of things — TV ratings, taxes, campaigns, firefighting, water management and Twitter, to name a few — but the stakes for his exaggerations have rarely been so high. Indicating that a cure might be around the corner

may cause inadequate preparation for the possibility that the disease could spread more widely through the U.S.

"I observe that the president has been listening, but since he's not a scientist I don't think he understands the nuances," said William Schaffner, an infectious disease specialist at Vanderbilt University. "And besides, he has an understandable tendency to walk on the sunny side of the street."

The White House is known to control the information that comes across the president's desk, and use visual aids to instruct him on foreign policy decisions or severe weather. But with the coronavirus — a disease even the nation's top health experts admit is still quite mysterious — the president is learning about the science behind the virus as the experts are. And in the meantime, he's sharing some inaccurate theories and asking confounding questions about how a vaccine might work, all while the cameras roll.

Already, Trump has muddied the waters on the difference between a vaccine entering various trial phases and it being ready for widespread public use. While vaccines are able to be quickly developed by researchers, it takes time to get the vaccine on the market. Trump has also raised questions about whether a vaccine for the flu could work on this completely different virus.

"You take a solid flu vaccine, you don't think that could have an impact, or much of an impact, on corona?" Trump asked.

"No," a pharmaceutical researcher quickly replied.

The president has long been a source of dubious information on vaccines. As a presidential candidate, Trump tweeted discredited theories that vaccines cause autism and also spouted the theory during a September 2015 debate.

Andrew Wakefield, the British doctor disciplined for fraud over his claim that the MMR vaccine caused autism, attended Trump's inauguration. A short time later, Robert F. Kennedy Jr., who also blames vaccines for many ills, said Trump had promised to establish a commission to investigate such theories — but nothing came of it.

Yet during last year's measles epidemic — the worst in 27 years — Trump did urge people to vaccinate their children.

A senior White House official pushed back on the notion that the president was confusing important information, arguing that Trump was trying to clarify medical vernacular that might be unclear to the public.

"It's not confusion, he's just asking questions," the official said. "There's just a lot of back and forth when you're talking about vaccines versus treatment."

Vaccine scientists have been amazed at the speed with which the National Institutes of Health and vaccine makers are assembling candidate vaccines to prevent coronavirus. While most vaccines take years or decades to develop, the 12-18 month scenario that Fauci has laid out is realistic, according to medical experts. Although it's far from assured.

"The concern we have is, 12-18 months may be too late," said Kathryn Edwards, a pediatric infectious disease expert, also at Vanderbilt. "The bulk of the outbreaks could be over by then."

If conditions are desperate enough a year from now, the FDA might authorize use of a vaccine without incontrovertible evidence that it protects against disease.

But putting out a vaccine before it's been tested in epidemic conditions could be risky, Edwards said. For instance, during tests of some earlier vaccines against SARS and MERS, which are similar to the recent coronavirus, some animals developed so-called immune enhancement, meaning they got sicker when exposed to the virus than unvaccinated animals. A similar phenomenon may have occurred in some children who were injected with dengue virus vaccines in the Philippines in 2018.

Several vaccines are being studied, but the one moving the fastest is produced by Moderna Therapeutics of Cambridge, Mass., with scientists from Fauci's institute.

The first phase of the trial is set to be hosted at a Kaiser-Permanente research institute located in Seattle, but the outbreak of disease there has complicated the plan. The 50 or so study subjects will have to be carefully monitored to assure none of them is infected with the virus during the trial, which is aimed solely at confirming that the vaccine is safe, one scientist familiar with the trial said.

Trump's allies said the president's rhetoric on a shortened vaccine timeline is helping accelerate the process.

"If President Trump went by the old messaging playbook, we wouldn't see a coronavirus vaccine for years. Instead he's aggressively pushing the NIH, [the Centers for Disease Control], our top researchers and even private drug companies to get it done immediately," said Jason Miller, senior communications adviser on the 2016 Trump campaign.

"And if President Trump ruffles a few feathers with his hyperbole in the pursuit of a cure to keep people safe, there will be zero complaints," he added. "Good for him."

To view online [click here](#).

6 things about what's in the coronavirus funding package — and what got left out ([back](#))

By POLITICO Staff

The \$8.3 billion emergency coronavirus funding package would fund the development of new treatments, boost funding to purchase medical supplies and ship more than \$400 million in grants to states and localities for preparedness within 30 days.

The sprawling legislation also left some health industries happier than others. Drugmakers could benefit from some of the language on purchasing vaccines and other treatments developed to

fight the virus. But Congress punted on other decisions, like whether to extend liability protections for medical mask and other device manufacturers.

Following are some of the key provisions:

Vaccines and treatments

The package would send \$826 million to the National Institute of Allergy and Infectious Diseases to drive the development of coronavirus vaccines, treatments and tests. The FDA would get \$61 million to speed up review of these new therapies and respond to possible drug and device shortages stemming from manufacturing disruptions at the virus' epicenter in China.

States and localities

Despite a growing outcry over the cost of testing and treating patients, Congress didn't explicitly address how to handle funding for mandatory quarantines or the uninsured. The package would send \$950 million in state and local grants, with half of the money due within 30 days. States will receive a minimum of \$4 million.

The funding comes as a coronavirus response is already putting major stress on state and local health departments, which are historically underfunded. They're already spending money on staff, supplies and mandated quarantines. The legislation would reimburse states and counties for what they spent to prepare for and mitigate the virus between Jan. 20 and whenever the funding package is enacted. Funds can be used to build or renovate facilities.

Stockpiles and supplies

The package includes about \$3.1 billion to purchase medical supplies for state and local health departments to beef up the Strategic National Stockpile, the largest national repository of emergency treatments. It will also provide additional resources for states and assist federal efforts to develop vaccines and therapeutics, as well as hospital preparedness.

Another \$300 million would help the government buy vaccines and treatments once they are approved. Democrats and Republicans had argued over how to ensure the government doesn't overpay for these products. The legislation specifies that products purchased with these funds must meet federal acquisition guidance "on fair and reasonable pricing." It also empowers the HHS secretary to ensure that any vaccines, drugs or diagnostic tests developed from funds provided by the bill "will be affordable in the commercial market," but doesn't specify how affordability will be determined.

However, language in the bill says that HHS can't delay the development of these products in an effort to maintain affordable prices, a win for Republicans and the drug industry, who argue that government constraints on pricing will limit private industry investment in coronavirus treatments.

Democrats were initially pushing for the inclusion of a provision that would allow HHS to take away a drug company's intellectual property protection on a vaccine or medication if the price was deemed too high. Versions of the legislation circulating late last week including this

language. But pushback from the drug industry and Republicans prompted lawmakers to strike the provision.

The bill additionally doesn't include a provision introduced by Rep. Don Bacon (R-Neb.) that would have amended the Public Readiness and Emergency Preparedness Act to reduce legal liability on device manufacturers during an emergency. The National Association of Manufacturers backed the effort, warning that mask manufacturers needed "additional legal certainty" as an incentive to produce the millions of new masks that health officials say are necessary to safely fight coronavirus.

Community health centers

Community health centers on the front lines of the social safety net would get \$100 million just as their funding is set to expire at the end of May. Another \$10 million would go to the National Institute of Environmental Health Sciences to put together trainings for health care workers on the front lines of the outbreak to avoid becoming infected.

Telehealth

The package would also lift constraints on Medicare's payments for telehealth so beneficiaries could freely consult their doctors remotely, avoiding hospital and physician offices where they might risk exposure to the virus. Telehealth groups were hoping for a provision that would waive restrictions during all national emergencies, but this appears more narrowly tailored to the coronavirus.

International programs

The legislation includes \$300 million to continue the CDC's programs to detect and respond to international disease outbreaks, and \$435 million for global health programs at the State Department. State's international disaster assistance fund would get \$300 million to provide humanitarian aid and address health needs in countries where the coronavirus is spreading. Trump's fiscal 2021 budget request proposed cutting several international public health programs.

Adriel Bettelheim, Sarah Oweremohle, Sarah Karlin-Smith, Rachel Roubein, Dan Diamond, Susannah Luthi, Brianna Ehley, Dan Goldberg and Lauren Morello contributed to this report.

To view online [click here](#).

House swiftly passes bipartisan \$8.3B coronavirus package ([back](#))

By Caitlin Emma and Jennifer Scholtes

The House on Wednesday passed an \$8.3 billion emergency coronavirus package, just hours after congressional negotiators clinched a bipartisan deal to tackle the spreading epidemic.

The lower chamber approved the measure in an overwhelming 415-2 vote. It now heads to the Senate, which could clear the bill as soon as Thursday and send it off to President Donald Trump for his signature. The two nay votes were from Republican Reps. Andy Biggs of Arizona and Ken Buck of Colorado.

"While we all ardently hope that this public health emergency does not worsen, House Democrats will not hesitate to act again if we must augment this funding with more resources," House Appropriations Chairwoman Nita Lowey (D-N.Y.) said on the floor ahead of the vote. Lowey also stressed to reporters that \$8.3 billion is "a lot of money," which should be used "efficiently and effectively."

The bill, H.R. 6074 (116), includes about \$7.7 billion in new discretionary spending to bolster vaccine development, research, equipment stockpiles and state and local health budgets, as government officials and health workers fight to contain the outbreak, which has claimed 11 lives in the U.S. and sickened more than 100 people across more than a dozen states.

Meanwhile, House and Senate leaders have stepped up their response to the outbreak with an onslaught of meetings — including a pair of briefings by Vice President Mike Pence at the Capitol on Wednesday — to coordinate the federal response.

Congress' four most powerful leaders, Speaker Nancy Pelosi, Senate Majority Leader Mitch McConnell, Senate Minority Leader Chuck Schumer and House Minority Leader Kevin McCarthy, also received a closed-door briefing Wednesday on the potential impact of the virus on U.S. Capitol operations.

Both Pelosi and McCarthy left the briefing confident that they would keep the Capitol open for business until further notice.

Under the agreement, more than \$400 million would be shipped off to state and local governments within 30 days after the bill is enacted, with each state receiving no less than \$4 million.

The package would also authorize \$490 million in mandatory spending by lifting constraints on Medicare's payments for telehealth so beneficiaries can freely consult their doctors remotely, avoiding hospitals and physicians' offices where they might risk exposure to the virus.

It would provide \$3.1 billion to beef up medical supplies and supplement the Strategic National Stockpile, including \$100 million for community health centers. About \$826 million would go to the National Institute of Allergy and Infectious Diseases for the development of coronavirus vaccines, treatments and tests. The Centers for Disease Control and Prevention would receive \$2.2 billion, including a total of \$950 million to support the response efforts of state and local health agencies.

Under the deal, \$61 million would go to the FDA for vaccines and other efforts to counter the virus, plus keeping up with shortages in medical products and trying to boost U.S. manufacturing of those items. For aiding the global fight against the bug, congressional leaders laid out almost \$1.3 billion for the State Department and the United States Agency for International

Development, including raising the cap from \$10 million to \$100 million for emergency evacuations.

The Small Business Administration would receive \$20 million to increase the number of loans given to businesses affected by the outbreak. The package also includes a provision requiring the Trump administration to replace \$136 million that it recently shifted from various health accounts, including mental health and substance abuse programs, in order to pad out its coronavirus response.

The agreement comes after several days of partisan bickering over vaccine affordability and other issues that had ensnared the bipartisan, bicameral talks. Negotiators ultimately agreed to include \$300 million "to help ensure that, when a vaccine is developed, Americans can receive it regardless of their ability to pay," according to a House Democratic aide.

Vaccine affordability had been one of the biggest holdups to a final package. Democrats had pressed for significant funding to purchase large amounts of coronavirus diagnostics, treatments and vaccines when they become available, which would then be made available to the public free of cost, according to a senior Democratic aide.

The aide claimed that Republicans tried to eliminate the "fair and reasonable price" federal procurement standard for the vaccines and treatments that will be developed and purchased with the emergency funds. "Fair and reasonable price" is a basic standard to prevent price gouging in federal contracts.

Republicans, however, argued they are trying to fight Democratic efforts to create a new set of price controls and that they are not asking for changes to the underlying procurement standards.

"There's some things that we think would have discouraged pharmaceutical companies from making investments and participating — we want everybody at the table — and I think we found the right mix," said Rep. Tom Cole of Oklahoma, the top Republican on the spending panel overseeing HHS.

"[We] reassured our friends on the other side, hey, we want to all make sure nobody profits unduly, but we want to make sure we get a product, and want to make sure that product's available to all Americans."

The package far exceeds the \$1.25 billion in new funding requested by the Trump administration. Lawmakers on both sides of the aisle were alarmed by what they deemed as the president's paltry request to fight the bug amid criticism that his administration has bungled its response and failed to keep the American people clued in about the potential severity of the outbreak.

Even though the multibillion-dollar infusion is expected to be signed into law quickly, many in Congress say they worry about the administration's ability to coordinate response across all 50 states and territories to ensure enough test kits are available, that people who are infected are quickly isolated and that health workers are following protocol.

The half-hour, back-to-back briefings on Wednesday frustrated some lawmakers, who complained that there was not nearly enough time to question Pence and other Trump administration health officials.

Yet while Democrats remain wary of the administration's ability to manage the crisis, several said Pence provided as reassuring an update as they have received thus far. Regular briefings by Pence and his public health team are expected to take place in the coming days and weeks.

"Absolutely not," House Majority Whip Jim Clyburn (D-S.C.) said when asked if he had confidence in the administration's response. "They're just fooling around. It just reminds me so much of [Hurricane] Katrina."

"It's being jerry-built," Rep. Mark Takano (D-Calif.) said of the response plan. "I think we can legitimately say that they're piecing it all together."

Top infectious disease expert Anthony Fauci, FDA Commissioner Stephen Hahn and White House coronavirus response coordinator Debbie Birx also joined Pence at the briefings.

Pence's biggest takeaway, according to Democrats, is that members should hold town halls, both in person and over the phone, to relay information about the virus and its spread.

"The vice president clearly wanted us to communicate to our constituents, and give out enough information as possible, as accurately as possible. What you want to avoid is panic," House Majority Leader Steny Hoyer (D-Md.) said afterwards.

Sarah Ferris, Jesse Naranjo, John Bresnahan, Sarah Oweremohle and Heather Caygle contributed to this report.

To view online [click here](#).

FDA issues third-ever ban on medical device ([back](#))

By David Lim

FDA today finalized a ban on electrical stimulation devices intended to treat self-injurious or aggressive behavior.

The move comes after several Democrats called for the FDA to ban such devices in a letter to FDA Commissioner Stephen Hahn on Feb. 10. The senators called the use of the devices, often on people with disabilities, a "barbaric — and disproven — practice."

"Through advancements in medical science, there are now more treatment options available to reduce or stop self-injurious or aggressive behavior, thus avoiding the substantial risk ESDs present," said William Maisel, director of the Office of Product Evaluation and Quality in the FDA's device center, in a statement.

The ban, the third FDA has ever issued for a medical device, takes effect in 30 days. FDA is allowing a 180-day deadline for electrical stimulation devices already in use on an individual to allow a physician-monitored transition period to another treatment.

The agency estimates 45-50 people are currently exposed to the device at Judge Rotenberg Educational Center in Canton, Massachusetts.

To view online [click here](#).

FDA issues guidance on insulin's shift to the biologic pathway ([back](#))

By Sarah Oweremohle

FDA this morning [issued final guidance](#) on how insulin can be licensed as a biologic.

The document is part of the agency's timeline for shifting insulin entirely out of the drug category in a bid to encourage more competition by opening the door to biosimilars. This month marks the deadline for that transition.

The guidance fleshes out questions about which products would need to transition from the drug pathway to the biologic one. FDA said that if a manufacturer's insulin is already approved under the new drug application process, it does not have to be resubmitted for a biologic license application.

There is no true generic insulin on the market right now, in part because the conventional pathway made it difficult to make identical products.

Congress first directed FDA to reclassify a small subset of biologic products, like insulin and growth hormones, nearly a decade ago.

To view online [click here](#).

U.K. competition watchdog fines 4 pharma companies for cartel deals ([back](#))

By Giorgio Leali

BRUSSELS — The U.K. Competition and Markets Authority today fined four drug companies for concluding anti-competitive agreements and sharing commercially sensitive information about the supply of the antidepressant nortriptyline.

In two separate decisions, the authority found that King Pharmaceuticals and Auden Mckenzie agreed to share the market for nortriptyline, and that King, Lexon and Alissa Healthcare Research shared commercially sensitive information to inflate the price of the antidepressant.

"These firms exchanged sensitive information and shared out supply to try and keep prices up, meaning the NHS — and ultimately the U.K. taxpayer — could have been paying over the odds for this vital drug," CMA Chief Executive Andrea Coscelli said in a press release.

King and Auden McKenzie "shared out between them the supply of nortriptyline to a large pharmaceutical wholesaler" and "also colluded to fix quantities and prices," the release noted.

King, Lexon and Alissa Healthcare exchanged information about prices, supply volumes and Alissa's plans to enter the market to keep nortriptyne prices up at a time when the value of the drug was falling. In September 2019, King and Alissa admitted they shared sensitive information.

The watchdog imposed fines of more than £3.4 million as well as a payment of £1 million directly to the NHS, marking the second time the CMA has secured a payment to the NHS.

The CMA also called on an executive at King to recuse himself from serving as a director of any U.K. company for seven years

To view online [click here.](#)

Coronavirus emergency bill stalled over vaccine cost concerns [\(back\)](#)

By Sarah Ferris, Sarah Oweremohle and Heather Caygle

House and Senate leaders have run into last-minute snags on a \$7.5 billion emergency package to combat the U.S. spread of coronavirus, including disputes over vaccine availability and hospital reimbursement costs.

Top Democrats say the House is still expected to vote on the package Wednesday, with the Senate likely to follow suit as soon as Thursday. But the timeline for unveiling that legislation has slipped, possibly as late as Wednesday morning, amid policy fights between the two parties.

With the number of U.S. cases steadily rising, Speaker Nancy Pelosi is negotiating with Senate Majority Leader Mitch McConnell to find a deal that could pass both chambers this week, doling out money quickly to state and local health departments.

The biggest issue, according to several people familiar with negotiations, involves a Democratic attempt to control the costs of vaccines and other treatments that are developed in response to the outbreak. Other issues include details of hospital reimbursement for uninsured patients and whether to pay for a provision to help expand telemedicine, which would cost roughly \$500 million.

"Vaccines should be affordable. It's just as simple as that," Rep. Rosa DeLauro (D-Conn.), a top appropriator, said as she left a Democratic leadership meeting on Tuesday night.

"It's going back and forth. That's where we are," DeLauro added. "There are no firm answers at the moment, but we're moving toward getting this done and getting it done this week because the need is so critical. We have to get it done this week."

Pelosi and her top deputies briefed their fellow Democrats on the status of the emergency funding package on Tuesday night and outlined the remaining issues. A final deal could still be reached Tuesday night, they said, but could take until Wednesday morning.

Senate Minority Leader Chuck Schumer had complained earlier Tuesday that Republican lawmakers were resisting Democratic efforts to stave off potential price-gauging of vaccines or other products.

"Our Republican friends don't want to see the kinds of limitations that we want to see," Schumer said after a briefing with members of the White House's coronavirus task force, including Vice President Mike Pence and HHS Secretary Alex Azar.

The 11th hour policy battles come after both parties had intended to present a united front against the potential epidemic, with House Majority Leader Steny Hoyer of Maryland and Republican leader Kevin McCarthy of California trading offers on details of the package as recently as Tuesday. Republicans and Democrats both stressed that the response to the virus should avoid mudslinging and fingerpointing.

Still, some of the final details of the massive funding package have come down to partisan talking points.

Democrats are insisting the spending package include significant funding to purchase large amounts of coronavirus diagnostics, treatments and vaccine, when it becomes available, which would then be made available to the public free of cost, according to a senior Democratic aide.

The Democratic aide said Republicans are trying to eliminate the "fair and reasonable price" federal procurement standard for the vaccines and treatments that will be developed and purchased with the emergency funds. "Fair and reasonable price" is a basic standard to prevent price gouging in federal contracts.

Republicans, however, argue they are trying to fight Democratic efforts to create a new set of price controls and that they are not asking for changes to the underlying procurement standards.

The administration's top scientists have said any coronavirus vaccine could be at least a year away from reaching the market. Moderna Therapeutics is working with National Institutes of Health on a vaccine while Johnson & Johnson has received funding from HHS's Biomedical Advanced Research and Development Authority.

The bill would provide funding for masks, ventilators, community preparations and vaccine development, Schumer said. But it's silent on how much vaccines developed with the government's backing should cost.

"We are not going to say the companies after we taxpayers have paid for it, 'now go out and make a huge profit.' That's not going to happen," said Senate Appropriations ranking member Patrick Leahy (D-Vt.).

Congressional leaders still plan to pass an emergency package by the end of this week, with funding levels much closer to the \$8.5 billion Democrats suggested than the Trump administration's \$2.5 billion request.

Both House and Senate leaders have stepped into overdrive as the global coronavirus outbreak poses a rising threat to the U.S., with 122 cases of the virus now reported.

Lawmakers have also dramatically stepped up their oversight of the Trump administration's response, which had drawn flak in the early days of the outbreak, with its mixed messaging and a slow rollout of tests as cases accumulate.

Senate Democrats on Tuesday confronted Pence over the federal government's response to the outbreak, even as leaders of both parties have quietly urged lawmakers to present a united front.

Multiple Democrats said Pence and the task force did not have enough answers on testing kits, costs of care and what will happen to people who do not have insurance.

Lawmakers including Democratic Sens. Patty Murray and Maria Cantwell of Washington, where nine deaths have been confirmed, challenged Pence during the hourlong meeting, which became contentious at times, according to attendees.

"The failure to develop and distribute working test kits to public health agencies has really cost us valuable time," Murray said afterward. "I'm hearing from people personally across our state who are frustrated. They believe they have been exposed, they are sick, they want to get tested — but they have nowhere to go."

Roughly \$900 million in the bill would go toward purchasing equipment including masks and ventilators. Murray said that officials told senators they had stockpiled masks, but that there were not enough.

Separately, health insurers want assurances the government will help pay the cost of widespread testing or expensive treatment.

"There's not enough test kits. We don't know how wide it is. And it's because the president dropped the ball early," said Sen. Jon Tester (D-Mont.).

Meanwhile, at the Senate Republican lunch, one attendee said senators suggested to Pence that the administration's medical experts be the "point people" for the federal response.

"No real pushback other than the recommendation that they just use people that are not politically appointed, real professionals in the area that way there can't be argument — oh, this is just political spin, it's coming from doctors," the attendee said.

Pence, who President Donald Trump designated the lead on the virus response last week, made the rounds as the Trump administration tried to move past a raucous few days of partisan finger-pointing.

Earlier on Tuesday, Pence hosted a group of House members who belong to the bipartisan Problem Solvers Caucus in the White House situation room. His message, according to several attendees, was to avoid political bickering as the U.S. grapples with a health crisis with a scale that remains unknown.

Rep. Stephanie Murphy (D-Fla.) laid out concerns with the administration's outreach, including mixed messaging from Trump himself and various health agencies, according to multiple people in the room.

Murphy, whose home city of Orlando includes Disney World, pressed Pence on which source of information should be trusted. Pence instructed her to refer to the CDC's website.

Another Democrat, Rep. Dean Phillips of Minnesota, challenged information the administration has presented about the risk of transmission. He later said he urged the administration to be as transparent and "as conservative" as possible.

Sarah Karlin-Smith, Caitlin Emma, Andrew Desiderio, Marianne LeVine and Susannah Luthi contributed to this report.

To view online [click here](#).

CDC opens up coronavirus testing, Pence says ([back](#))

By Brianna Ehley and Meridith McGraw

The CDC is broadly expanding who can be tested for the coronavirus, Vice President Mike Pence announced Tuesday, as the Trump administration scrambles to detect cases that may have been missed because of delays in testing.

Under the new guidance, "any American can get tested" if a doctor suspects the virus, Pence told reporters at the White House. He added that people no longer need to show specific symptoms as the CDC had previously required. The change could dramatically increase demand for testing at a time when public health experts are concerned that the country's testing capacity is still weeks behind.

Pence said the new testing guidelines came after several governors informed him "there was an impression that tests would not be administered to people who were only mildly symptomatic." It also comes after a California patient last week was confirmed positive for the virus days after being denied a test under CDC criteria.

The agency previously advised doctors to only test patients if they had known exposure to someone with the virus, travel history to an affected region or had symptoms of a serious respiratory illness.

The Trump administration in recent days has faced criticism for delays in testing because of earlier problems with its diagnostic tests. Pence said the U.S. plans to send 2,500 new test kits out by the end of the week, which he claimed can test 1.5 million samples. Public health labs say patients typically require at least two samples.

Pence also said private companies are expected to dramatically boost the amount of test kits on the market, though experts question whether there are enough laboratories to test a large surge of samples.

As of Tuesday, officials have confirmed 77 cases in the U.S. across 13 states and nine deaths, all reported in Washington state.

Seven of those deaths involved patients from a nursing home near Seattle. Pence said he spoke with Washington Gov. Jay Inslee earlier Tuesday. A CDC team is on the ground in Washington, and the Centers for Medicare and Medicaid Services has deployed investigators to the nursing home.

President Donald Trump and Pence visited the National Institutes of Health on Tuesday to discuss treatments and the development of a vaccine, which agency Director Anthony Fauci said won't likely be ready until next year.

Officials reiterated that the immediate risk to the American public remains low, though cautioned that could quickly change.

"The big unknown that I think we're going to be able to address as we get much more widespread ability to test is the degree of infection that might be out there," Fauci said.

Concerns of broader community spread come just as a \$7.5 billion emergency funding package for coronavirus response efforts stalled on Capitol Hill Tuesday over disagreements about vaccine availability and hospital reimbursement costs. State and local health departments, already strapped for cash, say they need funding to prepare especially in the event that the virus becomes widespread in their communities.

Joining Pence at the briefing — which was not televised — were members of the coronavirus task force including Deborah Birx, who is leading the response; CMS Administrator Seema Verma; CDC Director Robert Redfield; and FDA Commissioner Stephen Hahn.

Pence said he plans to meet Wednesday with airline industry executives to discuss "contact tracing data" and greater cooperation among the airports tasked with screening people coming back into the United States.

David Lim contributed to this report.

To view online [click here](#).

DOJ sues Mallinckrodt for shortchanging Medicaid on rebates [\(back\)](#)

By Sarah Karlin-Smith

The Justice Department on Tuesday [joined in a whistleblower lawsuit](#) accusing drugmaker Mallinckrodt of defrauding Medicaid by knowingly underpaying hundreds of millions of dollars in rebates the company owed stemming from large price increases for its H.P. Acthar Gel.

Mallinckrodt and its predecessor company Questcor are alleged to have avoided inflation-based penalties on rebate obligations by characterizing an old version of the treatment — which has been on the market since 1952 — as a new drug based on a new approved use for infantile spasm the FDA issued in 2010. The Justice Department alleges the company knowingly mischaracterized the new approval to CMS as an entirely new drug application, instead of a supplement to an existing FDA application. Acthar has 19 approved uses for conditions including multiple sclerosis, rheumatoid arthritis and lupus.

Drug companies must pay penalties to Medicaid when they raise the prices of their drugs above the inflation rate. Those rebates are based on the drug's price since 1990 or when it was first marketed, whichever date is later.

But in 2013, Questcor allegedly began calculating and paying rebates as if the drug was first marketed that year, while at the same time raising the price by more than \$20,000 per unit. The activity allowed the company to avoid hundreds of millions of dollars in Medicaid rebates.

By 2016, CMS said it discovered that Mallinckrodt had wrongly characterized the product as a new drug and asked it to correct underpayments since 2013 that at that time totaled \$258 million. The company has refused to make these payments, DOJ said.

[Mallinckrodt has denied wrongdoing and filed suit against CMS](#) over the rebate dispute in 2019. The company on Tuesday cited that ongoing case, saying a federal court in Washington, D.C., "previously barred CMS in 2019 from taking enforcement action against Mallinckrodt while this case is now awaiting a decision." The company accused the U.S. Attorney in Massachusetts, which is leading the whistleblower lawsuit, of attempting an "end-run around that Court's order by pursuing new enforcement litigation."

Questcor, now part of Mallinckrodt, acquired Acthar in 2001. At that time the drug cost about \$50 per 5 ml vial. It now costs nearly \$40,000 per vial.

The lawsuit in the U.S. District Court for the District of Massachusetts is just the latest legal trouble for Mallinckrodt, which last week [announced a proposed \\$1.6 billion settlement](#) with thousands of U.S. municipalities and 47 states and territories to resolve litigation over its alleged role in fueling the opioid epidemic. The company's speciality generics unit would file for Chapter 11 bankruptcy as part of that deal.

To view online [click here](#).

AI was supposed to save health care. What if it makes it more expensive? [\(back\)](#)

By Arthur Allen

NEW YORK — Last year, Mount Sinai Hospital switched on an artificial intelligence program to search the hospital's records for evidence of malnourished patients in its wards. The numbers it turned up were eye-popping: 20 percent more cases were diagnosed than in the previous year.

Around the same time, Barbara Murphy, chief of the renowned health system's department of medicine, was helping to develop another AI program, to predict whether diabetic patients are at near-term risk of kidney disease and to help prioritize specialist visits for those who are. One of the early findings, according to Murphy: "We probably need some more nephrologists."

As hospital systems around the country unleash machine learning algorithms — computer models that function like millions of unblinking eyes inspecting patient records — such findings are becoming more common. The algorithms, deployed in hospitals over the past couple of years, are often designed to help locate the sickest patients, but in some cases, they also provide more opportunities to bill.

"One of the ways that we get reimbursed for stays is being able to treat and document what's going on," said Robbie Freeman, Mount Sinai's vice president for clinical innovation. "We can document that malnutrition. It means the hospital will get credit for that patient and paid for the care."

The specialists who are introducing machine learning and other tools say they should make health care more efficient by enabling better identification of riskier problems before they become tragic, expensive conditions. For example, Murphy's algorithm could help doctors intervene to prevent diabetics from needing dialysis.

But there's a big risk of overdiagnosis and recommendations for procedures or drugs that might not be necessary, said Kenneth Mandl of Harvard Medical School, who created a new term — "biomarkup" — for the tendency of new detection to spur more spending in medicine. Marketing and innovation fever tend to stimulate the use of tests that indicate risks for diseases like cancer and stroke before there is reliable data showing the tests lead to improved patient outcomes, he said.

As algorithms point out health risks that haven't always been captured in the course of normal medicine, "the risks of overdiagnosis go up, and so can the risks of potential harms," David Kent, a doctor and researcher at Tufts University, said at a recent FDA-sponsored event.

A recent study by Google scientists, for example, showed that one of the company's computer models was better than doctors at reading mammograms to detect breast cancers. Speedy algorithms like the one Google deployed will allow radiologists to work faster and lead to more positive findings, Dell Medical School dermatologist Adewole Adamson [wrote recently in the New England Journal of Medicine](#).

But the problem is, the algorithm won't know which of those growths require attention or treatment, Adamson wrote. So, more biopsies will probably be ordered, with the possibility of more overdiagnosis and higher spending.

Computerized triage

Hospital systems around the country are testing machine-learning algorithms that detect everything from smoldering blood infections or pneumonia to social issues that affect health, like poor housing and lack of access to transportation or nutritious food. How they deploy the programs may have a major impact on costs.

Many of the algorithms deliver a risk score — for instance, they might say a patient has a 60 percent chance of suffering a fall. Hospitals can then display the risk number on clinicians' computer screens in green, yellow or red, depending on what level of risk they decide is worth addressing.

Setting those thresholds is a delicate matter. If a "red" score is set too low, doctors will be flooded with alerts and probably ignore them. If the risk threshold is too high, clinicians run the risk of missing a serious condition that could harm a patient — and potentially expose their institution to legal jeopardy.

"There is always a tradeoff," says Michelle Gong, chief of critical care at the Montefiore Health System in the Bronx. "You have to select a level of sensitivity you think is safe but doesn't create too many alarms."

Liability and safety concerns could push hospital systems to set thresholds to detect more cases, leading to more medical intervention, and more billing, because "each false negative could represent a loss of life," said Keith Dreyer, chief data science officer for Partners HealthCare. Bad drivers kill tens of thousands of people a year, but a single death caused by a driverless car in 2018 caused Uber to suspend its testing of the vehicles, Dreyer noted.

Not everyone agrees that algorithms inevitably will drive up health spending. If algorithms are increasing costs, they probably aren't being implemented correctly, said Eric Topol, director of the Scripps Research Translational Institute.

Connie Lehman, chief of breast imaging at Massachusetts General Hospital, said algorithms she has been testing there could reduce unnecessary consults by eliminating more false positives that could lead to sonograms and biopsies. If they were widely used, "you could immediately see lower costs," she said.

In short, say Topol and others — including several AI leaders interviewed at four New York City-area hospital systems recently — the successful use of algorithms depends on so much more than just good technology. The industry's uncertainty over how to deploy them is a major reason they haven't had much impact on health care yet, said Parsa Mirhaji, director of the Center for Health Data Innovations at Montefiore.

"The coding is the easy part," said Charles Esenwa, a neurologist at Montefiore who is trying to assess stroke risks in the hospital's population with an algorithm that accounts for socioeconomic

issues like housing and access to healthy food. Scientists need to work with accurate data that reflects the population they were working with, he said.

Yindalon Aphinyanaphongs, who leads a team implementing AI at New York University's Langone Health System, sees it as a four-step process: building a model, assuring it delivers information to clinicians effectively, convincing doctors to use the information and making sure it benefits patients.

Getting buy-in from doctors is a big part of the process. They've already been burned by difficult-to-use electronic health records, which promised more progress than they delivered, noted Andrew Racine, chief medical officer at Montefiore.

The "black box" aspect of machine learning — the fact that computer models may make predictions based on calculations that are too complex to explain — could make it challenging to communicate the findings to clinicians. Health systems have taken different approaches to communicating algorithm results.

At Mount Sinai, the clinician gets a drop-down list of vital signs or other data that went into the computer's decision-making process, according to Freeman. But at Montefiore, an algorithm for acute respiratory distress syndrome — a severe lung condition often overlooked — doesn't convey the underlying data to doctors. So much information goes into the model — including 35 different measures — that it would only confuse clinicians, said Gong. Instead, hospital staff are instructed to respond to red alerts for severe cases by calling her critical care team for a consultation.

Doctors should get accustomed to not knowing the "why" behind an algorithm result, informaticist Blackford Middleton said at a medical informatics event in Washington.

"You'd never expect a pilot to understand every sensor on a plane," he said. "Who can understand all the proteins and metabolites at the same time?"

AI as a nudge

For the most part, AI right now is being used as a kind of electronic triage, helping clinicians sort out the cases that require the most attention. At best, it may help them notice patterns or prod them to alter treatments in ways that could be lifesaving.

Gong has a federal grant to evaluate whether machine learning can help identify patients with acute respiratory distress. When doctors misdiagnose it as typical pneumonia, their treatments can aggravate the disease or even kill the patient.

Elsewhere, algorithms operate like electronic nags: At NewYork-Presbyterian, for example, the hospital uses AI to crawl through data and find anomalies in patient care, then nudges staff about them. One algorithm helps smooth patient discharges by reporting when a patient needs physical therapy and an MRI before going home, said Daniel Barchi, the system's chief information officer. Better coordination can get a patient out of the hospital faster, saving money and, hopefully, getting them on the road to recovery faster, he said.

To view online [click here](#).

Sandoz to pay \$195M for generic price-fixing ([back](#))

By Leah Nysten and Sarah Karlin-Smith

Sandoz will pay \$195 million to resolve charges that it fixed prices on at least five generic drugs, the Justice Department said Monday.

The second-largest generic drug company in the world admitted it fixed prices between 2013 and 2015 on more than \$500 million in sales, including drugs commonly used to treat skin conditions, hypertension and lung infections in cystic fibrosis patients. The Justice Department filed the charges Monday in a Pennsylvania federal court; under a deferred prosecution agreement, those charges will be dismissed after three years.

Antitrust prosecutors said Sandoz raised prices on some drugs by as much as 1,000 percent. Court filings indicate Sandoz fixed prices with Rising Pharmaceuticals — another company that has entered into an agreement with DOJ — as well as three other unnamed rivals.

While the criminal filings don't name Sandoz's alleged co-conspirators, court filings in a related civil antitrust suit by state attorneys general do implicate companies by name. Based on the descriptions in DOJ's filing, "Company C" is Teva, with whom Sandoz admitted to fixing prices on a lung infection drug.

Sandoz said in a statement that all the employees involved in the wrongdoing have been fired. It also said it is setting aside \$185 million to resolve claims it overcharged federal government programs like Medicare and Medicaid.

"We take seriously our compliance with antitrust laws," Sandoz President Carol Lynch said in a statement, "We are disappointed that this misconduct occurred in the face of our clear antitrust compliance policies and multiple trainings — and in full contravention of the company's values."

Justice Department officials said they opted to enter a deferred prosecution agreement with Sandoz in lieu of requiring the company to plead guilty to the charges, in part because of Health and Human Services regulations that might have required the company to stop doing business with the federal government after a guilty plea.

Sandoz is the third company to resolve its involvement in the Justice Department's ongoing investigation into price-fixing of generic drugs. Rising and Heritage Pharmaceuticals have also paid criminal fines and entered into deferred prosecution agreements.

The Sandoz admission of guilt comes after former company executive Hector Armando Kellum [pleaded guilty in February](#) to fixing pricing on generic drugs from March 2013 through June 2015.

Prosecutors also indicted Ara Aprahamian earlier in February. Aprahamian is accused of conspiring to increase prices and allocate customers for numerous drugs while at Taro Pharmaceutical, including medications used for arthritis and skin conditions. He plans to contest the charges.

Former Heritage Pharma executives Jeffrey Glazer and Jason Malek have previously pleaded guilty to price fixing of off-patent medicines. Rising and the Heritage executives are cooperating with DOJ's broader investigation.

To view online [click here](#).

'You don't want to go to war with a president' ([back](#))

By Sarah Oweremohle

Anthony Fauci might be the one person everyone in Washington trusts right now.

But at 79, the director of the National Institute of Allergy and Infectious Diseases is in the thick of one of the biggest battles of 35 years in the role: the race to contain coronavirus when the nation is deeply polarized and misinformation can spread with one tweet — sometimes, from the president himself.

"You should never destroy your own credibility. And you don't want to go to war with a president," Fauci, who has been the country's top infectious diseases expert through a dozen outbreaks and six presidents, told POLITICO in an interview Friday. "But you got to walk the fine balance of making sure you continue to tell the truth."

And the truth about coronavirus? "I don't think that we are going to get out of this completely unscathed," he said. "I think that this is going to be one of those things we look back on and say boy, that was bad."

The plainspoken scientist with a heavy Brooklyn accent has navigated outbreaks from HIV to Ebola, Zika and the anthrax scare with an ability to talk frankly yet reassuringly about threats, to explain science, public health and risk to the public in a way few can match.

But in this outbreak, he's not always the comforting public face amid crisis.

As the Trump administration scrambles to contain the fast-spreading infection and consolidate control under Vice President Mike Pence, Fauci's visibility has been subject to the vagaries of a president who wants to declare the outbreak under control. Over the weekend, Pence and HHS Secretary Alex Azar made the rounds of the Sunday talk shows, not government doctors or scientists.

Fauci sat down with POLITICO in his office Friday, amid dozens of photos of himself with presidents, politicians and celebrities from Magic Johnson to Barbra Streisand. It was just hours

after reports that the White House had ordered Fauci off the airwaves sparked a firestorm of protest from senators, former government officials and public health experts.

Fauci denied being muzzled. He did say that Pence's office wanted him to run interviews past it for re-clearance once Pence was named the White House's point person on the virus.

But public health experts and Democrats have slammed President Donald Trump's repeated reassurances about the disease, which has raced across six continents, created economic disruption — and taken 3,000 lives and counting.

Republicans have countered that the left is overstating the risk, spreading panic and trying to take Trump down.

Fauci has openly tempered expectations for a quick coronavirus vaccine — and an end to the epidemic — on the press conference stage with Trump, even as the president promised everything was under control and a vaccine would be ready soon.

Now even some Republicans are concerned that the president is underselling what some health officials have said is an inevitable worsening U.S. outbreak. And Fauci is who they want to hear from.

"If I'm buying real estate in New York, I'll listen to the president of the United States. If I'm asking about infectious diseases, I'm going to listen to Tony Fauci," Rep. Tom Cole (R-Okla.) said recently.

Giving a president advice can be a heady experience. Fauci has done it dozens of times, for four Republicans and two Democrats. "There's a temptation that you have to fight to tell the president what you think he wants to hear. I've seen really good people do that," says Fauci, who took over the agency in 1984, just a few years after switching his professional focus to a fast-emerging and then-mysterious new illness, HIV/AIDS.

Grappling with the AIDS epidemic and the Reagan administration's initial slow-go approach that divided Washington, Fauci became the public face of the response at a time when Ronald Reagan did not even broach the issue until his second term. Fauci often brings that up as a White House failure.

But these days are different. Trump fires off tweets about coronavirus, promising a vaccine will arrive "soon" (Fauci says in a best-case scenario it will be a year — and that might be optimistic), or says in press conferences that "we are totally prepared" (Fauci and other health officials warn the risk could change in a moment's notice). The president also referred to a coronavirus "hoax" in a campaign rally — the night before the first death from the virus was reported in the U.S.

And then there is Congress. Fauci likes to say that he has testified before Congress more than anyone in the nation's history. Over more than three decades he has been called to the Hill a dozen times a year to explain the threat of Ebola, Zika, anthrax or a pandemic flu.

He remembers the days of lawmakers hurling barbs across party lines about the AIDS response. But today, "the degree of divisiveness is one of almost an emotional dislike of the other person," he said.

Republicans reportedly stormed out of a recent closed-door briefing on the infection after Rep. Rosa DeLauro (D-Conn.) ripped into the administration's coronavirus response. Democrats have called for the White House to replace Pence as point person on the virus, arguing he has no public health experience.

The truth, Fauci says, is that Democrats and Republicans alike may not appreciate the range of what could happen now.

"It could be really, really bad. I don't think it's gonna be, because I think we'd be able to do the kind of mitigation. It could be mild. I don't think it's going to be that mild either. It's really going to depend on how we mobilize."

Critics say the administration has already stumbled with a slow rollout of diagnostic tests and narrow guidelines for who uses them, meaning that some patients waited days to find out if they are infected and the virus began spreading. Fauci said that restricted guidance — specifically the idea that someone would not get tested if they had not been in known contact with infected people — was unwise. He predicted more cases would emerge in the coming days — and they have.

There have already been scapegoats for the response. CDC Director Robert Redfield took the blame Saturday when Trump misidentified the gender of the first U.S. death. Sources also pointed to CDC on Sunday over concerns about the cleanliness of labs making diagnostic tests, even as some current and former administration officials blamed Azar for the bungled response. CDC's respiratory disease lead Nancy Messonnier also took heat from administration officials a week earlier after her statement that a U.S. outbreak was inevitable helped send the stock market tumbling.

"It's really, really tough because you have to be honest with the American public and you don't want to scare the hell out of them," Fauci said. "And then other times, in attempts to calm people down, [leaders] have had people be complacent about it. This is particularly problematic in a 'gotcha' town like Washington."

And yet, Fauci has not only survived the town for decades but managed to make his priorities those of the presidents, above all HIV. Along with Redfield and HHS Assistant Secretary for Health Brett Giroir, Fauci helped engineer getting the president include a pledge to ending HIV transmission in his State of the Union address last year.

But many challenges are still ahead, including sometimes contradicting the president he doesn't want to "go to war" with. Fauci says it will be OK: he knows that "even if it's uncomfortable" his years of truth-telling have earned him a backlog of respect.

The 79-year-old also has no plans of retiring anytime soon — not least because one of his top goals, developing an HIV vaccine, remains elusive.

"I feel like I'm 45. And I act like I'm 35," Fauci said. "When I start to feel like I don't have the energy to do the job, whatever my age, I'll walk away and write my book."

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Azar in the crosshairs for delays in virus tests [\(back\)](#)

By Dan Diamond and Adam Cancryn

Even as the Centers for Disease Control and Prevention takes blame for testing delays that may have led to hundreds of Americans being quietly infected with the coronavirus, officials inside the health department and the White House are increasingly pointing the finger at one leader: Health and Human Services Secretary Alex Azar, who they say failed to coordinate the response, as agency chiefs waited for instructions that came too late and other deputies were largely cut out of the process.

Numerous problems with the Trump administration's testing regimen have come to light: Coronavirus tests developed by CDC were flawed, possibly because the lab itself was contaminated. The resulting lack of test capacity forced U.S. officials to screen a limited number of patients across January and February, with the CDC testing fewer than 500 Americans at the same time that China was likely testing at least 1 million of its own residents. Meanwhile, public health officials had no fallback testing option until the Food and Drug Administration granted approval for hospitals and other labs to develop their own homegrown tests on Saturday — more than six weeks after the first U.S. case of coronavirus was identified.

Public health officials acknowledge that CDC and other parts of the government have repeatedly stumbled in the early days of the outbreak, but say that the 52-year-old Azar, a former drug company executive who took over the department in 2018, did not reach out early or often enough to goad his subordinates into action.

"This was a management failure," said one administration official, charging that Azar didn't adequately plan for a worst-case coronavirus scenario that's grown more likely by the day — even though Azar touted his bona fides as a veteran of the George W. Bush administration, where he helped fight crises like SARS and an anthrax scare. "CDC and FDA should have been working hand-in-hand to get Plan B, Plan C and Plan D ready to go," the official said.

"The administration's response has been reactive, not proactive," added a former HHS official. "A lot of what has happened has been driven by outside pressure," like public health labs sounding the alarm that they were unable to perform the CDC's tests.

Azar was abruptly removed as leader of the U.S. government's coronavirus response last Wednesday night and replaced by Vice President Mike Pence. The health secretary is still technically chairing the coronavirus task force, but decision-making, media requests and even task force membership have increasingly been run through the White House. Since Azar's removal as coronavirus-response leader, several of his deputies and rivals have been added to the task force.

POLITICO spoke to 17 current and former officials and individuals close to the Trump administration. Interviews with officials in HHS, who declined to comment on record for fear of retaliation, indicated that Azar's failure to reach out to a wider circle of advisers is typical of his management style, which has grown increasingly distrustful of his own aides.

The surgeon general is supposed to be the nation's chief spokesperson on threats to public health, but Surgeon General Jerome Adams had been little seen or heard from during the coronavirus threat until Azar was removed from leading the effort last week. Pence immediately added Adams to the task force, and the surgeon general this weekend began issuing coronavirus guidance on social media and appearing on national TV programs.

The FDA oversees drug and lab test development, but Commissioner Stephen Hahn also wasn't included on the Azar-led task force and has been frequently sidelined during the crisis. Hahn's most notable public moment was being summoned out of the crowd by Pence on Saturday to answer a question directed to President Donald Trump during a White House press conference.

Pence also added Hahn to the coronavirus task force after growing upset during a recent meeting that nobody could adequately answer a question about threats to the nation's drug supply, two people with knowledge of the situation said.

While Hahn's agency on Saturday did roll out instructions to let certain health organizations develop their own coronavirus lab tests, "FDA has been trying for some time to issue that guidance," said one official, who added that the agency was waiting on approval from HHS and Azar. Another official said Hahn had begun devising the strategy weeks ago.

An HHS spokesperson defended Azar's leadership and the administration's broader strategy of trying to contain the virus across January and February, arguing that it bought valuable time to prepare the nation for an outbreak.

"HHS has been working with public health systems since day 1 — that's how we've been catching these cases and educating the American public on what to do if they become symptomatic," the spokesperson said. "The task force has held countless briefings with members of Congress and state and local leaders, so they can appropriately prepare and educate their constituencies."

Asked if Azar was responsible for the CDC's testing failures, the spokesperson took issue with the framing. "Because of CDC surge capacity, there has been no backlog of tests despite the diagnostic issue," the spokesperson said, referencing problems that prevented many tests from working. "It's unfair to say testing has been limited."

Public health groups have argued there was no testing backlog because CDC capacity problems forced HHS to limit testing to Americans who were returning from China or people close to a confirmed case, rather than expanding the testing more widely — and picking up potential cases of the virus spreading in the community.

The HHS spokesperson also defended Adams' and Hahn's involvement in coronavirus planning, saying that the two officials have been part of coronavirus meetings for weeks. A senior administration official said Hahn particularly has been involved in White House planning.

Senior officials contend that Azar is operating under fear of offending Trump or his allies, which has led him to keep Adams, Hahn and his other underlings on a tight leash, while jockeying for credit to stay in the president's good graces. Azar's widely publicized feud last fall with Medicare chief Seema Verma, which contributed to the department's failure to come up with an alternative to Obamacare and necessitated a series of emergency White House meetings, highlighted some of these tendencies, the officials said.

Azar and his top aides also have for months frozen out Adams, who is close to Verma, and at times openly questioned Adams' ability to handle basic duties and stay on message. Adams played down coronavirus fears in a Monday interview on "Fox and Friends," predicting that more people globally would die from the flu.

Azar's supporters dispute that he has undermined Adams. An individual familiar with Azar's thinking said the HHS secretary has a good working dynamic with the surgeon general and the two men recently had lunch together. Azar has been "very impressed" with Adams' recent television appearances and hopes to have him play a larger role on coronavirus messaging, the individual said.

POLITICO on Monday morning reported that Verma was being added to the task force. The individual familiar with Azar's thinking said the health secretary supports her addition to the group and also pushed for bringing Veterans Affairs Secretary Robert Wilkie on board, arguing that the officials will be important inclusions as coronavirus becomes more of a domestic issue that poses a risk to health systems, the individual said.

Meanwhile, criticism for the stalled coronavirus tests has mounted on CDC and its director, Robert Redfield, amid that agency's high-profile stumbles in recent weeks. CDC supported quarantining hundreds of Americans aboard a cruise ship, which backfired as coronavirus rapidly spread on board, and Redfield also took blame for wrongly briefing Trump and Pence on Saturday, leading Trump to misidentify the first U.S. coronavirus death, a man in his 50s, as a "wonderful woman."

But two individuals said Redfield was wrongly being set up by some HHS officials as the fall guy for the administration's biggest coronavirus misstep — the lab-testing failure — arguing that the CDC chief had worked to speed the tests while advocating for a fallback lab-testing option but was waiting on Azar's permission to move forward on Plan B. "He's great on this," said one senior administration official, adding that Redfield is "busting his ass with a very hard job [and] working harder than any other senior official at HHS."

An HHS spokesperson said that CDC was taking steps to improve testing. "CDC and FDA have been working together to correct the issue with the diagnostic in a timely manner and worked together to make alternatives more readily available that meet the appropriate accuracy standards for testing," the spokesperson said.

The health department's slow response also has set off a round of finger-pointing among top officials and Azar's deputies, reigniting longstanding feuds at a crucial moment when the Trump administration needs to work in lockstep. Officials at CDC and Robert Kadlec, the HHS assistant secretary for preparedness and response, have jockeyed over coronavirus quarantine rules and

evacuating at-risk Americans, the latest skirmish between two agencies that have spent years battling over which gets to be in charge of the nation's emergency medical stockpile.

White House officials also have clashed with Azar and accused him of giving overly optimistic guidance to Trump, a battle that dates back a year and has encompassed numerous policies. Meanwhile, an HHS whistleblower and an FDA scientist have stepped forward to warn that the department's coronavirus response has been disorganized and could put Americans at risk. Azar has said he supports whistleblowers and vowed full investigations.

The disjointed, at-times-chaotic coronavirus response has alarmed allies of the HHS secretary, who worry Azar will ultimately shoulder much of the blame within the administration and from the public for failing to contain the outbreak.

The public health crisis threatens to become the defining episode of Azar's tenure, people close to him lamented in recent days, overshadowing more than two years of work on various policy initiatives and linking his legacy as health secretary to the administration's struggles to combat a fast-spreading virus that could linger for months — potentially infecting thousands, disrupting Americans' daily lives and grinding to a halt the once-strong economy that Trump officials view as key to the president's reelection.

"Right now, there's probably hundreds or low thousands of cases ... that aren't reported yet," Trump's former FDA Commissioner Scott Gottlieb said on "Face the Nation" Sunday, referencing a new estimate of spreading coronavirus in Washington state. "One of the mistakes, one of the challenges was getting the diagnostic testing in place."

Having failed to track and quash isolated cases, it may be too late to now guard against a widespread outbreak of coronavirus in the United States. Health officials have increasingly shifted their mindset from "containment" — stopping the virus altogether — to "mitigation," or preventing the virus' worst effects on Americans. Chris Meekins, a former Trump administration HHS emergency-preparedness official, on Sunday said the risk of significant U.S. outbreaks had risen from 33 percent to 75 percent in the last week alone.

Azar's job is not believed to be in imminent jeopardy, people close to the White House said, in part because firing the nation's top health official in the midst of an outbreak would prompt further questions about the administration's response effort.

But Azar — who already has few friends within the White House, which weighed a list of potential replacements in December — has been further weakened internally by his brief period leading Trump's coronavirus task force, during which he battled repeatedly with national security staffers over strategy and frustrated White House officials who at times questioned whether he was withholding information.

Meanwhile, Azar's attempts to publicly play down the risks of the virus — saying for weeks that there were just more than a dozen U.S. cases — were criticized by some officials as too-optimistic at the time and, in retrospective, seen as incautious. The HHS secretary repeated the message across four congressional hearings last week and national TV briefings, even as it turned out the virus was silently spreading in the United States.

"Focusing on just 15 cases was a tragic health care disservice," said a former HHS official. "Hospitals and health providers needed to know about the risks and get ready to take more steps."

Sarah Karlin-Smith contributed to this report.

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FDA approves generic version of 'pharma bro' drug ([back](#))

By Arthur Allen

The FDA today approved the first generic version of Daraprim, which sparked outrage over rising pharmaceutical prices when "pharma bro" Martin Shkreli bought the drug's patent and jacked up its price by 5,000 percent.

FDA approved the medicine — whose generic name is pyrimethamine — to treat toxoplasmosis, a parasitic infection that strikes people with weakened immune systems, such as patients with AIDS.

Shkreli's Turing Pharmaceuticals bought the 62-year-old drug in 2015 and hiked its price from \$13.50 to \$750 per pill, drawing anger in congressional hearings and contributing to efforts by Congress and the White House to check rising drug prices.

In 2018, Shkreli was sentenced to seven years in federal prison for an unrelated fraud scheme. Last month, [the Federal Trade Commission filed a complaint](#) in federal court against Vyera Pharmaceuticals, Shkreli's renamed company, alleging that, as Turing, it made illegal deals to prevent potential generic competitors from getting Daraprim samples or raw ingredients.

The FDA said it was [posting the names of all drugs](#) to which it had been alerted about efforts to limit distribution of samples to prospective generic applicants, Commissioner Stephen Hahn said in a news release. Daraprim was on the list, he said.

The generic's manufacturer, Cerovene Inc., did not immediately respond to calls and emails seeking information about the new drug's price.

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TOP NEWS

Squabble over mask shortage erupts as coronavirus spreads

By Dan Diamond and David Lim

The mask supply is a growing concern for the administration as more outbreaks of coronavirus are being reported in multiple states.

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Squabble over mask shortage erupts as coronavirus spreads [\(back\)](#)

By Dan Diamond and David Lim

A squabble is breaking out over whether respirator mask manufacturers need more protection from legal liability as the Trump administration presses them to ramp up production amid a major shortage during the coronavirus crisis.

With officials estimating the U.S. has only 1 percent of the masks needed for health workers in a full pandemic, Trump administration and mask makers wanted a provision added to the emergency coronavirus spending bill to protect manufacturers if wearers get sick. But House Democrats, including Speaker Nancy Pelosi, viewed the effort as an expansive legal waiver and blocked it from being added to the final version.

The \$8.3 billion spending bill will come up for a vote in the Senate Thursday after passing the House on Wednesday. It won't be changed now, but manufacturers and White House officials are warning that the omission could lead to hoarding of masks and not enough supply for nurses and doctors.

The fight echoes the post-9/11 debate over whether the government should accept liability for anti-terrorism technologies that fail to prevent future attacks or antidotes to anthrax that were produced on a large scale.

Under the 2005 PREP Act, the government assumes the cost of liability claims when it asks companies to provide products in response to a public emergency. But the protection doesn't apply to items like industrial masks because they're not regulated by the FDA, according to Charles Johnson, president of the International Safety Equipment Association.

The mask supply is a growing concern for the administration as more outbreaks of coronavirus are being reported in multiple states. The CDC is trying to speed masks to health care workers under an emergency use authorization granted Monday that allows more types of respirators, like industrial masks, to be used in health care settings. The FDA already allows a subset of respirators to be used in health care settings.

HHS this week said the U.S. has about 1 percent of the required respirator masks needed to equip health workers in a full-blown pandemic, estimating the medical system would need as many as 3.5 billion N95 respirator masks in a year.

Administration officials say the lack of liability protections means manufacturers including 3M, Dräger and Moldex could potentially face a wave of individual lawsuits, even for circumstances like someone wrongly wearing the mask and contracting the virus. Vice President Mike Pence and other members of the White House Coronavirus Task Force are set to meet with 3M CEO Mike Roman Thursday afternoon to talk about supply chain matters.

"This liability issue makes it harder for the industry to step up and do the right thing when the government asks them to do so," said Johnson, who supports expanding the PREP Act's protections. "The masks may be slower to market and into the hands of the people who need them."

"I have worked alongside manufacturers like 3M, who have a plant in Nebraska, who are working around the clock manufacturing protection devices," added Rep. Don Bacon (R-Neb.), the lead sponsor of the provision. "Manufacturers must be willing and able to respond in the event of an outbreak — this legislation would have done just that."

3M officials have said Congress' failure to include the language in the spending package could lead to hoarding of masks.

The health department has warned that the provision was an important step to enlist the industry to fight coronavirus, said two individuals with knowledge of the deliberations. A White House official confirmed that the administration supported the provision.

"We can't expect companies to go above and beyond to meet the needs of the American people when they have the looming threat of litigation hanging over their heads," said one individual with knowledge of the talks.

But Democrats balked at adding the measure. "The committees raised early objections to including an expansive liability waiver in the supplemental and the Speaker agreed," said a senior Democratic aide.

Congressional aides familiar also say the industry needs to demonstrate evidence that a blanket liability shield is needed in order to make enough masks to fight the coronavirus outbreak. They also said the administration hadn't actively pushed for the provision, which introduces complications around who's going to pay to cover liability — and could leave Congress on the hook to come up with the funding.

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A few months? Trump's vaccine hyperbole complicates coronavirus message ([back](#))

By Arthur Allen and Meridith McGraw

Nearly every time President Donald Trump has talked about a coronavirus vaccine, he has gotten a real-time fact check from a health expert sitting nearby.

"So you're talking over the next few months, you think you could have a vaccine?" Trump asked during a meeting with top health officials on Monday.

"You won't have a vaccine," corrected Health and Human Services Secretary Alex Azar after some cross talk. "You'll have a vaccine to go into testing."

"All right, so you're talking within a year," Trump said moments later.

"A year to a year and a half," interjected Anthony Fauci, a government veteran of disease outbreaks under six presidents.

At a time when the federal government is trying to carefully control messaging about the possibility of a cure for a disease that has already claimed the lives of 11 Americans, the president's penchant for on-camera hyperbole has been a constant challenge.

Trump has long claimed to know more than the authorities on a long list of things — TV ratings, taxes, campaigns, firefighting, water management and Twitter, to name a few — but the stakes for his exaggerations have rarely been so high. Indicating that a cure might be around the corner

may cause inadequate preparation for the possibility that the disease could spread more widely through the U.S.

"I observe that the president has been listening, but since he's not a scientist I don't think he understands the nuances," said William Schaffner, an infectious disease specialist at Vanderbilt University. "And besides, he has an understandable tendency to walk on the sunny side of the street."

The White House is known to control the information that comes across the president's desk, and use visual aids to instruct him on foreign policy decisions or severe weather. But with the coronavirus — a disease even the nation's top health experts admit is still quite mysterious — the president is learning about the science behind the virus as the experts are. And in the meantime, he's sharing some inaccurate theories and asking confounding questions about how a vaccine might work, all while the cameras roll.

Already, Trump has muddied the waters on the difference between a vaccine entering various trial phases and it being ready for widespread public use. While vaccines are able to be quickly developed by researchers, it takes time to get the vaccine on the market. Trump has also raised questions about whether a vaccine for the flu could work on this completely different virus.

"You take a solid flu vaccine, you don't think that could have an impact, or much of an impact, on corona?" Trump asked.

"No," a pharmaceutical researcher quickly replied.

The president has long been a source of dubious information on vaccines. As a presidential candidate, Trump tweeted discredited theories that vaccines cause autism and also spouted the theory during a September 2015 debate.

Andrew Wakefield, the British doctor disciplined for fraud over his claim that the MMR vaccine caused autism, attended Trump's inauguration. A short time later, Robert F. Kennedy Jr., who also blames vaccines for many ills, said Trump had promised to establish a commission to investigate such theories — but nothing came of it.

Yet during last year's measles epidemic — the worst in 27 years — Trump did urge people to vaccinate their children.

A senior White House official pushed back on the notion that the president was confusing important information, arguing that Trump was trying to clarify medical vernacular that might be unclear to the public.

"It's not confusion, he's just asking questions," the official said. "There's just a lot of back and forth when you're talking about vaccines versus treatment."

Vaccine scientists have been amazed at the speed with which the National Institutes of Health and vaccine makers are assembling candidate vaccines to prevent coronavirus. While most vaccines take years or decades to develop, the 12-18 month scenario that Fauci has laid out is realistic, according to medical experts. Although it's far from assured.

"The concern we have is, 12-18 months may be too late," said Kathryn Edwards, a pediatric infectious disease expert, also at Vanderbilt. "The bulk of the outbreaks could be over by then."

If conditions are desperate enough a year from now, the FDA might authorize use of a vaccine without incontrovertible evidence that it protects against disease.

But putting out a vaccine before it's been tested in epidemic conditions could be risky, Edwards said. For instance, during tests of some earlier vaccines against SARS and MERS, which are similar to the recent coronavirus, some animals developed so-called immune enhancement, meaning they got sicker when exposed to the virus than unvaccinated animals. A similar phenomenon may have occurred in some children who were injected with dengue virus vaccines in the Philippines in 2018.

Several vaccines are being studied, but the one moving the fastest is produced by Moderna Therapeutics of Cambridge, Mass., with scientists from Fauci's institute.

The first phase of the trial is set to be hosted at a Kaiser-Permanente research institute located in Seattle, but the outbreak of disease there has complicated the plan. The 50 or so study subjects will have to be carefully monitored to assure none of them is infected with the virus during the trial, which is aimed solely at confirming that the vaccine is safe, one scientist familiar with the trial said.

Trump's allies said the president's rhetoric on a shortened vaccine timeline is helping accelerate the process.

"If President Trump went by the old messaging playbook, we wouldn't see a coronavirus vaccine for years. Instead he's aggressively pushing the NIH, [the Centers for Disease Control], our top researchers and even private drug companies to get it done immediately," said Jason Miller, senior communications adviser on the 2016 Trump campaign.

"And if President Trump ruffles a few feathers with his hyperbole in the pursuit of a cure to keep people safe, there will be zero complaints," he added. "Good for him."

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6 things about what's in the coronavirus funding package — and what got left out ([back](#))

By POLITICO Staff

The \$8.3 billion emergency coronavirus funding package would fund the development of new treatments, boost funding to purchase medical supplies and ship more than \$400 million in grants to states and localities for preparedness within 30 days.

The sprawling legislation also left some health industries happier than others. Drugmakers could benefit from some of the language on purchasing vaccines and other treatments developed to

fight the virus. But Congress punted on other decisions, like whether to extend liability protections for medical mask and other device manufacturers.

Following are some of the key provisions:

Vaccines and treatments

The package would send \$826 million to the National Institute of Allergy and Infectious Diseases to drive the development of coronavirus vaccines, treatments and tests. The FDA would get \$61 million to speed up review of these new therapies and respond to possible drug and device shortages stemming from manufacturing disruptions at the virus' epicenter in China.

States and localities

Despite a growing outcry over the cost of testing and treating patients, Congress didn't explicitly address how to handle funding for mandatory quarantines or the uninsured. The package would send \$950 million in state and local grants, with half of the money due within 30 days. States will receive a minimum of \$4 million.

The funding comes as a coronavirus response is already putting major stress on state and local health departments, which are historically underfunded. They're already spending money on staff, supplies and mandated quarantines. The legislation would reimburse states and counties for what they spent to prepare for and mitigate the virus between Jan. 20 and whenever the funding package is enacted. Funds can be used to build or renovate facilities.

Stockpiles and supplies

The package includes about \$3.1 billion to purchase medical supplies for state and local health departments to beef up the Strategic National Stockpile, the largest national repository of emergency treatments. It will also provide additional resources for states and assist federal efforts to develop vaccines and therapeutics, as well as hospital preparedness.

Another \$300 million would help the government buy vaccines and treatments once they are approved. Democrats and Republicans had argued over how to ensure the government doesn't overpay for these products. The legislation specifies that products purchased with these funds must meet federal acquisition guidance "on fair and reasonable pricing." It also empowers the HHS secretary to ensure that any vaccines, drugs or diagnostic tests developed from funds provided by the bill "will be affordable in the commercial market," but doesn't specify how affordability will be determined.

However, language in the bill says that HHS can't delay the development of these products in an effort to maintain affordable prices, a win for Republicans and the drug industry, who argue that government constraints on pricing will limit private industry investment in coronavirus treatments.

Democrats were initially pushing for the inclusion of a provision that would allow HHS to take away a drug company's intellectual property protection on a vaccine or medication if the price was deemed too high. Versions of the legislation circulating late last week including this

language. But pushback from the drug industry and Republicans prompted lawmakers to strike the provision.

The bill additionally doesn't include a provision introduced by Rep. Don Bacon (R-Neb.) that would have amended the Public Readiness and Emergency Preparedness Act to reduce legal liability on device manufacturers during an emergency. The National Association of Manufacturers backed the effort, warning that mask manufacturers needed "additional legal certainty" as an incentive to produce the millions of new masks that health officials say are necessary to safely fight coronavirus.

Community health centers

Community health centers on the front lines of the social safety net would get \$100 million just as their funding is set to expire at the end of May. Another \$10 million would go to the National Institute of Environmental Health Sciences to put together trainings for health care workers on the front lines of the outbreak to avoid becoming infected.

Telehealth

The package would also lift constraints on Medicare's payments for telehealth so beneficiaries could freely consult their doctors remotely, avoiding hospital and physician offices where they might risk exposure to the virus. Telehealth groups were hoping for a provision that would waive restrictions during all national emergencies, but this appears more narrowly tailored to the coronavirus.

International programs

The legislation includes \$300 million to continue the CDC's programs to detect and respond to international disease outbreaks, and \$435 million for global health programs at the State Department. State's international disaster assistance fund would get \$300 million to provide humanitarian aid and address health needs in countries where the coronavirus is spreading. Trump's fiscal 2021 budget request proposed cutting several international public health programs.

Adriel Bettelheim, Sarah Oweremohle, Sarah Karlin-Smith, Rachel Roubein, Dan Diamond, Susannah Luthi, Brianna Ehley, Dan Goldberg and Lauren Morello contributed to this report.

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House swiftly passes bipartisan \$8.3B coronavirus package ([back](#))

By Caitlin Emma and Jennifer Scholtes

The House on Wednesday passed an \$8.3 billion emergency coronavirus package, just hours after congressional negotiators clinched a bipartisan deal to tackle the spreading epidemic.

The lower chamber approved the measure in an overwhelming 415-2 vote. It now heads to the Senate, which could clear the bill as soon as Thursday and send it off to President Donald Trump for his signature. The two nay votes were from Republican Reps. Andy Biggs of Arizona and Ken Buck of Colorado.

"While we all ardently hope that this public health emergency does not worsen, House Democrats will not hesitate to act again if we must augment this funding with more resources," House Appropriations Chairwoman Nita Lowey (D-N.Y.) said on the floor ahead of the vote. Lowey also stressed to reporters that \$8.3 billion is "a lot of money," which should be used "efficiently and effectively."

The bill, H.R. 6074 (116), includes about \$7.7 billion in new discretionary spending to bolster vaccine development, research, equipment stockpiles and state and local health budgets, as government officials and health workers fight to contain the outbreak, which has claimed 11 lives in the U.S. and sickened more than 100 people across more than a dozen states.

Meanwhile, House and Senate leaders have stepped up their response to the outbreak with an onslaught of meetings — including a pair of briefings by Vice President Mike Pence at the Capitol on Wednesday — to coordinate the federal response.

Congress' four most powerful leaders, Speaker Nancy Pelosi, Senate Majority Leader Mitch McConnell, Senate Minority Leader Chuck Schumer and House Minority Leader Kevin McCarthy, also received a closed-door briefing Wednesday on the potential impact of the virus on U.S. Capitol operations.

Both Pelosi and McCarthy left the briefing confident that they would keep the Capitol open for business until further notice.

Under the agreement, more than \$400 million would be shipped off to state and local governments within 30 days after the bill is enacted, with each state receiving no less than \$4 million.

The package would also authorize \$490 million in mandatory spending by lifting constraints on Medicare's payments for telehealth so beneficiaries can freely consult their doctors remotely, avoiding hospitals and physicians' offices where they might risk exposure to the virus.

It would provide \$3.1 billion to beef up medical supplies and supplement the Strategic National Stockpile, including \$100 million for community health centers. About \$826 million would go to the National Institute of Allergy and Infectious Diseases for the development of coronavirus vaccines, treatments and tests. The Centers for Disease Control and Prevention would receive \$2.2 billion, including a total of \$950 million to support the response efforts of state and local health agencies.

Under the deal, \$61 million would go to the FDA for vaccines and other efforts to counter the virus, plus keeping up with shortages in medical products and trying to boost U.S. manufacturing of those items. For aiding the global fight against the bug, congressional leaders laid out almost \$1.3 billion for the State Department and the United States Agency for International

Development, including raising the cap from \$10 million to \$100 million for emergency evacuations.

The Small Business Administration would receive \$20 million to increase the number of loans given to businesses affected by the outbreak. The package also includes a provision requiring the Trump administration to replace \$136 million that it recently shifted from various health accounts, including mental health and substance abuse programs, in order to pad out its coronavirus response.

The agreement comes after several days of partisan bickering over vaccine affordability and other issues that had ensnared the bipartisan, bicameral talks. Negotiators ultimately agreed to include \$300 million "to help ensure that, when a vaccine is developed, Americans can receive it regardless of their ability to pay," according to a House Democratic aide.

Vaccine affordability had been one of the biggest holdups to a final package. Democrats had pressed for significant funding to purchase large amounts of coronavirus diagnostics, treatments and vaccines when they become available, which would then be made available to the public free of cost, according to a senior Democratic aide.

The aide claimed that Republicans tried to eliminate the "fair and reasonable price" federal procurement standard for the vaccines and treatments that will be developed and purchased with the emergency funds. "Fair and reasonable price" is a basic standard to prevent price gouging in federal contracts.

Republicans, however, argued they are trying to fight Democratic efforts to create a new set of price controls and that they are not asking for changes to the underlying procurement standards.

"There's some things that we think would have discouraged pharmaceutical companies from making investments and participating — we want everybody at the table — and I think we found the right mix," said Rep. Tom Cole of Oklahoma, the top Republican on the spending panel overseeing HHS.

"[We] reassured our friends on the other side, hey, we want to all make sure nobody profits unduly, but we want to make sure we get a product, and want to make sure that product's available to all Americans."

The package far exceeds the \$1.25 billion in new funding requested by the Trump administration. Lawmakers on both sides of the aisle were alarmed by what they deemed as the president's paltry request to fight the bug amid criticism that his administration has bungled its response and failed to keep the American people clued in about the potential severity of the outbreak.

Even though the multibillion-dollar infusion is expected to be signed into law quickly, many in Congress say they worry about the administration's ability to coordinate response across all 50 states and territories to ensure enough test kits are available, that people who are infected are quickly isolated and that health workers are following protocol.

The half-hour, back-to-back briefings on Wednesday frustrated some lawmakers, who complained that there was not nearly enough time to question Pence and other Trump administration health officials.

Yet while Democrats remain wary of the administration's ability to manage the crisis, several said Pence provided as reassuring an update as they have received thus far. Regular briefings by Pence and his public health team are expected to take place in the coming days and weeks.

"Absolutely not," House Majority Whip Jim Clyburn (D-S.C.) said when asked if he had confidence in the administration's response. "They're just fooling around. It just reminds me so much of [Hurricane] Katrina."

"It's being jerry-built," Rep. Mark Takano (D-Calif.) said of the response plan. "I think we can legitimately say that they're piecing it all together."

Top infectious disease expert Anthony Fauci, FDA Commissioner Stephen Hahn and White House coronavirus response coordinator Debbie Birx also joined Pence at the briefings.

Pence's biggest takeaway, according to Democrats, is that members should hold town halls, both in person and over the phone, to relay information about the virus and its spread.

"The vice president clearly wanted us to communicate to our constituents, and give out enough information as possible, as accurately as possible. What you want to avoid is panic," House Majority Leader Steny Hoyer (D-Md.) said afterwards.

Sarah Ferris, Jesse Naranjo, John Bresnahan, Sarah Owerhohle and Heather Caygle contributed to this report.

To view online [click here](#).

FDA issues third-ever ban on medical device ([back](#))

By David Lim

FDA today finalized a ban on electrical stimulation devices intended to treat self-injurious or aggressive behavior.

The move comes after several Democrats called for the FDA to ban such devices in a letter to FDA Commissioner Stephen Hahn on Feb. 10. The senators called the use of the devices, often on people with disabilities, a "barbaric — and disproven — practice."

"Through advancements in medical science, there are now more treatment options available to reduce or stop self-injurious or aggressive behavior, thus avoiding the substantial risk ESDs present," said William Maisel, director of the Office of Product Evaluation and Quality in the FDA's device center, in a statement.

The ban, the third FDA has ever issued for a medical device, takes effect in 30 days. FDA is allowing a 180-day deadline for electrical stimulation devices already in use on an individual to allow a physician-monitored transition period to another treatment.

The agency estimates 45-50 people are currently exposed to the device at Judge Rotenberg Educational Center in Canton, Massachusetts.

To view online [click here](#).

FDA issues guidance on insulin's shift to the biologic pathway ([back](#))

By Sarah Oweremohle

FDA this morning [issued final guidance](#) on how insulin can be licensed as a biologic.

The document is part of the agency's timeline for shifting insulin entirely out of the drug category in a bid to encourage more competition by opening the door to biosimilars. This month marks the deadline for that transition.

The guidance fleshes out questions about which products would need to transition from the drug pathway to the biologic one. FDA said that if a manufacturer's insulin is already approved under the new drug application process, it does not have to be resubmitted for a biologic license application.

There is no true generic insulin on the market right now, in part because the conventional pathway made it difficult to make identical products.

Congress first directed FDA to reclassify a small subset of biologic products, like insulin and growth hormones, nearly a decade ago.

To view online [click here](#).

U.K. competition watchdog fines 4 pharma companies for cartel deals ([back](#))

By Giorgio Leali

BRUSSELS — The U.K. Competition and Markets Authority today fined four drug companies for concluding anti-competitive agreements and sharing commercially sensitive information about the supply of the antidepressant nortriptyline.

In two separate decisions, the authority found that King Pharmaceuticals and Auden Mckenzie agreed to share the market for nortriptyline, and that King, Lexon and Alissa Healthcare Research shared commercially sensitive information to inflate the price of the antidepressant.

"These firms exchanged sensitive information and shared out supply to try and keep prices up, meaning the NHS — and ultimately the U.K. taxpayer — could have been paying over the odds for this vital drug," CMA Chief Executive Andrea Coscelli said in a press release.

King and Auden McKenzie "shared out between them the supply of nortriptyline to a large pharmaceutical wholesaler" and "also colluded to fix quantities and prices," the release noted.

King, Lexon and Alissa Healthcare exchanged information about prices, supply volumes and Alissa's plans to enter the market to keep nortriptyne prices up at a time when the value of the drug was falling. In September 2019, King and Alissa admitted they shared sensitive information.

The watchdog imposed fines of more than £3.4 million as well as a payment of £1 million directly to the NHS, marking the second time the CMA has secured a payment to the NHS.

The CMA also called on an executive at King to recuse himself from serving as a director of any U.K. company for seven years

To view online [click here](#).

Coronavirus emergency bill stalled over vaccine cost concerns ([back](#))

By Sarah Ferris, Sarah Oweremohle and Heather Caygle

House and Senate leaders have run into last-minute snags on a \$7.5 billion emergency package to combat the U.S. spread of coronavirus, including disputes over vaccine availability and hospital reimbursement costs.

Top Democrats say the House is still expected to vote on the package Wednesday, with the Senate likely to follow suit as soon as Thursday. But the timeline for unveiling that legislation has slipped, possibly as late as Wednesday morning, amid policy fights between the two parties.

With the number of U.S. cases steadily rising, Speaker Nancy Pelosi is negotiating with Senate Majority Leader Mitch McConnell to find a deal that could pass both chambers this week, doling out money quickly to state and local health departments.

The biggest issue, according to several people familiar with negotiations, involves a Democratic attempt to control the costs of vaccines and other treatments that are developed in response to the outbreak. Other issues include details of hospital reimbursement for uninsured patients and whether to pay for a provision to help expand telemedicine, which would cost roughly \$500 million.

"Vaccines should be affordable. It's just as simple as that," Rep. Rosa DeLauro (D-Conn.), a top appropriator, said as she left a Democratic leadership meeting on Tuesday night.

"It's going back and forth. That's where we are," DeLauro added. "There are no firm answers at the moment, but we're moving toward getting this done and getting it done this week because the need is so critical. We have to get it done this week."

Pelosi and her top deputies briefed their fellow Democrats on the status of the emergency funding package on Tuesday night and outlined the remaining issues. A final deal could still be reached Tuesday night, they said, but could take until Wednesday morning.

Senate Minority Leader Chuck Schumer had complained earlier Tuesday that Republican lawmakers were resisting Democratic efforts to stave off potential price-gauging of vaccines or other products.

"Our Republican friends don't want to see the kinds of limitations that we want to see," Schumer said after a briefing with members of the White House's coronavirus task force, including Vice President Mike Pence and HHS Secretary Alex Azar.

The 11th hour policy battles come after both parties had intended to present a united front against the potential epidemic, with House Majority Leader Steny Hoyer of Maryland and Republican leader Kevin McCarthy of California trading offers on details of the package as recently as Tuesday. Republicans and Democrats both stressed that the response to the virus should avoid mudslinging and fingerpointing.

Still, some of the final details of the massive funding package have come down to partisan talking points.

Democrats are insisting the spending package include significant funding to purchase large amounts of coronavirus diagnostics, treatments and vaccine, when it becomes available, which would then be made available to the public free of cost, according to a senior Democratic aide.

The Democratic aide said Republicans are trying to eliminate the "fair and reasonable price" federal procurement standard for the vaccines and treatments that will be developed and purchased with the emergency funds. "Fair and reasonable price" is a basic standard to prevent price gouging in federal contracts.

Republicans, however, argue they are trying to fight Democratic efforts to create a new set of price controls and that they are not asking for changes to the underlying procurement standards.

The administration's top scientists have said any coronavirus vaccine could be at least a year away from reaching the market. Moderna Therapeutics is working with National Institutes of Health on a vaccine while Johnson & Johnson has received funding from HHS's Biomedical Advanced Research and Development Authority.

The bill would provide funding for masks, ventilators, community preparations and vaccine development, Schumer said. But it's silent on how much vaccines developed with the government's backing should cost.

"We are not going to say the companies after we taxpayers have paid for it, 'now go out and make a huge profit.' That's not going to happen," said Senate Appropriations ranking member Patrick Leahy (D-Vt.).

Congressional leaders still plan to pass an emergency package by the end of this week, with funding levels much closer to the \$8.5 billion Democrats suggested than the Trump administration's \$2.5 billion request.

Both House and Senate leaders have stepped into overdrive as the global coronavirus outbreak poses a rising threat to the U.S., with 122 cases of the virus now reported.

Lawmakers have also dramatically stepped up their oversight of the Trump administration's response, which had drawn flak in the early days of the outbreak, with its mixed messaging and a slow rollout of tests as cases accumulate.

Senate Democrats on Tuesday confronted Pence over the federal government's response to the outbreak, even as leaders of both parties have quietly urged lawmakers to present a united front.

Multiple Democrats said Pence and the task force did not have enough answers on testing kits, costs of care and what will happen to people who do not have insurance.

Lawmakers including Democratic Sens. Patty Murray and Maria Cantwell of Washington, where nine deaths have been confirmed, challenged Pence during the hourlong meeting, which became contentious at times, according to attendees.

"The failure to develop and distribute working test kits to public health agencies has really cost us valuable time," Murray said afterward. "I'm hearing from people personally across our state who are frustrated. They believe they have been exposed, they are sick, they want to get tested — but they have nowhere to go."

Roughly \$900 million in the bill would go toward purchasing equipment including masks and ventilators. Murray said that officials told senators they had stockpiled masks, but that there were not enough.

Separately, health insurers want assurances the government will help pay the cost of widespread testing or expensive treatment.

"There's not enough test kits. We don't know how wide it is. And it's because the president dropped the ball early," said Sen. Jon Tester (D-Mont.).

Meanwhile, at the Senate Republican lunch, one attendee said senators suggested to Pence that the administration's medical experts be the "point people" for the federal response.

"No real pushback other than the recommendation that they just use people that are not politically appointed, real professionals in the area that way there can't be argument — oh, this is just political spin, it's coming from doctors," the attendee said.

Pence, who President Donald Trump designated the lead on the virus response last week, made the rounds as the Trump administration tried to move past a raucous few days of partisan finger-pointing.

Earlier on Tuesday, Pence hosted a group of House members who belong to the bipartisan Problem Solvers Caucus in the White House situation room. His message, according to several attendees, was to avoid political bickering as the U.S. grapples with a health crisis with a scale that remains unknown.

Rep. Stephanie Murphy (D-Fla.) laid out concerns with the administration's outreach, including mixed messaging from Trump himself and various health agencies, according to multiple people in the room.

Murphy, whose home city of Orlando includes Disney World, pressed Pence on which source of information should be trusted. Pence instructed her to refer to the CDC's website.

Another Democrat, Rep. Dean Phillips of Minnesota, challenged information the administration has presented about the risk of transmission. He later said he urged the administration to be as transparent and "as conservative" as possible.

Sarah Karlin-Smith, Caitlin Emma, Andrew Desiderio, Marianne LeVine and Susannah Luthi contributed to this report.

To view online [click here](#).

CDC opens up coronavirus testing, Pence says [\(back\)](#)

By Brianna Ehley and Meridith McGraw

The CDC is broadly expanding who can be tested for the coronavirus, Vice President Mike Pence announced Tuesday, as the Trump administration scrambles to detect cases that may have been missed because of delays in testing.

Under the new guidance, "any American can get tested" if a doctor suspects the virus, Pence told reporters at the White House. He added that people no longer need to show specific symptoms as the CDC had previously required. The change could dramatically increase demand for testing at a time when public health experts are concerned that the country's testing capacity is still weeks behind.

Pence said the new testing guidelines came after several governors informed him "there was an impression that tests would not be administered to people who were only mildly symptomatic." It also comes after a California patient last week was confirmed positive for the virus days after being denied a test under CDC criteria.

The agency previously advised doctors to only test patients if they had known exposure to someone with the virus, travel history to an affected region or had symptoms of a serious respiratory illness.

The Trump administration in recent days has faced criticism for delays in testing because of earlier problems with its diagnostic tests. Pence said the U.S. plans to send 2,500 new test kits out by the end of the week, which he claimed can test 1.5 million samples. Public health labs say patients typically require at least two samples.

Pence also said private companies are expected to dramatically boost the amount of test kits on the market, though experts question whether there are enough laboratories to test a large surge of samples.

As of Tuesday, officials have confirmed 77 cases in the U.S. across 13 states and nine deaths, all reported in Washington state.

Seven of those deaths involved patients from a nursing home near Seattle. Pence said he spoke with Washington Gov. Jay Inslee earlier Tuesday. A CDC team is on the ground in Washington, and the Centers for Medicare and Medicaid Services has deployed investigators to the nursing home.

President Donald Trump and Pence visited the National Institutes of Health on Tuesday to discuss treatments and the development of a vaccine, which agency Director Anthony Fauci said won't likely be ready until next year.

Officials reiterated that the immediate risk to the American public remains low, though cautioned that could quickly change.

"The big unknown that I think we're going to be able to address as we get much more widespread ability to test is the degree of infection that might be out there," Fauci said.

Concerns of broader community spread come just as a \$7.5 billion emergency funding package for coronavirus response efforts stalled on Capitol Hill Tuesday over disagreements about vaccine availability and hospital reimbursement costs. State and local health departments, already strapped for cash, say they need funding to prepare especially in the event that the virus becomes widespread in their communities.

Joining Pence at the briefing — which was not televised — were members of the coronavirus task force including Deborah Birx, who is leading the response; CMS Administrator Seema Verma; CDC Director Robert Redfield; and FDA Commissioner Stephen Hahn.

Pence said he plans to meet Wednesday with airline industry executives to discuss "contact tracing data" and greater cooperation among the airports tasked with screening people coming back into the United States.

David Lim contributed to this report.

To view online [click here](#).

DOJ sues Mallinckrodt for shortchanging Medicaid on rebates [\(back\)](#)

By Sarah Karlin-Smith

The Justice Department on Tuesday [joined in a whistleblower lawsuit](#) accusing drugmaker Mallinckrodt of defrauding Medicaid by knowingly underpaying hundreds of millions of dollars in rebates the company owed stemming from large price increases for its H.P. Acthar Gel.

Mallinckrodt and its predecessor company Questcor are alleged to have avoided inflation-based penalties on rebate obligations by characterizing an old version of the treatment — which has been on the market since 1952 — as a new drug based on a new approved use for infantile spasm the FDA issued in 2010. The Justice Department alleges the company knowingly mischaracterized the new approval to CMS as an entirely new drug application, instead of a supplement to an existing FDA application. Acthar has 19 approved uses for conditions including multiple sclerosis, rheumatoid arthritis and lupus.

Drug companies must pay penalties to Medicaid when they raise the prices of their drugs above the inflation rate. Those rebates are based on the drug's price since 1990 or when it was first marketed, whichever date is later.

But in 2013, Questcor allegedly began calculating and paying rebates as if the drug was first marketed that year, while at the same time raising the price by more than \$20,000 per unit. The activity allowed the company to avoid hundreds of millions of dollars in Medicaid rebates.

By 2016, CMS said it discovered that Mallinckrodt had wrongly characterized the product as a new drug and asked it to correct underpayments since 2013 that at that time totaled \$258 million. The company has refused to make these payments, DOJ said.

[Mallinckrodt has denied wrongdoing and filed suit against CMS](#) over the rebate dispute in 2019. The company on Tuesday cited that ongoing case, saying a federal court in Washington, D.C., "previously barred CMS in 2019 from taking enforcement action against Mallinckrodt while this case is now awaiting a decision." The company accused the U.S. Attorney in Massachusetts, which is leading the whistleblower lawsuit, of attempting an "end-run around that Court's order by pursuing new enforcement litigation."

Questcor, now part of Mallinckrodt, acquired Acthar in 2001. At that time the drug cost about \$50 per 5 ml vial. It now costs nearly \$40,000 per vial.

The lawsuit in the U.S. District Court for the District of Massachusetts is just the latest legal trouble for Mallinckrodt, which last week [announced a proposed \\$1.6 billion settlement](#) with thousands of U.S. municipalities and 47 states and territories to resolve litigation over its alleged role in fueling the opioid epidemic. The company's speciality generics unit would file for Chapter 11 bankruptcy as part of that deal.

To view online [click here](#).

AI was supposed to save health care. What if it makes it more expensive? [\(back\)](#)

By Arthur Allen

NEW YORK — Last year, Mount Sinai Hospital switched on an artificial intelligence program to search the hospital's records for evidence of malnourished patients in its wards. The numbers it turned up were eye-popping: 20 percent more cases were diagnosed than in the previous year.

Around the same time, Barbara Murphy, chief of the renowned health system's department of medicine, was helping to develop another AI program, to predict whether diabetic patients are at near-term risk of kidney disease and to help prioritize specialist visits for those who are. One of the early findings, according to Murphy: "We probably need some more nephrologists."

As hospital systems around the country unleash machine learning algorithms — computer models that function like millions of unblinking eyes inspecting patient records — such findings are becoming more common. The algorithms, deployed in hospitals over the past couple of years, are often designed to help locate the sickest patients, but in some cases, they also provide more opportunities to bill.

"One of the ways that we get reimbursed for stays is being able to treat and document what's going on," said Robbie Freeman, Mount Sinai's vice president for clinical innovation. "We can document that malnutrition. It means the hospital will get credit for that patient and paid for the care."

The specialists who are introducing machine learning and other tools say they should make health care more efficient by enabling better identification of riskier problems before they become tragic, expensive conditions. For example, Murphy's algorithm could help doctors intervene to prevent diabetics from needing dialysis.

But there's a big risk of overdiagnosis and recommendations for procedures or drugs that might not be necessary, said Kenneth Mandl of Harvard Medical School, who created a new term — "biomarkup" — for the tendency of new detection to spur more spending in medicine. Marketing and innovation fever tend to stimulate the use of tests that indicate risks for diseases like cancer and stroke before there is reliable data showing the tests lead to improved patient outcomes, he said.

As algorithms point out health risks that haven't always been captured in the course of normal medicine, "the risks of overdiagnosis go up, and so can the risks of potential harms," David Kent, a doctor and researcher at Tufts University, said at a recent FDA-sponsored event.

A recent study by Google scientists, for example, showed that one of the company's computer models was better than doctors at reading mammograms to detect breast cancers. Speedy algorithms like the one Google deployed will allow radiologists to work faster and lead to more positive findings, Dell Medical School dermatologist Adewole Adamson [wrote recently in the New England Journal of Medicine](#).

But the problem is, the algorithm won't know which of those growths require attention or treatment, Adamson wrote. So, more biopsies will probably be ordered, with the possibility of more overdiagnosis and higher spending.

Computerized triage

Hospital systems around the country are testing machine-learning algorithms that detect everything from smoldering blood infections or pneumonia to social issues that affect health, like poor housing and lack of access to transportation or nutritious food. How they deploy the programs may have a major impact on costs.

Many of the algorithms deliver a risk score — for instance, they might say a patient has a 60 percent chance of suffering a fall. Hospitals can then display the risk number on clinicians' computer screens in green, yellow or red, depending on what level of risk they decide is worth addressing.

Setting those thresholds is a delicate matter. If a "red" score is set too low, doctors will be flooded with alerts and probably ignore them. If the risk threshold is too high, clinicians run the risk of missing a serious condition that could harm a patient — and potentially expose their institution to legal jeopardy.

"There is always a tradeoff," says Michelle Gong, chief of critical care at the Montefiore Health System in the Bronx. "You have to select a level of sensitivity you think is safe but doesn't create too many alarms."

Liability and safety concerns could push hospital systems to set thresholds to detect more cases, leading to more medical intervention, and more billing, because "each false negative could represent a loss of life," said Keith Dreyer, chief data science officer for Partners HealthCare. Bad drivers kill tens of thousands of people a year, but a single death caused by a driverless car in 2018 caused Uber to suspend its testing of the vehicles, Dreyer noted.

Not everyone agrees that algorithms inevitably will drive up health spending. If algorithms are increasing costs, they probably aren't being implemented correctly, said Eric Topol, director of the Scripps Research Translational Institute.

Connie Lehman, chief of breast imaging at Massachusetts General Hospital, said algorithms she has been testing there could reduce unnecessary consults by eliminating more false positives that could lead to sonograms and biopsies. If they were widely used, "you could immediately see lower costs," she said.

In short, say Topol and others — including several AI leaders interviewed at four New York City-area hospital systems recently — the successful use of algorithms depends on so much more than just good technology. The industry's uncertainty over how to deploy them is a major reason they haven't had much impact on health care yet, said Parsa Mirhaji, director of the Center for Health Data Innovations at Montefiore.

"The coding is the easy part," said Charles Esenwa, a neurologist at Montefiore who is trying to assess stroke risks in the hospital's population with an algorithm that accounts for socioeconomic

issues like housing and access to healthy food. Scientists need to work with accurate data that reflects the population they were working with, he said.

Yindalon Aphinyanaphongs, who leads a team implementing AI at New York University's Langone Health System, sees it as a four-step process: building a model, assuring it delivers information to clinicians effectively, convincing doctors to use the information and making sure it benefits patients.

Getting buy-in from doctors is a big part of the process. They've already been burned by difficult-to-use electronic health records, which promised more progress than they delivered, noted Andrew Racine, chief medical officer at Montefiore.

The "black box" aspect of machine learning — the fact that computer models may make predictions based on calculations that are too complex to explain — could make it challenging to communicate the findings to clinicians. Health systems have taken different approaches to communicating algorithm results.

At Mount Sinai, the clinician gets a drop-down list of vital signs or other data that went into the computer's decision-making process, according to Freeman. But at Montefiore, an algorithm for acute respiratory distress syndrome — a severe lung condition often overlooked — doesn't convey the underlying data to doctors. So much information goes into the model — including 35 different measures — that it would only confuse clinicians, said Gong. Instead, hospital staff are instructed to respond to red alerts for severe cases by calling her critical care team for a consultation.

Doctors should get accustomed to not knowing the "why" behind an algorithm result, informaticist Blackford Middleton said at a medical informatics event in Washington.

"You'd never expect a pilot to understand every sensor on a plane," he said. "Who can understand all the proteins and metabolites at the same time?"

AI as a nudge

For the most part, AI right now is being used as a kind of electronic triage, helping clinicians sort out the cases that require the most attention. At best, it may help them notice patterns or prod them to alter treatments in ways that could be lifesaving.

Gong has a federal grant to evaluate whether machine learning can help identify patients with acute respiratory distress. When doctors misdiagnose it as typical pneumonia, their treatments can aggravate the disease or even kill the patient.

Elsewhere, algorithms operate like electronic nags: At New York-Presbyterian, for example, the hospital uses AI to crawl through data and find anomalies in patient care, then nudges staff about them. One algorithm helps smooth patient discharges by reporting when a patient needs physical therapy and an MRI before going home, said Daniel Barchi, the system's chief information officer. Better coordination can get a patient out of the hospital faster, saving money and, hopefully, getting them on the road to recovery faster, he said.

To view online [click here](#).

Sandoz to pay \$195M for generic price-fixing ([back](#))

By Leah Nysten and Sarah Karlin-Smith

Sandoz will pay \$195 million to resolve charges that it fixed prices on at least five generic drugs, the Justice Department said Monday.

The second-largest generic drug company in the world admitted it fixed prices between 2013 and 2015 on more than \$500 million in sales, including drugs commonly used to treat skin conditions, hypertension and lung infections in cystic fibrosis patients. The Justice Department filed the charges Monday in a Pennsylvania federal court; under a deferred prosecution agreement, those charges will be dismissed after three years.

Antitrust prosecutors said Sandoz raised prices on some drugs by as much as 1,000 percent. Court filings indicate Sandoz fixed prices with Rising Pharmaceuticals — another company that has entered into an agreement with DOJ — as well as three other unnamed rivals.

While the criminal filings don't name Sandoz's alleged co-conspirators, court filings in a related civil antitrust suit by state attorneys general do implicate companies by name. Based on the descriptions in DOJ's filing, "Company C" is Teva, with whom Sandoz admitted to fixing prices on a lung infection drug.

Sandoz said in a statement that all the employees involved in the wrongdoing have been fired. It also said it is setting aside \$185 million to resolve claims it overcharged federal government programs like Medicare and Medicaid.

"We take seriously our compliance with antitrust laws," Sandoz President Carol Lynch said in a statement, "We are disappointed that this misconduct occurred in the face of our clear antitrust compliance policies and multiple trainings — and in full contravention of the company's values."

Justice Department officials said they opted to enter a deferred prosecution agreement with Sandoz in lieu of requiring the company to plead guilty to the charges, in part because of Health and Human Services regulations that might have required the company to stop doing business with the federal government after a guilty plea.

Sandoz is the third company to resolve its involvement in the Justice Department's ongoing investigation into price-fixing of generic drugs. Rising and Heritage Pharmaceuticals have also paid criminal fines and entered into deferred prosecution agreements.

The Sandoz admission of guilt comes after former company executive Hector Armando Kellum pleaded guilty in February to fixing pricing on generic drugs from March 2013 through June 2015.

Prosecutors also indicted Ara Aprahamian earlier in February. Aprahamian is accused of conspiring to increase prices and allocate customers for numerous drugs while at Taro Pharmaceutical, including medications used for arthritis and skin conditions. He plans to contest the charges.

Former Heritage Pharma executives Jeffrey Glazer and Jason Malek have previously pleaded guilty to price fixing of off-patent medicines. Rising and the Heritage executives are cooperating with DOJ's broader investigation.

To view online [click here](#).

'You don't want to go to war with a president' ([back](#))

By Sarah Oweremohle

Anthony Fauci might be the one person everyone in Washington trusts right now.

But at 79, the director of the National Institute of Allergy and Infectious Diseases is in the thick of one of the biggest battles of 35 years in the role: the race to contain coronavirus when the nation is deeply polarized and misinformation can spread with one tweet — sometimes, from the president himself.

"You should never destroy your own credibility. And you don't want to go to war with a president," Fauci, who has been the country's top infectious diseases expert through a dozen outbreaks and six presidents, told POLITICO in an interview Friday. "But you got to walk the fine balance of making sure you continue to tell the truth."

And the truth about coronavirus? "I don't think that we are going to get out of this completely unscathed," he said. "I think that this is going to be one of those things we look back on and say boy, that was bad."

The plainspoken scientist with a heavy Brooklyn accent has navigated outbreaks from HIV to Ebola, Zika and the anthrax scare with an ability to talk frankly yet reassuringly about threats, to explain science, public health and risk to the public in a way few can match.

But in this outbreak, he's not always the comforting public face amid crisis.

As the Trump administration scrambles to contain the fast-spreading infection and consolidate control under Vice President Mike Pence, Fauci's visibility has been subject to the vagaries of a president who wants to declare the outbreak under control. Over the weekend, Pence and HHS Secretary Alex Azar made the rounds of the Sunday talk shows, not government doctors or scientists.

Fauci sat down with POLITICO in his office Friday, amid dozens of photos of himself with presidents, politicians and celebrities from Magic Johnson to Barbra Streisand. It was just hours

after reports that the White House had ordered Fauci off the airwaves sparked a firestorm of protest from senators, former government officials and public health experts.

Fauci denied being muzzled. He did say that Pence's office wanted him to run interviews past it for re-clearance once Pence was named the White House's point person on the virus.

But public health experts and Democrats have slammed President Donald Trump's repeated reassurances about the disease, which has raced across six continents, created economic disruption — and taken 3,000 lives and counting.

Republicans have countered that the left is overstating the risk, spreading panic and trying to take Trump down.

Fauci has openly tempered expectations for a quick coronavirus vaccine — and an end to the epidemic — on the press conference stage with Trump, even as the president promised everything was under control and a vaccine would be ready soon.

Now even some Republicans are concerned that the president is underselling what some health officials have said is an inevitable worsening U.S. outbreak. And Fauci is who they want to hear from.

"If I'm buying real estate in New York, I'll listen to the president of the United States. If I'm asking about infectious diseases, I'm going to listen to Tony Fauci," Rep. Tom Cole (R-Okla.) said recently.

Giving a president advice can be a heady experience. Fauci has done it dozens of times, for four Republicans and two Democrats. "There's a temptation that you have to fight to tell the president what you think he wants to hear. I've seen really good people do that," says Fauci, who took over the agency in 1984, just a few years after switching his professional focus to a fast-emerging and then-mysterious new illness, HIV/AIDS.

Grappling with the AIDS epidemic and the Reagan administration's initial slow-go approach that divided Washington, Fauci became the public face of the response at a time when Ronald Reagan did not even broach the issue until his second term. Fauci often brings that up as a White House failure.

But these days are different. Trump fires off tweets about coronavirus, promising a vaccine will arrive "soon" (Fauci says in a best-case scenario it will be a year — and that might be optimistic), or says in press conferences that "we are totally prepared" (Fauci and other health officials warn the risk could change in a moment's notice). The president also referred to a coronavirus "hoax" in a campaign rally — the night before the first death from the virus was reported in the U.S.

And then there is Congress. Fauci likes to say that he has testified before Congress more than anyone in the nation's history. Over more than three decades he has been called to the Hill a dozen times a year to explain the threat of Ebola, Zika, anthrax or a pandemic flu.

He remembers the days of lawmakers hurling barbs across party lines about the AIDS response. But today, "the degree of divisiveness is one of almost an emotional dislike of the other person," he said.

Republicans reportedly stormed out of a recent closed-door briefing on the infection after Rep. Rosa DeLauro (D-Conn.) ripped into the administration's coronavirus response. Democrats have called for the White House to replace Pence as point person on the virus, arguing he has no public health experience.

The truth, Fauci says, is that Democrats and Republicans alike may not appreciate the range of what could happen now.

"It could be really, really bad. I don't think it's gonna be, because I think we'd be able to do the kind of mitigation. It could be mild. I don't think it's going to be that mild either. It's really going to depend on how we mobilize."

Critics say the administration has already stumbled with a slow rollout of diagnostic tests and narrow guidelines for who uses them, meaning that some patients waited days to find out if they are infected and the virus began spreading. Fauci said that restricted guidance — specifically the idea that someone would not get tested if they had not been in known contact with infected people — was unwise. He predicted more cases would emerge in the coming days — and they have.

There have already been scapegoats for the response. CDC Director Robert Redfield took the blame Saturday when Trump misidentified the gender of the first U.S. death. Sources also pointed to CDC on Sunday over concerns about the cleanliness of labs making diagnostic tests, even as some current and former administration officials blamed Azar for the bungled response. CDC's respiratory disease lead Nancy Messonnier also took heat from administration officials a week earlier after her statement that a U.S. outbreak was inevitable helped send the stock market tumbling.

"It's really, really tough because you have to be honest with the American public and you don't want to scare the hell out of them," Fauci said. "And then other times, in attempts to calm people down, [leaders] have had people be complacent about it. This is particularly problematic in a 'gotcha' town like Washington."

And yet, Fauci has not only survived the town for decades but managed to make his priorities those of the presidents, above all HIV. Along with Redfield and HHS Assistant Secretary for Health Brett Giroir, Fauci helped engineer getting the president include a pledge to ending HIV transmission in his State of the Union address last year.

But many challenges are still ahead, including sometimes contradicting the president he doesn't want to "go to war" with. Fauci says it will be OK: he knows that "even if it's uncomfortable" his years of truth-telling have earned him a backlog of respect.

The 79-year-old also has no plans of retiring anytime soon — not least because one of his top goals, developing an HIV vaccine, remains elusive.

"I feel like I'm 45. And I act like I'm 35," Fauci said. "When I start to feel like I don't have the energy to do the job, whatever my age, I'll walk away and write my book."

To view online [click here](#).

Azar in the crosshairs for delays in virus tests [\(back\)](#)

By Dan Diamond and Adam Cancryn

Even as the Centers for Disease Control and Prevention takes blame for testing delays that may have led to hundreds of Americans being quietly infected with the coronavirus, officials inside the health department and the White House are increasingly pointing the finger at one leader: Health and Human Services Secretary Alex Azar, who they say failed to coordinate the response, as agency chiefs waited for instructions that came too late and other deputies were largely cut out of the process.

Numerous problems with the Trump administration's testing regimen have come to light: Coronavirus tests developed by CDC were flawed, possibly because the lab itself was contaminated. The resulting lack of test capacity forced U.S. officials to screen a limited number of patients across January and February, with the CDC testing fewer than 500 Americans at the same time that China was likely testing at least 1 million of its own residents. Meanwhile, public health officials had no fallback testing option until the Food and Drug Administration granted approval for hospitals and other labs to develop their own homegrown tests on Saturday — more than six weeks after the first U.S. case of coronavirus was identified.

Public health officials acknowledge that CDC and other parts of the government have repeatedly stumbled in the early days of the outbreak, but say that the 52-year-old Azar, a former drug company executive who took over the department in 2018, did not reach out early or often enough to goad his subordinates into action.

"This was a management failure," said one administration official, charging that Azar didn't adequately plan for a worst-case coronavirus scenario that's grown more likely by the day — even though Azar touted his bona fides as a veteran of the George W. Bush administration, where he helped fight crises like SARS and an anthrax scare. "CDC and FDA should have been working hand-in-hand to get Plan B, Plan C and Plan D ready to go," the official said.

"The administration's response has been reactive, not proactive," added a former HHS official. "A lot of what has happened has been driven by outside pressure," like public health labs sounding the alarm that they were unable to perform the CDC's tests.

Azar was abruptly removed as leader of the U.S. government's coronavirus response last Wednesday night and replaced by Vice President Mike Pence. The health secretary is still technically chairing the coronavirus task force, but decision-making, media requests and even task force membership have increasingly been run through the White House. Since Azar's removal as coronavirus-response leader, several of his deputies and rivals have been added to the task force.

POLITICO spoke to 17 current and former officials and individuals close to the Trump administration. Interviews with officials in HHS, who declined to comment on record for fear of retaliation, indicated that Azar's failure to reach out to a wider circle of advisers is typical of his management style, which has grown increasingly distrustful of his own aides.

The surgeon general is supposed to be the nation's chief spokesperson on threats to public health, but Surgeon General Jerome Adams had been little seen or heard from during the coronavirus threat until Azar was removed from leading the effort last week. Pence immediately added Adams to the task force, and the surgeon general this weekend began issuing coronavirus guidance on social media and appearing on national TV programs.

The FDA oversees drug and lab test development, but Commissioner Stephen Hahn also wasn't included on the Azar-led task force and has been frequently sidelined during the crisis. Hahn's most notable public moment was being summoned out of the crowd by Pence on Saturday to answer a question directed to President Donald Trump during a White House press conference.

Pence also added Hahn to the coronavirus task force after growing upset during a recent meeting that nobody could adequately answer a question about threats to the nation's drug supply, two people with knowledge of the situation said.

While Hahn's agency on Saturday did roll out instructions to let certain health organizations develop their own coronavirus lab tests, "FDA has been trying for some time to issue that guidance," said one official, who added that the agency was waiting on approval from HHS and Azar. Another official said Hahn had begun devising the strategy weeks ago.

An HHS spokesperson defended Azar's leadership and the administration's broader strategy of trying to contain the virus across January and February, arguing that it bought valuable time to prepare the nation for an outbreak.

"HHS has been working with public health systems since day 1 — that's how we've been catching these cases and educating the American public on what to do if they become symptomatic," the spokesperson said. "The task force has held countless briefings with members of Congress and state and local leaders, so they can appropriately prepare and educate their constituencies."

Asked if Azar was responsible for the CDC's testing failures, the spokesperson took issue with the framing. "Because of CDC surge capacity, there has been no backlog of tests despite the diagnostic issue," the spokesperson said, referencing problems that prevented many tests from working. "It's unfair to say testing has been limited."

Public health groups have argued there was no testing backlog because CDC capacity problems forced HHS to limit testing to Americans who were returning from China or people close to a confirmed case, rather than expanding the testing more widely — and picking up potential cases of the virus spreading in the community.

The HHS spokesperson also defended Adams' and Hahn's involvement in coronavirus planning, saying that the two officials have been part of coronavirus meetings for weeks. A senior administration official said Hahn particularly has been involved in White House planning.

Senior officials contend that Azar is operating under fear of offending Trump or his allies, which has led him to keep Adams, Hahn and his other underlings on a tight leash, while jockeying for credit to stay in the president's good graces. Azar's widely publicized feud last fall with Medicare chief Seema Verma, which contributed to the department's failure to come up with an alternative to Obamacare and necessitated a series of emergency White House meetings, highlighted some of these tendencies, the officials said.

Azar and his top aides also have for months frozen out Adams, who is close to Verma, and at times openly questioned Adams' ability to handle basic duties and stay on message. Adams played down coronavirus fears in a Monday interview on "Fox and Friends," predicting that more people globally would die from the flu.

Azar's supporters dispute that he has undermined Adams. An individual familiar with Azar's thinking said the HHS secretary has a good working dynamic with the surgeon general and the two men recently had lunch together. Azar has been "very impressed" with Adams' recent television appearances and hopes to have him play a larger role on coronavirus messaging, the individual said.

POLITICO on Monday morning reported that Verma was being added to the task force. The individual familiar with Azar's thinking said the health secretary supports her addition to the group and also pushed for bringing Veterans Affairs Secretary Robert Wilkie on board, arguing that the officials will be important inclusions as coronavirus becomes more of a domestic issue that poses a risk to health systems, the individual said.

Meanwhile, criticism for the stalled coronavirus tests has mounted on CDC and its director, Robert Redfield, amid that agency's high-profile stumbles in recent weeks. CDC supported quarantining hundreds of Americans aboard a cruise ship, which backfired as coronavirus rapidly spread on board, and Redfield also took blame for wrongly briefing Trump and Pence on Saturday, leading Trump to misidentify the first U.S. coronavirus death, a man in his 50s, as a "wonderful woman."

But two individuals said Redfield was wrongly being set up by some HHS officials as the fall guy for the administration's biggest coronavirus misstep — the lab-testing failure — arguing that the CDC chief had worked to speed the tests while advocating for a fallback lab-testing option but was waiting on Azar's permission to move forward on Plan B. "He's great on this," said one senior administration official, adding that Redfield is "busting his ass with a very hard job [and] working harder than any other senior official at HHS."

An HHS spokesperson said that CDC was taking steps to improve testing. "CDC and FDA have been working together to correct the issue with the diagnostic in a timely manner and worked together to make alternatives more readily available that meet the appropriate accuracy standards for testing," the spokesperson said.

The health department's slow response also has set off a round of finger-pointing among top officials and Azar's deputies, reigniting longstanding feuds at a crucial moment when the Trump administration needs to work in lockstep. Officials at CDC and Robert Kadlec, the HHS assistant secretary for preparedness and response, have jockeyed over coronavirus quarantine rules and

evacuating at-risk Americans, the latest skirmish between two agencies that have spent years battling over which gets to be in charge of the nation's emergency medical stockpile.

White House officials also have clashed with Azar and accused him of giving overly optimistic guidance to Trump, a battle that dates back a year and has encompassed numerous policies. Meanwhile, an HHS whistleblower and an FDA scientist have stepped forward to warn that the department's coronavirus response has been disorganized and could put Americans at risk. Azar has said he supports whistleblowers and vowed full investigations.

The disjointed, at-times-chaotic coronavirus response has alarmed allies of the HHS secretary, who worry Azar will ultimately shoulder much of the blame within the administration and from the public for failing to contain the outbreak.

The public health crisis threatens to become the defining episode of Azar's tenure, people close to him lamented in recent days, overshadowing more than two years of work on various policy initiatives and linking his legacy as health secretary to the administration's struggles to combat a fast-spreading virus that could linger for months — potentially infecting thousands, disrupting Americans' daily lives and grinding to a halt the once-strong economy that Trump officials view as key to the president's reelection.

"Right now, there's probably hundreds or low thousands of cases ... that aren't reported yet," Trump's former FDA Commissioner Scott Gottlieb said on "Face the Nation" Sunday, referencing a new estimate of spreading coronavirus in Washington state. "One of the mistakes, one of the challenges was getting the diagnostic testing in place."

Having failed to track and quash isolated cases, it may be too late to now guard against a widespread outbreak of coronavirus in the United States. Health officials have increasingly shifted their mindset from "containment" — stopping the virus altogether — to "mitigation," or preventing the virus' worst effects on Americans. Chris Meekins, a former Trump administration HHS emergency-preparedness official, on Sunday said the risk of significant U.S. outbreaks had risen from 33 percent to 75 percent in the last week alone.

Azar's job is not believed to be in imminent jeopardy, people close to the White House said, in part because firing the nation's top health official in the midst of an outbreak would prompt further questions about the administration's response effort.

But Azar — who already has few friends within the White House, which weighed a list of potential replacements in December — has been further weakened internally by his brief period leading Trump's coronavirus task force, during which he battled repeatedly with national security staffers over strategy and frustrated White House officials who at times questioned whether he was withholding information.

Meanwhile, Azar's attempts to publicly play down the risks of the virus — saying for weeks that there were just more than a dozen U.S. cases — were criticized by some officials as too-optimistic at the time and, in retrospective, seen as incautious. The HHS secretary repeated the message across four congressional hearings last week and national TV briefings, even as it turned out the virus was silently spreading in the United States.

"Focusing on just 15 cases was a tragic health care disservice," said a former HHS official. "Hospitals and health providers needed to know about the risks and get ready to take more steps."

Sarah Karlin-Smith contributed to this report.

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FDA approves generic version of 'pharma bro' drug ([back](#))

By Arthur Allen

The FDA today approved the first generic version of Daraprim, which sparked outrage over rising pharmaceutical prices when "pharma bro" Martin Shkreli bought the drug's patent and jacked up its price by 5,000 percent.

FDA approved the medicine — whose generic name is pyrimethamine — to treat toxoplasmosis, a parasitic infection that strikes people with weakened immune systems, such as patients with AIDS.

Shkreli's Turing Pharmaceuticals bought the 62-year-old drug in 2015 and hiked its price from \$13.50 to \$750 per pill, drawing anger in congressional hearings and contributing to efforts by Congress and the White House to check rising drug prices.

In 2018, Shkreli was sentenced to seven years in federal prison for an unrelated fraud scheme. Last month, [the Federal Trade Commission filed a complaint](#) in federal court against Vyera Pharmaceuticals, Shkreli's renamed company, alleging that, as Turing, it made illegal deals to prevent potential generic competitors from getting Daraprim samples or raw ingredients.

The FDA said it was [posting the names of all drugs](#) to which it had been alerted about efforts to limit distribution of samples to prospective generic applicants, Commissioner Stephen Hahn said in a news release. Daraprim was on the list, he said.

The generic's manufacturer, Cerovene Inc., did not immediately respond to calls and emails seeking information about the new drug's price.

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Subject:	POLITICO Pro Breaking News: Senate sends \$8.3B coronavirus response bill to Trump
Date:	2020/03/05 14:25:09
Priority:	Normal
Type:	Note

The Senate cleared an \$8.3 billion emergency funding bill in a 96-1 vote this afternoon to combat the coronavirus, sending the measure on for President Donald Trump's signature.

The bill, H.R. 6074 (116), will kick almost \$6.5 billion to the Department of Health and Human Services, nearly \$1.3 billion to the State Department and \$20 million to the Small Business Administration, as the federal government rallies to aid state and local response to the virus that has sickened more than 160 people in more than a dozen states.

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Date:	2020/03/05 14:25:14
Priority:	Normal
Type:	Note

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Subject:	Re: Statement by the AHIP Board of Directors: Taking Action to Address Coronavirus COVID-19
Date:	2020/03/05 14:56:45
Priority:	Normal
Type:	Note

Thanks for flagging Matt!

Gary M. Beck
 Director of External Affairs
 Department of Health and Human Services

On Mar 5, 2020, at 2:54 PM, Eyles, Matt <MEyles@ahip.org>wrote:

Guys – We had an AHIP Board meeting today and just put out the following statement about our commitment to taking action on Coronavirus and coverage for testing and other actions by health insurers. Wanted to make sure you saw first and shared with the Secretary. Let me know if you have any questions and welcome any feedback.

Best,
 Matt

Matthew Eyles | President & Chief Executive Officer
 America's Health Insurance Plans

601 Pennsylvania Ave, NW | South Building, Suite 500 | Washington, DC 20004
 202.778.3269 (o) | (b)(6) (c)

From: Grow, Kristine <kgrow@ahip.org>
Sent: Thursday, March 5, 2020 2:44 PM
To: Grow, Kristine <kgrow@ahip.org>
Subject: Statement by the AHIP Board of Directors: Taking Action to Address Coronavirus COVID-19

<image002.jpg>

Statement by the AHIP Board of Directors

Taking Action to Address Coronavirus COVID-19

March 5, 2020

As the Board of Directors for America's Health Insurance Plans, we are fully committed to help America's powerful health care system meet the challenges posed by the Coronavirus strain COVID-19.

As our country prepares for the possibility of widespread infections and takes action to mitigate the impact, our priority is the health and well-being of the people we serve. There are three critical areas health insurance providers are proactively addressing right now: Prevention, testing, and treatment.

We are taking decisive action to help prevent the spread of this disease, to ensure that people have coverage for and access to needed testing, and to help patients who are infected receive the care and treatment they need. Specifically, we are taking critical steps to:

1. • **Work with public and private-sector partners to implement solutions so that out-of-pocket costs are not a barrier to people seeking testing for, and treatment of, COVID-19.**
 - • We will cover needed diagnostic testing when ordered by a physician. We will take action to ease network, referral, and prior authorization requirements and/or waive patient cost sharing. We will also take action so that patients will have continuous access to their regular prescription medications while at the same time avoiding potential problems such as drug shortages.
 - • We will develop solutions for state and federal policymakers to provide more guidance and more flexibility so that changes to preventive services, benefit design, and treatment options can help people immediately.
2. • **Partner with doctors, hospitals, and other care providers to ensure that effective treatment is available for those who are infected.**
 - • We are sharing information with clinicians, mobilizing our network providers, and coordinating through care management programs to ensure that they have the best, most immediate data to identify, diagnose, and treat infections.
 - • We are encouraging the use of telehealth, at-home care, and other technology-enabled options to expand access to care and avoid potential risks of infection. State and federal policymakers can expand access to these effective solutions with additional policy flexibility.

3. • **Educate and inform the people we serve on the most effective ways to prevent the spread of this disease.**
- We will continue to work directly with the Centers for Disease Control and Prevention (CDC); federal agencies and task forces; and every necessary partner in states, cities, and counties across the country to coordinate efforts, share information, mitigate health risks, and keep Americans informed.
 - We are proactively engaging the American people, particularly those who are most at-risk for infection such as seniors and patients with chronic diseases, on common-sense steps that everyone can take to stay healthy.

Health insurance providers will devote our resources, insights, and abilities to collaborate with key partners to confront and resolve this challenge. Working together with federal, state and community leaders; clinicians; pharmacies; drug makers; medical equipment providers; and other essential partners, we are confident that we can collectively overcome this challenge and keep the American people safe and healthy.

Kristine Grow | Senior Vice President, Communications
America's Health Insurance Plans
601 Pennsylvania Ave, NW | South Building, Suite 500 | Washington, DC 20004
(202) 778-3227 (phone) | (b)(6) (cell)

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Subject:	VPOTUS pool report #5 (gaggle)
Date:	2020/03/05 15:09:01
Priority:	Normal
Type:	Note

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From: Alex Leary <alex.leary@wsj.com>
Date: March 5, 2020 at 1:50:09 PM CST
Subject: [EXTERNAL] VPOTUS pool report #5 (gaggle)

VP and Gov. Walz took questions from reporters:

At the top, VP spoke of mask availability and again credited 3M for increasing capacity of N95 respirators but said, “We think there’s work to be done” alluding to other producers and steps that can be taken.

VP said the administration would work with Congress on extending legal protections under the public health emergency POTUS has declared for 3M and manufacturers to sell another type of mask.

Asked about concern over a mask shortage, VP said: “We are ready today, but we want to be ready tomorrow. As we are expanding testing around the country there are going to be more cases. We’re going to find more Americans have contracted the coronavirus.”

He repeated that most people will recover fully but said there is a vulnerable population and health care providers who need the supplies.

Dr. Birx, who also joined the gaggle, said there could be more mild cases of people unknowingly spreading the virus and that’s why the government wants to expand testing.

She said masks are helpful for infected persons from spreading it to others, but

masks won't protect a healthy person because you will pull air in from the sides and that includes potential virus particles. This follows VP's earlier call for healthy people not to buy masks.

VP expressed confidence on tests being distributed, but when pressed he acknowledged, "we don't have enough tests today to meet what we anticipate will be the demand going forward.

"For those who we believe have been exposed, for those who are showing symptoms, we've been able to provide the testing," he added. "But as more Americans take an interest in this or have concerns about this, we want to make sure they have access to a coronavirus test as well and we've made real progress on that in the last several days."

Motorcade headed back to airport.

Alex Leary
Wall Street Journal
(202) 306-4807

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Subject:	RE: COCA Call - COVID-19 What Clinicians Need to Know to Prepare of COVID-19 in the US
Date:	2020/03/05 16:10:55
Priority:	Normal
Type:	Note

Awesome. Thank you.

From: Schwartz, Erica (HHS/OASH) <Erica.Schwartz@hhs.gov>
Sent: Thursday, March 5, 2020 3:03 PM
To: Adams, Jerome (HHS/OASH) <Jerome.Adams@hhs.gov>
Cc: Wright, Janet (HHS/OASH) <Janet.Wright@HHS.GOV>
Subject: COCA Call - COVID-19 What Clinicians Need to Know to Prepare of COVID-19 in the US

VADM Adams,

My notes are attached. Dr. Wright can certainly add to my notes. Nothing really new – most of the information we have read about.

v/r,

RADM Erica Schwartz, MD, JD, MPH

Deputy Surgeon General
Office of the Surgeon General
United States Public Health Service
U.S. Department of Health and Human Services
200 Independence Ave SW, Suite 701-H
Washington, DC 20201
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The White House

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FOR IMMEDIATE RELEASE

March 5, 2020

REMARKS BY VICE PRESIDENT PENCE
IN MEETING AT THE 3M INNOVATION CENTER

3M Innovation Center
Maplewood, Minnesota

12:36 P.M. CST

GOVERNOR WALZ: Well, good afternoon, everyone. And thank you for coming. A special thank you to 3M, a proud Minnesota company -- one that's at the forefront of so many

innovations, and especially now. And you're going to hear a little bit from Dr. Birx about some of those innovations and the role that 3M will play in making sure that Minnesotans and Americans are safe.

I'd like to say a special thank you to the Vice President, a colleague in Congress that I had the pleasure to work with for many years. And I mentioned, the other day, the National Governors Association was on a call, and it's very reassuring to governors to hear another governor -- a former governor -- talk about what the state's response is and that collaboration between local, state, federal, and our private sector partners.

And it's assuring to me to be in this room to see all the coordination that's going on and the preparations that are being made to protect Minnesotans and Americans.

So we're just grateful for this visit, Mr. Vice President, and certainly grateful to 3M. Mike.

MR. ROMAN: Well, thank you, Governor. And I just would like to say thank you to Vice President Pence and your delegation for joining us today. And, Governor Walz and your team, I really appreciate the chance to come in and talk about how we can work together on pandemic preparedness. It's something our team takes very seriously. It's a very important role for us. We appreciate the time to talk about how our people, products, and technology can help make a difference.

So thank you very much for being here.

THE VICE PRESIDENT: Well, thank you, Mike. And, Governor, thank you for those gracious words. More importantly, thank you to you and Health Commissioner Malcolm for the outstanding work that you're doing for the people of Minnesota here.

As the President said, we're all in this together. And he wanted me to be here in Minnesota to build on the strong partnership that we have, with your administration, here to protect the people of Minnesota as our nation deals with the coronavirus. But I'm also here, as Governor Walz said, because not only is this a whole-of-government approach, it's a

whole-of-America approach.

And 3M is a great company and based here in Minnesota, but has impacts in our healthcare community -- in particular, all over America. And I'm truly grateful, Mike, for the report that we had today, that decisions were made here at 3M, literally at the outset of the coronavirus. 3M made the decision, literally, to go to full capacity here in the United States in the production of the respiratory masks, the N95 masks that you create with such professionalism.

I want to commend you, Mike, for that decision. And just as much, I want to commend the outstanding workforce at your facilities across the country and here in Minnesota that have made that -- made that a reality. It's made a real difference.

President Trump made it clear that we have no higher priority than the health and safety of the American people. And our priority is to ensure that Americans who have contracted the coronavirus receive the treatment and therapeutic support that every American would want a family member to receive.

But what brings me here today is we also want to make sure that our healthcare workers have the personal protective equipment to be able to minister to people as we continue to deal with the coronavirus in communities around the country.

The good news is that, thanks to the unprecedented efforts that President Trump took in January, we believe that the risk to the average American of contracting the coronavirus remains low. In January, the President declared a public health emergency. We suspended all travel out of China into the United States. We quarantined returning Americans from China and from the Diamond Princess cruise line where there had been infections.

It's heartbreaking that, at the present moment, that we have lost 11 Americans. Our condolences go to their families. But the good news is the vast majority of those who have contracted the coronavirus in our country are receiving treatment and doing well and on the road to recovery.

But going forward, the President and I have been working with our entire team and with members of Congress in both political parties to ensure that not only do our federal agencies have the resources to confront the coronavirus in this country, but also that state governments and local health officials have the resources moving forward.

And I'm encouraged that the Congress voted yesterday, the Senate will vote today, on legislation that will provide nearly \$8 billion in support, including more than \$3 billion to procure medical supplies like masks, and to make sure that those that are dealing with the coronavirus, as well as those that are providing them healthcare, have the protective equipment that they have.

It's really what brings us here today. We just finished a very productive and substantive discussion with the leadership team here in the state, and also here at 3M, about your production capacity with regard to respirators -- as they are known, the "respiratory mask." But we're going to continue to work very closely with you to ensure that now that you're at full production level here at 3M, that we work with other companies around the country that also create these very same products.

But I do have a word to the average American about how you can help as well: Unless you are ill, you have no need to buy a mask. And one of the ways that healthy Americans can support our efforts to be there for patients and to be there for healthcare providers is to not purchase masks on the commercial market.

I'm going to ask Dr. Deborah Birx to speak to this issue. She's my right arm at the White House. She's one of the leading experts in the world on infectious diseases. But I thought -- I thought, Deb, if you want to reflect a little bit on the products that are created here at 3M and how important they are to our healthcare providers, and how Americans -- healthy Americans -- can help by not going out and purchasing a mask so that more are available on the marketplace for our patients and our healthcare community, I'd be grateful.

DR. BIRX: Thank you, Mr. Vice President. And I really want to thank 3M who just taught me all about the differential masks in front of us.

So they made it very clear that this mask that you get in most of the drugstores, which we

often refer to as "mask," are only helpful if you're the one that's infected. So it will protect others from your germs. So, wearing this as a healthy person will not protect you. But a sick person wearing this mask will help protect others from getting infected.

And then we went through the two different kinds of these respiratory protection masks, which are really the healthcare provider masks, and really understanding the difference between the green one and the white one. And I want to really appreciate that to really understand that this is mostly a surgical mask for use in surgical, but these can be adapted to be used in the healthcare facilities.

And we're really having a discussion about what that would take to really protect others. And the electrostatic material that's in here, that really is the function that keeps all of the nanoparticles and traps them.

So it really was a very educational experience, and I really want to thank you because, before coming in here, I really didn't understand clearly the difference. And so really understanding why healthcare providers need these masks and that the average American purchasing these masks will do nothing for them. But if you are sick, you should wear one.

So thank you. This was incredibly helpful for me.

THE VICE PRESIDENT: Well, thank you, Dr. Birx. And Dr. Stephen Hahn is the head of the FDA and, I know, has been working with manufacturers, like 3M, around the country to make sure that we have the medical protective equipment.

And, Dr. Hahn, your thoughts.

DR. HAHN: I think it was very instructive. We're working with 3M to try to determine which healthcare workers can use which of these masks according to the CDC guidance. And as you know, we issued some guidance earlier this week on some flexibility around these masks. So it's an ongoing project.

THE VICE PRESIDENT: Well, thank you, Dr. Hahn. Let me just say again how grateful we are to you, Mike, and all of the great workforce here at 3M. You're playing a vital role in the life of our nation every day, but especially in times like this.

And so we are grateful that when word first reached our shores about the coronavirus, 3M already went to full capacity in this country. And we're going to look for ways of working with the Congress, working with healthcare providers, and state leaders like Governor Walz, to make sure and fully utilize those resources and make sure that the broadest range of what you're producing here can be available as we deal with the coronavirus.

But let me close again by saying to the people of Minnesota: The reality is that despite the fact that we now have cases in the United States of America -- more than 100, including those that returned to our country -- the risk to the average healthy American of contracting the coronavirus remains low. We believe that that is a result of strong actions that President Trump has taken, strong support by governors across the country, putting the health and wellbeing of our people first. And we're going to continue to work to keep it that way. We're expanding tests. There will be more cases.

Our focus today is on what we believe, increasingly, is the more vulnerable population. It appears from some of the worldwide data that we have collected that seniors, and particularly seniors who have other health challenges, represent the most vulnerable population. And so, yesterday, President Trump announced that we're raising the guidelines for infectious diseases at our nursing homes here in Minnesota and all across the country. And we're increasing inspections of our nursing homes so that we'll be focusing on our vulnerable population in an increasing way.

But to every American, I think seeing the leadership at the federal level and the strong bipartisan support for legislation that's moved forward to make billions of dollars available to confront the coronavirus; seeing the strong collaboration in states across the country, including here in Minnesota, and the strong participation of our business community -- I just want to ensure the people of this great state that, at the President's direction, we're going to continue to lean into this.

You should know we're ready, and we're going to continue to bring the full resources of the federal government to bear to confront the spread of the coronavirus in the United States. So, thank you all.

END

12:48 P.M. CST

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Subject:	For review: SNS Policy Paper - COVID-19 Daily (3/5) Disaster Leadership Group Meeting
Date:	2020/03/05 18:25:35
Priority:	Normal
Type:	Note

Dear Disaster Leadership Group (DLG) Members,

Thank you for joining the DLG meeting this afternoon. Attached for your further review is an updated draft of the paper outlining policy options for distributing SNS assets to the states. We are asking that you review this draft and provide feedback to us by **10:00am on Friday, March 6**. Please note that we are looking for **substantive feedback only**. As noted at the DLG today, we will briefly discuss this during tomorrow's meeting. Also attached is the Summary of Conclusions from today's meeting.

If you have any questions or concerns, please reach out to me at Daniel.Dodgen@hhs.gov and kindly copy DLGDESK@hhs.gov.

Thank you,

Daniel Dodgen, Ph.D.

Senior Advisor

Office of the Assistant Secretary for Preparedness and Response (ASPR)

Office of Strategy, Policy, Planning and Requirements (SPPR)

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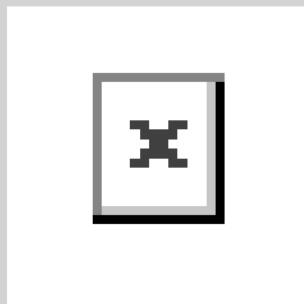
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Subject:	February 2020 Newsletter
Date:	2020/03/05 18:28:40
Priority:	Normal
Type:	Note

February 2020 Newsletter



Sorry for the lateness in sending our February Newsletter.....very busy times.....

Coronavirus, now known as COVID-19, has been the top news story for several weeks in the U.S. and

across the world. We know the best way to keep on top of the developments is through reliable resources such as the World Health Organization (WHO), Centers for Disease Control and Prevention, Vice President's Task Force on Coronavirus, National Institute of Allergy and Infectious Diseases, and state and local public health departments.

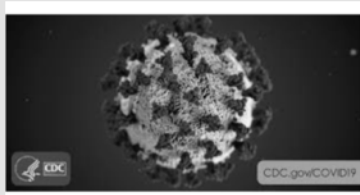
Yesterday, Vice President Pence stated that the testing of individuals for COVID-19 is now considered an Essential Benefit and covered under all insurances. If anyone suspects they might have or been exposed to COVID-19, they should contact their primary care provider by phone and seek instructions on next steps and where to go for testing.

It is in times like these that we are reminded of the major sacrifices and contributions that our front line healthcare providers and public health play in caring for those in need. Every day they are there to support those in need while acutely aware of some of the dangers they confront. Remember to give thanks and extend a 'hand bump or elbow bump' to our healthcare providers.

February's Newsletter includes:

- • COVID-19 Interventions and Data
- • Dr. Brian Isetts Podcast
- • IHC Comfort Scales and Menus
- • Patients as Partners in Diagnostic Research
- • Step 2 in Nursing Home Transformation
- • CMS Quality Conference
- • Celebrations

COVID-19 Interventions and Data



On February 4, the Centers for Medicare and Medicaid Services announced several interventions to address the spread of COVID-19. CMS stated that effective immediately and, until further notice, State Survey Agencies and Accrediting Organizations will focus their facility inspections exclusively on issues related to infection control and other serious health and safety threats, such as allegations of abuse – beginning with nursing homes and hospitals. Critically, this shift in approach, first announced yesterday by CMS Director Seema Verma will allow inspectors to focus their energies on addressing the spread of COVID-19. This change in focus is in the hopes of stopping the spread of coronavirus in practice communities where patients and residents are at greater risk for serious harm.

As providers know, CMS and CDC have helpful voluntary spreadsheets for conducting a self-assessment of infection control and prevention practices for nursing homes ,hospitals , and dialysis centers

In keeping these spreadsheets current through ongoing organizational review, one should be able to avoid new infections and allow everyone to know how to manage present on admission infections. Additionally, CMS Director Seema Verma specifically stated that statutorily-required inspections will also continue in the 15,000 nursing homes across the country using the approximately 8,200 state survey agency surveyors. Surveys will be conducted according to the following approach:

- • “All immediate jeopardy complaints (a situation in which entity noncompliance has placed the health and safety of recipients in its care at risk for serious injury, serious harm, serious impairment or death or harm) and allegations of abuse and neglect;
- • Complaints alleging infection control concerns, including facilities with potential COVID-19 or other respiratory illnesses;
- • Statutorily required recertification surveys (Nursing Home, Home Health, Hospice, and ICF/IID facilities);
- • Any re-visits necessary to resolve current enforcement actions;
- • Initial certifications;
- • Surveys of facilities/hospitals that have a history of infection control deficiencies at the immediate jeopardy level in the last three years;
- • Surveys of facilities/hospitals/dialysis centers that have a history of infection control deficiencies at lower levels than immediate jeopardy.”

CMS urged all provider staff to review their protocols and refer to a Q&A that has been prepared on infection prevention issues and also other issues related to managing the COVID-19 Surveys by State Surveyor organizations.

Data. One of the best resources that has emerged in tracking national and international trends is through Johns Hopkins. The site is routinely updated and provides a dashboard on confirmed cases geographically as well as deaths and recovered cases. To view the site, click here

Dr. Brian Isetts

Changing Role of Pharmacy and Pharmacists Podcast





In Project Patient Care's **February 2020 Podcast** we highlight the changing role of pharmacy and pharmacists as part of the care team for patients. We explore how pharmacists are engaged with patients, families, caregivers, and care teams in identifying the best medication treatment programs for patients and helping patients understand and self-manage their medications. We even venture into a not too far away futuristic discussion on the key role of precision medicine and pharmacogenomics!

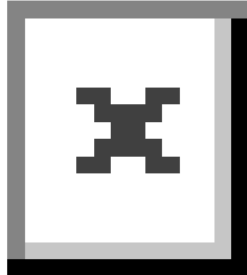
Our February Champion Change Agent, Brian Isetts, Ph.D., BCPS, FAPhA, is a Professor at the University of Minnesota College of Pharmacy, and a pharmacist with 30 years of experience as a practitioner, educator and researcher. Brian has devoted his career to building a medication use system our country deserves where persons and families can confidently manage their medications. He has many notable accomplishments including three years of service at the Centers for Medicare & Medicaid Services in Washington D.C. where he was a federal co-lead for reducing adverse drug events across 4,000 hospitals in America.

Dr. Isetts sets the bar high for the role of the pharmacist in engaging patients in their medication management plan. His goal is to train, educate, and model a systems approach that will lead to zero adverse events through engagement of patients and providers in coordinating and managing medication treatment.

Project Patient Care Podcasts cover a variety of timely topics and we always include healthcare patient or provider leaders that understand the value of engaging patients, families, and caregivers in health and healthcare improvements. Check out the past, but still timely, podcasts by clicking **here**

IHC Comfort Scales and Menu Options





In our Podcast with Dr. Brian Isetts, we discussed the ongoing challenges with the Opioid Crisis in the United States. Having collaborated with the Iowa Health Collaborative, known as IHC, Brian was involved and familiar with their approach to engaging patients and care teams in managing pain without the usage of opioids.

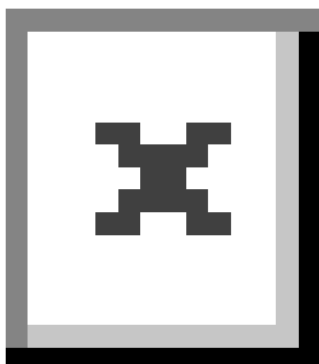
"The IHC Comfort Scale was created by IHC to reframe pain assessment to a comfort focused assessment. The goal is to utilize the IHC Comfort Scale in place of the pain scale with regular patient encounters. Ask the patient, "What is your comfort level." Allow them to use the scale and point to their comfort level as necessary. Accompanying the scale is the IHC Comfort Menu to be used in conjunction with the IHC Comfort Scale. Once a patient has identified their comfort level, the menu can be used to suggest options to increase the patient's comfort level. The IHC Comfort Menu items can be

modified to better fit what your facility has to offer. It can also be modified to fit patient preference."

The Scales and Menus are available for outpatient and inpatient settings and are in both English and Spanish. To view them on the IHC website, click [Here](#) The IHC Scales and Menus are also available on the [PPC Podcast page](#) as resources identified by Dr. Isetts.

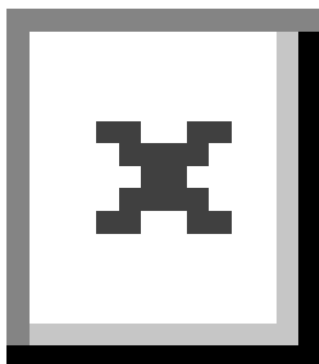
Patients as Partners in Diagnostic Research





Project Patient Care was the patient engagement lead on a Patient Centered Outcomes Research Institute (PCORI) Award under the Society to Improve Diagnosis in Medicine. The National Academy of Medicine (NAM) recently released a Perspectives report on the Patients Improving Research in Diagnosis. While co-developing a curriculum for patients, families, and caregivers on how to effectively participate in the design of research studies, the team developed a diagnostic process that helped patients function as partners and is highlighted in the NAM article entitled, "**What If?: Transforming Diagnostic Research by Leveraging a Diagnostic Process Map to Engage Patients in Learning from Errors.**" Co-authors included Sue Sheridan, Pat Merryweather, Diana Rusz, and Dr. Gordon Schiff.

Step 2 in Nursing Home Transformation



Part 2 of the Five Part Strategy for Nursing Home Transformatn was announced by CMS Director Seema Verma on February 18. The Five Part Strategy includes:

- Strengthen Oversight
- Enhance Enforcement
- Increase Transparency
- Improve Quality
- Put Patients Over

Paperwork.

Part 2 of the Strategy includes strengthening State Survey Agencies (SSA) and their surveyors so that nursing homes can eventually be evaluated on a national basis and not just within states. SSA performance is now assessed using the recently developed using the *State Performance Standards System*.

CMS also targeted key areas for additional enforcement on quality of care including the inappropriate use of

anti-psychotic medications and lack of meeting nurse staffing standards.

To view CMS Director Seema Verma Blog on Part 2 of the Five Part Nursing Home Strategy, Click [Here](#) To view the "National Partnership to Improve Dementia Care in Nursing Homes: Antipsychotic Medication Use Data Report (October 2019)" and see where your state is in reducing anti-psychotic medications, click [Here](#).

CMS Quality Conference





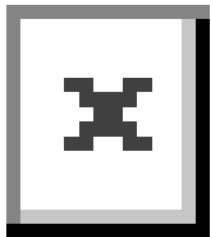
Acting Director of CMS Center for Clinical Standards and Quality (CCSQ) Jean Moody-Williams opened the February 23-25, 2020 CMS Quality Conference followed by CMS Director Seema Verma.

Both Jean and Seema had a lively discussion on Strategic directions including:

- 'CMS establishing clear and reasonable expectations for quality by setting government standards and quality measures... in other words, the rules of the road,
- CMS will strengthen oversight and enforcement of those standards to ensure accountability.

□ - CMS will promote transparency, competition, and consumer choice by providing the public with the information needed to make decisions about their care; And

- CMS will work to modernize quality improvement efforts for all through advances in data analytics and technology, while prioritizing resources for those that need it most.'



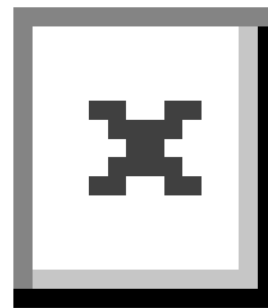
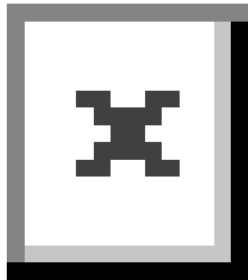
The end of the Grand Plenary was a very exciting celebration of two patients that received transplants. Jean Moody-Williams discussed the transplant journeys with Precious McCowan, a kidney transplant recipient, and Dr. Robert Montgomery, a heart transplant recipient.



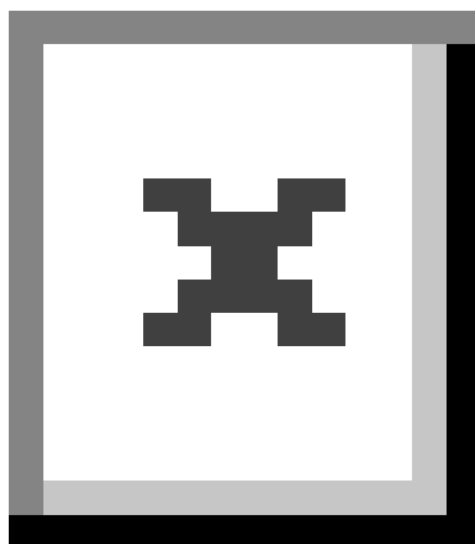
Jean Moody-Williams and Pat re-connecting with Pat thanking Jean for her leadership and vision for transformation.

CELEBRATE GOOD TIMES!!!

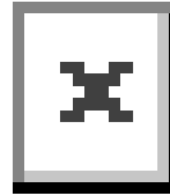
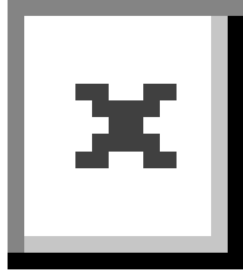
On February 15, Marty Hatlie and his partner of 40 years, Chuck Holland, were surrounded by their large and extended families and friends as they were joined together in marriage. It was a beautiful ceremony and reception filled with love, friendship, and fun as they exchanged their vows and then danced through the night. Several patient safety advocates joined in the celebration.



SHARING SKILLS AND KNOWLEDGE

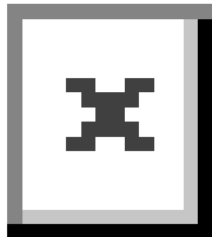


National Institute of Rural Development leadership meeting in India focused on addressing the water and sanitation issues as 19% of Indians have no access to clean water and 56% have no access to toilets.



Pat visited several Rotary grant project sites that she is working on with the Indians, including a dialysis center, free clinic, school for 1000 impoverished girls, and a Blood Bank for Thalassemia and hospitalized patients.

Pat led a Women's Leadership track with women from India, Thailand, and USA on the importance of STEM and toilet facilities for girls to continue with their education at the Water, Waste Management Conference in Hyderabad, India.



□ **We Love to Hear From You!**

We are always happy to hear from you - please feel free to contact us at any time.

Contact us at:

Telephone: 312-445-6477

E-mail: Pat Merryweather-Arges pmerryweather@projectpatientcare.org

Thank you!

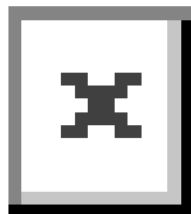
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Subject:	HHS International SPOTREP: COVID-19 (Update #125)
Date:	2020/03/05 18:35:36
Priority:	Normal
Type:	Note

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HHS International SPOTREP: COVID-19 (Update #125)

Source: Interagency

What:

- • **Grand Princess** cruise ship with 2,383 passengers and 1,110 crew were scheduled to return to Port of San Francisco March 5; 100 COVID-19 tests delivered March 5; tests will be prioritized for flu-positive passengers (2) and crew members (4) along with 68 holdovers from previous sailing; final disposition of ship pending
- • 2 suspected COVID-19 cases on Viking Sun cruise ship off the coast of East Java, Indonesia; 930 passengers (556 AMCITs)
- • 2 New York and 1 Washington school districts closed, reopening March 9 and March 14, respectively; 2 Georgia schools closed until March 12; Yeshiva University closed until March 10
- • HHS to procure 500 million N95 respirators over the next 18 months for the Strategic National Stockpile to support healthcare workers in COVID-19 outbreaks

For further information, please see the attached Senior Leader Brief (SLB), which includes the **05Mar20** CDC SITREP for Novel Coronavirus.

When: 05Mar20 1845ET

Where: International

Why: CIR: Disease – International

Actions/Follow-Up: The SOC will continue to monitor this incident and report as needed. *This message was distributed to the 2019 nCoV IMT, 2019 nCoV Interagency, 2019 nCoV IST, 2019 nCoV Senior Leadership Distribution Lists.*

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Prepared by: Brian Pittman, Watch Officer

Approved by: Brandon W. Britton, Senior Watch Officer

Secretary's Operations Center

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Subject:	COVID-19 PMO Call Due Outs 05Mar20
Date:	2020/03/05 18:43:23
Priority:	Normal
Type:	Note

General Updates

(b)(5)

- CMS has many distribution channels (*1 distro has over 1M recipients*); utilize them for messaging (*POC Brady Brooks*)

(b)(5)

- Labs are receiving testing kits; pushing priority for WA and CA
- New Guidance from CMS posted online (LTCs, triage, etc.)

(b)(5)

Due-Outs - Follow Up:

(b)(5)

V/r,

Sam Imbriale, MPH
Director, Information Management Division
Director (Acting), Secretary's Operations Center
Cell: (b)(6)
Samuel.imbriale@hhs.gov

Sent from mobile device - please excuse typos.

Sender:	Imbriale, Samuel (OS/ASPR/SIIM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=USERE7E54524>
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(CDC/DDPHSIS/CPR/DEO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6c7dafbd0efc48ff92f9ff030fe9c95b-david.maple>; Harrison, Brian (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>; Berger, Sherri (CDC/OCOO/OD) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=813a9180b08c4a24a48d1d674a7b6b42-Berger, She>; Hall, Bill (HHS/ASPA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02b39f27f3b4469a960054b23545cc24-Hall, Bill>; Orsega, Susan (OS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d8171c34a0cd4581a49f33cb8f60f684-Orsega, Sus>; Wong, Diana (OS/ASPR/SIIM) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ea0c8b32a33b4ac586c2b5aa89c0df34-Wong, Diana>; Asher, Jason (OS/ASPR/SIIM) (CTR) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=72930e15a70d47b9ab4ef286622321a9-Asher, Jaso>; Clay, Matt (OS/ASPR/SIIM) (CTR) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7137fe008b3143fc95c219c276b771c3-Clay, Matt>; Seiler, Brittney (OS/ASPR/SIIM) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6aaf930ef7475faa25d8e1d9640808-Seiler, Bri>; Saxon, Bobby (CMS/CCIIO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08f6f33b24e24f00a2cf3650a8393f25-SYTP>; Lekan, Scott (ACF) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90a98b322aba4ec2ae332c84a1ddc613-Lekan, Scot>; Payne, Skip (CMS/OA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=94ba9f17f14149b7b9d64b4b481059fa-PU1K>; Johnson, Robert (OS/ASPR/BARDA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0851e89240324306b78740a4a60745e2-Johnson, Ro>; Disbrow, Gary (OS/ASPR/BARDA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0fd5845defda4dc0bb45f8fac629cf09-Disbrow, Ga>; Bright, Rick (OS/ASPR/BARDA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric>; Lambert, Linda (OS/ASPR/BARDA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce6824b6a92a4a4e893ea7b54e17eb3c-Lambert, Li>; Wallace, Rodney (OS/ASPR/BARDA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4654f8f0cf4623b9e47465e9e1037a-Wallace, Ro>; Johnson, Lynn (ACF) </o=ExchangeLabs/ou=Exchange Administrative Group

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Sent Date:	2020/03/05 18:43:21
Delivered Date:	2020/03/05 18:43:23

From:	White House: Office of the Vice President <info@mail.whitehouse.gov>
To:	Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd. (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>
Subject:	VPOTUS pool report #7 (Washington State arrival)
Date:	2020/03/05 18:44:53
Priority:	Normal
Type:	Note

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From: Alex Leary <alex.leary@wsj.com>
Date: March 5, 2020 at 3:37:14 PM PST
Subject: [EXTERNAL] VPOTUS pool report #7 (Washington State arrival)

AF2 touched down at 3:36 p.m. local time. VP will motorcade to the state emergency operations center.

From the VP's office:

Upon arrival in Tacoma, WA at McChord Field Airport, the Vice President will be met by the following individuals:

Governor Jay Inslee
Congressman Adam Smith
Congressman Rick Larsen
Congresswoman Cathy McMorris Rodgers
Congresswoman Jaime Herrera Beutler
Congresswoman Suzan DelBene
Congressman Derek Kilmer
Congressman Dan Newhouse
Congresswoman Pramila Jayapal
Congresswoman Kim Schrier

From McChord Field Airport, the Vice President will depart by motorcade to the

State Emergency Operations Center in Tacoma, WA. Upon arrival, the Vice President will be met by Major General Bret D. Daugherty, the Adjutant General of Washington State. The Vice President will then proceed to a roundtable discussion.

The full list of attendees are as follows:

Governor Jay Inslee
Congressman Adam Smith
Congressman Rick Larsen
Congresswoman Cathy McMorris Rodgers
Congresswoman Jaime Herrera Beutler
Congresswoman Suzan DelBene
Congressman Derek Kilmer
Congressman Dan Newhouse
Congresswoman Pramila Jayapal
Congresswoman Kim Schrier
Major General Bret D. Daugherty, *The Adjutant General, State of Washington*
Dr. John Wiesman, DrPH, MPH, *Secretary of Health, State of Washington*
Administrator Seema Verma, *Centers for Medicare and Medicaid Services*
Dr. Robert R. Redfield, MD, *Director, Center for Disease*
Dr. Debbi Birx, *White House Coronavirus Coordinator*
Mayor Jenny Durkan, *Mayor, Seattle, State of Washington*
Reagan Dunn, *King County Council, State of Washington*
Bruce Dammeier, *Peirce County Executive, State of Washington*

Following the roundtable, the Vice President will tour the State Emergency Operations Center and then give a press briefing.

Alex Leary
Wall Street Journal
(202) 306-4807

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Sender:	White House: Office of the Vice President <info@mail.whitehouse.gov>
Recipient:	Harrison, Brian (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>
Sent Date:	2020/03/05 18:44:27
Delivered Date:	2020/03/05 18:44:53

From:	OS Secretarys Operations Center </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=32B1F28D808B43B6903C00083291303E-SECRETARYS>
To:	OS Secretarys Operations Center </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=32b1f28d808b43b6903c00083291303e-Secretarys>
Subject:	COVID-19 Open Media Report 05Mar20
Date:	2020/03/05 18:58:49
Priority:	Normal
Type:	Note

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Good evening all,

Attached is the 05Mar20 COVID-19 Open Media Report.

BLUF: Media reporting cases in 18 states, including first cases in Tennessee, Nevada, and New Jersey. Major event cancellations are occurring both in the United States and globally to prevent the spread of the virus. Media reports concerns that not enough tests will be available to meet demand. The Grand Princess cruise ship is being held at sea due to pending COVID-19 testing.

Epidemiology: Official case counts are distributed via the COVID-19 Morning CDC Updates and COVID-19 SLBs.

- □Traditional news media reports over 95,000 cases globally, and over 3,300 deaths worldwide.
- □COVID-19 cases were reported in new locations within the U.S.: Nevada (n=1), New Jersey (n=1), Tennessee (n=1), and Texas (n=1).
- □New York City reports new cases of community spread, bringing New York's total to 22 cases

Public Health/Clinical Response:

- □Israel institutes non-pharmaceutical measures, including forbidding public gatherings of over 5,000 people, requiring a 14-day quarantine of travelers from five European countries, and quarantining dozens of attendees of a soccer game that a COVID-19 case attended.
- □Congress sends President Trump \$8.3 billion emergency bill.
- □HHS Secretary Azar says that the government will have shipped tests to cover 75,000 people by the end of the week. However, Florida public health officials report that they have not received enough tests to meet federal testing guidelines.

Public Sentiment:

- □There is growing concern about a Seattle comic book convention, which is scheduled to go on as planned on March 12-15th. Attendance is typically around 100,000.

Supply Chain/ Economy:

- □Amazon, Microsoft, and other tech companies direct eligible employees in King County, WA to work from home through the end of March.

Healthcare System:

- □The Washington Department of Health reports that the outbreak is beginning to impact blood supply availability and urges those who are symptom free to donate. Expresses concern over low blood and platelet appointments as people choose to work from home

Please see the attached Open Media Report for additional information. *This message was distributed to the 2019 nCoV Distribution Lists.*

Prepared by:

Secretary's Operations Center

U.S. Department of Health and Human Services (HHS)
Assistant Secretary for Preparedness and Response (ASPR)
200 Independence Ave. S.W.
Washington D.C. 20201
Office (202) 619-7800
Fax: 800-514-4256
Email: hhs.soc@hhs.gov



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Recipient:	OS Secretarys Operations Center </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=32b1f28d808b43b6903c00083291303e-Secretarys>
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From:	OS Secretarys Operations Center </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=32B1F28D808B43B6903C00083291303E-SECRETARYS>
To:	OS Secretarys Operations Center </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=32b1f28d808b43b6903c00083291303e-Secretarys>
Subject:	COVID-19 Open Media Report 05Mar20
Date:	2020/03/05 18:58:50
Priority:	Normal
Type:	Note

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Prepared by:

Secretary's Operations Center

U.S. Department of Health and Human Services (HHS)
Assistant Secretary for Preparedness and Response (ASPR)
200 Independence Ave. S.W.
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Sent Date:	2020/03/05 18:58:34
Delivered Date:	2020/03/05 18:58:50

From:	Dulaigh, Joel (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02B15E96DC484DB29682C1D336E63441-DULAIGH, JO>
To:	Adams, Jerome (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=184fe51f7350400b8a99dabd65ac0db5-Adams, Jero>; Schwartz, Erica (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=603e84a0e3744a5d8dcdb759f5dcad91-Schwartz, E>; Wright, Janet (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f672e2527b4f44891fb4fbe08cdfd-Wright, Jan>; Heck, Mia (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70dbe2065d644b8dadbf56c5d63553d-Heck, Mia>; Anderson-Villaluz, Dennis (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=61dfc265c6ce45f686ad00f9dfd27901-Anderson-Vi>
Subject:	RE: Outline for OVP
Date:	2020/03/05 19:22:55
Priority:	Normal
Type:	Note

Sir,

Some edits – this is the current version along with proposed message:

Marc and Katie,

(b)(5)

(b)(5)

(b)(5)

(b)(5)

V/R,
Joel

CAPT Joel Dulaigh, ACNP-BC, FAANP
Chief of Staff to the Surgeon General
United States Public Health Service
U.S. Department of Health and Human Services
200 Independence Ave SW, Suite 701-H
Washington, DC 20201
Office Phone: 202-690-7511
Cell: (b)(6)
Direct Fax: 202.260.4405
Email: joel.dulaigh@hhs.gov

In Officio Salutis

From: Dulaigh, Joel (HHS/OASH)
Sent: Thursday, March 5, 2020 6:55 PM
To: Jerome Adams (HHS/OASH) (Jerome.Adams@hhs.gov) <Jerome.Adams@hhs.gov>; Schwartz, Erica (HHS/OASH) (Erica.Schwartz@hhs.gov) <Erica.Schwartz@hhs.gov>; Janet Wright (HHS/OASH) (Janet.Wright@HHS.GOV) <Janet.Wright@HHS.GOV>; Heck, Mia (HHS/OASH) (Mia.Heck@hhs.gov) <Mia.Heck@hhs.gov>; Anderson-Villaluz, Dennis (HHS/OASH) (Dennis.Anderson-villaluz@hhs.gov) <Dennis.Anderson-villaluz@hhs.gov>
Subject: Outline for OVP

Sir et al,
Please see below. Once approved, I will copy this into a message and send to Marc and Katie in OVP.

(b)(5)

(b)(5)

(b)(5)

(b)(5)

V/R,
Joel

CAPT Joel Dulaigh, ACNP-BC, FAANP
Chief of Staff to the Surgeon General
United States Public Health Service
U.S. Department of Health and Human Services
200 Independence Ave SW, Suite 701-H
Washington, DC 20201
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Direct Fax: 202.260.4405
Email: joel.dulaigh@hhs.gov

In Officio Salutis

Sender:	Dulaigh, Joel (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02B15E96DC484DB29682C1D336E63441-DULAIGH, JO>
Recipient:	Adams, Jerome (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=184fe51f7350400b8a99dabd65ac0db5-Adams, Jero>; Schwartz, Erica (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=603e84a0e3744a5d8dcdb759f5dcad91-Schwartz, E>; Wright, Janet (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f672e2527b4f44891fb4fbe08cdfd-Wright, Jan>; Heck, Mia (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group

	(FYDIBOHF23SPDLT)/cn=Recipients/cn=70dbe2065d644b8dadbf56c5d63553d-Heck, Mia>; Anderson-Villaluz, Dennis (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=61dfc265c6ce45f686ad00f9dfd27901-Anderson-Vi>
Sent Date:	2020/03/05 19:22:54
Delivered Date:	2020/03/05 19:22:55

From:	James Thomas <JWT@usa.net>
To:	Hunt, Michie (FDA/CDER) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1dd06aa20d5c4e6999fc6e5aca147932-michie.hunt>; Ashley, Donald (FDA/CDER) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51983358cd724f39848461c19b6c425f-donald.ashl>; Lenihan, Keagan (FDA/OC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cd1b7aba9034ddb936017780583af7d-keagan.leni>; Lee, Amy (FDA/CDER) (CTR) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95683f41b2e44735b7404895e43756b6-amy.lee.fda>; Demske, Gregory E (OIG/OCIG) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc2e07eb4b074476a47dde8675ed97db-gregory.dem>
CC:	Stephen E. Broden <sebroden@mac.com>; (b)(6)@aol.com>; (b)(6)@gmail.com>
Subject:	Re: Covid -19 Vaccine- Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor HHS 2019-01026 - Black Pastors and Black Healthcare Coalition
Date:	2020/03/05 19:31:51
Priority:	Normal
Type:	Note

Dear Michie Hunt and Attorney Richard Ashley, Gregory Demske, et al,

It looks like chloroquin stops Covid 19-

Can we make Chloroquin in the United States? What is the effective formulation

<https://www.ncbi.nlm.nih.gov/m/pubmed/32074550/>



PubMed Search

Top of Form

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↓ Full text

Breakthrough: Chloroquine phosphate has shown apparent efficacy in treatment of COVID-19 associated pneumonia in clinical studies.

Gao J, et al. Biosci Trends. 2020.

[Show full citation](#)

Abstract

The coronavirus disease 2019 (COVID-19) virus is spreading rapidly, and scientists are endeavoring to discover drugs for its efficacious treatment in China. Chloroquine phosphate, an old drug for treatment of malaria, is shown to have apparent efficacy and acceptable safety against COVID-19 associated pneumonia in multicenter clinical trials conducted in China. The drug is recommended to be included in

the next version of the Guidelines for the Prevention, Diagnosis, and Treatment of Pneumonia Caused by COVID-19 issued by the National Health Commission of the People's Republic of China for treatment of COVID-19 infection in larger populations in the future.

Kind Regards,

Jim Thomas
jwt@usa.net
215 771 7770

From: James Thomas <JWT@usa.net>
Date: Tuesday, March 3, 2020 at 2:49 PM
To: "Hunt, Michie" <Michie.Hunt@fda.hhs.gov>, "Ashley, Donald" <Donald.Ashley@fda.hhs.gov>, "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>, "Lee, Amy *" <Amy.Lee@fda.hhs.gov>, <Gregory.Demske@oig.hhs.gov>
Cc: "Stephen E. Broden" (b)(6)@mac.com, (b)(6)@aol.com" (b)(6)@aol.com>, (b)(6)@gmail.com>
Subject: Covid -19 Vaccine- Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor HHS 2019-01026 - Black Pastors and Black Healthcare Coalition

Dear Michie Hunt and Attorney Richard Ashley, Gregory Demske, et al,

You must be in fear like we are, that our supply chain and secret contracts between and among GPO's, PBMs, Hospitals, Hospital CEOs and Pharmaceutical Manufacturers, Media companies and others have caused a national security crisis. Corona virus deaths and damage will be amplified by the supply chain disruptions caused by critical medications being sourced in China and the root cause, the secret kickback contracts and lack of oversight of these contracts. These deaths could have been an still may be able to be avoided if you/we act quickly. Perhaps the answer includes implementing a vaccine in a few month timeframe and implementing other changes suggested for consideration below.

1. • The CBO needs the "Secret contracts" and the White House Must be informed.
 - a. • We can no longer pretend that HHS- OIG is not allowed to request the contracts.
 - b. • Note that the GPO GNYHA (Greater New York Hospital Association) and perhaps Lee Perelman and Jill Abramson has been stopping the NYTimes and others from writing about this issue until GNYHA sold out to Premier. This may be partisan politics.
 - c. • The CBO must no longer pretend that they do not understand the anticompetitive practices caused by the secret contracts and how stopping the kickbacks will improve competition and reduce high prices significantly as well as decrease the US dependence on sole source generic producers.
 - d. • Please be aware that that the Media(Television, Print and digital) are the final beneficiary of the money moving from the GPO's/PBM's to the Senators/Congressmen's campaigns to the Media.

2. • The Department of Justice should consider stopping prosecution of the Generic Manufacturers who are closing up shop in the United States. Teva, Mylan Mallinckrodt and others. The remaining generic manufacturers were colluding to remain afloat to combat the pricing schemes of the GPO/Hospital racketeering that result from the secret contracts that are supposed to be overseen by the HHS -OIG. Blame the GPO's and PBM's rather than those manufacturing medications in the USA. 80% of generic medication active ingredients are made in China and this is now an National Security Issue- no longer a threat.
3. • Please mandate quality transparency in our medications. It is the FDA and the that failed the people of the United States by not telling them(and the DOD) their medications often contained carcinogens and did not contain the correct amount of active ingredient and production cannot be overseen by the FDA adequately. The FDA and perhaps Amerisource Bergan failed to tell the Department of Defense about the origin of their medication precursors being foreign corporations and foreign governments.
4. • We ask that you contact the companies that have made successful vaccines that have no downside risk, no risk of harm such as Inovio Medical. Inovio made a DNA vaccine in 3hrs yet perhaps the FDA requires testing that will take months/years. You know there is no downside, no risk of traditional vaccines and no adjuvants and no refrigeration needed. So why delay? Inovio uses electroporation (device) rather than adjuvants like aluminum and has no egg albumin etc. Inovio can begin vaccination very quickly, Inovio can scale up us manufacturing very fast and safely. Please move quickly. Once again the FDA has the opportunity to prevent a catastrophe.
5. • We understand that the congressmen and senators may have purchased shares of the mRNA vaccine Stock, Moderna, prior to announcement that they would be chosen to get government funding but their product may be far inferior to the Inovio vaccine product. The mRNA vaccine candidate requires refrigeration with liquid nitrogen and has to be made into lipid nanoparticles with liver effects and costs many times more per dose. Please reveal any conflicts of interest and when they occurred.
6. • We need to show the world "why" this is happening, why we had our medical supply chain dependent upon China with large kickbacks and "why" select companies were allowed to have sole source contracts for so many years. It comes down to money and keeping those who make the money for the congressmen and senators (stock ownership increases their personal wealth) and campaign contributions from the PBMs and GPO's that keep Congress from repealing the safe harbor. (See Zeke Emanuel Statement)
 - a. • Those Senators and Congressmen who comply get rich and re-elected
 - b. • Perhaps Senatorial and Congressional or even White House staffers are paid by these organizations or think tanks sponsored by such organizations.
 - c. • Please beware of Joseph Grogan and Theo Merkel in the White House- they may not be acting in the interests of We the People of the United States of America.
 - d. • Please watch this video including Senator Blumenthal detailing issues.
 - i. <https://www.c-span.org/video/?c4817234/user-clip-gpo-question-sen-blumenthal>
 - ii. GPOs buying exclusivity.
7. • If for no other reason, we need to act because this is preferentially harming the Black community, a protected class.
 - a. • Insulin patent given away- yet price of insulin remains high.
 - b. • Shortages of Mag sulfate, bupivacaine, Pitocin and other meds needed to treat Pre-eclampsia

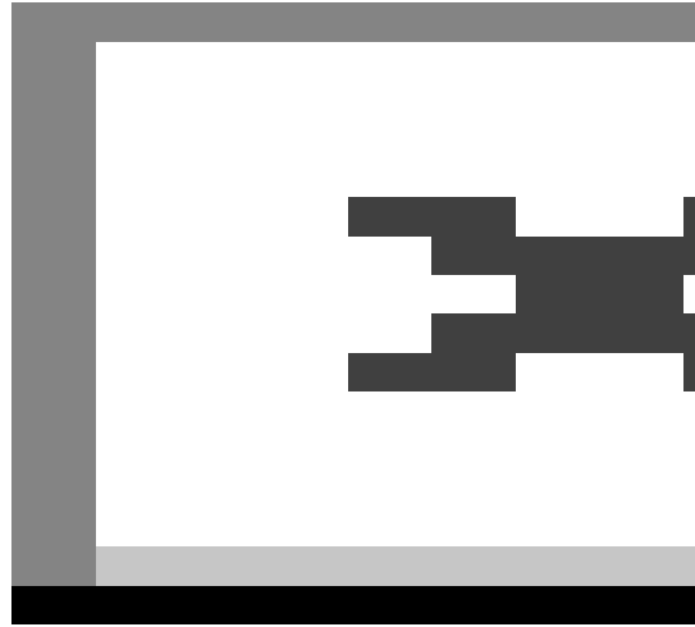
- c. • CVS taking over primary care with low cost generic “providers” getting paid as if they were Physicians and steering care to that which benefits CVS reimbursement rather than the patient.
- 8. • Please let the new director of the FDA know; he should be aware of Inovio since MD Anderson did not have access to the HPV vaccine in 2018 while he was there. Instead of directing a patient to an institution participating in the AZ/Inovio trial, MD Anderson just radiated the patient’s throat cancer and then asked Inovio to be part of the trial after the patient was sent away and no longer qualified for the trail because of the radiation. The patient died, bled to death when his carotid artery ruptured because of the radiation. Now MD Anderson is part of the Inovio trail at their own request- unheard of for an institution to request to be part of a trail. Too late for the patient and his family.
- 9. • Please let the hospitals and others know if Ultraviolet light kills the Covid-19 virus and that the hospitals need to sterilize rooms and air ducts etc with Ultraviolet light.
- 10. • Please emphasize the long incubation period and how we need to take universal precautions now.... No handshaking, no sharing cups/chalice (Churches must be warned and need to take on same responsibilities as food service industry) , cleaning surfaces with ultraviolet light, isolating potential contacts for longer than 2 weeks and more.

We need to know how or if the FDA or HHS has passed on the information we have given to you in the past. **Please document how or if you informed the Department of Defense or White House after we passed information about this National Security Threat on 9 April 2019 that is now a potential reality.**

Please tell us who you are passing this information and if you are not, please suggest who we should communicate with regarding each of these topics to those who can and are willing to make a timely difference. We are patriots and not suicidal. We ask that anyone in this email chain who has “dual citizenship” or “dual allegiances” declare them and recuse themselves. We look forward to and work toward transparency in medication quality for We the People of the United States. Perhaps anyone who is working against the interest of the USA should be considered a domestic or foreign enemy. We remain grateful for your help on this pressing issue and on behalf of myself and others, offer you,

Kind Regards,

Jim Thomas
jwt@usa.net
215 771 7770



cid:image001.jpg@01D5F16A.E8F511A0

From: James Thomas <JWT@usa.net>

Date: Tuesday, December 10, 2019 at 6:34 PM

To: "Hunt, Michie" <Michie.Hunt@fda.hhs.gov>, "Ashley, Donald" <Donald.Ashley@fda.hhs.gov>, "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>, "Lee, Amy" <Amy.Lee@fda.hhs.gov>

Cc: "Stephen E. Broden" <(b)(6)@mac.com>, "(b)(6)@aol.com" <(b)(6)@aol.com>, "(b)(6)@gmail.com" <(b)(6)@gmail.com>

Subject: Re: Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor HHS 2019-01026 - Black Pastors and Black Healthcare Coalition

Dear Dr. Michie Hunt and Attorney Richard Ashley et al,

Thank you for your help. Since last communication we have made some progress on the issue of the looming National Security Threat. It seems when we, the Physicians and Black Pastors along with the Black Healthcare Coalition warned the FDA about the National Security Risk on April 9th, 2019, the FDA may or may not have notified the Department of Defense(DOD) nor the Joint Chiefs of Staff about the United States inability to make the antidote to anthrax and other critical medications within the United States.

The Physicians, Black Pastors and Black Healthcare Coalition and others, including a knowledgeable author on the subject may or may not have notified the DOD and others directly as well, and after giving the DOD lead time. Now Physicians around the country have been working toward making the American public aware of this important National Security issue. The FDA's report on drug shortages was very disheartening, for the FDA did not elucidate the existence of the secret contracts between GPO's /PBM's and manufacturers as well as hospitals as the root cause of the shortages and sole or limited source contracting. We are a country of laws and as such our laws and regulations have created the drug shortages. We know just as the FAA has imbedded people who have allegiances to Boeing imbedded in their organization so does the FDA and HHS have imbedded people who have allegiances to other entities such as the PBMs, GPO's, hospitals and health insurance companies as well as other entities that benefit financially from the high prices and limited suppliers and even from cheap generic precursors made in China that cost little but are sold for high prices and great profits through the "Sharebacks".

Next is the problem of disinformation that is going on by the GPO's and PBM's who are attacking the Medication manufacturers.

It is not "Big Pharma" that is the source of the problems. It is the GPOs (Group Purchasing Organizations) and PBM(pharmacy Benefit Manager) middle men, Hospitals and Insurance companies that make billions yet manufacture nothing and do so through the legalized kickbacks or sharebacks via contract law.

<https://duckduckgo.com/?q=nomiddlemen.org+gpo&t=hr&iar=videos&iax=videos&ia=videos&iai=aQhsPLcFwN8>

All should be aware that it is the GPOs and PBMs and the lack of actual oversight by HHS OIG over their secret contracts that govern the kickbacks and sole source/limited source contracting is the root cause of the kickbacks/ sharebacks that divert money from manufacturers willing to make medications in the United States to these middlemen. It seems those who have been assigned to this task from the FDA are by and large pharmacists rather than economists and Dr. Michie Hunt's background may be critical in making the FDA as well as HHS aware, of the contracts and the pricing and quality issues they are creating. If you do not tell HHS and ask the HHS- OIG to exposed the secret contracts then there will be more problems going forward.

<https://healthpolicy.duke.edu/events/drug-shortage-task-force>
you can see it here. At 7hrs and 44min into the discussion...

2 minute excerpt can be found here:

https://protect2.fireeye.com/url?k=63313462-3f643d71-6331055d-0cc47adb5650-dbc3ca907d905d80&u=https://www.dropbox.com/s/mt7ub1ml9tjdrps/IMG_8952.mov?dl=0

These secret contracts are indeed the root cause of a national security issue; the United States cannot make critical medications in the United States including but not limited to Ciprofloxacin and Doxycycline, the antidote to anthrax. Please ask for the contracts; as Mr. Todd Ebert says they have never been requested. We humbly request that the Department of Defense as well as the department of Justice and Anti-Trust divisions of the US Government and or those who would oversee Racketeering issues, encourage the FDA and HHS to request the contracts and perform their fiduciary responsibility.

The Senators know:

Questions from Sen. Richard Blumenthal (D-CT) on anticompetitive GPO practices, Justice Department Antitrust chief Makan Delrahim said that because of the Medicare anti-kickback safe harbor, "...some of these GPOs are buying exclusivity at the risk of innovation, at the risk of cost, at the risk of lives of patients": WATCH the C-Span Video: <https://www.c-span.org/video/?c4817234/user-clip-gpo-question-sen-blumenthal>

Zeke Emanuel knows: he said (at the Wharton 50th anniversary of LDI) that the reason we have GPO's and PBM's is to fund senatorial and congressional campaigns both at a federal and state level. Paraphrasing..."Campaigns cost millions as you are finding and the PBMs and GPO's contribute to those campaigns." ... as do those who make money from the GPO's ie the Hospital Association.. both HAP(Hospital Association of PA) and AHA(American Hospital Association) as well as the PBM's such as CVS/Caremark.

The hospital's know: Hospitals own the GPO's and their CEO's get kickbacks directly from the GPO's. The hospitals are part of the problem. The hospital kickbacks are the part of the reason for the shortages and high prices. They may not even tell patients that medications are in shortage at their hospital and the GPOs may preferentially harm smaller hospitals so they will go bankrupt. (Hospital bankruptcy's are happening now) Big hospitals seem to comply with the GPO practice. See excerpt from article below:

"As a member-driven enterprise, it is common knowledge that Premier and other GPOs "share back" with their members and owners. In fact, many hospital executives who are part of the Premier alliance have learned to rely on that share back as an integral part of their annual compensation."source: Healthcare Matters Thomas Finn - July 22, 2013 6:45 AM Question: since hospital CEO's benefit from GPO purchasing decisions are they fiduciaries for the hospital patients? We know the Attorney Generals are fiduciaries for the people of the state with regard to Non-profits so have they investigated?.

<https://nebula.wsimg.com/09cac886d7a44b22d0e78cef17f1c4ee?AccessKeyId=62BC662C928C06F7384C&disposition=0&alloworigin=1>

Everyone seems to know yet the FDA and HHS desire to but are being prevented by "insiders" or imbedded people perhaps in the upper echelons of their organizations from requesting the contracts... Why?

We are now cautioning HHS and the FDA that the contracts must be revealed urgently in order to stop the GPO's/PBMs and Senators from proposing a solution that will further undermine the National Security of the United States and the ability to have cost effective and safe pharmaceutical markets. Senator Collins from Maine and Senator Tina Smith have seemingly teamed up with Premier, a GPO who's contracts and sharebacks/kickbacks are part of the real root cause of the drug shortages. Perhaps Premier and other GPO's and PBM's should not be entrusted to be the "solution".

The National Security risk is now public information as is the fact that wild boars in the DMZ between North Korea and south may be perhaps biological weapons and biological delivery from one Korea to another or just a random event..... wild boars infected with swine flu. Note that transparency in the contents of our medications is important as well. Let's work toward transparency so that we can regain the trust of the American people with regard to our medications and kickback oversight as the root cause of our medications being made in china and containing carcinogens.

<https://protect2.fireeye.com/url?k=89e95b23-d5bc5230-89e96a1c-0cc47adb5650-dc7534e44e2b7ef3&u=https://www.dailynk.com/english/around-1000-asf-infected-pigs-die-pyongyang-sources-report/>

<https://www.livescience.com/pigs-blood-stream-african-swine-fever.html>

<https://www.telegraph.co.uk/news/2019/10/14/south-korea-deploys-snipers-thermal-vision-drones-kill-infected/>

This loss of pork, which is 80% of the protein intake of North Korea will likely cause dire straits because of the US economic Sanctions. Perhaps our pork supply is plentiful and hopefully safer. We also need to use our pigs to make heparin within the United States rather than getting our Heparin from China; Heparin is made using Pig products such as intestines and it is believed that currently the US gets their heparin from China and it is in shortage.

Please let us know if we Physicians, Pastors, members of the Black Healthcare Coalition and Patriots can be of service as we stay ahead of this growing threat. The sooner the secret contracts are revealed the faster the Department of Defense and others can react to this National Security Crisis. Please consider recommending that the new OIG of HHS, request the secret contracts as soon as possible. If you do not the fictitious high prices of medications and the stranglehold the GPO's and PBMs and now Insurance companies like Aetna and Cigna who are in the scheme having purchased PBM's themselves.

Once again, because of the attacks on our computers and other issues, if the medication shortages and deaths, as well as our national security weakness is all planned by the FDA and HHS, hospitals senators and congressmen and others to support campaign financing as outlined by Zeke Emanuel, then please let us know so that we can stop trying to bring this to light and stop asking for HHS to investigate the secret contracts governing the kickbacks. Please keep in mind that the high prices of Insulin, and Daraprim among many others and the scarcity of magnesium sulfate, bupivacaine and Pitocin and other medications preferentially affects Black Americans and other protected classes. Thanks again for your kindness and grateful for your help on this issue.

Kind Regards,

Jim Thomas

From: James Thomas JWT@usa.net

To: among others:

Shamsuddin, Samir * <Samir.Shamsuddin@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Ashley, Donald <Donald.Ashley@fda.hhs.gov>; Hunt, Michie <Michie.Hunt@fda.hhs.gov>; Lee, Amy * <Amy.Lee@fda.hhs.gov>

Date: Tuesday, April 9, 2019 at 8:26 PM

Subject: Re: Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Docket No. FDA-2018-N-3272: Identifying the Root Causes of Drug Shortages and Finding - Black Pastors and Black Healthcare Coalition

It seems that many Physicians who work late hours; some could not post to the website. Please forward our comments to Secretary Azar.

Many physicians have had computer issues, email issues, telephone issues and other issues.

Please note that this is likely an issue of National Security and all who are thwarting the Physicians and Pastors from rectifying this issue should perhaps be considered Domestic Enemies of the United States for the following reasons;

1. • Antidote to anthrax, the ingredients in ciprofloxacin or other medication precursors like doxycycline are no longer made in the United States and if the USA is attacked with we have some stockpiles for military but we have reason to believe we cannot make the precursors for our citizens. We can detail why this is critical if the US is attacked utilizing biological warfare. China may not want North Korea to use nuclear weapons, China may want them to use biologicals or even Opioids/synthetic opioids to kill the people of the United States if there is war.
2. • The antidote to Opioids is not Naloxone, it is Buprenorphine in a long acting form and must be induced shortly after giving Narcan or will send patient into chemical withdrawal. Fake rehab centers just use useless cognitive therapy that the LDI of Wharton School has proven does not work. Medically Assisted Therapy (MAT) ie timely Buprenorphine induction and longterm medical buprenorphine like sublocade or probupherine treatment is mandatory. These fake rehab centers who do not offer MAT profit handsomely from new laws that give them unlimited Medicaid funding and kickback money for legislators via campaign donations from this new source of money, unlimited Medicaid dollars. The largest recent increase is death from opioids is black males.
3. • Carcinogens in generic medications made in China and India and no option of generics made in the United States free of carcinogens or sustainably sourced.
4. • The HHS- IG (Daniel Levinson) having the fiduciary responsibility of oversight of the "Secret Contracts" but the office of Inspector General has never not ever requested these contracts for review of why we have medication shortages. He has not requested any of the "secret contracts" of the medications that are in shortage and not requested the "Secret Contracts" of Oxycontin, one of the few medications that has never been on shortage.

Some have suggested Daniel Best may have been killed rather than have committed suicide and his death should possibly be investigated as a National Security Issue as well. So unlikely to commit suicide at 5:45 am and blunt force trauma is difficult to self inflict.

We are Patriots as well as Pastors and Physicians who work tirelessly for our congregations, patients and for the safety of the United States citizens. Some of us are members of the military and work to support and defend the Constitution of the United States of America. Those who have known about the reason for the medication scarcity and high prices may not have the best interest of the United States in mind. It is rumored that XXXXXXXXXX father was a member of the Israel intelligence agency, HaMossad leModi in uletafkidim or "Mosssad". Dr. clearly knows the reason for the PBMs and GPO's financial prowess through high prices of cheap generics and low cost poor quality medications is campaign financing.

If all this medication scarcity and death of Black Americans is in keeping with the mission of the Constitution of the United States and the mission of HHS and FDA then please let us know so we can stop trying to solve this issue. We don't want to be targeted. If we are mistaken, please let us know and we will stop.

If it is a National Security issue, please consider supporting us, providing us secure channels of communication, and making anyone who is tampering with our computers or is aware of this National Security issue(Inability to produce critical antibiotic precursors in the United States), if indeed it is. Those responsible and who knew about this issue(including those tampering with our computers) and did nothing should be held accountable as a potential foreign or domestic enemies of the United States of America.

Please consider and let us know.

Kind Regards,

LCDR Flight Surgeon, USNR(I)

From: James Thomas <JWT@usa.net>

Date: Monday, April 15, 2019 at 3:48 PM

To: "Hunt, Michie" <Michie.Hunt@fda.hhs.gov>, "Ashley, Donald"

<Donald.Ashley@fda.hhs.gov>, "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>, "Lee, Amy
*" <Amy.Lee@fda.hhs.gov>

Cc: "Stephen E. Broden" <(b)(6)@mac.com>, <(b)(6)@aol.com>

<(b)(6)@aol.com>, <(b)(6)@gmail.com>

Subject: Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor HHS 2019-01026 - Black Pastors and Black Healthcare Coalition

Dear Dr. Hunt,

Thank you for the kindness of your reply. Perhaps the header of this email should have been changed to the above and included HHS 2019-01026.

Here's the comment

link: <https://www.federalregister.gov/documents/2019/02/06/2019-01026/fraud-and-abuse-removal-of-safe-harbor-protection-for-rebates-involving-prescription-pharmaceuticals>

Comments on this issue of Safe Harbor and the Secret Contracts that delineate the kickbacks/safe harbor, were due by April 8 2019 at midnight, not January 11 2019 and many could not add their comments to the above link as we could not, on behalf of Pastors Broden, Childress and Short, the Black Pastors and the Black Healthcare Coalition as the below correspondence was authorized to be posted but was not uploaded by the website. We tried for many hours, right up until the close of the comment period and that is why within a few minutes you were emailed as well as Seema Verma at . 12:02 am on 9 April 2019 to be precise. We are sorry to have failed the people we represent on this important issue.

Is there someone at HHS that might be amenable to adding these comments? We tried diligently and these comments, especially noting that HHS-OIG who is resigning, seems to have had the fiduciary responsibility all along although he has never requested the contracts in his 15+ years on the job. This issue not only disproportionately affects Black Americans but likely has ***National Security*** implications; it is very important to get this information to HHS- Secretary Azar and others.

If you would be so kind, please consider forwarding so that HHS might take the submission because of the documented glitch in the system. We hope you see the value of our comments and selfless dedication of the Pastors and Physicians as well as Patients who support transparency on this issue of quality, price, cost of inputs and availability of medications as well as the safety and security of all of us, ... We the People of the United States of America.

Thanks for your consideration, and thanks for all your help. We are all very grateful for your time and dedication.

Kind Regards,

LCDR Jim Thomas, MD MBA
jwt@usa.net
215 771 7770

From: "Hunt, Michie" <Michie.Hunt@fda.hhs.gov>

Date: Monday, April 15, 2019 at 1:48 PM

To: James Thomas <JWT@usa.net>
Cc: "Ashley, Donald" <Donald.Ashley@fda.hhs.gov>, "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>, "Lee, Amy *" <Amy.Lee@fda.hhs.gov>
Subject: RE: Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Docket No. FDA-2018-N-3272: Identifying the Root Causes of Drug Shortages and Finding - Black Pastors and Black H...

Dear Mr. Thomas,

The reason your comments will not upload to the website is that the docket is closed. As explained in the [Federal Register Notice](#) announcing the public meeting on drug shortages that we held last November, the docket was open until January 11, 2019. It is customary that, whenever we solicit public comments, we open a docket for a set period of time: often 60 days, though in this case the docket was open much longer. Once it closes, we generally do not accept further comments and electronic submissions will not upload.

Best regards,

Michie I. Hunt, Ph.D., M.B.A.
Program Manager, Agency Drug Shortages Task Force

Center for Drug Evaluation and Research
Office of Executive Programs
U.S. Food and Drug Administration
Tel: 301 796 3504
michie.hunt@fda.hhs.gov



[cid:image001.png@01D1C57E.DFA022A0](#)

From: James Thomas <JWT@usa.net>
Sent: Tuesday, April 09, 2019 12:03 AM
To: Lee, Amy * <Amy.Lee@fda.hhs.gov>; Hunt, Michie <Michie.Hunt@fda.hhs.gov>; Ashley, Donald <Donald.Ashley@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Shamsuddin, Samir * <Samir.Shamsuddin@fda.hhs.gov>; Verma, Seema (CMS) <Seema.Verma@cms.hhs.gov>

Subject: Re: Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Docket No. FDA-2018-N-3272: Identifying the Root Causes of Drug Shortages and Finding - Black Pastors and Black H...

Dear Dr. Hunt, Amy and Mr.Ashley,

My comments would not upload to the website. Therefore please submit the ones sent to you earlier today as below. It seems there has been some interference in the website.

Kind Regards,

Jim Thomas
jwt@usa.net
215 771 7770

From: James Thomas <JWT@usa.net>

Date: Monday, April 8, 2019 at 4:32 PM

To: "Lee, Amy *" <Amy.Lee@fda.hhs.gov>, "Hunt, Michie" <Michie.Hunt@fda.hhs.gov>, "Ashley, Donald" <Donald.Ashley@fda.hhs.gov>, "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>, "Shamsuddin, Samir *" <Samir.Shamsuddin@fda.hhs.gov>, <Seema.Verma@cms.hhs.gov>

Cc: "Stephen E. Broden" <(b)(6)@mac.com>, "(b)(6)" <(b)(6)@aol.com>, "(b)(6)" <(b)(6)@aol.com>, "(b)(6)" <(b)(6)@gmail.com>

Subject: Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Docket No. FDA-2018-N-3272: Identifying the Root Causes of Drug Shortages and Finding - Black Pastors and Black Healthcare Coalition

Dear Mr. Ashley, Dr. Hunt, et al,

This Message has been approved in its preliminary form by Pastor Broden, Rev. Childress and Dr. Short on Behalf of the Black Healthcare Coalition. If there are corrections needed we will modify. Please let us know.

Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees

More safe harbors mean more lack of transparency. Focus Should be on GPO's not PBM's. The PBM's are now Insurance companies like Cigna and Aetna and others.

It is very important that each and every State Attorney General be notified that HHS Inspector General has the fiduciary responsibility to oversee the Secret Contracts between the GPO's (PBM's/ Now Insurance companies) and the Medication Manufacturers. Although HHS has the ability and responsibility to oversee these Secret Contracts that outline the kickbacks that created the shortages of even generic medications, HHS IG has not requested these contracts... not ever! Deaths among Black Americans affected by these shortages is apparent in New Jersey where it has become a nationally known that perhaps Black New Jersey's peri-Maternal mortality exceeds that of some undeveloped countries. The Attorney General of NJ should be insisting on seeing the secret contracts themselves as

should the Black Americans who seem to be disproportionately affected and let's hope citizens of protected classes such as Black Americans are not being targeted by the GPO's and Insurance Companies, the entities formerly known as PBM's. Note that Diovan that contains carcinogen NDMA and others, has been lauded as a medication that should be given to Black Americans above all others for Hypertension yet it contains carcinogens. We conclude that a starting dose of valsartan/hydrochlorothiazide (160/12.5 mg) is as effective as high-dose amlodipine (10 mg) in reducing blood pressure in blacks with stage 1 and stage 2 hypertension, and valsartan/hydrochlorothiazide is better tolerated.(Hypertension. 2005;46:508-513.

Noninferiority study says give Diovan or Valsartan to Black Americans!

The State Attorney Generals should consider listing the names of the CEO's of the GPO's, Insurance companies, government Attorneys and even perhaps Zeke Emanuel, who knew about this scheme to make the US Government and American people pay high prices for cheap generics sometimes even containing carcinogens perhaps to fund Legislators campaigns. Since this is may be fraud, similar to the fraud that was committed when the Sackler family bribed the FDA and said Oxycontin was not as addictive as other medications, perhaps the "corporate veil" can be pierced and their CEOs and anyone, including academicians, who knew about this scheme, could perhaps be held personally responsible for the deaths and morbidity and even pay reparations for such actions and inaction. Just like the Sackler's art collections may be used to make reparations to the millions of people they harmed, so could perhaps the millions of dollars these GPOs and Insurance Companies and their CEOs made be used for reparations to the people they harmed. Perhaps the US Government has a claim as well, the Government has paid high prices for cheap generics when the real cost of input materials for these medications, especially generics, is low. Is the Health and Human Services IG, Mr. Levinson, aware that he has the ability to request these secret contracts and never asked for them, at least not yet. We ask that the Attorneys please help the Physicians protect our patients, the People of the United States of America. The US Citizens are willing to pay a bit more for organic food, just think how much more they would be willing to pay for medications that don't contain any carcinogens, are made in the United States and/or perhaps even "Organic" or contain sustainably/reliably sourced ingredients.

The Non-Profit academic institutions and Medical Societies also may have a role in this and the **Attorney Generals of the States as well as the US Attorney General have the obligation to oversee all Non-profit organizations** from the Universities and hospitals/ healthcare networks that own GPOs to Foundations. If they are using Non-profits for partisan politics and even to get themselves elected is this a problem?

Note that "Insulin for Free" is not the answer. That scheme is like Medicare for all will keep the secret high prices in place and guarantee high profits for CVS's Larry Merlo and tax exempt Hospitals and GPO's and others while increasing our US citizens taxes to pay for high priced cheap junk generics made in China or India. Instead we need transparency in quality and cost of inputs and pricing to allow citizens to benefit from a free market and innovation.

The US Citizens need to be told that CMS's plan is to pay CVS lots of money! CVS is going to get paid more per hour for having a Nurse or Phys Assistant in a minute clinic see a simple (level2) patient than a Physician seeing a complex (level4) patient in their office that takes far more time. And all the liability may be transferred to physicians via contract law. An 80yr old granny see a man or woman in a long coat called "Doctor" and assumes they are a Physician when in reality they may be a Nurse Practitioner or Phys Assistant with a "Doctorate" that has had a fraction of the training and experience of a Physician. Will those nurses and Assistants employed by CVS be told what to prescribe?

Please consider looking into if CVS or other GPO's or PBM/Insurance company combos has ties to officials at CMS. The new payment scheme does not make logical sense unless designed specifically to enrich CVS and bankrupt Independent Physicians.

Please consider asking Dr. Scott Gottlieb and Daniel Levinson to remain and perform their fiduciary responsibility prior to quitting. They should not take a job or pay from GPO's or the AHIP or Insurance companies or "Think Tanks" or academic institutions or hospitals that are funded directly or indirectly by this scheme of kickbacks to PBM/Insurance companies and GPO's.

[https://en.m.wikipedia.org/wiki/America's Health Insurance Plans](https://en.m.wikipedia.org/wiki/America's_Health_Insurance_Plans)

AHIP is interesting

Problems at the FDA and HHS are documented and longstanding

<https://protect2.fireeye.com/url?k=90920828-ccc7013b-90923917-0cc47adb5650-fb49ab6863417c09&u=https://www.whistleblowers.org/wp-content/uploads/2018/11/letter2presidentobama.pdf>

and so how do we know HHS never asked for the secret contracts??? The FDA and Todd Ebert confirmed FDA/HHS never asked for the contracts....he said it directly at the hearing in Nov 2018 Run by Duke Margolis

<https://healthpolicy.duke.edu/events/drug-shortage-task-force>
you can see it here. At 7hrs and 44min into the discussion...

and in this article search Inspector or HHS-IG and see how they never asked. It is not a movie, just a searchable text of the GAO hearing document that outlines the fact that HHS-IG is the one who has never requested the secret contracts or "Killer Contracts" between GPOs and their "slaves", the medication and device manufacturers.

<https://protect2.fireeye.com/url?k=7ea2cbc3-22f7c2d0-7ea2fafc-0cc47adb5650-21dee553eddee65a&u=http://www.puncturemovie.com/wp-content/themes/Romix/pdfs/group-purchasing-government-accountability.pdf>

the text is searchable- please consider searching for Inspector or OIG

GPOs are subject to certain federal laws that HHS, DOJ, and FTC are responsible for enforcing. According to HHS Office of Inspector General (HHS-OIG) officials, since 2004, the office has not routinely exercised its authority to request and review disclosures related to GPOs' contract administrative fees, but it has collected information on GPOs' contract administrative fees while conducting audits of hospitals' cost reports. While HHS-OIG is responsible for enforcing the Anti-Kickback statute, the law and regulation do not require routine monitoring of GPO written agreements and disclosures.

HHS, DOJ, and FTC Have Overseen Aspects of GPO Activities According to HHS-OIG officials, since 2004, the office has not routinely exercised its authority to request and review disclosures related to GPOs' contract administrative fees, but it has collected information on GPOs' contract administrative fees while conducting audits of hospitals' cost reports.

the FDA has known corruption exists for years and even wrote to Pres Obama

<https://protect2.fireeye.com/url?k=e7a05839-bbf5512a-e7a06906-0cc47adb5650-87b0834f89f9650f&u=https://www.whistleblowers.org/wp-content/uploads/2018/11/letter2presidentobama.pdf>

Can FDA Attorneys, directors and HHS IGs abruptly quit and leave without being held accountable?

The FDA and HHS should be supportive: The FDA and HHS asked Physicians why we had drug shortages and we are telling them.... The FDA should not harm us for bringing this to light, for they asked Pastors and Physicians to do so.

Some of our pastors and physicians may have had their computers hacked and their email addresses allegedly “tagged” on the “Dark web” or other entity. We Pastors and Physicians may need protections as we move toward **transparency in cost of inputs for medications, price of medications and the varying quality of medications. Only with transparency in Cost of making a product, Pricing of a product (which should be based on cost of inputs) and Quality variability of products can we ask the American people to make decisions on price they are willing to pay for each product.**

The people of the United States of America deserve to know that the Drug shortages and deaths of their loved ones have and are caused by the Secret Contracts and the HHS- IG should not just turn tail and run but should take his fiduciary responsibility seriously and reveal every secret contract for each medication that has ever been in shortage and for Oxycontin that has never been in shortage. Let’s investigate in an open and transparent way.

We are not suicidal and hope we will not be killed; we are, just as you all are, very dedicated to transparency, truth, justice and high quality healthcare for all: We the People of the United States of America.

Kind Regards,

Jim Thomas
jwt@usa.net
215 771 7770

Sender:	James Thomas <JWT@usa.net>
Recipient:	Hunt, Michie (FDA/CDER) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1dd06aa20d5c4e6999fc6e5aca147932-michie.hunt>; Ashley, Donald (FDA/CDER) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51983358cd724f39848461c19b6c425f-donald.ashl>; Lenihan, Keagan (FDA/OC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cd1b7aba9034ddb936017780583af7d-keagan.leni>; Lee, Amy (FDA/CDER) (CTR) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95683f41b2e44735b7404895e43756b6-amy.lee.fda>; Demske, Gregory E (OIG/OCIG) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc2e07eb4b074476a47dde8675ed97db-gregory.dem>; Stephen E. Broden <(b)(6)@mac.com>; <(b)(6)@aol.com>; <(b)(6)@gmail.com>

Sent Date:	2020/03/05 19:31:19
Delivered Date:	2020/03/05 19:31:51
Message Flags:	Unread

From:	White House: Office of the Vice President <info@mail.whitehouse.gov>
To:	Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd. (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>
Subject:	VPOTUS pool report #10 ("tip of the spear")
Date:	2020/03/05 20:04:03
Priority:	Normal
Type:	Note

-->





From: Alex Leary <alex.leary@wsj.com>

Date: March 5, 2020 at 4:44:02 PM PST

Subject: [EXTERNAL] VPOTUS pool report #10 (“tip of the spear”)

Inside the state EOC, Gov. Inslee said Washington is the “tip of the spear” and the nation is looking to the state for its response.

VP, standing next to the governor, said: “I know all of you have been working 24/7” and making America proud.

“We’re with you,” VP said, adding the full resources of the federal government are being made available.

“We know you’re the front line,” VP said.
VP and Gov. Inslee then went over to look up at a large video screen showing the John Hopkins coronavirus tracking map.

VP went around the room, talking with officials and giving elbow bumps. “How are you holding up?” VP asked a woman.

Up next, a roundtable discussion.

Alex Leary
Wall Street Journal
(202) 306-4807

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Sender:	White House: Office of the Vice President <info@mail.whitehouse.gov>
Recipient:	Harrison, Brian (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>
Sent Date:	2020/03/05 20:02:39
Delivered Date:	2020/03/05 20:04:03

From:	OS Secretarys Operations Center </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=32B1F28D808B43B6903C00083291303E-SECRETARYS>
To:	OS Secretarys Operations Center </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=32b1f28d808b43b6903c00083291303e-Secretarys>
Subject:	Summary: Maryland State Three Presumptive Positive COVID-19 Cases
Date:	2020/03/05 20:22:13
Priority:	Normal
Type:	Note

UNCLASSIFIED // FOR OFFICIAL USE ONLY

Good evening Dr. Kadlec,

BLUF: Three presumptive positives COVID-19 cases have been reported in Maryland State.

- Maryland Governor Larry Hogan's office reported that Maryland's Public Health Laboratory in Baltimore confirmed the three cases via tweet on 05Mar20.
- Additional demographic information on the three Maryland presumptive positive cases are unknown at this time.
- The patients are suspected of contracting COVID-19 due to previous travel.
- CDC EOC cannot confirm these cases at this time.

The SOC will continue to monitor this incident and report as needed. *This notification is limited distribution and is intended for HHS Senior Leadership Only. **DO NOT FORWARD.** This notification was sent to the COVID-19 Senior Leadership distribution list.*

Very Respectfully,

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Secretary's Operations Center

U.S. Department of Health and Human Services (HHS)
Assistant Secretary for Preparedness and Response (ASPR)
200 Independence Ave. S.W.
Washington D.C. 20201
Office (202) 619-7800
Fax: 800-514-4256
Email: hhs.soc@hhs.gov

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Recipient:	OS Secretarys Operations Center </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=32b1f28d808b43b6903c00083291303e-Secretarys>
Sent Date:	2020/03/05 20:22:10
Delivered Date:	2020/03/05 20:22:13
Message Flags:	Unread

From:	OS Secretarys Operations Center </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=32B1F28D808B43B6903C00083291303E-SECRETARYS>
To:	OS Secretarys Operations Center </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=32b1f28d808b43b6903c00083291303e-Secretarys>
Subject:	Summary: Maryland State Three Presumptive Positive COVID-19 Cases
Date:	2020/03/05 20:22:13
Priority:	Normal
Type:	Note

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The SOC will continue to monitor this incident and report as needed. *This notification is limited distribution and is intended for HHS Senior Leadership Only. **DO NOT FORWARD.** This notification was sent to the COVID-19 Senior Leadership distribution list.*

Very Respectfully,

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Secretary's Operations Center

U.S. Department of Health and Human Services (HHS)
Assistant Secretary for Preparedness and Response (ASPR)
200 Independence Ave. S.W.
Washington D.C. 20201
Office (202) 619-7800
Fax: 800-514-4256
Email: hhs.soc@hhs.gov

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Recipient:	OS Secretarys Operations Center </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=32b1f28d808b43b6903c00083291303e-Secretarys>
Sent Date:	2020/03/05 20:22:10
Delivered Date:	2020/03/05 20:22:13

From:	White House: Office of the Vice President <info@mail.whitehouse.gov>
To:	Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd. (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>
Subject:	UPDATED VP DAILY GUIDANCE AND PRESS SCHEDULE FOR THURSDAY, MARCH 5, 2020
Date:	2020/03/05 20:33:08
Priority:	Normal
Type:	Note

-->



The White House

Office of the Vice President

FOR IMMEDIATE RELEASE

March 5, 2020

DAILY GUIDANCE AND PRESS SCHEDULE FOR THURSDAY MARCH 5, 2020

UPDATE: THE VICE PRESIDENT will participate in a press briefing at 5:45PM PST.

Pool Coverage

TV: Fox News

Print: WSJ

Wires: AP, Reuters, Bloomberg

EST

9:40 AM THE VICE PRESIDENT departs Washington, D.C. en route to Minneapolis, MN on Air Force Two

Joint Base Andrews

Pool Press

CST

11:15 AM THE VICE PRESIDENT arrives in Minneapolis, MN on Air Force Two

Minneapolis-St. Paul International Airport

Pre-Credentialed Press

12:00 PM THE VICE PRESIDENT meets with Mike Roman, Chairman and CEO of 3M

3M Innovation Center

Press Spray

1:45 PM THE VICE PRESIDENT departs Minneapolis, MN en route to Tacoma, WA on Air Force Two

Minneapolis-St. Paul International Airport

Pool Press

2:30 PM THE VICE PRESIDENT leads a White House Coronavirus Task Force conference call

Air Force Two

Closed Press

PST

3:15 PM THE VICE PRESIDENT arrives in Tacoma, WA on Air Force Two

McChord Field Airport

Pre-Credentialed Press

4:00 PM THE VICE PRESIDENT meets with Governor Jay Inslee, Governor of the State of Washington

State Emergency Operations Center

Press Spray

4:30 PM THE VICE PRESIDENT tours the State Emergency Operations Center

State Emergency Operations Center

Pool Press

5:45 PM THE VICE PRESIDENT participates in a press briefing with Governor Jay Inslee

Pierce County Readiness Center

Open Press

6:15 PM THE VICE PRESIDENT departs Tacoma, WA en route to Washington, D.C. on Air Force Two

McChord Field Airport

Pool Press

Friday, March 6, 2020

EST

1:40 AM THE VICE PRESIDENT arrives in Washington, D.C. on Air Force Two

Joint Base Andrews

Pool Press

###

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Sender: White House: Office of the Vice President <info@mail.whitehouse.gov>

Recipient:	Harrison, Brian (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>
Sent Date:	2020/03/05 20:31:56
Delivered Date:	2020/03/05 20:33:08

From:	McClune, Elizabeth (CDC/DDID/NCHHSTP/DVH) <ymt0@cdc.gov>
To:	Saha, Soumi <Soumi_Saha@premierinc.com>; Johnston, Darcie (HHS/IEA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6a8047840ca4406b5ac6bc5cf259937-Johnston, D>; Trueman, Laura (HHS/IEA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=99dcba4c6ea342c08d58f63e37d997e7-Trueman, La>; Beck, Gary (OS/IEA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a049f8137013412bbf472fc1833391be-Beck, Miche>; Waters, Cicely (OS/ASPR/OEA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00e638c4ddf64006bcc009e8032dd700-Waters, Cic>; Agler, Heather L (FDA/CDRH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8cf9dcfea71647b4b1e5735486d4f651-heather.agl>; Courtney, Brooke (FDA/OC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=435939b5eab748a989b326804d3437be-brooke.cour>; Ellis, Patricia (FDA/CDRH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c932cedfd47445fbb43c5d44998cb6bc-patricia.el>; Schwartz, Suzanne (FDA/CDRH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3bce62c458594ca8b15ecc04fe792094-suzanne.sch>; Ross, Aftin (FDA/CDRH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b804cc329cd34526b0a96646e110c493-aftin.ross.>; CDRH All Hazards Readiness Response and Cybersecurity <cdrharc@fda.hhs.gov>; Kannan, Lakshmi (FDA/CDRH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e1f4831b8694cc9b37b79bf9dba8169-lakshmi.kan>; Marders, Julia A (FDA/CDRH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb773cf0c4fd4025b6ca42cb032e3d2f-julia.marde>; Ricci, Linda J (FDA/CDRH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=be15b0fc5cd84cd89250e2b621bae7b3-lindaj.shoe>; Saltman, Adam (FDA/CDRH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6ad50d8fb21e421a85eb317ba610fe05-adam.saltma>; Deviceshortages <Deviceshortages@fda.hhs.gov>; Hazlett, Tosia C (FDA/CDRH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b04533bd31b404482e232380bcf0da1-tosia.hazle>; Krueger, Carol L (FDA/CDRH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d622b34312314c16a6afba84870539ad-carol.krueg>; CDC IMS State Coordination Task Force (SCTF) MCCM LNO <eocscfmcclno@cdc.gov>; Sunshine, Brittany J. (CDC/DDID/NCEZID/DPEI) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=664b148383f43ada9a8332ee9a784b8-brittany.su>; CDC IMS State Coordination Task Force (SCTF) Operations <eocscfops@cdc.gov>; Cantrell, Russell (CDC/DDPHSIS/CSTLTS/DPIFS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ef12ead7aa44ef9b07a5d5f8631bca6-Cantrell, R>; Gold, Rebecca (CDC/DDID/NCEZID/OD) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b8e0097bb1244308fd117ed7e46355d-Gold, Rebec>; Dowell, Chad (CDC/NIOSH/OD) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d0ccf610a94848f29ce046698e903f4c-Dowell, Cha>; Delaney, Lisa (CDC/NIOSH/OD) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58091a23f0c045eab2fa7446eb43bcb7-Delaney, Li>; Wolf, Laura (OS/ASPR/SIIM) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userb232d38c>; Christl, Thomas (OS/ASPR/SIIM) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f4ff7673b404ee289efb5329c319e90-Christl, Th>; Carlson, Craig (OS/ASPR/ICC/SIIM) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c86ecf95d0a41148f19ba99dfddeee7-Carlson, Cr>; Heartsfield, Bryan Keith (CDC/SNS/DSNS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2a2a168f00d4ba3ae7cf2823b00949d-bryan.heart>; Ottem, Ronald (Ron) (CDC/SNS/DSNS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1aedd8f312d94f81b2449b3d9ceb4add-Ottem, Rona>; Kadlec, Robert (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a182eda693d040d3832bae6efcf7a255-Kadlec, Rob>
CC:	Powell, Chaun <Chaun_Powell@premierinc.com>; Childs, Blair <Blair_Childs@PremierInc.com>
Subject:	RE: Premier Data Re PPE Allocations
Date:	2020/03/05 21:00:47
Priority:	Normal

Type: Note

Thank you Soumi,

We sincerely appreciate this information and your continued collaboration and partnership.

Liz

From: Saha, Soumi <Soumi_Saha@premierinc.com>

Sent: Thursday, March 5, 2020 12:05 PM

To: Johnston, Darcie (HHS/IEA) <Darcie.Johnston@hhs.gov>; Trueman, Laura (HHS/IEA) <Laura.Trueman@hhs.gov>; Beck, Gary (OS/IEA) <Gary.Beck@hhs.gov>; Waters, Cicely (OS/ASPR/OEA) <Cicely.Waters@hhs.gov>; Agler, Heather L (FDA/CDRH) <Heather.Agler@fda.hhs.gov>; Courtney, Brooke (FDA/OC) <Brooke.Courtney@fda.hhs.gov>; Ellis, Patricia (FDA/CDRH) <Patricia.Ellis@fda.hhs.gov>; Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Ross, Aftin (FDA/CDRH) <Aftin.Ross@fda.hhs.gov>; CDRH All Hazards Readiness Response and Cybersecurity <cdrharc@fda.hhs.gov>; Kannan, Lakshmi (FDA/CDRH) <Lakshmi.Kannan@fda.hhs.gov>; Marders, Julia A (FDA/CDRH) <Julia.Marders@fda.hhs.gov>; Ricci, Linda J (FDA/CDRH) <Linda.Ricci@fda.hhs.gov>; Saltman, Adam (FDA/CDRH) <Adam.Saltman@fda.hhs.gov>; Deviceshortages <Deviceshortages@fda.hhs.gov>; Hazlett, Tosia C (FDA/CDRH) <Tosia.Hazlett@fda.hhs.gov>; Krueger, Carol L (FDA/CDRH) <Carol.Krueger@fda.hhs.gov>; CDC IMS State Coordination Task Force (SCTF) MCCM LNO <eocsctfmccmlno@cdc.gov>; Sunshine, Brittany J. (CDC/DDID/NCEZID/DPEI) <ymz6@cdc.gov>; CDC IMS State Coordination Task Force (SCTF) Operations <eocsctfops@cdc.gov>; Cantrell, Russell (CDC/DDPHSIS/CSTLTS/DPIFS) <rbc5@cdc.gov>; McClune, Elizabeth (CDC/DDID/NCHHSTP/DVH) <ymt0@cdc.gov>; Gold, Rebecca (CDC/DDID/NCEZID/OD) <gsy7@cdc.gov>; Dowell, Chad (CDC/NIOSH/OD) <crd7@cdc.gov>; Delaney, Lisa (CDC/NIOSH/OD) <lkd2@cdc.gov>; Wolf, Laura (OS/ASPR/SIIM) <Laura.Wolf@hhs.gov>; Christl, Thomas (OS/ASPR/SIIM) <Thomas.Christl@hhs.gov>; Carlson, Craig (OS/ASPR/ICC/SIIM) <Craig.Carlson@hhs.gov>; Heartsfield, Bryan Keith (CDC/SNS/DSNS) <yji0@cdc.gov>; Ottem, Ronald (Ron) (CDC/SNS/DSNS) <rco9@cdc.gov>; Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>

Cc: Powell, Chaun <Chaun_Powell@premierinc.com>; Childs, Blair <Blair_Childs@PremierInc.com>

Subject: Premier Data Re PPE Allocations

CDC, ASPR, and FDA Teams,

In our ongoing effort to keep you abreast of supply chain threats as we all work together to ensure preparedness for COVID-19, we wanted to share some new data points. Premier has a unique perspective given that we work with such a large footprint in healthcare and can see more holistically what is happening across the supply chain.

As of this morning, there are 616 unique products that are on national allocation across 8 product categories of PPE. These categories include:

1. • Infection Control Apparel Gowns
 - a. • AAMI Level 1 Iso Gowns
 - b. • AAMI Level 2 Iso Gowns
 - c. • AAMI Level 3 Iso Gowns

2. • Surgical Gowns
 - a. • Non Sterile
 - b. • Sterile
 - i. AAMI Level 3 Gowns
 - ii. AAMI Level 4 Gowns
3. • Caps
4. • Shoe Covers
5. • Exam Gloves
6. • N95's
7. • Surgical Masks
 - a. • ASTM Level 1 Procedure Masks
 - b. • ASTM Level 1 Surgical Masks
 - c. • ASTM Level 3 Procedure Masks
 - d. • ASTM Level 3 Surgical Masks
8. • Face Shields & Eyewear

This level of allocation is unprecedented as we have never seen these levels of allocation before – this includes during natural disasters such as hurricanes or earthquakes as well as prior pandemics such as H1N1 or Ebola. If it is useful, we can supply specific SKUs on the product categories on allocation.

In addition, as of yesterday, we started seeing national allocations on the drug supply chain as well. There are now allocations placed on IV fluids and antiviral therapies.

This new data, coupled with Premier's [survey](#) that found that hospitals are only receiving 44% of PPE ordered, demonstrates that there is alarming strain on the supply chain.

We also know that there are several compounding factors that may place additional strain on the supply chain such as manufacturing facilities in China remaining closed beyond March 10th, additional export bans from other countries, quality and manufacturing issues that may take facilities offline such as what we saw with Cardinal surgical gowns earlier in the year, additional EtO facilities being shut down, and more.

We wanted to proactively share this information with you and understand 1) is the government aware of the magnitude of these supply chain pressures; 2) what is the government doing to prepare for a surge in demand should COVID-19 rapidly expand; and 3) are all of these products on the priority, ramp-up production list?

We continue to monitor the supply chain very holistically and continue to offer ourselves as a resource to you and the Administration's Coronavirus Task Force. We have immediate communication capability to thousands of hospitals and non-acute care sites of care. Please feel free to reach out with questions at any time and please continue to let us know how we can work together.

Thank you!

Soumi Saha, PharmD, JD
Senior Director of Advocacy
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Sender:	McClune, Elizabeth (CDC/DDID/NCHHSTP/DVH) <ymt0@cdc.gov>
Recipient:	Saha, Soumi <Soumi_Saha@premierinc.com>; Johnston, Darcie (HHS/IEA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6a8047840ca4406b5ac6bc5cf259937-Johnston, D>; Trueman, Laura (HHS/IEA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=99dcb4c6ea342c08d58f63e37d997e7-Trueman, La>; Beck, Gary (OS/IEA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a049f8137013412bbf472fc1833391be-Beck, Miche>; Waters, Cicely (OS/ASPR/OEA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00e638c4ddf64006bcc009e8032dd700-Waters, Cic>; Agler, Heather L (FDA/CDRH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8cf9dcfea71647b4b1e5735486d4f651-heather.agl>; Courtney, Brooke (FDA/OC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=435939b5eab748a989b326804d3437be-brooke.cour>; Ellis, Patricia (FDA/CDRH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c932cedfd47445fbb43c5d44998cb6bc-patricia.el>; Schwartz, Suzanne (FDA/CDRH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3bce62c458594ca8b15ecc04fe792094-suzanne.sch>; Ross, Aftin (FDA/CDRH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b804cc329cd34526b0a96646e110c493-aftin.ross.>; CDRH All Hazards Readiness Response and Cybersecurity <cdrharc@fda.hhs.gov>; Kannan, Lakshmi (FDA/CDRH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e1f4831b8694cc9b37b79bf9dba8169-lakshmi.kan>; Marders, Julia A (FDA/CDRH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb773cf0c4fd4025b6ca42cb032e3d2f-julia.marde>; Ricci, Linda J (FDA/CDRH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=be15b0fc5cd84cd89250e2b621bae7b3-lindaj.shoe>; Saltman, Adam (FDA/CDRH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6ad50d8fb21e421a85eb317ba610fe05-adam.saltma>; Deviceshortages <Deviceshortages@fda.hhs.gov>; Hazlett, Tosia C (FDA/CDRH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b04533bd31b404482e232380bcf0da1-tosia.hazle>; Krueger, Carol L (FDA/CDRH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d622b34312314c16a6afba84870539ad-carol.krueg>; CDC IMS State Coordination Task Force (SCTF) MCCM LNO <eocsctfmccmlno@cdc.gov>; Sunshine, Brittany J. (CDC/DDID/NCEZID/DPEI) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=664b1483838f43ada9a8332ee9a784b8-brittany.su>; CDC IMS State Coordination Task Force (SCTF) Operations <eocsctfops@cdc.gov>; Cantrell, Russell (CDC/DDPHSIS/CSTLTS/DPIFS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ef12ead7aa44ef9b07a5d5f8631bca6-Cantrell, R>; Gold, Rebecca (CDC/DDID/NCEZID/OD) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b8e0097bb1244308fd117ed7e46355d-Gold, Rebec>; Dowell, Chad (CDC/NIOSH/OD) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d0ccf610a94848f29ce046698e903f4c-Dowell, Cha>; Delaney, Lisa (CDC/NIOSH/OD) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58091a23f0c045eab2fa7446eb43bcb7-Delaney, Li>; Wolf, Laura (OS/ASPR/SIIM) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userb232d38c>; Christl, Thomas (OS/ASPR/SIIM) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f4ff7673b404ee289efb5329c319e90-Christl, Th>; Carlson, Craig (OS/ASPR/ICC/SIIM) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c86ecf95d0a41148f19ba99dfdddee7-Carlson, Cr>; Heartsfield, Bryan Keith (CDC/SNS/DSNS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2a2a168f00d4ba3ae7cf2823b00949d-bryan.heart>; Ottem, Ronald (Ron) (CDC/SNS/DSNS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1aedd8f312d94f81b2449b3d9ceb4add-Ottem, Rona>; Kadlec, Robert (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a182eda693d040d3832bae6efcf7a255-Kadlec, Rob>; Powell, Chaun <Chaun_Powell@premierinc.com>; Childs, Blair <Blair_Childs@PremierInc.com>
Sent Date:	2020/03/05 21:00:21

Delivered Date: 2020/03/05 21:00:47

From:	Clark Tibbs PhageVax-VHO <PhageVax@roadrunner.com>
To:	Balsamo, Ralph (OS/ASPR/BARDA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5154e90d1f17484293769cd43eb7447e-Balsamo, Ra>; Tegeris, John (OS/ASPR/BARDA) (CTR) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd48e9eb139645df8b45ea8439820e7f-Tegeris, Jo>; Armstrong, Kimberly (OS/ASPR/BARDA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5b778c7e17734740b14fbae4d3ed652c-Armstrong,>; Adams, Peter (OS/ASPR/BARDA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d68d0d59aeb425cbb0ea4a46a2b9365-Adams, Pete>; Erlandson, Karl (OS/ASPR/BARDA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f0ef5014c63481787389eb185da5e5f-Erlandson,>; Kadlec, Robert (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a182eda693d040d3832bae6efcf7a255-Kadlec, Rob>; Fauci, Anthony (NIH/NIAID) [E] </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=826965b24a314ffca7eddc6e8229aa7-anthony.fau>; Conrad, Patricia (NIH/NIAID) [E] </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3793ae43a1744d8f8aa56b600c0c975b-patricia.co>
Subject:	To ASPR-BARDA Ralph & John & Kim & Pete & Karl & Robert ... Update 3-5-20 ... (1) HHS work from home? ... (2) Dr. Evelina Angov ... (3) GE Wave 25 Plastic Bag Bioreactors
Date:	2020/03/05 21:05:17
Priority:	Normal
Type:	Note

Ralph Balsamo - Program Analyst
Office of the Director - Office of the Assistant Secretary for Preparedness and Response
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Peter Adams peter.adams@hhs.gov Karl Erlandson karl.erlandson@hhs.gov

(1)
I highly recommend that ALL HHS employees begin working from home NLT Monday, March 9th, 2020 ... until further notice.

Rationale: What will happen when the Top American medical-decision-makers get sick?
HHS Lab workers [PhDs on down] (home to work site and back) should begin using PPE ... without exception.

The new Coronavirus **COVID-19** ... can remain viable of surfaces for up to **8 to 9 days**.
Some victims may not show symptoms for up to **24 days+**

Some **COVID-19** Patients Test Positive DAYS AFTER Recovery [**5 to 13 days later**]
... have we learned anything from the PRC-model? Satellite pollution-registration shows many are back to work. We are no better.

Japan has shut down all of their schools for 1 month. We are no better.

-

(2)

I had a great conversation with Dr. Evelina Angov, with the Army today. We will talk again on Monday 3-9-20.

<https://www.ncbi.nlm.nih.gov/pubmed/?term=evelina+angov> She will stay on this all weekend, she said.

She is one of the best Codon Harmonization experts.

Remember that at least one person (during the WebEx) was asking about proper protein-folding of the epitope candidates?

Our company has worked with her in the past. I emailed most of what she will need to run some algorithms.

Her results can be synthesized and those substances will be the fusion-proteins that can be decorated onto the T-4 Phage heads at each of the 3 Phage Expert Team locations. Three locations for Redundancy of Personnel; for ConOps [Continuity of Operations] and Mass Manufacture using the **GE Wave 25 Plastic Bags** and/or other available Bioreactors. Any deviations will be noted.

-

(3) I write to our company's contacts at GE Life Sciences and asked for a quote for GE to obtain prompt certification from FDA for cGLP and cGMP ... if not already documented.

Respectfully, my cell phone is best with any questions.

Clark Tibbs, CEO

PhageVax, Inc. <https://protect2.fireeye.com/url?k=4f78b386-132dba95-4f7882b9-0cc47adb5650-9c46c5695484e721&u=http://www.phagevax.com/>

CAGE CODE: 4M4V6 www.sam.gov

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Subject:	Remarks by Vice President Pence and Governor Inslee Before a Roundtable Discussion Tacoma, WA
Date:	2020/03/05 21:18:00
Priority:	Normal
Type:	Note

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The White House

Office of the Vice President

FOR IMMEDIATE RELEASE

March 5, 2020

REMARKS BY VICE PRESIDENT PENCE
AND GOVERNOR INSLEE
BEFORE A ROUNDTABLE DISCUSSION

Pierce County Readiness Center
Tacoma, Washington

4:54 P.M. PST

GOVERNOR INSLEE: Mr. Vice President, thanks for being here. We appreciate you being

here. You've already done some things for our state, and we appreciate you. You brought an excellent team. They've already done some good things today.

THE VICE PRESIDENT: Thank you.

GOVERNOR INSLEE: So, thank you. I just want to introduce you to a couple people you may not have met: Mayor Durkan, of Seattle, who is joining us, who is going to have the best hockey franchise here shortly; King County Vice Chair of the Council, Reagan Dunn; and Bruce Dammeier, who is a Pierce County Executive.

And so we are very appreciative of you being here, and I hope you have just a couple comments for the group here.

THE VICE PRESIDENT: I do. Thank you, Governor Inslee, and thank you for greeting us. And I want to thank -- I just want to say thank you to your whole team here in the State of Washington.

The American people have watched with great concern as the coronavirus has taken hold in this community. Particularly, we think of the tragic loss of life. But the response of the State of Washington, of your Health Department, the response by the city of Seattle, Madam Mayor, and -- has really inspired the country. And the President wanted me to be here today just to make it crystal clear that we're with you. We're here to help.

I'm also grateful to be joined by so many members of the Washington delegation to our nation's capital, and I want to thank them for the swift and bipartisan efforts in moving the spending bill that the President will be signing tomorrow. It passed the Senate this afternoon. I think it represents the very best of -- of Washington, D.C. -- coming together, putting the health and wellbeing of the American people first. And it will make nearly \$8 billion available to not only federal agencies, but -- as you and I have discussed, Governor Inslee, it'll make resources available to state and local efforts as we confront the coronavirus as a nation.

So I look forward to our discussion and learning more about how our team at the White

House Task Force and all of our agencies can more effectively come alongside and support the efforts all across the Seattle area and here in the State of Washington.

And finally, Governor Inslee, thank you for your leadership in this moment in the life of your state. You and I served together for many years in Washington, D.C., but to see you bringing your experience serving in HHS early in your career, it's -- Washington State is setting a great example as states around the nation continue to experience the advent of the coronavirus in their communities.

We're going to continue to look to the example that you've set here and your health department has set here, and I want to thank you very much for your leadership.

GOVERNOR INSLEE: Thank you.

END 4:57 P.M. PST

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Delivered Date:	2020/03/05 21:18:00

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Subject:	Summary: Maryland State Three Presumptive Positive COVID-19 Cases Update
Date:	2020/03/05 21:52:32
Priority:	Normal
Type:	Note

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Good evening Dr. Kadlec,

BLUF: Three presumptive positives COVID-19 cases have been reported in the State of Maryland.

- Maryland Governor Larry Hogan declared a State of Emergency in Maryland in response to COVID-19.
- The three presumptive positive COVID-19 cases are all residents of Montgomery County, Maryland.
- The Montgomery County residents are a male and female couple in their 70's and another unrelated male in his 50's.
- The patients are suspected of contracting COVID-19 due to previous travel, the potential locations of the international travel have not been disclosed.
- CDC EOC cannot confirm these cases at this time.

The SOC will continue to monitor this incident and report as needed. *This notification is limited distribution and is intended for HHS Senior Leadership Only. **DO NOT FORWARD.** This notification was sent to the COVID-19 Senior Leadership distribution list.*

Very Respectfully,

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Secretary's Operations Center

U.S. Department of Health and Human Services (HHS)
Assistant Secretary for Preparedness and Response (ASPR)
200 Independence Ave. S.W.
Washington D.C. 20201
Office (202) 619-7800
Fax: 800-514-4256
Email: hhs.soc@hhs.gov



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From:	OS Secretarys Operations Center </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=32B1F28D808B43B6903C00083291303E-SECRETARYS>
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Sent Date:	2020/03/05 21:52:30
Delivered Date:	2020/03/05 21:52:32
Message Flags:	Unread

From:	Cohen, Mandy <Mandy.Cohen@dhhs.nc.gov>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>; Johnston, Darcie (HHS/IEA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6a8047840ca4406b5ac6bc5cf259937-Johnston, D>
CC:	Hahn, Stephen (FDA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0666f41e4514dd3b294a23789487280-stephen.hah>; 'jose.montero@cdc.hhs.gov' <jose.montero@cdc.hhs.gov>; 'robert.redfield@cdc.hhs.gov' <robert.redfield@cdc.hhs.gov>; 'anthony.fauci@cdc.hhs.gov' <anthony.fauci@cdc.hhs.gov>
Subject:	Concerns re COVID-19 laboratory supplies
Date:	2020/03/05 21:59:11
Priority:	Normal
Type:	Note

Secretary Azar and,

Please see my attached letter of concern. My team and I look forward to your further guidance.

Thank you,
Mandy Cohen

Mandy Cohen, MD, MPH

Secretary

North Carolina Department of Health and Human Services

Office: 919-855-4810

mandy.cohen@dhhs.nc.gov

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Sent Date:	2020/03/05 21:57:45
Delivered Date:	2020/03/05 21:59:11

From:	Kadlec, Robert (OS/ASPR/IO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A182EDA693D040D3832BAE6EFCF7A255-KADLEC, ROB>
SentVia:	Ford-Barnes, Arwenhthia (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d533abc24cbe44b79f6fddc6b08737a6-Ford-Barnes>
To:	Kadlec, Robert (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a182eda693d040d3832bae6efcf7a255-Kadlec, Rob>; <khussey@akingump.com>; Shuy, Bryan (OS/ASPR/IO) (Bryan.Shuy@hhs.gov) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdeb5ca04b6b4ed19fec2209b5f571e7-Shuy, Bryan>; Waters, Cicely (OS/ASPR/IO) (Cicely.Waters@hhs.gov) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00e638c4ddf64006bcc009e8032dd700-Waters, Cic>; Hassell, David (OS/ASPR/IO) (David.Hassell@hhs.gov) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aedbf0ff96e4119ac7a3b3abaf71a3d-Hassell, Da>; Callahan, Victoria (OS/ASPR/IO) (CTR) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95162cb185624a6ebe5fadf08484c141-Callanhan,>; Sauer, Michael (OS/ASPR) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc2ae02156624623b24d3a400f592229-Sauer, Mich>; <hbajnrauh@akingump.com>; Austin, Meredith (uscg.mil) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9d5f9850a051458eae1ef58335e3c19-Meredith.L.>; Ford-Barnes, Arwenhthia (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d533abc24cbe44b79f6fddc6b08737a6-Ford-Barnes>; Wolf, Laura (OS/ASPR/SIIM) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userb232d38c>; Sally Phillips (Sally.Phillips@hhs.gov) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d6ce8134846423cb83b5b28464edb60-Phillips, S>
Subject:	Honeywell re: COVID19
Date:	2020/03/05 21:58:26
Start Date:	2020/03/06 10:20:00
End Date:	2020/03/06 10:50:00
Priority:	Normal
Type:	Appointment
Location:	Dr. Robert Kadlec's Office - DHHS 200 Independence Ave, SW, Washington DC 20201 - (at the corner of Independence Ave and 3rd SW)

Please have your assistant send me the following by 10:00am tomorrow morning:

- Agenda
- Bios/and company summary of each of principals attending
- Slide deck/hand out material for your presentation

Arwenhthia Ford-Barnes

Executive Assistant to the ASPR | *Dr. Robert Kadlec*

Office: (202) 205-8905 Mobile: (b)(6)

Email: Arwenhthia.FordBarnes@hhs.gov

From: Hussey, Kendall <khussey@akingump.com>

Sent: Thursday, March 5, 2020 10:35 AM

To: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>

Cc: Bajnrauh, Heide <hbajnrauh@akingump.com>

Subject: Meeting request - Honeywell re: COVID19

Dr. Bob! and Bryan,

I hope you both are well – thank you for all you are doing, I can imagine it's incredibly overwhelming, but I greatly appreciate your hard work to keep everyone healthy and safe. Bryan, Dr. Bob was my direct boss on the HELP Committee's Bioterrorism and Public Health Preparedness Subcommittee years ago, when Sen. Richard Burr was the Chairman of the Subcommittee. Governor Tommy Thompson, our Akin Gump colleague, recommended that we reach out to you.

I am submitting a meeting request on behalf of our client – Honeywell, a leading manufacturer and supplier of personal protective equipment (PPE), including respirators. We understand that the federal government and Congress is doing all it can to ensure it is prepared in light of the coronavirus epidemic. To be helpful, we would appreciate the opportunity to meet with you to discuss how Honeywell can be a front line resource to support the public health response.

As this is a timely issue, we are available to meet **tomorrow, Friday, March 6th** if this works for your schedules.

You will be meeting with the following individuals:

- Will Lang, President, Honeywell PPE
- Brian Hovey, Chief Marketing Officer, Honeywell PPE
- Romina Khananisho, VP Global Government Relations
- Ben Nicholson, VP Global Government Relations
- Romina Khananisho, Vice President, Global Government Relations

Thank you for your consideration of this request. Please let me know if you have any questions!

Best,
Kendall

Kendall B. Hussey | Policy Advisor

AKIN GUMP STRAUSS HAUER & FELD LLP

2001 K Street N.W. | Washington, DC 20006 | USA | Direct: [+1 202.416.5207](tel:+12024165207) | Internal: [25207](tel:+12024165207)

Fax: [+1 202.887.4288](tel:+12028874288) | khussey@akingump.com | akingump.com | [Bio](#)

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	Hassell, Da>; Callahan, Victoria (OS/ASPR/IO) (CTR) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95162cb185624a6ebe5fadf08484c141-Callanhan,>; Sauer, Michael (OS/ASPR) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc2ae02156624623b24d3a400f592229-Sauer, Mich>; <hbajnrauh@akingump.com>; Austin, Meredith (uscg.mil) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9d5f9850a051458eaeed1ef58335e3c19-Meredith.L.>; Ford-Barnes, Arwenhithia (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d533abc24cbe44b79f6fddc6b08737a6-Ford-Barnes>; Wolf, Laura (OS/ASPR/SIIM) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userb232d38c>; Sally Phillips (Sally.Phillips@hhs.gov) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d6ce8134846423cb83b5b28464edb60-Phillips, S>
Sent Date:	2020/03/05 21:58:26

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Subject:	Honeywell re: COVID19
Date:	2020/03/05 21:58:26
Start Date:	2020/03/06 13:30:00
End Date:	2020/03/06 14:00:00
Priority:	Normal
Type:	Appointment
Location:	Dr. Robert Kadlec's Office - DHHS 200 Independence Ave, SW, Washington DC 20201 - (at the corner of Independence Ave and 3rd SW)

Please send bios/agenda items for discussion – if you anticipate a slide deck I must receive it by 11:00am – please send them to me at your earliest.

Arwenhthia Ford-Barnes

Executive Assistant to the ASPR | *Dr. Robert Kadlec*

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Email: Arwenhthia.FordBarnes@hhs.gov

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Kendall B. Hussey | Policy Advisor

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Subject:	CMS Develops Additional Code for Coronavirus Lab Tests
Date:	2020/03/05 22:35:29
Priority:	Normal
Type:	Note

CMS Develops Additional Code for Coronavirus Lab Tests

Mar 05, 2020

• Coding • Clinical labs

Agency Issues Fact Sheets Detailing Coverage under Programs

Today, the Centers for Medicare & Medicaid Services (CMS) took additional actions to ensure America's patients, healthcare facilities and clinical laboratories are prepared to respond to the 2019-Novel Coronavirus (COVID-19).

CMS has developed a second Healthcare Common Procedure Coding System (HCPCS) code that can be used by laboratories to bill for certain COVID-19 diagnostic tests to help increase testing and track new cases. In addition, CMS released new fact sheets that explain Medicare, Medicaid, Children's Health Insurance Program, and

Individual and Small Group Market Private Insurance coverage for services to help patients prepare as well.

“CMS continues to leverage every tool at our disposal in responding to COVID-19,” said CMS Administrator Seema Verma. “Our new code will help encourage doctors and laboratories to use these essential tests for patients who need them. At the same time, we are providing critical information to our 130 million beneficiaries, many of whom are understandably wondering what will be covered when it comes to this virus. CMS will continue to devote every available resource to this effort, as we cooperate with other government agencies to keep the American people safe.”

HCPCS is a standardized coding system that Medicare and other health insurers use to submit claims for services provided to patients. Last month, CMS developed the first HCPCS code (U0001) to bill for tests and track new cases of the virus. This code is used specifically for CDC testing laboratories to test patients for SARS-CoV-2. The second HCPCS billing code (U0002) announced today allows laboratories to bill for non-CDC laboratory tests for SARS-CoV-2/2019-nCoV (COVID-19). On February 29, 2020, the Food and Drug Administration (FDA) issued a new, streamlined policy for certain laboratories to develop their own validated COVID-19 diagnostics. This second HCPCS code may be used for tests developed by these additional laboratories when submitting claims to Medicare or health insurers. CMS expects that having specific codes for these tests will encourage testing and improve tracking.

The Medicare claims processing systems will be able to accept these codes starting on April 1, 2020, for dates of service on or after February 4, 2020. Local Medicare Administrative Contractors (MACs) are responsible for developing the payment amount for claims they receive for these newly created HCPCS codes in their respective jurisdictions until Medicare establishes national payment rates. Laboratories may seek guidance from their MAC on payment for these tests prior to billing for them. As with other laboratory tests, there is generally no beneficiary cost sharing under Original Medicare.

To ensure the public has clear information on coverage and benefits under CMS programs, the agency also released three fact sheets that cover diagnostic laboratory tests, immunizations and vaccines, telemedicine, drugs, and cost-sharing policies.

Medicare Fact Sheet Highlights: In addition to the diagnostic tests described above, Medicare covers all medically necessary hospitalizations, as well as brief “virtual check-ins,” which allows patients and their doctors to connect by phone or video chat.

Medicaid and Children’s Health Insurance Program (CHIP) Fact Sheet Highlights: Testing and diagnostic services are commonly covered services, and laboratory and x-ray services are a mandatory benefit covered and reimbursed in all states. States are required to provide both inpatient and outpatient hospital services to beneficiaries. All states provide coverage of hospital care for children and pregnant

women enrolled in CHIP. Specific questions on covered benefits should be directed to the respective state Medicaid and CHIP agency.

Individual and Small Group Market Insurance Coverage: Existing federal rules governing health insurance coverage, including with respect to viral infections, apply to the diagnosis and treatment of with Coronavirus (COVID-19). This includes plans purchased through [HealthCare.gov](https://www.healthcare.gov). Patients should contact their insurer to determine specific benefits and coverage policies. Benefit and coverage details may vary by state and by plan. States may choose to work with plans and issuers to determine the coverage and cost-sharing parameters for COVID-19 related diagnoses, treatments, equipment, telehealth and home health services, and other related costs.

Summary of CMS Public Health Action on COVID-19 to date:

On March 4, 2020, CMS issued a call to action to healthcare providers nationwide to ensure they are implementing longstanding infection control procedures and issued important guidance to help State Survey Agencies and Accrediting Organizations prioritize their inspections of healthcare facilities to focus exclusively on issues related to infection control and other serious health and safety threats. For more information on CMS actions to prepare for and respond to COVID-19, visit: <https://www.cms.gov/newsroom/press-releases/cms-announces-actions-address-spread-coronavirus>

On February 13, 2020, CMS issued a new HCPCS code for healthcare providers and laboratories to test patients for COVID-19 using the CDC-developed test. For more information about this code, visit: <https://www.cms.gov/newsroom/press-releases/public-health-news-alert-cms-develops-new-code-coronavirus-lab-test>

On February 6, 2020, CMS issued a memo to help the nation's healthcare facilities take critical steps to prepare for COVID-19. To view a copy of the memo and see more details, visit: <https://www.cms.gov/medicareprovider-enrollment-and-certificationsurvey/certificationgeninfo/policy-and-memos-states-and/information-healthcare-facilities-concerning-2019-novel-coronavirus-illness-2019-ncov>

On February 6, 2020, CMS also gave CLIA-certified laboratories information about how they can test for SARS-CoV-2. To read more about those efforts, visit: <https://www.cms.gov/medicareprovider-enrollment-and-certificationsurvey/certificationgeninfo/policy-and-memos-states-and/notification-surveyors-authorization-emergency-use-cdc-2019-novel-coronavirus-2019-ncov-real-time-rt>

For the updated information on the range of CMS activities to address COVID-19, visit: <https://www.cms.gov/About-CMS/Agency-Information/Emergency/EPRO/Current-Emergencies/Current-Emergencies-page>

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Sender:	Lemar, Naweed (OS/ASPA) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BDD222A2AC644600A7167233AF2271F8-LEMAR, NAWEE>
Recipient:	Billet, Courtney (NIH/NIAID) [E] </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb5c51123f2f41b98b61a37383994a8d-courtney.bi>; Bonds, Michelle E. (CDC/OD/OADC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=458a7c66b66a4e9ca7bc1963da0bcb81-michelle.bo>; Broido, Tara (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c3cd5c5afe049b6a8b48c25324c7465-Broido, Tar>; Brookes, Brady (CMS/OA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7a794d62ee454992a4268ae71690f3c1-BDI7>; Caliguiri, Laura (FDA/OC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40352e099c9a46dca3310df0ac5afd0e-laura.calig>; Ceballos, Kelly L. (CMS/OC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3fbfa09c7c634a7db7f1ead6ebca82d1-CQRF>; Conrad, Patricia (NIH/NIAID) [E] </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3793ae43a1744d8f8aa56b600c0c975b-patricia.co>; Galatas, Kate (CDC/OD/OADC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e6fa4be928e48408ba114add868123e-Galatas, Ka>; Giroir, Brett (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a56fce4755704c4ca031d621b46fd6f7-Girori, Bre>; Grigsby, Garrett (HHS/OS/OGA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7cd78b4810d44b17b8711aaede9a9023-Grigsby, Gl>; Harmon, Carrie E. (CDC/OD/OADC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2d702cd0aac4ff4bf7b8961805d3207-carolyn.har>; Harrison, Brian (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>; Heck, Mia (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70dbe2065d644b8dadbf56c5d63553d-Heck, Mia>; Heldman, Amy B. (CDC/OD/OADC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83a9fa86982a40238ae2f162b869ef39-Burnett, Am>; Imbriale, Samuel (OS/ASPR/SIIM) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7e54524>; Janik, Heather (FDA/OC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=04b3655a16034901a8719d871b0287cc-heather.jan>; Jenkins, Courtney (CMS/OC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=266d4cf0c71f464e87fd473cf82937b4-J3TB>; Johnston, Darcie (HHS/IEA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6a8047840ca4406b5ac6bc5cf259937-Johnston, D>; Kane, Elleen (OS/ASPR/OEA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user25dbd6c7>; Kerr, Lawrence (HHS/OS/OGA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8ce9de2e7497472bb758f8fd6e262c86-Kerr, Lawre>; Lepore, Loretta (CDC/OD/OCS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5089268744434ae3836b66685f37d8d4-loretta.lep>; LoPiccolo, Maria (CMS/OC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d2a5cb16f904b61afb2f723c1ce2b96-LJGC>; Mango, Paul (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d8863b643654b1aad9a38c952af613e-Mango, Paul>; McKeogh, Katherine (OS/ASPA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c652f2c415b44dff8369dd7f4596f030-McKeogh, Ka>;

McSeveney, Megan (FDA/OC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fadf614e90404f51b26d4ebc5b66b5e9-megan.mcsev>; Michael, Gretchen (OS/ASPR/OEA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0632b4526d6447b5af26552afde05c33-Michael, Gr>; Migliaccio-Grabill, Kate (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f902e34652a84a61ac85adaa853d80f6-Migliaccio,>; Monroe, Johnathan (CMS/OC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bac3634f930043efbc5ab5628376201f-MSGM>; Moughalian, Jen (HHS/ASFR) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1ec840c6a2d4adbbc91e420a23c7eaf-Moughalian,>; Murphy, Ryan (OS/ASPA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=314e69c69a844b47bdd9f74bc60a8d44-Murphy, Rya>; Oakley, Caitlin B. (OS/ASPA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e5ee4c35534c4af9bdac46789c034790-Oakley, Cai>; Pence, Laura (HHS/ASL) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d1027e80d2334093870fdb436c5576cd-Pence, Laur>; Pinson, Alexander (HHS/ASFR) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2bac2d04a0ca4d4fc87ca4d5e784d8fd4-Pinson, Ale>; Rebello, Heidi (FDA/OC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=97fe04738e9d4ad6bf21ae2f687dd211-heidi.rebel>; Robinson, Michael J (HHS/ASPA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user6f4e0ecd>; Sherman, Jennifer (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f30fe7fae664419fa654b20edccb1e78-Sherman, Je>; Shuy, Bryan (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdeb5ca04b6b4ed19fec2209b5f571e7-Shuy, Bryan>; Snyder, Elizabeth (fema.dhs.gov) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=69b06904775c40c0b3feef243384b50d-Elizabeth.S>; Stecker, Judy (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0280b227911b40b6b30a81b8574ede6b-Stecker, Ju>; Steele, Danielle (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38849c1f1ea74f2eb9eff75b531a9544-Steele, Dan>; Stover, Kathy (NIH/NIAID) [E] </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d2241aa54aa341ceb7ff993d88eba4df-kathy.stove>; Thornton, Cody R. (OS/ASPR/SIIM) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95c6126d2f9a4c1fb1174b59b0c3dc19-Thornton, C>; Trueman, Laura (HHS/IEA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=99dcb4c6ea342c08d58f63e37d997e7-Trueman, La>; Waters, Cicely (OS/ASPR/OEA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00e638c4ddf64006bcc009e8032dd700-Waters, Cic>; ASPA-Deputies </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=884d75c735db47cca76a4c0fc74a06b8-ASPA-Deputi>; Aldana, Karen (CMS/OC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d0464fed64d4ec9b8872aa4f78f5370-ASYX>; Arbes, Sarah (HHS/ASL) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=106db0ac70a241a8b1323647c093d9bf-Arbes, Sara>

Sent Date: 2020/03/05 22:35:28

Delivered Date: 2020/03/05 22:35:29

Message Flags: Unread

From:	Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd.YDIBOHF23SPDLT)/CN=RECIPIENTS/CN=314E69C69A844B47BDD9F74BC60A8D44-MURPHY, RYA>
To:	Stecker, Judy (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0280b227911b40b6b30a81b8574ede6b-Stecker, Ju>; McKeogh, Katherine (OS/ASPA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c652f2c415b44dff8369dd7f4596f030-McKeogh, Ka>
CC:	Arbes, Sarah (HHS/ASL) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=106db0ac70a241a8b1323647c093d9bf-Arbes, Sara>; Amin, Stacy (FDA/OC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8575c6e15e234834be21c0f7e315bddc-stacy.amin.>; Steele, Danielle (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38849c1f1ea74f2eb9eff75b531a9544-Steele, Dan>; Harrison, Brian (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>; Morse, Sara (HHS/ASL) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eb3a04f7dbde41049bfd10f490d3e178-Morse, Sara>; Pence, Laura (HHS/ASL) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d1027e80d2334093870fdb436c5576cd-Pence, Laur>; Charrow, Robert (HHS/OGC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00531138af454ce3ac0b5885bead345f-Charrow, Ro>; Lenihan, Keagan (FDA/OC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cd1b7aba9034ddb936017780583af7d-keagan.leni>; Hahn, Stephen <SH1@fda.hhs.gov>; Gross, Karas (FDA/OC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0196431bcda14a679c3f11d17b30a5ac-kara.gross.>
Subject:	RE: LDTs and EUAs -- privileged/deliberative
Date:	2020/03/05 22:37:26
Priority:	Normal
Type:	Note

I think so to. Can be provided as background.

From: Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov>
Sent: Thursday, March 5, 2020 10:35 PM
To: McKeogh, Katherine (OS/ASPA) <Katherine.McKeogh@hhs.gov>
Cc: Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; Arbes, Sarah (HHS/ASL) <Sarah.Arbes@hhs.gov>; Amin, Stacy (FDA/OC) <Stacy.Amin@fda.hhs.gov>; Steele, Danielle (HHS/IOS) <Danielle.Steele@hhs.gov>; Harrison, Brian (HHS/IOS) <Brian.Harrison@hhs.gov>; Morse, Sara (HHS/ASL) <Sara.Morse@hhs.gov>; Pence, Laura (HHS/ASL) <Laura.Pence@hhs.gov>; Charrow, Robert (HHS/OGC) <Robert.Charrow@hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Gross, Karas (FDA/OC) <Karas.Gross@fda.hhs.gov>
Subject: Re: LDTs and EUAs -- privileged/deliberative

I think we need to share.

Sent from my iPhone

On Mar 5, 2020, at 10:33 PM, McKeogh, Katherine (OS/ASPA) <Katherine.McKeogh@hhs.gov> wrote:

He's publishing at 3am so have to get back ASAP.

Katie McKeogh
Press Secretary
Office of the Assistant Secretary for Public Affairs
U.S. Department of Health and Human Services

On Mar 5, 2020, at 10:30 PM, Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>wrote:

(b)(5)

From: Arbes, Sarah (HHS/ASL) <Sarah.Arbes@hhs.gov>
Sent: Thursday, March 5, 2020 10:22 PM
To: Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; Amin, Stacy (FDA/OC) <Stacy.Amin@fda.hhs.gov>; Steele, Danielle (HHS/IOS) <Danielle.Steele@hhs.gov>; Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov>; Harrison, Brian (HHS/IOS) <Brian.Harrison@hhs.gov>; McKeogh, Katherine (OS/ASPA) <Katherine.McKeogh@hhs.gov>; Morse, Sara (HHS/ASL) <Sara.Morse@hhs.gov>; Pence, Laura (HHS/ASL) <Laura.Pence@hhs.gov>
Cc: Charrow, Robert (HHS/OGC) <Robert.Charrow@hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Gross, Karas (FDA/OC) <Karas.Gross@fda.hhs.gov>
Subject: RE: LDTs and EUAs -- privileged/deliberative

(b)(5)

From: Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>
Sent: Thursday, March 5, 2020 10:18 PM
To: Amin, Stacy (FDA/OC) <Stacy.Amin@fda.hhs.gov>; Steele, Danielle (HHS/IOS) <Danielle.Steele@hhs.gov>; Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov>; Harrison, Brian (HHS/IOS) <Brian.Harrison@hhs.gov>; McKeogh, Katherine (OS/ASPA) <Katherine.McKeogh@hhs.gov>; Morse, Sara (HHS/ASL) <Sara.Morse@hhs.gov>; Arbes, Sarah (HHS/ASL) <Sarah.Arbes@hhs.gov>; Pence, Laura (HHS/ASL) <Laura.Pence@hhs.gov>
Cc: Charrow, Robert (HHS/OGC) <Robert.Charrow@hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Gross, Karas (FDA/OC) <Karas.Gross@fda.hhs.gov>
Subject: RE: LDTs and EUAs -- privileged/deliberative

Hey Stacy – thank you so much for putting this together. (b)(5)

(b)(5)

(b)(5)

- Ryan

draft, pre-decisional, deliberative communication

From: Amin, Stacy <Stacy.Amin@fda.hhs.gov>

Sent: Thursday, March 5, 2020 9:59 PM

To: Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; Steele, Danielle (HHS/IOS) <Danielle.Steele@hhs.gov>; Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov>; Harrison, Brian (HHS/IOS) <Brian.Harrison@hhs.gov>; McKeogh, Katherine (OS/ASPA) <Katherine.McKeogh@hhs.gov>; Morse, Sara (HHS/ASL) <Sara.Morse@hhs.gov>; Arbes, Sarah (HHS/ASL) <Sarah.Arbes@hhs.gov>; Pence, Laura (HHS/ASL) <Laura.Pence@hhs.gov>

Cc: Charrow, Robert (HHS/OGC) <Robert.Charrow@hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Gross, Karas (FDA/OC) <Karas.Gross@fda.hhs.gov>

Subject: LDTs and EUAs -- privileged/deliberative

(b)(5)

(b)(5)

(b)(5)

(b)(5)

Stacy Cline Amin
Chief Counsel
Food and Drug Administration
Deputy General Counsel
Department of Health and Human Services

Sender:	Murphy, Ryan (OS/ASPA) </o=EXCHANGELABS/ou=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=314E69C69A844B47BDD9F74BC60A8D44-MURPHY, RYA>
Recipient:	Stecker, Judy (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0280b227911b40b6b30a81b8574ede6b-Stecker, Ju>; McKeogh, Katherine (OS/ASPA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c652f2c415b44dff8369dd7f4596f030-McKeogh, Ka>; Arbes, Sarah (HHS/ASL) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=106db0ac70a241a8b1323647c093d9bf-Arbes, Sara>; Amin, Stacy (FDA/OC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8575c6e15e234834be21c0f7e315bddc-stacy.amin.>; Steele, Danielle (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38849c1f1ea74f2eb9eff75b531a9544-Steele, Dan>; Harrison, Brian (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>; Morse, Sara (HHS/ASL) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eb3a04f7dbde41049bfd10f490d3e178-Morse, Sara>; Pence, Laura (HHS/ASL) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d1027e80d2334093870fdb436c5576cd-Pence, Laur>; Charrow, Robert (HHS/OGC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00531138af454ce3ac0b5885bead345f-Charrow, Ro>; Lenihan, Keagan (FDA/OC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cd1b7aba9034ddb936017780583af7d-keagan.leni>; Hahn, Stephen <SH1@fda.hhs.gov>; Gross, Karas (FDA/OC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0196431bcda14a679c3f11d17b30a5ac-kara.gross.>
Sent Date:	2020/03/05 22:37:25
Delivered Date:	2020/03/05 22:37:26
Message Flags:	Unread

From:	Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd.YDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0280B227911B40B6B30A81B8574EDE6B-STECKER, JU>
To:	McKeogh, Katherine (OS/ASPA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c652f2c415b44dff8369dd7f4596f030-McKeogh, Ka>
CC:	Amin, Stacy (FDA/OC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8575c6e15e234834be21c0f7e315bddc-stacy.amin.>; Murphy, Ryan (OS/ASPA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=314e69c69a844b47bdd9f74bc60a8d44-Murphy, Rya>; Arbes, Sarah (HHS/ASL) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=106db0ac70a241a8b1323647c093d9bf-Arbes, Sara>; Steele, Danielle (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38849c1f1ea74f2eb9eff75b531a9544-Steele, Dan>; Harrison, Brian (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>; Morse, Sara (HHS/ASL) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eb3a04f7dbde41049bfd10f490d3e178-Morse, Sara>; Pence, Laura (HHS/ASL) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d1027e80d2334093870fdb436c5576cd-Pence, Laur>; Charrow, Robert (HHS/OGC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00531138af454ce3ac0b5885bead345f-Charrow, Ro>; Lenihan, Keagan (FDA/OC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cd1b7aba9034ddb936017780583af7d-keagan.leni>; Hahn, Stephen <SH1@fda.hhs.gov>; Gross, Karas (FDA/OC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0196431bcda14a679c3f11d17b30a5ac-kara.gross.>
Subject:	Re: LDTs and EUAs -- privileged/deliberative
Date:	2020/03/05 22:37:30
Priority:	Normal
Type:	Note

Thank you.

Sent from my iPhone

On Mar 5, 2020, at 10:36 PM, McKeogh, Katherine (OS/ASPA) <Katherine.McKeogh@hhs.gov> wrote:

Understood. With Judy/Stacy/Ryan clearance, I will send this to Glenn.

Katie McKeogh
Press Secretary
Office of the Assistant Secretary for Public Affairs
U.S. Department of Health and Human Services

On Mar 5, 2020, at 10:35 PM, Amin, Stacy <Stacy.Amin@fda.hhs.gov> wrote:

(b)(5)

From: McKeogh, Katherine (OS/ASPA) <Katherine.McKeogh@hhs.gov>
Sent: Thursday, March 5, 2020 10:33 PM

To: Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>
Cc: Arbes, Sarah C (OS) <Sarah.Arbes@hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Steele, Danielle (OS) <Danielle.Steele@hhs.gov>; Stecker, Judy (OS) <Judy.Stecker@hhs.gov>; Harrison, Brian (OS) <Brian.Harrison@hhs.gov>; Morse, Sara N (OS) <Sara.Morse@hhs.gov>; Pence, Laura (OS) <Laura.Pence@hhs.gov>; Charrow, Robert (OS) <Robert.Charrow@hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>
Subject: Re: LDTs and EUAs -- privileged/deliberative

He's publishing at 3am so have to get back ASAP.

Katie McKeogh
Press Secretary
Office of the Assistant Secretary for Public Affairs
U.S. Department of Health and Human Services

On Mar 5, 2020, at 10:30 PM, Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov> wrote:

(b)(5)

From: Arbes, Sarah (HHS/ASL) <Sarah.Arbes@hhs.gov>
Sent: Thursday, March 5, 2020 10:22 PM
To: Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; Amin, Stacy (FDA/OC) <Stacy.Amin@fda.hhs.gov>; Steele, Danielle (HHS/IOS) <Danielle.Steele@hhs.gov>; Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov>; Harrison, Brian (HHS/IOS) <Brian.Harrison@hhs.gov>; McKeogh, Katherine (OS/ASPA) <Katherine.McKeogh@hhs.gov>; Morse, Sara (HHS/ASL) <Sara.Morse@hhs.gov>; Pence, Laura (HHS/ASL) <Laura.Pence@hhs.gov>
Cc: Charrow, Robert (HHS/OGC) <Robert.Charrow@hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Gross, Karas (FDA/OC) <Karas.Gross@fda.hhs.gov>
Subject: RE: LDTs and EUAs -- privileged/deliberative

(b)(5)

From: Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>
Sent: Thursday, March 5, 2020 10:18 PM
To: Amin, Stacy (FDA/OC) <Stacy.Amin@fda.hhs.gov>; Steele, Danielle (HHS/IOS) <Danielle.Steele@hhs.gov>; Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov>; Harrison, Brian (HHS/IOS) <Brian.Harrison@hhs.gov>; McKeogh, Katherine (OS/ASPA) <Katherine.McKeogh@hhs.gov>; Morse, Sara (HHS/ASL) <Sara.Morse@hhs.gov>; Arbes, Sarah (HHS/ASL) <Sarah.Arbes@hhs.gov>; Pence, Laura (HHS/ASL) <Laura.Pence@hhs.gov>

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Subject: RE: LDTs and EUAs -- privileged/deliberative

Hey Stacy – thank you so much for putting this together. (b)(5)

(b)(5)

- Ryan

draft, pre-decisional, deliberative communication

From: Amin, Stacy <Stacy.Amin@fda.hhs.gov>

Sent: Thursday, March 5, 2020 9:59 PM

To: Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; Steele, Danielle (HHS/IOS) <Danielle.Steele@hhs.gov>; Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov>; Harrison, Brian (HHS/IOS) <Brian.Harrison@hhs.gov>; McKeogh, Katherine (OS/ASPA) <Katherine.McKeogh@hhs.gov>; Morse, Sara (HHS/ASL) <Sara.Morse@hhs.gov>; Arbes, Sarah (HHS/ASL) <Sarah.Arbes@hhs.gov>; Pence, Laura (HHS/ASL) <Laura.Pence@hhs.gov>

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Subject: LDTs and EUAs -- privileged/deliberative

(b)(5)

(b)(5)

(b)(5)

(b)(5)

Stacy Cline Amin
Chief Counsel
Food and Drug Administration
Deputy General Counsel
Department of Health and Human Services

Sender:	Stecker, Judy (OS/IOS) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0280B227911B40B6B30A81B8574EDE6B-STECKER, JU>
Recipient:	McKeogh, Katherine (OS/ASPA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c652f2c415b44dff8369dd7f4596f030-McKeogh, Ka>; Amin, Stacy (FDA/OC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8575c6e15e234834be21c0f7e315bddc-stacy.amin.>; Murphy, Ryan (OS/ASPA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=314e69c69a844b47bdd9f74bc60a8d44-Murphy, Rya>; Arbes, Sarah (HHS/ASL) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=106db0ac70a241a8b1323647c093d9bf-Arbes, Sara>; Steele, Danielle (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38849c1f1ea74f2eb9eff75b531a9544-Steele, Dan>; Harrison, Brian (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>; Morse, Sara (HHS/ASL) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eb3a04f7dbde41049bfd10f490d3e178-Morse, Sara>; Pence, Laura (HHS/ASL) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d1027e80d2334093870fdb436c5576cd-Pence, Laur>; Charrow, Robert (HHS/OGC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00531138af454ce3ac0b5885bead345f-Charrow, Ro>; Lenihan, Keagan (FDA/OC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cd1b7aba9034ddb936017780583af7d-keagan.leni>; Hahn, Stephen <SH1@fda.hhs.gov>; Gross, Karas (FDA/OC) </o=ExchangeLabs/ou=Exchange Administrative Group

	(FYDIBOHF23SPDLT)/cn=Recipients/cn=0196431bcda14a679c3f11d17b30a5ac-kara.gross.>
Sent Date:	2020/03/05 22:37:30
Message Flags:	Unread

From:	Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd.OUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C652F2C415B44DFF8369DD7F4596F030-MCKEOGH, KA>
To:	Murphy, Ryan (OS/ASPA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=314e69c69a844b47bdd9f74bc60a8d44-Murphy, Rya>
CC:	Amin, Stacy (FDA/OC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8575c6e15e234834be21c0f7e315bddc-stacy.amin.>; Arbes, Sarah (HHS/ASL) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=106db0ac70a241a8b1323647c093d9bf-Arbes, Sara>; Steele, Danielle (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38849c1f1ea74f2eb9eff75b531a9544-Steele, Dan>; Stecker, Judy (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0280b227911b40b6b30a81b8574ede6b-Stecker, Ju>; Harrison, Brian (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>; Morse, Sara (HHS/ASL) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eb3a04f7dbde41049bfd10f490d3e178-Morse, Sara>; Pence, Laura (HHS/ASL) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d1027e80d2334093870fdb436c5576cd-Pence, Laur>; Charrow, Robert (HHS/OGC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00531138af454ce3ac0b5885bead345f-Charrow, Ro>; Lenihan, Keagan (FDA/OC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cd1b7aba9034ddb936017780583af7d-keagan.leni>; Hahn, Stephen <SH1@fda.hhs.gov>; Gross, Karas (FDA/OC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0196431bcda14a679c3f11d17b30a5ac-kara.gross.>
Subject:	Re: LDTs and EUAs -- privileged/deliberative
Date:	2020/03/05 22:40:27
Priority:	Normal
Type:	Note

Got it

Katie McKeogh
Press Secretary
Office of the Assistant Secretary for Public Affairs
U.S. Department of Health and Human Services

On Mar 5, 2020, at 10:40 PM, Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>wrote:

(b)(5)

From: McKeogh, Katherine (OS/ASPA) <Katherine.McKeogh@hhs.gov>
Sent: Thursday, March 5, 2020 10:38 PM
To: Amin, Stacy (FDA/OC) <Stacy.Amin@fda.hhs.gov>
Cc: Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; Arbes, Sarah (HHS/ASL) <Sarah.Arbes@hhs.gov>; Steele, Danielle (HHS/IOS) <Danielle.Steele@hhs.gov>; Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov>; Harrison, Brian (HHS/IOS) <Brian.Harrison@hhs.gov>; Morse, Sara (HHS/ASL) <Sara.Morse@hhs.gov>; Pence, Laura (HHS/ASL) <Laura.Pence@hhs.gov>; Charrow, Robert (HHS/OGC) <Robert.Charrow@hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Hahn, Stephen

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Subject: Re: LDTs and EUAs -- privileged/deliberative

(b)(5)

(b)(5)

Katie McKeogh
Press Secretary
Office of the Assistant Secretary for Public Affairs
U.S. Department of Health and Human Services

On Mar 5, 2020, at 10:36 PM, McKeogh, Katherine (OS/ASPA) <Katherine.McKeogh@hhs.gov>wrote:

Understood. With Judy/Stacy/Ryan clearance, I will send this to Glenn.

Katie McKeogh

Press Secretary
Office of the Assistant Secretary for Public Affairs
U.S. Department of Health and Human Services

On Mar 5, 2020, at 10:35 PM, Amin, Stacy <Stacy.Amin@fda.hhs.gov>wrote:

(b)(5)

From: McKeogh, Katherine (OS/ASPA) <Katherine.McKeogh@hhs.gov>
Sent: Thursday, March 5, 2020 10:33 PM
To: Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>
Cc: Arbes, Sarah C (OS) <Sarah.Arbes@hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Steele, Danielle (OS) <Danielle.Steele@hhs.gov>; Stecker, Judy (OS) <Judy.Stecker@hhs.gov>; Harrison, Brian (OS) <Brian.Harrison@hhs.gov>; Morse, Sara N (OS) <Sara.Morse@hhs.gov>; Pence, Laura (OS) <Laura.Pence@hhs.gov>; Charrow, Robert (OS) <Robert.Charrow@hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>
Subject: Re: LDTs and EUAs -- privileged/deliberative

He's publishing at 3am so have to get back ASAP.

Katie McKeogh
Press Secretary
Office of the Assistant Secretary for Public Affairs
U.S. Department of Health and Human Services

On Mar 5, 2020, at 10:30 PM, Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>wrote:

(b)(5)

From: Arbes, Sarah (HHS/ASL) <Sarah.Arbes@hhs.gov>
Sent: Thursday, March 5, 2020 10:22 PM
To: Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; Amin, Stacy (FDA/OC) <Stacy.Amin@fda.hhs.gov>; Steele, Danielle (HHS/IOS) <Danielle.Steele@hhs.gov>; Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov>; Harrison, Brian (HHS/IOS) <Brian.Harrison@hhs.gov>; McKeogh, Katherine (OS/ASPA) <Katherine.McKeogh@hhs.gov>; Morse, Sara (HHS/ASL) <Sara.Morse@hhs.gov>; Pence, Laura (HHS/ASL) <Laura.Pence@hhs.gov>
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Subject: RE: LDTs and EUAs -- privileged/deliberative

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Sent: Thursday, March 5, 2020 10:18 PM

To: Amin, Stacy (FDA/OC) <Stacy.Amin@fda.hhs.gov>; Steele, Danielle (HHS/IOS)
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<Brian.Harrison@hhs.gov>; McKeogh, Katherine (OS/ASPA) <Katherine.McKeogh@hhs.gov>; Morse,
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Subject: RE: LDTs and EUAs -- privileged/deliberative

Hey Stacy – thank you so much for putting this together. (b)(5)

(b)(5)

- Ryan

draft, pre-decisional, deliberative communication

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<Karas.Gross@fda.hhs.gov>

Subject: LDTs and EUAs -- privileged/deliberative

(b)(5)

Stacy Cline Amin
Chief Counsel
Food and Drug Administration
Deputy General Counsel
Department of Health and Human Services

Sender:	McKeogh, Katherine (OS/ASPA) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C652F2C415B44DFF8369DD7F4596F030-MCKEOGH, KA>
Recipient:	Murphy, Ryan (OS/ASPA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=314e69c69a844b47bdd9f74bc60a8d44-Murphy, Rya>; Amin, Stacy (FDA/OC) </o=ExchangeLabs/ou=Exchange Administrative Group

	(FYDIBOHF23SPDLT)/cn=Recipients/cn=8575c6e15e234834be21c0f7e315bddc-stacy.amin.>; Arbes, Sarah (HHS/ASL) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=106db0ac70a241a8b1323647c093d9bf-Arbes, Sara>; Steele, Danielle (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38849c1f1ea74f2eb9eff75b531a9544-Steele, Dan>; Stecker, Judy (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0280b227911b40b6b30a81b8574ede6b-Stecker, Ju>; Harrison, Brian (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>; Morse, Sara (HHS/ASL) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eb3a04f7dbde41049bfd10f490d3e178-Morse, Sara>; Pence, Laura (HHS/ASL) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d1027e80d2334093870fdb436c5576cd-Pence, Laur>; Charrow, Robert (HHS/OGC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00531138af454ce3ac0b5885bead345f-Charrow, Ro>; Lenihan, Keagan (FDA/OC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cd1b7aba9034ddb936017780583af7d-keagan.leni>; Hahn, Stephen <SH1@fda.hhs.gov>; Gross, Karas (FDA/OC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0196431bcd14a679c3f11d17b30a5ac-kara.gross.>
Sent Date:	2020/03/05 22:40:25
Delivered Date:	2020/03/05 22:40:27

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To:	Amin, Stacy (FDA/OC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8575c6e15e234834be21c0f7e315bddc-stacy.amin.>; Murphy, Ryan (OS/ASPA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=314e69c69a844b47bdd9f74bc60a8d44-Murphy, Rya>
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Subject:	RE: LDTs and EUAs -- privileged/deliberative
Date:	2020/03/05 23:05:34
Priority:	Normal
Type:	Note

(b)(5)

From: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Sent: Thursday, March 5, 2020 11:04 PM
To: McKeogh, Katherine (OS/ASPA) <Katherine.McKeogh@hhs.gov>; Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>
Cc: Arbes, Sarah (HHS/ASL) <Sarah.Arbes@hhs.gov>; Steele, Danielle (HHS/IOS) <Danielle.Steele@hhs.gov>; Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov>; Harrison, Brian (HHS/IOS) <Brian.Harrison@hhs.gov>; Morse, Sara (HHS/ASL) <Sara.Morse@hhs.gov>; Pence, Laura (HHS/ASL) <Laura.Pence@hhs.gov>; Charrow, Robert (HHS/OGC) <Robert.Charrow@hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Gross, Karas (FDA/OC) <Karas.Gross@fda.hhs.gov>
Subject: RE: LDTs and EUAs -- privileged/deliberative

(b)(5)

From: McKeogh, Katherine (OS/ASPA) <Katherine.McKeogh@hhs.gov>

Sent: Thursday, March 5, 2020 10:57 PM

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

Cc: Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Arbes, Sarah C (OS) <Sarah.Arbes@hhs.gov>; Steele, Danielle (OS) <Danielle.Steele@hhs.gov>; Stecker, Judy (OS) <Judy.Stecker@hhs.gov>; Harrison, Brian (OS) <Brian.Harrison@hhs.gov>; Morse, Sara N (OS) <Sara.Morse@hhs.gov>; Pence, Laura (OS) <Laura.Pence@hhs.gov>; Charrow, Robert (OS) <Robert.Charrow@hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>

Subject: Re: LDTs and EUAs -- privileged/deliberative

Follow up:

Thanks, got this. Will add some language though in my article, I already note the EUA letters vis a vis Zika but from what I determined the FDA did not stop the hospitals from conducting the tests and in one case has misunderstood what was on a lab website. And there was nothing -- ie, no Obama rule -- that prevented the administration from acting sooner on EUAs. I'm glad we've clarified that the LDT draft guidance was not an issue

Katie McKeogh
Press Secretary
Office of the Assistant Secretary for Public Affairs
U.S. Department of Health and Human Services

On Mar 5, 2020, at 10:40 PM, Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov> wrote:

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Katie McKeogh
Press Secretary
Office of the Assistant Secretary for Public Affairs
U.S. Department of Health and Human Services

On Mar 5, 2020, at 10:36 PM, McKeogh, Katherine (OS/ASPA) <Katherine.McKeogh@hhs.gov>wrote:

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Katie McKeogh
Press Secretary
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U.S. Department of Health and Human Services

On Mar 5, 2020, at 10:35 PM, Amin, Stacy <Stacy.Amin@fda.hhs.gov>wrote:

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Sent: Thursday, March 5, 2020 10:33 PM

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

Cc: Arbes, Sarah C (OS) <Sarah.Arbes@hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Steele, Danielle (OS) <Danielle.Steele@hhs.gov>; Stecker, Judy (OS) <Judy.Stecker@hhs.gov>; Harrison, Brian (OS) <Brian.Harrison@hhs.gov>; Morse, Sara N (OS) <Sara.Morse@hhs.gov>; Pence, Laura (OS) <Laura.Pence@hhs.gov>; Charrow, Robert (OS) <Robert.Charrow@hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>

Subject: Re: LDTs and EUAs -- privileged/deliberative

He's publishing at 3am so have to get back ASAP.

Katie McKeogh
Press Secretary
Office of the Assistant Secretary for Public Affairs
U.S. Department of Health and Human Services

On Mar 5, 2020, at 10:30 PM, Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>wrote:

(b)(5)

From: Arbes, Sarah (HHS/ASL) <Sarah.Arbes@hhs.gov>

Sent: Thursday, March 5, 2020 10:22 PM

To: Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; Amin, Stacy (FDA/OC) <Stacy.Amin@fda.hhs.gov>; Steele, Danielle (HHS/IOS) <Danielle.Steele@hhs.gov>; Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov>; Harrison, Brian (HHS/IOS) <Brian.Harrison@hhs.gov>; McKeogh, Katherine (OS/ASPA) <Katherine.McKeogh@hhs.gov>; Morse, Sara (HHS/ASL) <Sara.Morse@hhs.gov>; Pence, Laura (HHS/ASL) <Laura.Pence@hhs.gov>

Cc: Charrow, Robert (HHS/OGC) <Robert.Charrow@hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Gross, Karas (FDA/OC) <Karas.Gross@fda.hhs.gov>

Subject: RE: LDTs and EUAs -- privileged/deliberative

(b)(5)

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

Sent: Thursday, March 5, 2020 10:18 PM

To: Amin, Stacy (FDA/OC) <Stacy.Amin@fda.hhs.gov>; Steele, Danielle (HHS/IOS) <Danielle.Steele@hhs.gov>; Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov>; Harrison, Brian (HHS/IOS) <Brian.Harrison@hhs.gov>; McKeogh, Katherine (OS/ASPA) <Katherine.McKeogh@hhs.gov>; Morse, Sara (HHS/ASL) <Sara.Morse@hhs.gov>; Arbes, Sarah (HHS/ASL) <Sarah.Arbes@hhs.gov>; Pence, Laura (HHS/ASL) <Laura.Pence@hhs.gov>

Cc: Charrow, Robert (HHS/OGC) <Robert.Charrow@hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Gross, Karas (FDA/OC) <Karas.Gross@fda.hhs.gov>

Subject: RE: LDTs and EUAs -- privileged/deliberative

Hey Stacy – thank you so much for putting this together.

(b)(5)

(b)(5)

- Ryan

draft, pre-decisional, deliberative communication

From: Amin, Stacy <Stacy.Amin@fda.hhs.gov>

Sent: Thursday, March 5, 2020 9:59 PM

To: Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; Steele, Danielle (HHS/IOS) <Danielle.Steele@hhs.gov>; Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov>; Harrison, Brian (HHS/IOS) <Brian.Harrison@hhs.gov>; McKeogh, Katherine (OS/ASPA) <Katherine.McKeogh@hhs.gov>; Morse, Sara (HHS/ASL) <Sara.Morse@hhs.gov>; Arbes, Sarah (HHS/ASL) <Sarah.Arbes@hhs.gov>; Pence, Laura (HHS/ASL) <Laura.Pence@hhs.gov>

Cc: Charrow, Robert (HHS/OGC) <Robert.Charrow@hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Gross, Karas (FDA/OC) <Karas.Gross@fda.hhs.gov>

Subject: LDTs and EUAs -- privileged/deliberative

(b)(5)

Stacy Cline Amin
Chief Counsel
Food and Drug Administration
Deputy General Counsel
Department of Health and Human Services

Sender:	McKeogh, Katherine (OS/ASPA) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C652F2C415B44DFF8369DD7F4596F030-MCKEOGH, KA>
Recipient:	Amin, Stacy (FDA/OC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8575c6e15e234834be21c0f7e315bddc-stacy.amin.>; Murphy, Ryan (OS/ASPA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=314e69c69a844b47bdd9f74bc60a8d44-Murphy, Rya>; Arbes, Sarah (HHS/ASL) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=106db0ac70a241a8b1323647c093d9bf-Arbes, Sara>; Steele, Danielle (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group

	(FYDIBOHF23SPDLT)/cn=Recipients/cn=38849c1f1ea74f2eb9eff75b531a9544-Steele, Dan>; Stecker, Judy (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0280b227911b40b6b30a81b8574ede6b-Stecker, Ju>; Harrison, Brian (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>; Morse, Sara (HHS/ASL) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eb3a04f7dbde41049bfd10f490d3e178-Morse, Sara>; Pence, Laura (HHS/ASL) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d1027e80d2334093870fdb436c5576cd-Pence, Laur>; Charrow, Robert (HHS/OGC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00531138af454ce3ac0b5885bead345f-Charrow, Ro>; Lenihan, Keagan (FDA/OC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cd1b7aba9034ddb936017780583af7d-keagan.leni>; Hahn, Stephen <SH1@fda.hhs.gov>; Gross, Karas (FDA/OC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0196431bcda14a679c3f11d17b30a5ac-kara.gross.>
Sent Date:	2020/03/05 23:05:33
Delivered Date:	2020/03/05 23:05:34