From: Ross, Jennifer [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44AE562EA1D840A3ACA172D0CC23F368-ROSSJ]
Sent: 7/13/2020 6:12:45 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
Subject: Reminder: FW: For OCS Signature today: RE: EUA201916 Trax Management Services– PhoenixDx SARS-CoV-2 Multiplex EUA Request Package
Attachments: EUA201916 Trax Letter of Authorization 07-13-2020 FINAL.doc; 3-EUA201916 Trax HCP FS 07-13-2020 FINAL.docx; 4-EUA201916 Trax Patient FS 07-13-2020 FINAL.docx; 5-EUA201916 Trax IFU 07-13-2020.FINAL.docx

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From: Ross, Jennifer
Sent: Monday, July 13, 2020 4:47 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Subject: For OCS Signature today: RE: EUA201916 Trax Management Services– PhoenixDx SARS-CoV-2 Multiplex EUA Request Package

RADM Hinton,

Please sign this letter to authorize an EUA for Trax Management Services Inc.

2 fact sheets are attached and instructions for use.

This was cleared by CDRH today and OCC waives review.

Thanks,

Jennifer

Jennifer Ross, PhD, JD
Senior Regulatory Counsel

Office of Counterterrorism and Emerging Threats
Office of the Chief Scientist / U.S. Food and Drug Administration
Tel: 240-402-8155
Jennifer.Ross@fda.hhs.gov

FDA U.S. FOOD & DRUG ADMINISTRATION

From: Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
Sent: Monday, July 13, 2020 10:36 AM
To: Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>
Cc: Schlottmann, Silke <Silke.Schlottmann@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Conville, Patricia <Patricia.Conville@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Beaver, Renee <Renee.Beaver@fda.hhs.gov>; Sapsford, Kim E

<Kim.Sapsford@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; Sauer, Robert <Robert.A.Sauer@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Subject: EUA201916 Trax Management Services– PhoenixDx SARS-CoV-2 Multiplex EUA Request Package

Dear Jennifer and Claire,

Please find attached for your final review the EUA request package from Trax Management Services – *PhoenixDx SARS-CoV-2 Multiplex* (EUA201916) for the qualitative detection of nucleic acid from the SARS-CoV-2 in upper respiratory specimens (such as nasal, mid-turbinate, nasopharyngeal and oropharyngeal swabs) and BAL specimens:

1) EUA201916 – Trax Management Services Cover Letter
2) EUA201916 – Letter of Authorization
3) EUA201916 - HCP Fact Sheet
4) EUA201916 – Patient Fact Sheet
5) EUA201916 – PhoenixDx SARS-CoV-2 Multiplex IFU
6) EUA201916 – Lead Reviewer Memorandum
7) Molecular Real World Safety.MEMO.TO.FILE

CDRH considers these documents cleared.

Please let us know if you have any questions.

Thank you,

Tamara

Tamara Feldblyum, M.S., Ph.D.
Branch Chief,
Viral Respiratory and STI Branch
Division of Microbiology Devices | Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3106 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-6195
Tamara.Feldblyum@fda.hhs.gov

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 7/18/2020 8:57:18 AM
To: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
Subject: FW: For OCS Signature Today: RE: EUA200015/A003 Quest Diagnostics Amendment Request Package to Add Sample Pooling.
Attachments: EUA200015 A003 Quest LOA re-issue 07182020 FINAL.doc; 3-EUA200015 A003 Quest HCP FS 07182020 FINAL.docx; 4-EUA200015 A003 Quest Patient FS 07182020 FINAL.docx; 5a-EUA200015.A003 IFU 1200pmPT 7 17 2020 redline JR CD DMD JR.docx; 5b-EUA200015 A002 Quest Specimen Accessing SOP unchanged.doc; 5c-EUA200015 A002 SelfCollectionInstructions IFU unchanged.pdf; EUA200015 A003 Quest LOA re-issue 07182020 FINAL.pdf

From: Hinton, Denise
Sent: Saturday, July 18, 2020 8:56 AM
To: Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
Cc: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Subject: FW: For OCS Signature Today: RE: EUA200015/A003 Quest Diagnostics Amendment Request Package to Add Sample Pooling.

From: Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
Sent: Saturday, July 18, 2020 8:42 AM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: For OCS Signature Today: RE: EUA200015/A003 Quest Diagnostics Amendment Request Package to Add Sample Pooling.

RADM Hinton,

Please sign this letter to authorize an EUA for Quest.

2 fact sheets are also attached and 3 instructions (one with redline CDRH is cleaning up, but in the interest of time we are proceeding with signature).

It was cleared by CDRH below, changes accepted by K.Sapsford for CDRH, and OCC (C.Dennis) cleared this morning.

Thanks!

Jennifer

Jennifer Ross, PhD, JD
Senior Regulatory Counsel

Office of Counterterrorism and Emerging Threats
Office of the Chief Scientist / U.S. Food and Drug Administration
Tel: 240-402-8155
Jennifer.Ross@fda.hhs.gov

FDA U.S. FOOD & DRUG ADMINISTRATION

From: Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
Sent: Friday, July 17, 2020 5:10 PM
To: Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>
Cc: St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Beaver, Renee <Renee.Beaver@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; Sauer, Robert <Robert.A.Sauer@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Zaritsky, Luna <Luna.Zaritsky@fda.hhs.gov>
Subject: EUA200015/A003 Quest Diagnostics Amendment Request Package to Add Sample Pooling.

Dear Jennifer and Claire,

Please find attached for your final review the EUA amendment request package for Quest Diagnostics SARS-CoV-2 rRT-PCR Test (EUA200015/A003) to add sample pooling to the intended use.

1) EUA200015/A003 – Quest Diagnostics cover email
2) EUA200015/A003 – Letter of authorization – re-issue (redline and clean)
3) EUA200015/A003 – Updated HCP Fact Sheet (redline and clean)
4) EUA200015/A003 – Updated Patient Fact Sheet (redline and clean)
5) EUA200015/A003 – Instructions for Use/SOP files
a. Updated Instructions for Use (redline and clean)
b. Specimen Accessing SOP – unchanged from previous EUA re-issued May 27, 2020 (part of the home collection)
c. Patient IFU for home collection – unchanged from the previous EUA re-issued May 27, 2020
6) EUA200015/A003 – Lead Reviewer Memorandum
7) EUA200015/A003 – Molecular Specimen Pooling Memo-to-File – additional conditions for authorized laboratories with respect to sample pooling.

CDRH considers these documents cleared.

Please let us know if you have any questions.

Thank you,

Tamara

Tamara Feldblyum, M.S., Ph.D.
Branch Chief,
Viral Respiratory and STI Branch
Division of Microbiology Devices | Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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White Oak, Bldg. 66, Rm. 3106 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-6195
Tamara.Feldblyum@fda.hhs.gov

From: Fisher, Robert [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=93F0CC92E98C4881BD675C3121B343BD-ROBERT.FISH]
Sent: 7/27/2020 11:14:01 AM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
Subject: messaging challenges
Attachments: 20JUL - Positive Narratives on COVID-19 Vaccine and Treatment Development in China Gain Traction - GEC.pdf

FYSA...

Robert W. Fisher, Ph.D.
Senior Advisor for CBRN and Pandemic Influenza
Office of Counterterrorism and Emerging Threats (OCET)
Office of the Chief Scientist, Office of the Commissioner
U.S. Food and Drug Administration
(w)301-796-8518
(m) (b)(6)
robert.fisher@fda.hhs.gov

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 7/27/2020 12:00:59 PM
To: Ross, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44ae562ea1d840a3aca172d0cc23f368-RossJ]
CC: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]
Subject: Signed: RE: EUA200481 Sandia National Laboratories – The SNL-NM 2019 nCoV Real-Time RT-PCR Diagnostic Assay EUA Request Package
Attachments: EUA200481 Sandia National Laboratories Letter of Authorization 07-27-2020 FINAL.doc; 3-EUA200481 Sandia National Laboratories HCP FS 07-27-2020 FINAL.docx; 4-EUA200481 Sandia National Laboratories Patient FS 07-27-2020 FINAL.docx; 5-EUA200481 Sandia National Laboratories EUA Summary 07-27-2020.fhb v2 FINAL.docx; 6-EUA200481 Sandia National Laboratories SOP 07-27-2020 FINAL.docx; EUA200481 Sandia National Laboratories Letter of Authorization 07-27-2020 FINAL.pdf

Thank you,
Denise

From: Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
Sent: Monday, July 27, 2020 10:54 AM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Subject: For OCS Signature Today: RE: EUA200481 Sandia National Laboratories – The SNL-NM 2019 nCoV Real-Time RT-PCR Diagnostic Assay EUA Request Package

RADM Hinton,

Please sign this letter to issue and EUA to Sandia National Laboratories.

2 facts sheets, EUA Summary, and SOP are attached.

This was cleared by CDRH and OCC waives review.

Thanks,

Jennifer

Jennifer Ross, PhD, JD
Senior Regulatory Counsel

Office of Counterterrorism and Emerging Threats
Office of the Chief Scientist / U.S. Food and Drug Administration
Tel: 240-402-8155
Jennifer.Ross@fda.hhs.gov

FDA U.S. FOOD & DRUG ADMINISTRATION

From: Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
Sent: Monday, July 27, 2020 9:36 AM
To: Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>
Cc: Benahmed, Faiza H. <Faiza.Benahmed@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Conville, Patricia <Patricia.Conville@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Schuck, Brittany <Brittany.Schuck@fda.hhs.gov>; Goldberg, Brittany <Brittany.Goldberg@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; Sauer, Robert <Robert.A.Sauer@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Beaver, Renee <Renee.Beaver@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: EUA200481 Sandia National Laboratories – The SNL-NM 2019 nCoV Real-Time RT-PCR Diagnostic Assay EUA Request Package

Dear Jennifer, Liz, and Claire,

Please find attached for your final review and OCET and OCC clearance the EUA request package from Sandia National Laboratories - SNL-NM 2019 nCoV Real-Time RT-PCR Diagnostic Assay EUA Request Package (EUA20481) for the qualitative detection of nucleic acid from the SARS-CoV-2 in upper respiratory specimens (including nasopharyngeal swab, anterior nasal swab , mid-turbinate nasal swab and oropharyngeal swab, nasal washes, nasal aspirates) and bronchoalveolar lavage specimens:

1) EUA200481 – Sandia National Laboratories Cover Email
2) EUA200481 – Letter of authorization
3) EUA200481 - HCP Fact Sheet
4) EUA200481 – Patient Fact Sheet
5) EUA200481 – EUA Summary
6) EUA200481 – Lab SOP
7) EUA200481 – Lead Reviewer Memo

This is another NAT LDT being authorized with the updated and streamlined LOA for NAT LDTs and the generic fact sheets for HCPs and Patients.

CDRH considers these documents cleared.

Thank you for your continuous support and help,

Let Patti, Faiza and me know if you have any questions.

Thank You.
Uwe

Uwe Scherf, M.Sc., Ph.D.
Director, Division of Microbiology Devices

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 7/27/2020 12:12:28 PM
To: Ross, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44ae562ea1d840a3aca172d0cc23f368-RossJ]
Subject: Signed: EUA200041 Eli Lilly – Lilly SARS-CoV-2 Assay EUA Request Package
Attachments: EUA200041 Eli Lilly Letter of Authorization 07-27-2020 FINAL.doc; 3-EUA200041 Eli Lilly HCP FS 07-27-2020 FINAL.docx; 4-EUA200041 Eli Lilly Patient FS 07-27-2020 FINAL.docx; 5-EUA200041 Eli Lilly EUA Summary 07-27-2020 FINAL.docx; 6-EUA200041 Eli Lilli PCR-Extraction Combined SOP 07-27-2020 redline.docx; EUA200041 Eli Lilly Letter of Authorization 07-27-2020 FINAL.pdf

Signed – thank you,

Denise

From: Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
Sent: Monday, July 27, 2020 12:10 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Subject: For OCS Signature Today: RE: EUA200041 Eli Lilly – Lilly SARS-CoV-2 Assay EUA Request Package

RADM Hinton,

Please sign this letter to issue and EUA too Eli Lilly and Company.

2 fact sheets are attached, EUA Summary and SOP.

This was cleared by CDRH today and OCC waives review.

Thanks,

Jennifer

Jennifer Ross, PhD, JD
Senior Regulatory Counsel

Office of Counterterrorism and Emerging Threats
Office of the Chief Scientist / U.S. Food and Drug Administration
Tel 240-402-8155
Jennifer.Ross@fda.hhs.gov

FDA U.S. FOOD & DRUG ADMINISTRATION

From: Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
Sent: Monday, July 27, 2020 9:57 AM
To: Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>
Cc: Hellyer, Tobin <Tobin.Hellyer@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Conville, Patricia

<Patricia.Conville@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Schuck, Brittany <Brittany.Schuck@fda.hhs.gov>; Garcia, Maria <Maria.Garcia@fda.hhs.gov>; Goldberg, Brittany <Brittany.Goldberg@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; Sauer, Robert <Robert.A.Sauer@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Beaver, Renee <Renee.Beaver@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: EUA200041 Eli Lilly – Lilly SARS-CoV-2 Assay EUA Request Package

Dear Jennifer, Liz, and Claire,

Please find attached for your final review and OCET/OCC clearance the EUA request package from Eli Lilly – Lilly SARS-CoV-2 Assay EUA Request Package (EUA20041) for the qualitative detection of SARS-CoV-2 RNA in nasopharyngeal swabs, oropharyngeal (throat) swabs, anterior nasal swabs, mid-turbinate nasal swabs, nasal aspirates, nasal washes and bronchoalveolar lavage (BAL) fluid:

1) EUA200041 – Eli Lilly Cover Letter
2) EUA200041 – Letter of Authorization
3) EUA200041 - HCP Fact Sheet
4) EUA200041 – Patient Fact Sheet
5) EUA200041 – EUA Summary
6) EUA200041 – Lab SOP
7) EUA200041 – Lead Reviewer Memo

This is another NAT LDT being authorized with the updated and streamlined LOA for NAT LDTs and the generic fact sheets for HCPs and Patients.

CDRH considers these documents cleared.

Thank you for your continuous support and help,

Let Patti, Tobin and me know if you have any questions.

Thank You.
Uwe

Uwe Scherf, M.Sc., Ph.D.
Director, Division of Microbiology Devices

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 1/23/2020 1:38:39 PM
To: Stecker, Judy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e205440400ab4f629be1faccfe0846fc-HHS-Judy.St]
CC: Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Steele, Danielle (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=634b96dc13cf48f3971ce676b65e952f-HHS-Daniell]; Mango, Paul (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2fe1932caf0249d2a0c6af5fb82c9ec5-HHS-Paul.Ma]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; McGowan, Robert K (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e6175b088b1d49a4bfa2de3862800d4a-HHS-omc2-cd]
Subject: Re: CDC wants FDA to evaluate emergency use for new Wuhan virus test

We are preparing for this and will be ready when we receive.

Sent from my iPhone

On Jan 23, 2020, at 1:10 PM, Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov> wrote:

Sent from my iPhone

Begin forwarded message:

From: POLITICO Pro Health Care <politicoemail@politicopro.com>
Date: January 23, 2020 at 12:45:34 PM EST
To: "Stecker, Judy (OS/IOS)" <Judy.Stecker@hhs.gov>
Subject: CDC wants FDA to evaluate emergency use for new Wuhan virus test
Reply-To: "POLITICO subscriptions" <reply-fe971c727160017c75-553241_HTML-880489367-1376319-199953@politicoemail.com>

CDC wants FDA to evaluate emergency use for new Wuhan virus test

By David Lim

01/23/2020 12:44 PM EST

The Centers for Disease Control and Prevention plans to ask the FDA to authorize emergency use of a newly developed diagnostic test to detect the Wuhan coronavirus that CDC leaders want to share with state and local health agencies in the coming weeks.

The authorization would follow a precedent set during outbreaks of Zika, Ebola and Middle East Respiratory Syndrome — and would give local health officials a similar test federal researchers used to confirm the first case of the coronavirus in the United States, in Washington state.

The FDA issues emergency use authorizations, or EUAs, when unapproved medical products can be used to diagnose serious or life-threatening diseases when there are no available alternatives. For that to happen, HHS Secretary Alex Azar would have to declare circumstances justify the test's need, FDA spokesperson Megan

McSeveney said in an email.

There is no commercially available diagnostic test for the Wuhan coronavirus that's approved by the FDA. The outbreak has killed at least 17 people and sickened more than 600 and prompted Chinese authorities to lock down four cities to try to contain transmission.

The FDA granted emergency authorizations after CDC developed tests in response to the outbreak of Ebola in West Africa from 2014 to 2016 and the Zika virus epidemic in North and South America in 2015 and 2016.

"We stand ready to use our authorities to the fullest extent to help facilitate the development and availability of diagnostic tests for this virus, as we did during previous outbreaks," McSeveney said. FDA would not confirm if CDC already applied for an EUA for its diagnostic test.

China shared the genetic sequence of the virus to help countries develop diagnostic kits Jan. 12 and CDC finalized development of a new test last weekend. For now, any samples from infected patients have to be sent to the CDC's headquarters in Atlanta.

“Any time there is a new infectious disease outbreak and you don’t have a standard diagnostic test, initial cases are going to be diagnosed using a laboratory developed test,” said Amesh Adalja, an infectious disease expert and assistant professor at the Johns Hopkins Center for Health Security. “In the early days of an outbreak, the CDC is often the only source of testing until it can be pushed out to state and local health departments.”

The CDC test works by directly detecting the viral genome in an actively or recently infected individual, said Christopher Mores, an arbovirologist and professor of global health at the George Washington University Milken Institute School of Public Health.

“It’s a really rapid test; once the sample gets to the laboratory it’s only a matter of a couple of hours to get the test result,” Mores said. “I’m sure their goal is to get this out to state and city laboratories that are in their network as quickly as possible.”

The World Health Organization said Tuesday it is working on a research and development blueprint to speed the development of diagnostic tests and is coordinating global work among researchers and other experts.

But even as tests to detect the virus become more widely available, they will not be used as a screening tool at airports, according to Mores.

“There isn’t a more rapid test that can be deployed at screening centers at airports at this point, that isn’t something we will see anytime soon” Mores said. “It will be screening based on travel history, contact with infected individuals and symptoms.”

CDC staff began screening travelers on Jan. 17 at New York's John F. Kennedy International Airport, San Francisco International Airport and Los Angeles International Airport — and plans to expand operations to Chicago O'Hare International Airport and Hartsfield-Jackson Atlanta International Airport this week as soon as it has the capacity to do so, according to Martin Cetron, director of the agency's Division of Global Migration and Quarantine.

“All of the people who originate in Wuhan and travel into the United States ... will be rerouted into these five,” Cetron said.

To view online:
https://protect2.fireeye.com/url?k=f6a58b2b-aaf1a200-f6a5ba14-0cc47a6d17cc-c9a538c087ddc9dc&u=https://subscriber.politicopro.com/health-care/article/2020/01/cdc-wants-fda-to-evaluate-emergency-use-for-new-wuhan-virus-test-1868701

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 1/27/2020 6:35:32 PM
To: Copeland, Jakea [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7fe05ed233c42b68be990b12ae2c8c8-Jakea.Copel]; Flowers, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9418b62ec07642d7bc53c564e008f5ce-Susan.Flowe]
Subject: FW: help with CDC and HHS re EUA provisions in VALID
Attachments: FDA CDC discussion on VALID.docx

You all working on time for a discussion?

From: Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
Sent: Monday, January 27, 2020 12:13 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Flowers, Susan <Susan.Flowers@fda.hhs.gov>
Cc: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>
Subject: RE: help with CDC and HHS re EUA provisions in VALID

Thank you! Attached is a background document.

+ Karas and Lauren from OL.
- Anna **(b)(5)**

Elizabeth

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Monday, January 27, 2020 10:08 AM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Flowers, Susan <Susan.Flowers@fda.hhs.gov>
Cc: Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Subject: Re: help with CDC and HHS re EUA provisions in VALID

+ Susan to find some time. Happy to discuss and help.

Sent from my iPhone

On Jan 26, 2020, at 9:12 PM, Abram, Anna <Anna.Abram@fda.hhs.gov> wrote:

I am able to engage on general EUA policy matters. Party specific matters should be directed to Erika to screen for me. Copying her on this reply.

From: Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
Sent: Sunday, January 26, 2020 8:43 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>
Cc: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
Subject: help with CDC and HHS re EUA provisions in VALID

Keagan and Anna,

We wanted to flag for you that an issue has come up with (b)(5)

(b)(5)

Elizabeth

Elizabeth Hillebrenner
Associate Director for Scientific and Regulatory Programs

Center for Devices and Radiological Health
Office of the Center Director
U.S. Food and Drug Administration
Tel: 301-796-6346
elizabeth.hillebrenner@fda.hhs.gov

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 1/28/2020 1:03:58 PM
To: Copeland, Jakea [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7fe05ed233c42b68be990b12ae2c8c8-Jakea.Copel]
Subject: FW: TELECON: Weekly CBER Meeting with the Commissioner and Chief of Staff
Attachments: CBER Agenda for January 29.docx

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Tuesday, January 28, 2020 12:48 PM
To: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Cc: Jenkins, Charlene <Charlene.Jenkins@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Witten, Celia (CBER) <Celia.Witten@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: RE: TELECON: Weekly CBER Meeting with the Commissioner and Chief of Staff

Dear Frank,

Please see the attached. Thanks very much.

Best Regards,
Peter

From: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Sent: Tuesday, January 28, 2020 12:26 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Jenkins, Charlene <Charlene.Jenkins@fda.hhs.gov>
Subject: RE: TELECON: Weekly CBER Meeting with the Commissioner and Chief of Staff

Hi Dr. Marks,

I know you're generally on this without a reminder or inquiry, simply a gentle reminder that agenda items are for tomorrow's Weekly CBER Mtg, if you have them to us by 4:30 PM today, we'll be able to send the Commissioner with a hardcopy.

Thank you,
Frank

-----Original Appointment-----
From: Sheehy, Janice **On Behalf Of** Hahn, Stephen
Sent: Monday, December 30, 2019 11:56 AM
To: Hahn, Stephen; Marks, Peter; Witten, Celia (CBER); Keagan Lenihan (Keagan.Lenihan@fda.hhs.gov); Anna Abram - FDA (Anna.Abram@fda.hhs.gov)
Cc: Tierney, Julia
Subject: TELECON: Weekly CBER Meeting with the Commissioner and Chief of Staff
When: Wednesday, January 29, 2020 2:30 PM-3:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: 1-877-465-7975,,**(b)(6)** #

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 1/28/2020 7:57:24 PM
To: Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb7760891384232a7cd9086fcbb1a3b-Anna.Abram]
Subject: FW: [URGENT RESPONSE REQUESTED] (b)(5)
Attachments: Coronavirus Jan 2020 Sent on Jan 24 Updated Jan 27.pptx

Importance: High

Here we go. You got this response?

From: Agler, Heather L <Heather.Agler@fda.hhs.gov>
Sent: Tuesday, January 28, 2020 7:48 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>
Cc: CDRH All Hazards Readiness Response and Cybersecurity <cdrharc@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: [URGENT RESPONSE REQUESTED] (b)(4)
Importance: High

Hi Keagan and Anna

Today a supply chain risk management company, (b)(4), reached out to us to see if we could participate in a Roundtable discussion on the novel coronavirus (nCoV). They are a company that maps supply chains and monitors for supply chain issues. The open session was mentioned during the ASPR Supply Chain Task Group Meeting today. We wanted to flag it for the Commissioner and the other Centers. I am not sure who would be the right person to participate and if we would be able to participate. But we wanted to alert the Commissioner's Office about the ask. We alerted OCET to the ask as well. We also may want to let Laura Wolf (ASPR) know in case it would make sense for their office to participate instead of FDA. There are three roundtables scheduled:

Conference call with their customers and suppliers
BY INVITE ONLY
Date & Time: Tomorrow, Jan. 29 at 9 am PT / 12 pm ET
Link to register: (b)(4)
(b)(4)

Conference call (for any supply chain organization, partner, etc.)
OPEN TO ALL
Date & Time: Thursday, Jan. 30 at 9 am PT / 12 pm ET
Link to register: (b)(4)
(b)(4)

Conference call w/Healthcare Transparency Initiative (HTI) – Hospitals and GPOs
BY INVITE ONLY
Date & Time: Thursday, Jan. 30 at 10:30 am PT / 1:30 pm ET
Link to register: (b)(4)
(b)(4)

(b)(4) just wants to get as much information shared at these roundtables as they can. The other two people on the roundtable are: (b)(4) and (b)(4) (b)(4) The format would be the following:

- Slides given by (b)(4) (attached to this email, information is very helpful on the current situation)

- Each Roundtable participant would give an update on the situation (5-10 minutes)
- Roundtable participants would field questions from the audience and ask questions of the audience.

If we have questions for the audience ahead of time, we can send them in advance. They would like to know as soon as possible if we can participate. Please let me know next steps.

Thank you,
Heather

Heather L. Agler, Ph.D.
Innovation Program
All-Hazards Readiness, Response, and Cybersecurity (ARC) – *formerly EMCM*
Division of All-Hazards Response, Science and Strategic Partnerships (DARSS)
Office of Strategic Partnerships and Technology Innovation (OST)
Center for Devices and Radiological Health
U.S. Food and Drug Administration
(p) 301-796-6340
Heather.Agler@fda.hhs.gov

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 1/31/2020 5:06:01 PM
To: Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: FW: Vaccine TPs
Attachments: Considerations in coronavirus vaccine development 013120.docx

Updated talkers for AMA meeting.

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Friday, January 31, 2020 4:56 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Abram, Anna <Anna.Abram@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>
Subject: RE: Vaccine TPs

Dear Keagan,

Here is a slightly updated version of the TPs. Don't expect any more edits for now on our end until we have some more data.

Best Regards,
Peter

From: Marks, Peter
Sent: Friday, January 31, 2020 8:04 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Anna Abram (Anna.Abram@fda.hhs.gov) <Anna.Abram@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Cho, David S (CBER) (David.Cho@fda.hhs.gov) <David.Cho@fda.hhs.gov>
Subject: Vaccine TPs

Dear Keagan,

Please see the attached talking points on vaccine development. We have tried to distill this down and use the least technical language. Just let me know if you have any questions.

Best Regards,
Peter

From: Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]
Sent: 2/2/2020 6:50:27 PM
To: Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]
CC: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: Re: (b)(4)

Sensitivity: Company Confidential

Meant to +Stacy also. Thank you.

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Date: February 2, 2020 at 6:44:59 PM EST
To: Abram, Anna <Anna.Abram@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: Fwd: (b)(4)
Importance: High

Hi Anna and Keagan -

(b)(5)

Thanks
Anand

From: Ashley Rhoades <Ashley.Rhoades@gilead.com>
Date: February 2, 2020 at 6:18:33 PM EST
To: Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Paul Tomkins (b)(6) Diana Brainard (b)(6) Leighann Timbs (b)(6)
Subject: (b)(4)
Importance: High

Dear Dr. Shah:

(b)(4)

Any assistance you can provide, would be appreciated. I can be reached directly at: (b)(6) Alternatively and if needed, you can reach out to Leighann Timbs at (b)(6)

Best,
Ashley Rhoades

Ashley Rhoades, MBS, RAC | Senior Associate, Regulatory Affairs
(650) 425 5190 | (b)(6)
Gilead Sciences, Inc. | 333 Lakeside Drive | Foster City, CA 94404 | United States

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 2/2/2020 9:32:29 PM
To: Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]
CC: Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: Re **(b)(4)**

(b)(5)

Thank you.

Sent from my iPhone

On Feb 2, 2020, at 9:25 PM, Amin, Stacy <Stacy.Amin@fda.hhs.gov> wrote:

(b)(5)

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Sunday, February 2, 2020 7:31 PM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.g ov>
Subject: RE: **(b)(4)**
Sensitivity: Confidential

Thanks Anna and Michael. I'll reply as per Anna.
Anand

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Date: February 2, 2020 at 7:24:50 PM EST
To: Mair, Michael <Michael.Mair@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>, Amin, Stacy <Stacy.Amin@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: **(b)(4)**

(b)(5) Anand, thanks so much for flagging. **(b)(5)**

(b)(5)

Thanks!

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Date: February 2, 2020 at 7:21:21 PM EST
To: Abram, Anna <Anna.Abram@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>, Amin, Stacy <Stacy.Amin@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: **(b)(4)**

(b)(5)

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Sent: Sunday, February 2, 2020 6:59 PM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: Re: **(b)(4)**
Sensitivity: Confidential

(b)(5)

Internal confidential

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Date: February 2, 2020 at 6:45:00 PM EST
To: Abram, Anna <Anna.Abram@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: Fwd: **(b)(4)**
Importance: High

Hi Anna and Keagan -

(b)(5)

Thanks
Anand

From: Ashley Rhoades **(b)(6)**
Date: February 2, 2020 at 6:18:33 PM EST
To: Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Paul Tomkins **(b)(6)**, Diana Brainard **(b)(6)**, Leighann Timbs **(b)(6)**
Subject: **(b)(4)**
Importance: High

Dear Dr. Shah:

(b)(4)

Any assistance you can provide, would be appreciated. I can be reached directly at: (b)(6) Alternatively and if needed, you can reach out to Leighann Timbs at (b)(6)

Best,
Ashley Rhoades

Ashley Rhoades, MBS, RAC | Senior Associate, Regulatory Affairs
<image1.jpg>
(650) 425 5190 |
<image2.jpg>
(b)(6)
Gilead Sciences, Inc. | 333 Lakeside Drive | Foster City, CA 94404 | United States

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 2/3/2020 5:16:15 PM
To: Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]
Subject: FW: CDC defends U.S. response to coronavirus amid Chinese criticism

(b)(5)

From: POLITICO Pro Health Care <politicoemail@politicopro.com>
Sent: Monday, February 3, 2020 5:02 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: CDC defends U.S. response to coronavirus amid Chinese criticism

CDC defends U.S. response to coronavirus amid Chinese criticism

By Brianna Ehley, Sarah Owermohle

02/03/2020 03:23 PM EST

U.S. health officials on Monday defended steps they've taken to contain the Wuhan coronavirus, including a ban on recent travelers to China, after Chinese officials accused the Trump administration of fearmongering and not helping contain the outbreak.

"We made an aggressive decision in front of an unprecedented threat that action now had the biggest potential to slow this thing down," Nancy Messonnier, the CDC's Director for the National Center for Immunization and Respiratory Diseases, told reporters. She noted that China had gone as far as locking down Wuhan, a city of 11 million at the epicenter of the outbreak.

The virus has killed 362 people and sickened 17,391, mostly in China, according to the World Health Organization. No new countries reported cases in the past 24 hours.

Messonnier said CDC experts are still waiting to see if the agency is designated part of a WHO-organized mission to China to assess the outbreak. A CDC spokesperson told POLITICO that China's health department invited HHS to be part of the mission, but "CDC has not officially been named as part of the group."

A spokesperson for the WHO said that a group of international experts could land in China as soon as this week but did not immediately respond to questions about CDC's status.

"What I've seen is that in situations like this, science should trump everything else," Messonnier said. "And that is certainly what we're hoping, is that scientific expertise of the larger global community will be brought to bear on this really complicated, difficult situation."

The Trump administration last week dramatically ramped up its response, including plans to evacuate up to 1,000 U.S. residents from the Wuhan region. HHS Secretary Alex Azar declared the outbreak a national public health emergency and the CDC quarantined 195 Americans who were evacuated from Wuhan last Wednesday, the first such action the agency has taken in half a century.

Azar will shift as much as $136 million within the health department to fight the outbreak, an HHS spokesperson confirmed Monday. Azar told Congress on Sunday that he would increase CDC funds by as much as $75 million, said one individual familiar with the notification. Azar also said he would redirect as much as $52 million to the HHS emergency-response office, and up to $8 million to the HHS global affairs office.

Some of the administration's actions have created friction with Beijing as officials there struggle to respond to a

public health crisis and coordinate with other countries.

The Chinese foreign ministry on Monday accused the U.S. of creating an atmosphere of fear, contending it "inappropriately overreacted" by warning Americans not to travel to China and temporarily banning foreigners who traveled to the country.

Messonnier said the response was intended to slow the spread of the virus in the United States. She declined to comment on whether tensions with China were hampering U.S. efforts to study the virus, and said the CDC stands ready to travel to China if it is extended the invitation.

Messonnier also said that a CDC-prepared diagnostic test could be distributed to states by the end of the week, contingent on the FDA granting an emergency use authorization.

The CDC has confirmed 11 coronavirus cases in the United States. including two involving people who were in close proximity to infected people who had recently traveled from Wuhan.

Dan Diamond and David Lim contributed to this report.

To view online:
https://subscriber.politicopro.com/health-care/article/2020/02/cdc-defends-us-response-to-coronavirus-amid-chinese-criticism-1874315

From: Tootle, William [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0900DA296E4A474DA740EF1C47E6F1BD-WILLIAM.TOO]
Sent: 2/4/2020 9:57:19 AM
To: Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Tyler, James [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddb047ff73e640b29259d7ca22611e67-James.Tyler]; Wong, Eric [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d297edf2c28b4219a30b385f8dd3ab37-Eric.Wong]
Subject: RE: Coronavirus

Thanks

Bill Tootle

Director, Office of Budget
U.S. Food and Drug Administration
4041 Powder Mill Road,
Beltsville, MD 20705

Phone: 301-796-4710/4579

From: Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Sent: Tuesday, February 4, 2020 8:50 AM
To: Tootle, William <William.Tootle@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Tyler, James <James.Tyler@fda.hhs.gov>; Wong, Eric <Eric.Wong@fda.hhs.gov>
Subject: RE: Coronavirus

A few edits from me.

From: Tootle, William <William.Tootle@fda.hhs.gov>
Sent: Tuesday, February 4, 2020 8:40 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Tyler, James <James.Tyler@fda.hhs.gov>; Wong, Eric <Eric.Wong@fda.hhs.gov>
Subject: Re: Coronavirus

(b)(5)

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Date: February 4, 2020 at 7:11:10 AM EST
To: Tootle, William <William.Tootle@fda.hhs.gov>
Cc: Anderson, Erika <Erika.Anderson@fda.hhs.gov>, Tyler, James <James.Tyler@fda.hhs.gov>, Wong, Eric <Eric.Wong@fda.hhs.gov>
Subject: Re: Coronavirus

(b)(5)

Sent from my iPhone

On Feb 3, 2020, at 10:41 PM, Tootle, William <William.Tootle@fda.hhs.gov> wrote:

Hi Keagan and Erika,

(b)(5)

(b)(5) Attached is our one-page write-up based on the information gathered from the centers. Let me know if you are OK with us sending this to ASFR.

Thanks

Bill Tootle

Director, Office of Budget
U.S. Food and Drug Administration
4041 Powder Mill Road,
Beltsville, MD 20705

Phone: 301-796-4710/4579

<Coronavirus supplemental Request Summary_02.03.20 .docx>

From: Helms Williams, Emily [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=873BE46F1B1A4D2B8DF3FE67137CBDC8-HELMSWILLIA]
Sent: 2/4/2020 11:56:21 AM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]
Subject: FW: Weekly EOS-LAS Report 02/03/20
Attachments: Weekly Report FEB 03 2020.docx

Here is this week's report from CDER, which lists a few upcoming approvals on p. 3, but they have all been on prior reports. It also includes a heads up about **(b)(5)** (see p. 4).

Please let me know if I can work with CDER to provide more information on these or any of the other items listed in the report.

Thanks,
Emily

From: McLatchy, Johanna <Johanna.McLatchy@fda.hhs.gov>
Sent: Monday, February 3, 2020 4:07 PM
To: Helms Williams, Emily <Emily.HelmsWilliams@fda.hhs.gov>
Subject: Weekly EOS-LAS Report 02/03/20

Hi Emily,
Please see the attached Weekly Report for the week of Feb 03.

Thanks,
Johanna

Johanna Mclatchy
Staff Director
Executive Operations Staff (EOS)

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Executive Operations
Email: Johanna.Mclatchy@fda.hhs.gov
Tel: 301-796-3788

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 2/4/2020 6:15:48 PM
To: Tootle, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0900da296e4a474da740ef1c47e6f1bd-William.Too]
CC: Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Tyler, James [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddb047ff73e640b29259d7ca22611e67-James.Tyler]; Wong, Eric [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d297edf2c28b4219a30b385f8dd3ab37-Eric.Wong]; Sigg, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=37695069dc214f5cb20e6056dd4d7cf7-sigg]
Subject: RE: Coronavirus

Thanks!

From: Tootle, William <William.Tootle@fda.hhs.gov>
Sent: Tuesday, February 4, 2020 5:36 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Tyler, James <James.Tyler@fda.hhs.gov>; Wong, Eric <Eric.Wong@fda.hhs.gov>; Sigg, Jim <Jim.Sigg@fda.hhs.gov>
Subject: RE: Coronavirus

(b)(5)

I will share this with ASFR now too. Apparently, they are (b)(5) to OMB tomorrow.

Bill Tootle

Director, Office of Budget
U.S. Food and Drug Administration
4041 Powder Mill Road,
Beltsville, MD 20705

Phone: 301-796-4710/4579

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Tuesday, February 4, 2020 1:53 PM
To: Tootle, William <William.Tootle@fda.hhs.gov>
Cc: Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Tyler, James <James.Tyler@fda.hhs.gov>; Wong, Eric <Eric.Wong@fda.hhs.gov>
Subject: Re: Coronavirus

Ok. Thanks.

Sent from my iPhone

On Feb 4, 2020, at 8:39 AM, Tootle, William <William.Tootle@fda.hhs.gov> wrote:

(b)(5)

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Date: February 4, 2020 at 7:11:10 AM EST
To: Tootle, William <William.Tootle@fda.hhs.gov>
Cc: Anderson, Erika <Erika.Anderson@fda.hhs.gov>, Tyler, James <James.Tyler@fda.hhs.gov>, Wong, Eric <Eric.Wong@fda.hhs.gov>
Subject: Re: Coronavirus

(b)(5)

Sent from my iPhone

On Feb 3, 2020, at 10:41 PM, Tootle, William <William.Tootle@fda.hhs.gov> wrote:

Hi Keagan and Erika,

(b)(5)

(b)(5) Attached is our one-page write-up based on the information gathered from the centers. Let me know if you are OK with us sending this to ASFR.

Thanks

Bill Tootle

Director, Office of Budget
U.S. Food and Drug Administration
4041 Powder Mill Road,
Beltsville, MD 20705

Phone: 301-796-4710/4579

<Coronavirus supplemental Request Summary_02.03.20 .docx>

From: Rebello, Heidi [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2834CE193CA949799EF063E34A2CFA0B-HEIDI.REBEL]
Sent: 2/5/2020 2:33:05 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: RE: CDC sending hundreds of coronavirus testing kits to U.S., foreign labs

Yes, we cleared her remarks.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, February 5, 2020 2:22 PM
To: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: Re: CDC sending hundreds of coronavirus testing kits to U.S., foreign labs

Was she approved to say this?

Sent from my iPhone

On Feb 5, 2020, at 2:19 PM, Rebello, Heidi <Heidi.Rebello@fda.hhs.gov> wrote:

This is a result of Denise's participation in the CDC media call today.

From: Stark, Angela <Angela.Stark@fda.hhs.gov>
Sent: Wednesday, February 5, 2020 2:18 PM
To: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>
Subject: FW: CDC sending hundreds of coronavirus testing kits to U.S., foreign labs

FYI only. See reference to Denise's line on the call about 35 test developers requesting info.

From: POLITICO Pro Health Care <politicoemail@politicopro.com>
Sent: Wednesday, February 5, 2020 2:10 PM
To: Stark, Angela <Angela.Stark@fda.hhs.gov>
Subject: CDC sending hundreds of coronavirus testing kits to U.S., foreign labs

CDC sending hundreds of coronavirus testing kits to U.S., foreign labs

By David Lim

02/05/2020 02:09 PM EST

The CDC today is starting to ship Wuhan coronavirus diagnostic test kits to public health laboratories, likely accelerating efforts to detect new cases.

The diagnostic, which received emergency use authorization from the FDA Tuesday, will allow states to begin reporting confirmed cases without first sending samples to CDC headquarters in Atlanta, according to Nancy Messonnier, CDC's director of the Center for the National Center for Immunization and Respiratory Diseases.

The agency will initially send 200 diagnostic kits to U.S. labs and another 200 to international laboratories, Messonnier told reporters. Each kit can test 700-800 patient samples, she said.

"Distribution of these tests will improve the global capacity to detect and respond to this new virus, as well as greatly enhance our national capacity," Messonnier said. "Availability of this test is a starting place for greater

commercial availability of diagnostic testing for nCoV."

Government officials said it will take a few days before the labs complete verification and begin reporting out cases. More test kits are being manufactured and will be made available for distribution, but each laboratory will only receive one test kit for the time being, according to Messonnier.

FDA Chief Scientist Denise Hinton said the agency has provided 35 diagnostic developers specifications for the data that needs to be developed for an application for emergency use authorization, which is intended to expedite the development of additional tests.

To view online:
https://subscriber.politicopro.com/health-care/whiteboard/2020/02/cdc-sending-hundreds-of-coronavirus-testing-kits-to-us-foreign-labs-3976348

From: Stark, Angela [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D04B10A5E0EC40FFA2EBFEDD711E83AF-ANGELA.STAR]
Sent: 2/7/2020 8:25:36 AM
To: Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Janik, Heather [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbebeee5ffeeb7f3d-Heather.Jan]
CC: Rath, Prakash (FDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91bc5673db6c416e87a453f8b9527cc0-Prakash.Rat]; Aguilar, Paul [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f4e6056acec4bc98fdb07bb0548dc86-Paul.Aguila]
Subject: Re: [EXTERNAL] Coronavirus draws attention to FDA oversight of Chinese drugs — Is there hope yet for the Senate drug bill? — Biogen scores a big patent win

Full article below. I think it's fairly balanced and our messages did get in (5th paragraph)

CORONAVIRUS DRAWS ATTENTION TO FDA OVERSIGHT OF CHINESE DRUGS — Lawmakers are raising concerns anew about the U.S. reliance on foreign drug manufacturing amid the Wuhan coronavirus outbreak that has pushed FDA inspectors out of China. The novel disease outbreak could spark medical product shortages if the epidemic is not resolved swiftly, experts say.

The challenges come as Chinese drug manufacturing has been in Congress's spotlightfollowing a series of warnings last year about contaminated batches of foreign-made drugs.

"There is emerging and I think correct issues about ... how much we rely on production in China for basic drugs and all kinds of medical supplies," Rep. Greg Walden, the House Energy and Commerce committee ranking Republican, said this week.

About 60 percent of factories manufacturing drug ingredients and finished medicines for U.S. patients are located overseas with China and India accounting for 40 percent of them.

FDA told POLITICO that manufacturers of FDA-regulated products have not reported any impacts on the supply chain that are creating the potential for shortages of critical medical products — but the situation is evolving. Due to coronavirus agency staff is departing the country and all FDA travel to China is canceled. FDA said it is deciding on a "case-by-case" basis whether to conduct inspections in the country, but experts say it is unlikley much work is occurring due to the staffing situation

Risk mitigation — There are ways FDA could try and mitigate harm from any lack of inspections, said Howard Sklamberg, a partner at Akin Gump and former deputy commissioner for global regulatory operations and policy who oversaw FDA's inspections office.

If FDA got information about a potential public health risk from a facility in China it couldn't inspect due to coronavirus it could potentially issue an import alert that would block those products from coming into the U.S.

He said they could also test and sample drugs at ports of entry in the U.S or try and obtain data remotely from manufacturers.

"The mere fact that there is currently a delay in inspection in China does not raise alarm," he said. The risks, he added, particularly of shortages will depend on how long this crisis goes on.

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Date: February 7, 2020 at 8:11:09 AM EST
To: Gross, Karas <Karas.Gross@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Janik, Heather <Heather.Janik@fda.hhs.gov>
Cc: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>, Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>, Stark, Angela <Angela.Stark@fda.hhs.gov>
Subject: Re: [EXTERNAL] Coronavirus draws attention to FDA oversight of Chinese drugs — Is there hope yet for the Senate drug bill? — Biogen scores a big patent win

Plus Angela per Heather's out of office

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Date: February 7, 2020 at 7:55:51 AM EST
To: Gross, Karas <Karas.Gross@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Janik, Heather <Heather.Janik@fda.hhs.gov>
Cc: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>, Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>
Subject: Re: [EXTERNAL] Coronavirus draws attention to FDA oversight of Chinese drugs — Is there hope yet for the Senate drug bill? — Biogen scores a big patent win

I stayed within our tps. They did not ask about our staff or travel to China. Murray's staffer asked about inspection impact and I explained the health and safety of our colleagues was a top concern and we were looking at inspection impacts on a case by case basis and that obviously there is a range of types of inspections that have varying degrees of public health impact (routine surveillance vs for cause etc)

Can we pull the entire article to see the fuller context?

From: Gross, Karas <Karas.Gross@fda.hhs.gov>

Date: February 7, 2020 at 7:41:47 AM EST
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Janik, Heather <Heather.Janik@fda.hhs.gov>
Cc: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>, Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>
Subject: Re: [EXTERNAL] Coronavirus draws attention to FDA oversight of Chinese drugs — Is there hope yet for the Senate drug bill? — Biogen scores a big patent win

Sorry img

From: Gross, Karas <Karas.Gross@fda.hhs.gov>
Date: February 7, 2020 at 7:40:47 AM EST
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Janik, Heather <Heather.Janik@fda.hhs.gov>
Cc: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>, Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>
Subject: Fwd: [EXTERNAL] Coronavirus draws attention to FDA oversight of Chinese drugs — Is there hope yet for the Senate drug bill? — Biogen scores a big patent win

Anything I can share with Laura? I can have team check through IMF as well.

From: Pence, Laura (HHS/ASL) <Laura.Pence@hhs.gov>
Date: February 7, 2020 at 7:36:15 AM EST
To: Gross, Karas <Karas.Gross@fda.hhs.gov>
Subject: Fwd: [EXTERNAL] Coronavirus draws attention to FDA oversight of Chinese drugs — Is there hope yet for the Senate drug bill? — Biogen scores a big patent win

(b)(5)

Begin forwarded message:

From: "McMillin, Virginia D. EOP/WHO" **(b)(6)**
Date: February 7, 2020 at 7:16:38 AM EST
To: "Pence, Laura (HHS/ASL)" <Laura.Pence@hhs.gov>
Subject: Fwd: [EXTERNAL] Coronavirus draws attention to FDA oversight of Chinese drugs — Is there hope yet for the Senate drug bill? — Biogen scores a big patent win

(b)(5)

Due to coronavirus agency staff is departing the country and all FDA travel to China is canceled.

Virginia McMillin
Special Assistant to the President
Office of Legislative Affairs
(b)(6)

Begin forwarded message:

From: POLITICO Pro's Prescription Pulse <politicoemail@politicopro.com>
Date: February 7, 2020 at 7:04:16 AM EST
To: "McMillin, Virginia D. EOP/WHO" <Virginia.D.McMillin@who.eop.gov>
Subject: [EXTERNAL] Coronavirus draws attention to FDA oversight of Chinese drugs — Is there hope yet for the Senate drug bill? — Biogen scores a big patent win
Reply-To: "POLITICO, LLC" <reply-fe831c74736c0c7474-630347_HTML-1002034518-1376319-0@politicoemail.com>

Due to coronavirus agency staff is departing the country and all FDA travel to China is canceled.

From: Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]
Sent: 2/7/2020 9:35:27 AM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]
CC: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: Fwd: Immediate follow up requested re remdesivir export for nCoV trial
Importance: High

FYI

From: Diana Brainard <Diana.Brainard@gilead.com>
Date: February 7, 2020 at 9:19:33 AM EST
To: OS Secretarys Operations Center <hhs.soc@hhs.gov>
Cc: Bright, Rick (OS) <Rick.Bright@hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Merdad Parsey <merdad.parsey@gilead.com>
Subject: Immediate follow up requested re remdesivir export for nCoV trial
Importance: High

Dear Office of the Secretary,

I am writing to update you since our most recent communication yesterday, 2/6, when we provided additional information regarding our continued openness to share information with FDA and others within the government from these critical placebo-controlled, randomized trials in China.

This is an urgent situation, and we have received no further communication from you.

These delays have significantly impacted the study and the ability to generate data to determine the safety and efficacy of remdesivir for nCoV infection.

We need a decision in the next hour or we will have a delay through the weekend that will results in an even more substantial impact for these important trials.

Please communicate.

Appreciatively,
Diana

Diana M Brainard, MD
Senior Vice President
HIV and Emerging Viruses
Gilead Sciences, Inc
Tel: 650-522-4761

From: Felberbaum, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4819A643CA2945CDB1A2631B83E69673-MICHAEL.FEL]
Sent: 2/7/2020 12:36:59 PM
To: McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Stark, Angela [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d04b10a5e0ec40ffa2ebfedd711e83af-Angela.Star]; Meyer, Lyndsay [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00176f0991c84d34b3927bfb410d5483-Lyndsay.Mey]
Subject: RE: language re: remdesivir
Attachments: nCoR Talking Points Trimmed.docx

Thanks. I added this to the trimmed down talkers.

From: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
Sent: Friday, February 07, 2020 12:32 PM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Stark, Angela <Angela.Stark@fda.hhs.gov>; Meyer, Lyndsay <Lyndsay.Meyer@fda.hhs.gov>
Subject: language re: remdesivir

(b)(5)

Megan McSeveney
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-4514/Cell (b)(6)
Megan.McSeveney@fda.hhs.gov

FDA U.S. FOOD & DRUG ADMINISTRATION

From: Stark, Angela [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D04B10A5E0EC40FFA2EBFEDD711E83AF-ANGELA.STAR]
Sent: 2/7/2020 3:43:44 PM
To: Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Janik, Heather [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbebeee5ffeeb7f3d-Heather.Jan]
CC: Rath, Prakash (FDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91bc5673db6c416e87a453f8b9527cc0-Prakash.Rat]; Aguilar, Paul [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f4e6056acec4bc98fdb07bb0548dc86-Paul.Aguila]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]
Subject: RE: [EXTERNAL] Coronavirus draws attention to FDA oversight of Chinese drugs — Is there hope yet for the Senate drug bill? — Biogen scores a big patent win

The story from last night has been expanded into a 2nd piece and updated with SH's comments from the presser.

UPDATED: Lawmakers see threat of shortages of Chinese drug imports

By Sarah Karlin-Smith

02/06/2020 10:17 PM EST

The World Health Organization warned Friday of shortages of protective medical gear because of the Wuhan coronavirus, adding to worries that the U.S. could face shortages of drugs or medical devices made in China if the epidemic persists.

Even before the outbreak, Congress had begun to scrutinize the Chinese medicine industry following warnings last year about contaminated batches of foreign-made drugs. A U.S. government watchdog in the fall urged lawmakers to reduce dependence on Chinese pharmaceutical imports. And now, the Food and Drug Administration has pulled its inspectors out of China because of the spreading epidemic.

New FDA commissioner Stephen Hahn said no shortages of drugs or devices in the U.S. have been reported, but acknowledged, "the situation is fluid." And concern is being voiced on both sides of the aisle and in the White House.

"There is emerging, and I think correct, issues about … how much we rely on production in China for basic drugs and all kinds of medical supplies," said Rep. Greg Walden, the House Energy and Commerce ranking Republican, earlier this week

Rep. Anna Eshoo (D-Calif.), chairwoman of the House Energy and Commerce Health Subcommittee, said Thursday evening that China's control of the global supply of many pharmaceutical ingredients is keeping her up at night. She complained she's not getting answers from U.S. officials on what overseas factories may be shut down amid quarantines.

"We have every reason to worry because we don't know," Eshoo said. "Have any of the agencies on behalf of the administration done an inventory? ... I think they don't know."

White House economic adviser Larry Kudlow said earlier this week coronavirus could lead to a drop in exports and production in China, particularly in the pharmaceutical sector.

The WHO alert focused on personal protective equipment like masks and respirators that medical and public health personnel need to protect themselves as they treat patients and try to contain the virus' spread. The novel strain of coronavirus has already killed at least 638 people and infected more than 31,000, mostly in China.

Demand for such protective equipment is up to 100 times higher than normal, and prices are up to 20 times higher, WHO chief Tedros Adhanom Ghebreyesus said. Shortages have been exacerbated by widespread inappropriate use outside of patient care. For instance most people outside the hard-hit areas don't need to wear masks, but they are becoming an increasingly common sight. And there have been reports of people stockpiling.

Robert Kadlec, Health and Human Services assistant secretary for preparedness and response, urged people not to use masks when they aren't necessary at a press briefing of the president's coronavirus task force. "If you use them now, you won't have them later if you need them," he said.

WHO said it could not provide information on whether the protective equipment shortages stem from a slowdown in Chinese manufacturing, or other causes. Nor would WHO say whether it is monitoring for other medical product shortages or doing inventories of health-related manufacturing in China that could be affected.

About 60 percent of factories manufacturing drug ingredients and finished medicines for U.S. patients are located overseas, with China and India accounting for 40 percent. China provides the raw material used in 13 percent of U.S. drugs, and the GAO estimates there are about 400 drug manufacturing facilities in that country. In some cases, there may not be alternate suppliers for the U.S. market.

"I'm not sure that there's all that much flexibility in terms of active pharmaceutical ingredients," said Stephen Ostroff, who served two separate stints as FDA's acting commissioner between 2015 and 2017. He also noted that U.S. supplies must come from FDA-approved and inspected manufacturers. "It's not like you can just sort of hopscotch to a different manufacturer and say, well, you make it now," Ostroff said.

Sens. Marco Rubio and Chris Murphy on Thursday requested information about how the coronavirus has impacted FDA's ability to oversee the nearly $13 billion-worth of drugs, medical devices and food imports that come from China. "We are concerned that the pandemic could impact the FDA's ability to monitor compliance with good manufacturing standards and the ability for Chinese manufacturers to maintain supplies to meet demand in the United States and the growing demand of China," they wrote to new FDA Commissioner Stephen Hahn.

FDA told POLITICO that manufacturers of FDA-regulated products have not reported any supply chain impact, though the situation is evolving. U.S. health facilities have not reported any significant imminent shortages either. That too could change over time if the crisis is prolonged.

Even before the coronavirus outbreak the FDA had told Congress it lacks the staffing needed for oversight in China. It said its work is also hampered by language barriers and its limited ability to conduct surprise inspections there.

Now because of the virus, FDA agency staff is departing China and all FDA travel to the country is canceled. FDA said it is deciding on a "case-by-case" basis whether to conduct inspections there but experts doubt much work is occurring given the staffing situation.

"With cessation of nonessential travel to China by U.S. citizens, that would most likely curtail any inspections by FDA personnel not based in China," said Ostroff. "And it's almost certain that personnel based in the FDA China office are not traveling around the country conducting inspections. That likely has an impact on facility inspections for medical products, especially drugs and medical devices."

"Safety is the highest priority of the FDA, and we will continue to work to balance the safety of our staff with the safety of the products the American public relies on," the FDA said in a statement.

Any reduction in inspections would raise alarms for GAO, which has been pointing out key gaps in the agency's foreign inspections process and capacity.

"If FDA has suspended or slowed down inspections, that would only impact further those concerns that we have," said Mary Denigan-Macauley, director of health care, public health and private markets for GAO.

While newly approved drugs wouldn't be able to come into the country without an inspection, companies can continue to ship already approved drugs to the U.S., but "we won't know the quality of those drugs," Denigan-Macauley added.

Even under perfect circumstances FDA only inspects a small fraction of facilities making drugs in any given year, so the agency tries to focus on the riskiest sites, she said.

At the request of Senate Minority Leader Chuck Schumer , GAO is looking at the U.S. dependence on China and other international drug manufacturers. Based on past work on drug shortages, they know that a lack of redundancy — having few sources for a specific product — in drug manufacturing can be problematic for the continuous supply of medicines.

"It is something that is a concern. It is a national security concern, as well, particularly if they're making the countermeasures that we need for our own homeland security," Denigan-Macauley said.

Erin Fox, a University of Utah specialist in drug shortages, said health systems and hospitals don't tend to keep large stocks of products on hand, likely just weeks or maybe months worth. Wholesalers who distribute to hospitals "also don't have a ton of product on hand because it's money sitting there," she said.

"Everyone's trying to be lean and this whole 'just in time' inventory system is how drug shortages happen and are pretty severe pretty quickly," she said. There's also little transparent information about the location of key drug manufacturing plants or what products they are making, so it would be hard for health systems to prepare for shortfalls due to disruption to Chinese manufacturing.

The FDA does have ways to try to mitigate harm from any lack of inspections, said Howard Sklamberg, a partner at Akin Gump, who oversaw FDA's inspection office when he was deputy commissioner for global regulatory operations and policy.

If FDA got information about a potential public health risk from a facility in China it couldn't inspect due to coronavirus, it could potentially issue an import alert that would block those products from coming into the U.S.

"That would be a temporary measure until [FDA] could inspect or otherwise get information to assure itself there's not a public health risk," Sklamberg said.

He said they could also test and sample drugs at ports of entry in the U.S. or try to obtain data remotely from manufacturers.

"The mere fact that there is currently a delay in inspection in China does not raise alarm," Sklamberg said. The risks, he added, particularly of shortages, will depend on how long the crisis goes on.

Adam Cancryn and Brianna Ehley contributed to this report.

To view online:
https://subscriber.politicopro.com/health-care/article/2020/02/lawmakers-see-threat-of-shortages-of-chinese-drug-imports-1876062

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Sent: Friday, February 7, 2020 8:11 AM
To: Gross, Karas <Karas.Gross@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>
Cc: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Stark, Angela <Angela.Stark@fda.hhs.gov>
Subject: Re: [EXTERNAL] Coronavirus draws attention to FDA oversight of Chinese drugs — Is there hope yet for the Senate drug bill? — Biogen scores a big patent win

Plus Angela per Heather's out of office

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Date: February 7, 2020 at 7:55:51 AM EST
To: Gross, Karas <Karas.Gross@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Janik, Heather <Heather.Janik@fda.hhs.gov>
Cc: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>, Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>
Subject: Re: [EXTERNAL] Coronavirus draws attention to FDA oversight of Chinese drugs — Is there hope yet for the Senate drug bill? — Biogen scores a big patent win

I stayed within our tps. They did not ask about our staff or travel to China. Murray's staffer asked about inspection impact and I explained the health and safety of our colleagues was a top concern and we were looking at inspection impacts on a case by case basis and that obviously there is a range of types of inspections that have varying degrees of public health impact (routine surveillance vs for cause etc)

Can we pull the entire article to see the fuller context?

From: Gross, Karas <Karas.Gross@fda.hhs.gov>
Date: February 7, 2020 at 7:41:47 AM EST
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Janik, Heather <Heather.Janik@fda.hhs.gov>
Cc: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>, Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>
Subject: Re: [EXTERNAL] Coronavirus draws attention to FDA oversight of Chinese drugs — Is there hope yet for the Senate drug bill? — Biogen scores a big patent win

Sorry img

From: Gross, Karas <Karas.Gross@fda.hhs.gov>
Date: February 7, 2020 at 7:40:47 AM EST
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Janik, Heather <Heather.Janik@fda.hhs.gov>
Cc: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>, Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>
Subject: Fwd: [EXTERNAL] Coronavirus draws attention to FDA oversight of Chinese drugs — Is there hope yet for the Senate drug bill? — Biogen scores a big patent win

Anything I can share with Laura? I can have team check through IMF as well.

From: Pence, Laura (HHS/ASL) <Laura.Pence@hhs.gov>
Date: February 7, 2020 at 7:36:15 AM EST
To: Gross, Karas <Karas.Gross@fda.hhs.gov>
Subject: Fwd: [EXTERNAL] Coronavirus draws attention to FDA oversight of Chinese drugs — Is there hope yet for the Senate drug bill? — Biogen scores a big patent win

(b)(5)

Begin forwarded message:

From: "McMillin, Virginia D. EOP/WHO" **(b)(6)**
Date: February 7, 2020 at 7:16:38 AM EST
To: "Pence, Laura (HHS/ASL)" <Laura.Pence@hhs.gov>
Subject: Fwd: [EXTERNAL] Coronavirus draws attention to FDA oversight of Chinese drugs — Is there hope yet for the Senate drug bill? — Biogen scores a big patent win

(b)(5)

Due to coronavirus agency staff is departing the country and all FDA travel to China is canceled.

Virginia McMillin
Special Assistant to the President
Office of Legislative Affairs
(b)(6)

Begin forwarded message:

From: POLITICO Pro's Prescription Pulse <politicoemail@politicopro.com>
Date: February 7, 2020 at 7:04:16 AM EST
To: "McMillin, Virginia D. EOP/WHO" **(b)(6)**
Subject: [EXTERNAL] Coronavirus draws attention to FDA oversight of Chinese drugs — Is there hope yet for the Senate drug bill? — Biogen scores a big patent win
Reply-To: "POLITICO, LLC" <reply-fe831c74736c0c7474-630347_HTML-1002034518-1376319-0@politicoemail.com>

Due to coronavirus agency staff is departing the country and all FDA travel to China is canceled.

From: Abram, Anna [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FB77660891384232A7CD9086FCBB1A3B-ANNA.ABRAM]
Sent: 2/8/2020 10:49:50 AM
To: Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: Re: WaPo CoV zoonotic disease article

(b)(5) Very timely piece.

From: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Date: February 8, 2020 at 9:39:02 AM EST
To: Abram, Anna <Anna.Abram@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: Re: WaPo CoV zoonotic disease article

(b)(5)

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Date: February 8, 2020 at 8:52:10 AM EST
To: Hahn, Stephen <SH1@fda.hhs.gov>, Solomon, Steven M <Steven.Solomon@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Amin, Stacy <Stacy.Amin@fda.hhs.gov>, Anderson, Erika <Erika.Anderson@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: WaPo CoV zoonotic disease article

FYI

Health

Coronavirus came from bats or possibly pangolins amid 'acceleration' of new zoonotic infections

Joel Achenbach

Feb. 7, 2020 at 1:01 p.m. EST

The outbreak of a new kind of coronavirus in central China is loaded with mysteries, and among the biggest is how the virus made the jump from an animal host into humans. This global health crisis is a reminder of the danger of zoonosis — the ability of pathogens, including bacteria and viruses, to enter the human population from an animal host.

The coronavirus is similar to two viruses that circulate in bats, but it might have skipped through another species before infecting humans.

Suspicion has fallen on the pangolin, an endangered, highly trafficked creature that looks like a cross between an anteater and an armadillo. Its scales are prized in traditional Chinese medicine, although they are made of keratin, just like fingernails. In recent days some researchers have noted that a coronavirus previously identified in pangolins is more closely related to the novel coronavirus than any virus identified so far.

AD

It is not clear whether any bats or pangolins, live or dead, were on sale in December at the Huanan Seafood Wholesale Market in Wuhan, where more than half of the people first identified with the virus had shopped. And it is possible that the viral leap into humans occurred somewhere else, as some early cases occurred in people with no known link to it.

The disease detectives need to nail down the host species because there could be a population of animals capable of sparking new outbreaks, said Melissa Nolan, an infectious-disease epidemiologist at the University of South Carolina.

"If we don't know what the intermediate host is and it's clearly capable of transmitting this infection, then we ultimately can't stop the spread of this virus," she said.

The World Health Organization has declared a public health emergency because of the outbreak, which has sickened more than 30,000 people, killing more than 630, mostly in China. The virus appears to be sufficiently contagious to become a global pandemic if not contained. It remains unclear whether the virus can be transmitted by infected people before they show symptoms.

In recent days scientists have wrestled with the sticky question of what to call the new coronavirus. Right now it is officially "2019-nCoV," which is inelegant at best and does little to describe the virus or the resulting disease in humans. One possibility is that the virus will be given a name that is a variant of SARS (sudden acute respiratory syndrome), a virus that killed 774 people in 37 countries before it was contained. The two coronaviruses are very similar genetically, and both are found in bats.

These bats carry the lethal Marburg virus, and disease detectives are tracking them to stop its spread

"They likely had a common ancestor in the bat population," said Stanley Perlman, a virologist at the University of Iowa who is part of the Coronavirus Study Group, a subset of the International Committee on the Taxonomy of Viruses.

"It's like a cousin," he said. "They probably started from a common ancestor some years ago in bats, and they mutated and evolved, and that's what you have now."

He said the committee favors including SARS in the name of the new virus.

"It's close to SARS. But it's not SARS. You could say a SARS-like virus, slash Wuhan, slash 2019," he said. "From a taxonomic point of view, it's so related to the previous virus, it needs to be included in its name."

After the emergence of Middle East respiratory syndrome (MERS) in Saudi Arabia in 2012, the WHO in 2015 asked national authorities, scientists and the news media to not name a virus after people, a geographic location, a cultural group or even a species of animal, because that can stigmatize communities or incite needless slaughtering of animals.

Scientists have identified about 400 emerging diseases since 1940, and more than 6 out of 10 have been zoonotic, according to a 2012 study published in the Lancet, a British medical journal. They include HIV from chimpanzees, Ebola and Marburg from bats, hantavirus from mice, MERS from camels, and swine flus and avian flus. Bats make up roughly a fifth of all mammal species and are frequent reservoirs of viruses that can potentially infect humans.

"We only know a really small fraction of the viruses that exist in wild animal populations. We've really just scratched the surface," said Christine Johnson, an epidemiologist at the University of California at Davis whose research has helped identify scores of coronaviruses in wild animals in Asia and Africa.

This "spillover" happens unpredictably. It is unclear why and how a virus that normally replicates in an animal starts to infect humans. No epidemic zoonotic disease in history has been predicted before the viral leap.

“Why it’s occurring now is really a mystery,” Perlman said. “You have people being around bats forever, eating bats and buying them in markets. Why did it take until December 2019?”

If the species that facilitated the jump from bats to humans is really a pangolin, that could complicate the search for its origins, said Benjamin Neuman, a virologist at Texas A&M University at Texarkana who is also in the Coronavirus Study Group. “If the illegal animal trade was at the root of this outbreak, it is going to be really difficult to trace, and I suspect most of the evidence is gone already — destroyed or spread out across the black market,” he said. “People aren’t going to want to talk, because of the consequences.”

In late December, four patients turned up ill in a hospital in Wuhan. Each had pneumonia-like symptoms and fever, and they tested negative for known diseases. Chinese authorities were on the lookout for a mystery illness such as this one, because they had seen it 17 years ago, when SARS flared in Guangdong province.

Life on Earth exists in a thick microbial soup. Survival typically requires collaboration with symbiotic organisms (for example, gut bacteria in humans) and the forbearance of potentially lethal pathogens. Few things are more enigmatic than viruses, which are just bare-bones strips of genetic material, either DNA or RNA, with some kind of protective coating.

On their own, outside a cell, viruses don’t do anything at all. They have no metabolism, no motion, no ability to reproduce. Scientists debate whether viruses, when outside a host, meet the standard for being alive. To reproduce, a virus has to enter the cell of a living host and hijack that cell’s machinery to make more of the virus.

“It’s switching between alive and not alive in its existence,” said Gary Whittaker, a Cornell University professor of virology, describing a virus as being somewhere “between chemistry and biology.”

Although the phenomenon of zoonosis has been happening among human beings and the animals they encounter for untold thousands of years, the modern world has made zoonotic epidemics more likely to occur, experts say. It’s a matter of numbers and geography. More people are coming into contact with more animals in more places, including habitats rarely or never visited by human beings — such as bat caves deep within a forest.

“We’re absolutely seeing an acceleration in the emergence of zoonotic disease,” said Jonathan Epstein, an epidemiologist at EcoHealth Alliance, a nonprofit group that studies emerging infectious diseases.

Changes in land use — agriculture, mining, etc. — play a huge role in creating opportunities for viral jumps. So do wild-animal markets. Authorities in China cracked down on sales of wild animals after SARS was linked to masked palm civets, catlike mammals. China later backed off some of the restrictions. Wild-animal markets remain common in much of the world.

Once a virus jumps into humans, population density becomes a factor in turning what might potentially be a small eruption of illnesses into an epidemic. A crowded city such as Wuhan, which has a population on the same order of magnitude as New York or London, creates conditions for person-to-person transmission.

Because these events have remained unpredictable, the public health responses have tended to be a game of catch-up, with communities desperately trying to contain the spread of the virus through quarantines, disease surveillance and rigorous hygiene practices. Eventually a vaccine can provide broad protection, but development takes many months or years.

Viruses have differing levels of contagiousness and virulence (the degree to which they make someone sick). The reproduction rate — how many people a sick person is likely to infect, on average — helps determine how widely it will spread. In a study in the Lancet, three University of Hong Kong scientists estimated that the coronavirus has a reproduction rate of 2.68, meaning every 10 sick people would eventually infect approximately 27 others.

"On the present trajectory [the coronavirus] could be about to become a global epidemic in the absence of mitigation," the report states. To prevent a large epidemic outside the city of Wuhan, "substantial, even draconian measures that limit population mobility should be seriously and immediately considered in affected areas," along with school closures and cancellation of mass gatherings, the authors state.

Global trade is a force multiplier for viruses. Viruses are not terribly stable outside a host, but if they can latch onto a globe-trotting species, they can go everywhere.

There are contradictory incentives for the virus. If it makes a person very sick and symptomatic — coughing, sneezing, throwing up, etc. — that can enhance the spread of the virus. But a sick person tends to be immobile and isolated and in contact with fewer people. A milder disease can spread more easily. Highly lethal viruses tend to burn themselves out quickly because there is no one left alive to spread them.

Transmission from one person to another usually requires a lot of the virus, said Nolan, the University of South Carolina epidemiologist.

"Our immune system does a good job of stopping infection in our body," she said. "There's a certain number when that pathogen can take over. Think about a mob. One person in the street probably can't topple a car, but if you had a 100 people in the street, they could probably push a car over if they're angry enough."

Out of control: How the world's health organizations failed to stop the Ebola disaster

What life is like for U.S. coronavirus evacuees under quarantine

We are swimming in a sea of viruses

What you need to know about coronavirus

Updated February 7, 2020

Follow our updates: Chinese health officials say they confirmed more than 31,000 cases of the novel coronavirus, more than 4,800 of them considered severe. The death toll surpassed 630.

Meanwhile, **quarantined on military bases, U.S. evacuees** resort to Zumba, stairwell races and accounting classes.

Chinese doctor Li Wenliang, who became a symbol of the Chinese government's failings after sounding warnings about the disease in December, **died Thursday after contracting the virus in Wuhan**. Within hours of his death, millions of Chinese tried to bypass censors to post the hashtag "We demand freedom of speech."

Are you in isolation or quarantine because of the coronavirus? We want to hear about it. Have you seen or experienced any discrimination, racism or xenophobia connected to the ongoing coronavirus epidemic? **Share your story.**

Mapping the spread of the new coronavirus: The United States, Germany, Sri Lanka, France, Cambodia, the Philippines, India, Thailand, Japan, Nepal, Hong Kong, Singapore, the United Arab Emirates, Canada, Vietnam, Macao and South Korea have all confirmed cases of the infection.

What is coronavirus and how does it spread? Coronaviruses are a large family of viruses whose effects range from causing the common cold to triggering much more serious diseases, such as severe acute respiratory syndrome, or SARS. **Here's what we know so far.**

From: Rath, Prakash (FDA) [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=91BC5673DB6C416E87A453F8B9527CC0-PRAKASH.RAT]
Sent: 2/9/2020 10:57:49 AM
To: Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Aguilar, Paul [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f4e6056acec4bc98fdb07bb0548dc86-Paul.Aguila]; McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]
Subject: RE: China Inspections Tear Sheet--AMA
Attachments: FYI - Sending at 5:15 pm TODAY - Slight updates - re: nCOV messaging on fda employees, inspections and shortages

See attached. All of those offices and folks provided input from my understanding. I didn't see anymore email traffic after the last email was shared with the group.

From: Gross, Karas <Karas.Gross@fda.hhs.gov>
Sent: Sunday, February 09, 2020 7:30 AM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Subject: Re: China Inspections Tear Sheet--AMA

I don't know who specifically reviewed (b)(5) (b)(5) Megan and/or Prakash can you correct me if I'm wrong and provide more specific clearance information. Thanks!

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Date: February 9, 2020 at 7:18:31 AM EST
To: Gross, Karas <Karas.Gross@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>, Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>, McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>, Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Subject: Re: China Inspections Tear Sheet--AMA

Thanks, Karas. Have ORA, OCC, and Mark Abdoo reviewed this latest version?

From: Gross, Karas <Karas.Gross@fda.hhs.gov>
Date: February 8, 2020 at 8:13:15 PM EST
To: Abram, Anna <Anna.Abram@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>, Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>, McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>, Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Subject: China Inspections Tear Sheet--AMA

Internal, confidential, pre-decisional

Hi Anna and Keagan-

(b)(5)

Once you all review and are in a good place, I can share these with Laura.

Thanks!
Karas

From: Abram, Anna [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FB77660891384232A7CD9086FCBB1A3B-ANNA.ABRAM]
Sent: 2/10/2020 4:19:15 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: RE: TWEETS for REVIEW: Coronavirus Update // Lab Awards

No, please loop me in directly on this chain. They did not include me.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Monday, February 10, 2020 4:10 PM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>
Subject: FW: TWEETS for REVIEW: Coronavirus Update // Lab Awards

Are you seeing his edits?

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Monday, February 10, 2020 3:25 PM
To: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Thorpe, Valarie <Valarie.Thorpe@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Stark, Angela <Angela.Stark@fda.hhs.gov>
Subject: RE: TWEETS for REVIEW: Coronavirus Update // Lab Awards

Hi Brad –
My inline edits / deletions in the sections highlighted below. In the first tweet, I deleted a phrase in the first sentence because you captured the point in the next sentence.
Otherwise good to go
Thanks
Anand

From: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>
Sent: Monday, February 10, 2020 3:18 PM
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Thorpe, Valarie <Valarie.Thorpe@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Stark, Angela <Angela.Stark@fda.hhs.gov>
Subject: TWEETS for REVIEW: Coronavirus Update // Lab Awards

Good afternoon… here are two threads for your review. The first is today's Coronavirus update. Thanks! --Brad

===

(b)(5)

(b)(5)

Brad Kimberly
Director, Social Media

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel 240-402-1002 | Cell (b)(6)
brad.kimberly@fda.hhs.gov

From: Caliguiri, Laura [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AA086F2D6C0346C49E996932D86AC62E-LAURA.CALIG]
Sent: 2/10/2020 4:52:21 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Janik, Heather [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbebeee5ffeeb7f3d-Heather.Jan]
Subject: RE: FYI For Coronavirus, US FDA Is At The Podium But Not On The Task Force

(b)(5)

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Monday, February 10, 2020 4:40 PM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>
Subject: RE: FYI For Coronavirus, US FDA Is At The Podium But Not On The Task Force

Good idea.

(b)(5)

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Sent: Monday, February 10, 2020 4:33 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>
Subject: RE: FYI For Coronavirus, US FDA Is At The Podium But Not On The Task Force

(b)(5)

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Monday, February 10, 2020 4:25 PM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>
Subject: FW: FYI For Coronavirus, US FDA Is At The Podium But Not On The Task Force

(b)(5) Can we work on this?

From: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Sent: Monday, February 10, 2020 4:22 PM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: FYI For Coronavirus, US FDA Is At The Podium But Not On The Task Force

For Coronavirus, US FDA Is At The Podium But Not On The Task Force

- 09 Feb 2020
- **ANALYSIS**

Derrick Gingery @dgingery derrick.gingery@informa.com

Executive Summary

The FDA is curiously not one of the HHS entities coordinating the US response to the outbreak, but must monitor for manufacturing disruptions and shortages, as well as approve new treatments and diagnostics.

Source: Screenshot of HHS webcast US FDA COMMISSIONER STEPHEN HAHN SPEAKS DURING AN HHS BRIEFING ABOUT CORONAVIRUS ON 7 FEBRUARY 2020. HE WAS CALLED UP FROM THE AUDIENCE TO ADDRESS MANUFACTURING ISSUES SINCE FDA IS NOT PART OF THE ADMINISTRATION'S TASK FORCE CHARGED WITH RESPONDING TO THE OUTBREAK.

The US response to coronavirus does not necessarily have the Food and Drug Administration sitting at the coordinating table, despite its key role in fighting and containing the outbreak.

However, like the most recent press conference on the subject, the FDA will be called up to offer its expertise.

President Trump's Coronavirus Task Force

- Alex Azar, HHS Secretary
- Robert O'Brien, assistant to the president for national security affairs
- Robert Redfield, CDC director
- Anthony Fauci, NIH National Institute of Allergy and Infectious Diseases director
- Stephen Biegun, State Department Deputy Secretary
- Ken Cuccinelli, Homeland Security Department acting deputy secretary
- Joel Szabat, Transportation Department acting under secretary for policy
- Matthew Pottinger, assistant to the president and deputy national security advisor
- Rob Blair, assistant to the president and senior advisor to the Chief of Staff
- Joseph Grogan, assistant to the president and director of the Domestic Policy Council
- Christopher Liddell, assistant to the president and deputy chief of staff for policy coordination
- Derek Kan, executive associate director, Office of Management and Budget

FDA Commissioner Stephen Hahn stepped into the coronavirus spotlight on 7 February, appearing at a press conference with Health and Human Services Secretary Alex Azar and others. Hahn was not on stage with coronavirus task force members, but was called up from the audience to respond to a question about the medical product supply chain. Hahn said that to date there have been no reports of disruptions related to facilities in China, the center of the outbreak.

"FDA is closely monitoring the situation," he said. "We're working with our government collaborators as well as manufacturers to monitor what's going on in the supply chain. At this moment we have received no reports from manufacturers about disruptions to the medical product supply chain. Obviously, the situation is fluid and we'll do everything we can to continue to monitor this and act accordingly."

The comments largely follow earlier assurances from the agency's drug shortage team that so far, the coronavirus (also known as 2019-nCoV) outbreak is not causing problems for the US drug supply. (Also see "Coronavirus Not Impacting Rx Manufacturing Supply Chain – Yet" - Pink Sheet, 29 Jan, 2020.)

The agency has discussed its activities since the outbreak began, created a website with updates and resources, but was not included on President Trump's coronavirus task force. The 12 spots were given to Azar, Centers for Disease Control and Prevention Director Robert Redfield, National Institute of Allergy and Infectious Diseases Director Anthony Fauci, and others. (*See box.*)

The FDA, HHS and White House would not explain why the FDA was not a member of the task force. The move seemed a bit odd, given that the FDA's role in the response. The agency already has provided an emergency use authorization for a CDC coronavirus diagnostic and is helping streamline the development of vaccines and other countermeasures.

The reason may be that there simply were not enough seats at the President's table. Anand Parekh, chief medical advisor at the Bipartisan Policy Center, told the *Pink Sheet* that HHS likely has its own intra-department leadership team that includes Hahn.

And while the response to the outbreak should not be distracted by jockeying for screen time, from a strictly logistical perspective, keeping the FDA in the loop would seem to be warranted. Indeed, even without a seat at the task force table, FDA will have close to the first and last word in the government's response to the outbreak – from authorizing the initial diagnostic to eventually, everyone hopes, approving a vaccine.

The coronavirus outbreak is among Hahn's first high-profile public appearances since taking office in December. (Also see "New US FDA Commissioner Stephen Hahn Heads to White Oak Under Vaping Cloud" - Pink Sheet, 12 Dec, 2019.) While he has conducted media interviews and given speeches internally, Hahn has not spent a lot of time in public view so far. (Also see "Hahn's Priorities For US FDA Eschew Hot-Button Issues, Focus on Traditional Themes" - Pink Sheet, 30 Jan, 2020.)

Treatment Could Reach Phase I In Two Months, Fauci Says

Aside from providing the EUA for the first coronavirus diagnostic, the FDA also soon could be monitoring and preparing for clinical trial results for a treatment.

Fauci said during the press conference that a randomized control trial comparing treatment with Gilead Sciences Inc.'s antiviral remdesivir plus the standard of care to remdesivir alone has started in China.

Moderna Inc. also is developing a messenger RNA vaccine against the coronavirus. (Also see "Coronavirus Efforts Could Benefit From Little-Used Medical Countermeasures Incentives" - Pink Sheet, 29 Jan, 2020.)

Fauci said so far there have been no glitches in efforts to insert the necessary gene into the messenger RNA and use it in an animal model. He said if all continues to go well, Phase I trials in humans could begin in two months.

In addition, GlaxoSmithKline PLC is lending adjuvant expertise to the Coalition for Epidemic Preparedness Innovations, a Norwegian public-private organization, to aid vaccine development. (Also see "GSK Joins Race To Tackle Coronavirus" - Scrip, 3 Feb, 2020.)

FDA Increasing Visitor Scrutiny

While the government is enforcing travel restrictions to contain the virus' spread into the US, the FDA is warning that its visitors also may face scrutiny.

The agency wrote on its website that because of the public health emergency, "visitors to FDA campuses and buildings may be asked questions related to recent international travel."

The virus is not an immediate threat in the US, but the statement suggests that sponsors may have to closely scrutinize the representatives they chose to send to the FDA headquarters in Maryland for in-person meetings.

In addition, the US has offered to send a team of experts to China to assist in their response and learn more about the virus. Azar said the Chinese government has not decided whether it will allow them there, although he expects eventually access will be granted.

From: Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]
Sent: 2/10/2020 5:04:09 PM
To: Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: RE: Telecon: Coronavirus Check-In

This is good to know – thank you

From: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Sent: Monday, February 10, 2020 5:02 PM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: RE: Telecon: Coronavirus Check-In

Feedback from Mark Raza which is very helpful:

(b)(5)

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Sent: Monday, February 10, 2020 4:38 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: RE: Telecon: Coronavirus Check-In

Agree we should hear the feedback from the centers to fully inform. I asked the IMG to work with them to provide a recommendation on this point by COB today.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Monday, February 10, 2020 4:22 PM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: RE: Telecon: Coronavirus Check-In

No further edits from me on the attachment.

Also, HHS is not going to let us be proactive on the comms for CEO touches, only reactive. With that in mind, is it worth reconsidering the effort going in to this? Depending on what we hear back from the Centers we might want to revisit.

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Sent: Monday, February 10, 2020 4:17 PM
To: Rom, Colin <Colin.Rom@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: RE: Telecon: Coronavirus Check-In

Thanks, Colin. I further revised in the attached.

If folks don't have further suggested edits, I'd recommend this for Stacy's legal scrub next.

Thanks.

From: Rom, Colin <Colin.Rom@fda.hhs.gov>
Sent: Monday, February 10, 2020 3:30 PM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: RE: Telecon: Coronavirus Check-In

(b)(5)

- Thanks for taking a few minutes to connect today

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Sent: Monday, February 10, 2020 1:16 PM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Telecon: Coronavirus Check-In

Thanks, Anand. Colin, why don't you take edits next and then I can offer further feedback when I emerge from the SCIF later this afternoon. Some quick thoughts - I'd recommend working **(b)(5)**

(b)(5)

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Monday, February 10, 2020 1:06 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Telecon: Coronavirus Check-In

PRE-DECISIONAL, CONFIDENTIAL

Draft talking points. Feel free to add / subtract

Target: <5 min phone call

(b)(5)

- Thanks for taking a few minutes to connect today

-----Original Appointment-----
From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Sunday, February 9, 2020 6:24 PM
To: Hahn, Stephen; Lenihan, Keagan; Abram, Anna; Amin, Stacy; Shah, Anand; Rom, Colin
Subject: Telecon: Coronavirus Check-In
When: Monday, February 10, 2020 8:30 AM-9:00 AM (UTC-05:00) Eastern Time (US & Canada).
Where: 1-877-465-7975,,,**(b)(6)**

From: Rebello, Heidi [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2834CE193CA949799EF063E34A2CFA0B-HEIDI.REBEL]
Sent: 2/10/2020 5:05:53 PM
To: Janik, Heather [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbebeee5ffeeb7f3d-Heather.Jan]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]
Subject: RE: FYI For Coronavirus, US FDA Is At The Podium But Not On The Task Force

We are receiving a number of inquiries related to supply chain.

From: Janik, Heather <Heather.Janik@fda.hhs.gov>
Sent: Monday, February 10, 2020 5:04 PM
To: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
Subject: RE: FYI For Coronavirus, US FDA Is At The Podium But Not On The Task Force

Thanks, Heidi, we definitely will. I know the one specific interest was Tom Burton in talking about the drug supply. Anna felt **(b)(5)**

(b)(5)

From: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Sent: Monday, February 10, 2020 5:03 PM
To: Janik, Heather <Heather.Janik@fda.hhs.gov>; Caliguiri, Laura <Laura .Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
Subject: RE: FYI For Coronavirus, US FDA Is At The Podium But Not On The Task Force

We have been asked about this before and our response has been that we are actively engaged and working with all levels of gov't in response to outbreak.
We are preparing social for the Commissioner every day to show engagement. Aiming for the joint statement with ASPR to go out by Wed.
Heather, if coronavirus comes up in any media interactions with SH please flag for us. We can also make sure we give you latest TPs before any touches with media.

From: Janik, Heather <Heather.Janik@fda.hhs.gov>
Sent: Monday, February 10, 2020 4:42 PM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
Subject: RE: FYI For Coronavirus, US FDA Is At The Podium But Not On The Task Force

(b)(5)

(b)(5)

Adding Heidi, Megan and Michael for their important insight via JIC and the press conference Friday.

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Sent: Monday, February 10, 2020 4:33 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>
Subject: RE: FYI For Coronavirus, US FDA Is At The Podium But Not On The Task Force

(b)(5)

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To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>
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(b)(5)

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Sent: Monday, February 10, 2020 4:22 PM
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Subject: FYI For Coronavirus, US FDA Is At The Podium But Not On The Task Force

For Coronavirus, US FDA Is At The Podium But Not On The Task Force

- 09 Feb 2020
- **ANALYSIS**
- 

Derrick Gingery @dgingery derrick.gingery@informa.com

Executive Summary

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- Stephen Biegun, State Department Deputy Secretary
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"FDA is closely monitoring the situation," he said. "We're working with our government collaborators as well as manufacturers to monitor what's going on in the supply chain. At this moment we have received no reports from manufacturers about disruptions to the medical product supply chain. Obviously, the situation is fluid and we'll do everything we can to continue to monitor this and act accordingly."

The comments largely follow earlier assurances from the agency's drug shortage team that so far, the coronavirus (also known as 2019-nCoV) outbreak is not causing problems for the US drug supply. (Also see "Coronavirus Not Impacting Rx Manufacturing Supply Chain – Yet" - Pink Sheet, 29 Jan, 2020.)

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In addition, the US has offered to send a team of experts to China to assist in their response and learn more about the virus. Azar said the Chinese government has not decided whether it will allow them there, although he expects eventually access will be granted.

From: Rebello, Heidi [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2834CE193CA949799EF063E34A2CFA0B-HEIDI.REBEL]
Sent: 2/10/2020 5:08:55 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: RE: TWEETS for REVIEW: Coronavirus Update // Lab Awards

I spoke with her.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Monday, February 10, 2020 4:38 PM
To: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: FW: TWEETS for REVIEW: Coronavirus Update // Lab Awards

Anna made this edit earlier to Megan on something else. Can you make sure she is editing appropriately and that the OMA team is getting those updates? Pls.

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Sent: Monday, February 10, 2020 4:35 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Thorpe, Valarie <Valarie.Thorpe@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Stark, Angela <Angela.Stark@fda.hhs.gov>
Subject: RE: TWEETS for REVIEW: Coronavirus Update // Lab Awards

Thank you for looping me in. We should (b)(5)
(b)(5)
(b)(5) Thanks, all.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Monday, February 10, 2020 4:21 PM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Thorpe, Valarie <Valarie.Thorpe@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Stark, Angela <Angela.Stark@fda.hhs.gov>
Subject: RE: TWEETS for REVIEW: Coronavirus Update // Lab Awards

+ Anna – pls include Anna in clearance for coronavirus tweets.

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Monday, February 10, 2020 3:25 PM
To: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Thorpe, Valarie <Valarie.Thorpe@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Stark, Angela <Angela.Stark@fda.hhs.gov>
Subject: RE: TWEETS for REVIEW: Coronavirus Update // Lab Awards

Hi Brad –
My inline edits / deletions in the sections highlighted below. In the first tweet, I deleted a phrase in the first sentence because you captured the point in the next sentence.

Otherwise good to go
Thanks
Anand

From: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>
Sent: Monday, February 10, 2020 3:18 PM
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Thorpe, Valarie <Valarie.Thorpe@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Stark, Angela <Angela.Stark@fda.hhs.gov>
Subject: TWEETS for REVIEW: Coronavirus Update // Lab Awards

Good afternoon… here are two threads for your review. The first is today's Coronavirus update. Thanks! --Brad

===

(b)(5)

Brad Kimberly
Director, Social Media

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel 240-402-1002 | Cel (b)(6)
brad.kimberly@fda.hhs.gov


FDA
U.S. FOOD & DRUG
ADMINISTRATION

From: Caliguiri, Laura [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AA086F2D6C0346C49E996932D86AC62E-LAURA.CALIG]
Sent: 2/10/2020 6:32:38 PM
To: Janik, Heather [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbebeee5ffeeb7f3d-Heather.Jan]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]
CC: Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]
Subject: RE: FYI For Coronavirus, US FDA Is At The Podium But Not On The Task Force

(b)(5)

From: Janik, Heather <Heather.Janik@fda.hhs.gov>
Sent: Monday, February 10, 2020 5:07 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
Subject: RE: FYI For Coronavirus, US FDA Is At The Podium But Not On The Task Force

Got it. Thanks. We'll hold until more info is available.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Monday, February 10, 2020 5:06 PM
To: Janik, Heather <Heather.Janik@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
Subject: RE: FYI For Coronavirus, US FDA Is At The Podium But Not On The Task Force

We are still culling that info. Too soon.

From: Janik, Heather <Heather.Janik@fda.hhs.gov>
Sent: Monday, February 10, 2020 5:04 PM
To: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
Subject: RE: FYI For Coronavirus, US FDA Is At The Podium But Not On The Task Force

Thanks, Heidi, we definitely will. I know the one specific interest was Tom Burton in talking about the drug supply. Anna felt **(b)(5)**

(b)(5)

From: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Sent: Monday, February 10, 2020 5:03 PM
To: Janik, Heather <Heather.Janik@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
Subject: RE: FYI For Coronavirus, US FDA Is At The Podium But Not On The Task Force

We have been asked about this before and our response has been that we are actively engaged and working with all levels of gov't in response to outbreak.
We are preparing social for the Commissioner every day to show engagement. Aiming for the joint statement with ASPR to go out by Wed.
Heather, if coronavirus comes up in any media interactions with SH please flag for us. We can also make sure we give you latest TPs before any touches with media.

From: Janik, Heather <Heather.Janik@fda.hhs.gov>
Sent: Monday, February 10, 2020 4:42 PM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
Subject: RE: FYI For Coronavirus, US FDA Is At The Podium But Not On The Task Force

(b)(5)

Adding Heidi, Megan and Michael for their important insight via JIC and the press conference Friday.

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Sent: Monday, February 10, 2020 4:33 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>
Subject: RE: FYI For Coronavirus, US FDA Is At The Podium But Not On The Task Force

(b)(5)

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Monday, February 10, 2020 4:25 PM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>
Subject: FW: FYI For Coronavirus, US FDA Is At The Podium But Not On The Task Force

(b)(5)

From: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Sent: Monday, February 10, 2020 4:22 PM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: FYI For Coronavirus, US FDA Is At The Podium But Not On The Task Force

For Coronavirus, US FDA Is At The Podium But Not On The Task Force

- 09 Feb 2020
- **ANALYSIS**
- 

Derrick Gingery @dgingery derrick.gingery@informa.com

Executive Summary

The FDA is curiously not one of the HHS entities coordinating the US response to the outbreak, but must monitor for manufacturing disruptions and shortages, as well as approve new treatments and diagnostics.

Source: Screenshot of HHS webcast US FDA COMMISSIONER STEPHEN HAHN SPEAKS DURING AN HHS BRIEFING ABOUT CORONAVIRUS ON 7 FEBRUARY 2020. HE WAS CALLED UP FROM THE AUDIENCE TO ADDRESS MANUFACTURING ISSUES SINCE FDA IS NOT PART OF THE ADMINISTRATION'S TASK FORCE CHARGED WITH RESPONDING TO THE OUTBREAK.

The US response to coronavirus does not necessarily have the Food and Drug Administration sitting at the coordinating table, despite its key role in fighting and containing the outbreak.

However, like the most recent press conference on the subject, the FDA will be called up to offer its expertise.

President Trump's Coronavirus Task Force

- Alex Azar, HHS Secretary
- Robert O'Brien, assistant to the president for national security affairs
- Robert Redfield, CDC director
- Anthony Fauci, NIH National Institute of Allergy and Infectious Diseases director
- Stephen Biegun, State Department Deputy Secretary
- Ken Cuccinelli, Homeland Security Department acting deputy secretary
- Joel Szabat, Transportation Department acting under secretary for policy
- Matthew Pottinger, assistant to the president and deputy national security advisor
- Rob Blair, assistant to the president and senior advisor to the Chief of Staff
- Joseph Grogan, assistant to the president and director of the Domestic Policy Council
- Christopher Liddell, assistant to the president and deputy chief of staff for policy coordination
- Derek Kan, executive associate director, Office of Management and Budget

FDA Commissioner Stephen Hahn stepped into the coronavirus spotlight on 7 February, appearing at a press conference with Health and Human Services Secretary Alex Azar and others. Hahn was not on stage with coronavirus task force members, but was called up from the audience to respond to a question about the medical product supply chain. Hahn said that to date there have been no reports of disruptions related to facilities in China, the center of the outbreak.

"FDA is closely monitoring the situation," he said. "We're working with our government collaborators as well as manufacturers to monitor what's going on in the supply chain. At this moment we have received no reports from manufacturers about disruptions to the medical product supply chain. Obviously, the situation is fluid and we'll do everything we can to continue to monitor this and act accordingly."

The comments largely follow earlier assurances from the agency's drug shortage team that so far, the coronavirus (also known as 2019-nCoV) outbreak is not causing problems for the US drug supply. (Also see "Coronavirus Not Impacting Rx Manufacturing Supply Chain – Yet" - Pink Sheet, 29 Jan, 2020.)

The agency has discussed its activities since the outbreak began, created a website with updates and resources, but was not included on President Trump's coronavirus task force. The 12 spots were given to Azar, Centers for Disease Control and Prevention Director Robert Redfield, National Institute of Allergy and Infectious Diseases Director Anthony Fauci, and others. (*See box.*)

The FDA, HHS and White House would not explain why the FDA was not a member of the task force. The move seemed a bit odd, given that the FDA's role in the response. The agency already has provided an emergency use authorization for a CDC coronavirus diagnostic and is helping streamline the development of vaccines and other countermeasures.

The reason may be that there simply were not enough seats at the President's table. Anand Parekh, chief medical advisor at the Bipartisan Policy Center, told the *Pink Sheet* that HHS likely has its own intra-department leadership team that includes Hahn.

And while the response to the outbreak should not be distracted by jockeying for screen time, from a strictly logistical perspective, keeping the FDA in the loop would seem to be warranted. Indeed, even without a seat at the task force table, FDA will have close to the first and last word in the government's response to the outbreak – from authorizing the initial diagnostic to eventually, everyone hopes, approving a vaccine.

The coronavirus outbreak is among Hahn's first high-profile public appearances since taking office in December. (Also see "New US FDA Commissioner Stephen Hahn Heads to White Oak Under Vaping Cloud" - Pink Sheet, 12 Dec, 2019.) While he has conducted media interviews and given speeches internally, Hahn has not spent a lot of time in public view so far. (Also see "Hahn's Priorities For US FDA Eschew Hot-Button Issues, Focus on Traditional Themes" - Pink Sheet, 30 Jan, 2020.)

Treatment Could Reach Phase I In Two Months, Fauci Says

Aside from providing the EUA for the first coronavirus diagnostic, the FDA also soon could be monitoring and preparing for clinical trial results for a treatment.

Fauci said during the press conference that a randomized control trial comparing treatment with Gilead Sciences Inc.'s antiviral remdesivir plus the standard of care to remdesivir alone has started in China.

Moderna Inc. also is developing a messenger RNA vaccine against the coronavirus. (Also see "Coronavirus Efforts Could Benefit From Little-Used Medical Countermeasures Incentives" - Pink Sheet, 29 Jan, 2020.)

Fauci said so far there have been no glitches in efforts to insert the necessary gene into the messenger RNA and use it in an animal model. He said if all continues to go well, Phase I trials in humans could begin in two months.

In addition, GlaxoSmithKline PLC is lending adjuvant expertise to the Coalition for Epidemic Preparedness Innovations, a Norwegian public-private organization, to aid vaccine development. (Also see "GSK Joins Race To Tackle Coronavirus" - Scrip, 3 Feb, 2020.)

FDA Increasing Visitor Scrutiny

While the government is enforcing travel restrictions to contain the virus' spread into the US, the FDA is warning that its visitors also may face scrutiny.

The agency wrote on its website that because of the public health emergency, "visitors to FDA campuses and buildings may be asked questions related to recent international travel."

The virus is not an immediate threat in the US, but the statement suggests that sponsors may have to closely scrutinize the representatives they chose to send to the FDA headquarters in Maryland for in-person meetings.

In addition, the US has offered to send a team of experts to China to assist in their response and learn more about the virus. Azar said the Chinese government has not decided whether it will allow them there, although he expects eventually access will be granted.

From: HHS Office of Public Affairs [hhsopa@hhs.gov]
Sent: 2/11/2020 10:16:39 AM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: Secretaries Alex Azar, Mike Pompeo: Our coronavirus response is protecting Americans

News Release

U.S. Department of Health and Human Services

202-690-6343
media@hhs.gov
www.hhs.gov/news
Twitter @SpoxHHS

FOR IMMEDIATE RELEASE
Tuesday, February 11, 2020

Secretaries Alex Azar, Mike Pompeo: Our coronavirus response is protecting Americans

USA TODAY
By Secretaries Alex Azar and Mike Pompeo
February 11, 2020

The first duty of the federal government is to keep our citizens safe. Since the United States first became aware on Dec. 30 of what has become known as the novel coronavirus, America's public health officials have closely monitored the situation, worked to understand the virus and taken steps to limit Americans' exposure to it.

Our task force is ensuring that our whole of government, layered, public health plan has the resources necessary to protect Americans. We've treated the sick, and traced back their travel history and contacts to minimize the spread of the virus. We've worked swiftly to screen and safely receive American travelers returning from China, and bar foreign travelers who have recently visited the epicenter of the outbreak.

Consistent with the World Health Organization International Health Regulations, our travel restrictions were intentionally devised to complement the Chinese government's policy of isolating approximately 50 million of its own citizens in Hubei province. Other nations, such as Italy and South Korea, have taken similar measures.

Thus far, the United States has only had 13 confirmed cases of the virus. We were saddened to hear last week that one American, a 60-year-old woman in Wuhan, China, has died. But we're undeterred in our vigilance to protect our people. And we're mobilizing resources around the world to help other nations fight the disease, too. This is American altruism at its finest.

Let's start with our efforts focused on the country where the virus first appeared — China. In the words of President Donald Trump, "We're offering them tremendous help." During the first week of January, the Centers for Disease Control and Prevention made an offer of assistance in order to understand the disease and help bolster response efforts.

The Department of Health and Human Services subsequently provided to the WHO a list of world-class medical professionals ready to deploy their skills in China and learn from China's efforts to combat this new coronavirus. In the last week of January, Secretary Azar personally extended an offer of help to Health Minister Ma Xiaowei; Secretary Pompeo did the same with Chinese State Councilor Yang Jiechi. We hope the mission

will commence immediately, whether bilaterally or under the auspices of the WHO.

We've also facilitated the delivery of vast amounts of medical supplies to the Chinese people. Just last week, the State Department helped transport 17.8 tons of relief supplies to Hubei. And more assistance will continue to be offered — the United States is prepared to spend up to $100 million in existing State and U.S. Agency for International Development funds to assist China and other impacted countries to contain and combat the virus.

While State managed the logistics, the donations themselves were provided by Samaritan's Purse, Boeing, Intermountain Healthcare and The Church of Jesus Christ of Latter-day Saints, and coordinated by a nongovernmental organization called Project HOPE. Time and again, when diseases and disasters strike, the American people have stepped up to help citizens of other countries without being asked. Our robust charitable giving and enthusiastic civil society groups are channeling the American people's concern for their fellow man.

Then there are America's actions to help the citizens of other countries, beyond China. CDC staff based in more than 60 countries are working closely with ministries of health and other health partners, often in conjunction with their colleagues at the State Department and other federal agencies.

For instance, the United States has made coronavirus test kits available to 191 qualified laboratories around the world; so far, labs from 36 countries have put in orders. We've deployed staff to train health professionals in 15 hospitals in Vietnam. In Kenya, health experts at the U.S. Embassy in Nairobi, as part of our Infectious Diseases Task Force, engaged the government early on to recommend best practices in airport screening and public health.

Our quick and effective reaction abroad is facilitated by partnerships that America has carefully nurtured over decades — long before the latest outbreak.

We believe our actions will slow the transmission of the virus to and within the United States and other countries, solidify our ties of friendship with our allies and partners, and help save lives by giving us more time to refine preparedness measures and better understand the virus.

We all hope that our concerted efforts will control the virus and cause it to subside. But the world doesn't need to wait for that day to see how America remains a force for good throughout the globe.

This op-ed originally appeared in USA Today on February 11, 2020.

###

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From: Abram, Anna [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FB77660891384232A7CD9086FCBB1A3B-ANNA.ABRAM]
Sent: 2/11/2020 12:35:21 PM
To: Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
CC: Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]
Subject: RE: Telecon: Coronavirus Check-In

Thank you, both.

From: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Sent: Tuesday, February 11, 2020 12:35 PM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Raza, Mark <Mark.Raza@fda.hhs.gov>
Subject: RE: Telecon: Coronavirus Check-In

Mark can you please provide?

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Sent: Tuesday, February 11, 2020 12:35 PM
To: Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: RE: Telecon: Coronavirus Check-In

Stacy, does Raza have a specific line edit to the 4th bullet?

I checked in with the IMG this am and as of OOB they had received some feedback, but were still hearing from the centers. And once the suggestions come in we'll need to run through Emily for ethics check before teeing up to the Commissioner.

Thanks.

From: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Sent: Monday, February 10, 2020 5:02 PM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: RE: Telecon: Coronavirus Check-In

Feedback from Mark Raza which is very helpful:

(b)(5)

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Sent: Monday, February 10, 2020 4:38 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: RE: Telecon: Coronavirus Check-In

Agree we should hear the feedback from the centers to fully inform. I asked the IMG to work with them to provide a recommendation on this point by COB today.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Monday, February 10, 2020 4:22 PM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: RE: Telecon: Coronavirus Check-In

No further edits from me on the attachment.

Also, HHS is not going to let us be proactive on the comms for CEO touches, only reactive. With that in mind, is it worth reconsidering the effort going in to this? Depending on what we hear back from the Centers we might want to revisit.

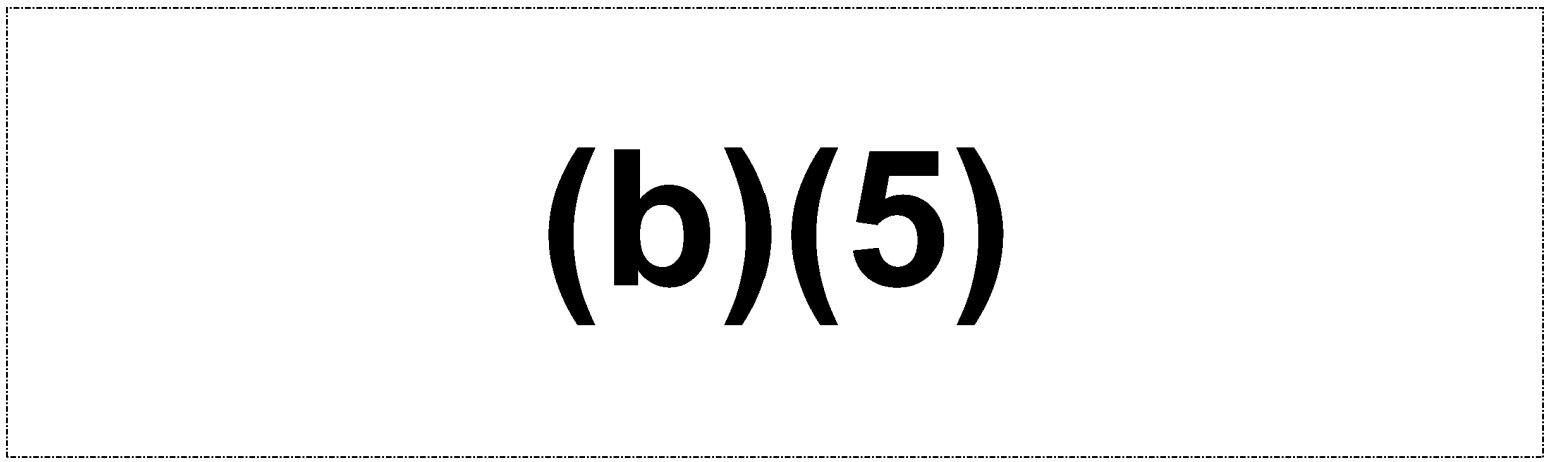
From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Sent: Monday, February 10, 2020 4:17 PM
To: Rom, Colin <Colin.Rom@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: RE: Telecon: Coronavirus Check-In

Thanks, Colin. I further revised in the attached.

If folks don't have further suggested edits, I'd recommend this for Stacy's legal scrub next.

Thanks.

From: Rom, Colin <Colin.Rom@fda.hhs.gov>
Sent: Monday, February 10, 2020 3:30 PM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: RE: Telecon: Coronavirus Check-In



(b)(5)

- Thanks for taking a few minutes to connect today

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Sent: Monday, February 10, 2020 1:16 PM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Telecon: Coronavirus Check-In

Thanks, Anand. Colin, why don't you take edits next and then I can offer further feedback when I emerge from the SCIF later this afternoon. Some quick thoughts - I'd recommend working i (b)(5)

(b)(5)

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Monday, February 10, 2020 1:06 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Telecon: Coronavirus Check-In

PRE-DECISIONAL, CONFIDENTIAL

Draft talking points. Feel free to add / subtract

Target: <5 min phone call

(b)(5)

- Thanks for taking a few minutes to connect today

-----Original Appointment-----
From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Sunday, February 9, 2020 6:24 PM
To: Hahn, Stephen; Lenihan, Keagan; Abram, Anna; Amin, Stacy; Shah, Anand; Rom, Colin

Subject: Telecon: Coronavirus Check-In
When: Monday, February 10, 2020 8:30 AM-9:00 AM (UTC-05:00) Eastern Time (US & Canada).
Where: 1-877-465-7975,,(b)(6)

From: Raza, Mark [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5811A7D72EE34AA78FF3C8CCB59F92EE-MRAZA]
Sent: 2/11/2020 12:44:19 PM
To: Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
Subject: RE: Telecon: Coronavirus Check-In

Re the following bullets:

(b)(5)

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Sent: Tuesday, February 11, 2020 12:35 PM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
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Sent: Monday, February 10, 2020 5:02 PM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: RE: Telecon: Coronavirus Check-In

Feedback from Mark Raza which is very helpful:

(b)(5)

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Sent: Monday, February 10, 2020 4:38 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: RE: Telecon: Coronavirus Check-In

Agree we should hear the feedback from the centers to fully inform. I asked the IMG to work with them to provide a recommendation on this point by COB today.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Monday, February 10, 2020 4:22 PM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: RE: Telecon: Coronavirus Check-In

No further edits from me on the attachment.

Also, HHS is not going to let us be proactive on the comms for CEO touches, only reactive. With that in mind, is it worth reconsidering the effort going in to this? Depending on what we hear back from the Centers we might want to revisit.

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Sent: Monday, February 10, 2020 4:17 PM
To: Rom, Colin <Colin.Rom@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: RE: Telecon: Coronavirus Check-In

Thanks, Colin. I further revised in the attached.

If folks don't have further suggested edits, I'd recommend this for Stacy's legal scrub next.

Thanks.

From: Rom, Colin <Colin.Rom@fda.hhs.gov>
Sent: Monday, February 10, 2020 3:30 PM

To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: RE: Telecon: Coronavirus Check-In

(b)(5)

- Thanks for taking a few minutes to connect today

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Sent: Monday, February 10, 2020 1:16 PM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Telecon: Coronavirus Check-In

Thanks, Anand. Colin, why don't you take edits next and then I can offer further feedback when I emerge from the SCIF later this afternoon. Some quick thoughts - I'd recommend workin (b)(5)

(b)(5)

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Monday, February 10, 2020 1:06 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Telecon: Coronavirus Check-In

PRE-DECISIONAL, CONFIDENTIAL

Draft talking points. Feel free to add / subtract

Target: <5 min phone call

(b)(5)

(b)(5)

- Thanks for taking a few minutes to connect today

-----Original Appointment-----
From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Sunday, February 9, 2020 6:24 PM
To: Hahn, Stephen; Lenihan, Keagan; Abram, Anna; Amin, Stacy; Shah, Anand; Rom, Colin
Subject: Telecon: Coronavirus Check-In
When: Monday, February 10, 2020 8:30 AM-9:00 AM (UTC-05:00) Eastern Time (US & Canada).
Where: 1-877-465-7975, (b)(6)

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 2/12/2020 8:40:34 AM
To: Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; McBride, Maren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]
Subject: FW: DUE 11:30 AM TODAY - AMA nCoV Tear Sheets for budget hearing
Attachments: FINAL CoV for Clearance 2.12.docx; 2.12.20 nCoV TOC.docx

Importance: High

Can you run clearance here?

From: Twomey, John K. (HHS/ASL) <John.Twomey@HHS.GOV>
Sent: Wednesday, February 12, 2020 7:14 AM
To: McGowan, Robert K (CDC) <omc2@cdc.gov>; Campbell, Amanda (CDC) <ons3@cdc.gov>; Charrow, Robert (OS) <Robert.Charrow@hhs.gov>; White, Caroline (OS) <Caroline.White@hhs.gov>; Zebley, Kyle (OS) <Kyle.Zebley@hhs.gov>; Grigsby, Garrett G (OS) <Garrett.Grigsby@hhs.gov>; Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>; Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Steele, Danielle (OS) <Danielle.Steele@hhs.gov>; Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>; Hall, Bill (OS) <bill.hall@hhs.gov>; Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>; Brennan, Patrick (OS) <Patrick.Brennan@hhs.gov>; Schmoyer, Michael (OS) <Michael.Schmoyer@hhs.gov>; Harrison, Brian (OS) <Brian.Harrison@hhs.gov>; Stecker, Judy (OS) <Judy.Stecker@hhs.gov>; Mango, Paul (OS) <Paul.Mango@hhs.gov>
Cc: Moughalian, Jen C (OS) <Jen.Moughalian@hhs.gov>; Shuy, Caitrin (OS) <Caitrin.Shuy@hhs.gov>; Hittle, Taylor (OS) <Taylor.Hittle@hhs.gov>; Pence, Laura (OS) <Laura.Pence@hhs.gov>; Morse, Sara N (OS) <Sara.Morse@hhs.gov>; Arbes, Sarah C (OS) <Sarah.Arbes@hhs.gov>; Dareshori, Zachary (OS) <Zachary.Dareshori@hhs.gov>; Bradway, Courtney B (OS) <Courtney.Bradway@hhs.gov>
Subject: DUE 11:30 AM TODAY - AMA nCoV Tear Sheets for budget hearing
Importance: High

All,

Attached are the draft tear sheets and table of contents for the Secretary's nCoV section of his budget briefing book. Please review the tear sheets which are relevant to you and submit any edits to Courtney.Bradway@hhs.gov and myself by **11:30 AM today**.

Please loop in relevant staff who I may have left off. I know there is a lot on this groups plate and this time frame is very tight. The Secretary is well prepared to discuss this topic but we want to be sure these tear sheets are tight as we expect him to get a lot of questions on this topic.

Thank you,

FINAL CoV for Clearance 2.12.d..

2.12.20 nCoV TOC.docx

John Twomey

Chief of Staff
Office of the Assistant Secretary for Legislation
U.S. Department of Health & Human Services
Cell: **(b)(6)**
Desk

From: Zebley, Kyle (HHS/OS/OGA) [Kyle.Zebley@hhs.gov]
Sent: 2/12/2020 11:22:23 AM
To: Twomey, John K (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dabd734e611a472d826cd89d9bc4a352-HHS-John.Tw]; McGowan, Robert K (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e6175b088b1d49a4bfa2de3862800d4a-HHS-omc2-cd]; Campbell, Amanda (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a88bfd63aaaf4a5398fddd4e28849e43-HHS-ons3-cd]; Charrow, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12441403d18b42559a072c648988b55a-HHS-Robert.]; White, Caroline (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a55bc6c3c0e84313889692f13a8bcf50-HHS-Carolin]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Steele, Danielle (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=634b96dc13cf48f3971ce676b65e952f-HHS-Daniell]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Hall, Bill (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e56218361cd4ffbacdd06ac2d7b809d-HHS-bill.ha]; Oakley, Caitlin B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8feed045e954557aa1e0052f925865f-HHS-Caitlin]; Brennan, Patrick (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e87181146141b1ba0978553d9ff156-HHS-Patrick]; Schmoyer, Michael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc457b777d57409d961efa1d49e1b4ba-HHS-Michael]; Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Stecker, Judy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e205440400ab4f629be1faccfe0846fc-HHS-Judy.St]; Mango, Paul (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2fe1932caf0249d2a0c6af5fb82c9ec5-HHS-Paul.Ma]
CC: Moughalian, Jen C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1227fced76ad4092bb5f1395d24c0d74-HHS-Jen.Mou]; Shuy, Caitrin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=875ab76b6ae34c4cad510d8e5ceddf9b-HHS-Caitrin]; Hittle, Taylor (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12b1c0c5b2344e6080a6a0b06b214482-HHS-Taylor.]; Pence, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3f21407a02d44cd4901bcce26f9b3074-HHS-Laura.P]; Morse, Sara N (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4080ee237c084683ae674366e5cde21d-HHS-Sara.Mo]; Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Dareshori, Zachary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3460db40e0d54c918d19bb70b52d8825-HHS-Zachary]; Bradway, Courtney B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=efbbfe51847c4c9c931699126d2b78f4-HHS-Courtne]
Subject: RE: DUE 11:30 AM TODAY - AMA nCoV Tear Sheets for budget hearing

Attachments: FINAL CoV for Clearance 2.12 955a - OGA.docx

A few thoughts from our team, John

FINAL CoV for Clearance 2.12 9...

From: Twomey, John K. (HHS/ASL) <John.Twomey@HHS.GOV>
Sent: Wednesday, February 12, 2020 9:06 AM
To: McGowan, Robert (Kyle) (CDC/OD/OCS) <omc2@cdc.gov>; Campbell, Amanda (CDC/OD/OCS) <ons3@cdc.gov>; Charrow, Robert (HHS/OGC) <Robert.Charrow@hhs.gov>; White, Caroline (HHS/OGC) <Caroline.White@hhs.gov>; Zebley, Kyle (HHS/OS/OGA) <Kyle.Zebley@hhs.gov>; Grigsby, Garrett (HHS/OS/OGA) <Garrett.Grigsby@hhs.gov>; Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Abram, Anna (FDA/OC) <Anna.Abram@fda.hhs.gov>; Steele, Danielle (HHS/IOS) <Danielle.Steele@hhs.gov>; Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>; Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>; Brennan, Patrick (OS/ASPA) <Patrick.Brennan@hhs.gov>; Schmoyer, Michael (OS/ONS) <Michael.Schmoyer@hhs.gov>; Harrison, Brian (HHS/IOS) <Brian.Harrison@hhs.gov>; Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov>; Mango, Paul (HHS/IOS) <Paul.Mango@hhs.gov>
Cc: Moughalian, Jen (HHS/ASFR) <Jen.Moughalian@hhs.gov>; Shuy, Caitrin (HHS/ASFR) <Caitrin.Shuy@hhs.gov>; Hittle, Taylor (HHS/ASFR) <Taylor.Hittle@hhs.gov>; Pence, Laura (HHS/ASL) <Laura.Pence@hhs.gov>; Morse, Sara (HHS/ASL) <Sara.Morse@hhs.gov>; Arbes, Sarah (HHS/ASL) <Sarah.Arbes@hhs.gov>; Dareshori, Zack (HHS/IOS) <Zachary.Dareshori@hhs.gov>; Bradway, Courtney (HHS/ASL) <Courtney.Bradway@hhs.gov>
Subject: RE: DUE 11:30 AM TODAY - AMA nCoV Tear Sheets for budget hearing

Folks do not need to edit the sitrep as we will update the Secretary's binder with the current report tomorrow morning.

From: Twomey, John K. (HHS/ASL)
Sent: Wednesday, February 12, 2020 7:14 AM
To: McGowan, Robert (Kyle) (CDC/OD/OCS) <omc2@cdc.gov>; Campbell, Amanda (CDC/OD/OCS) <ons3@cdc.gov>; Charrow, Robert (HHS/OGC) <Robert.Charrow@hhs.gov>; White, Caroline (HHS/OGC) <Caroline.White@hhs.gov>; Zebley, Kyle (HHS/OS/OGA) <Kyle.Zebley@hhs.gov>; Grigsby, Garrett (HHS/OS/OGA) <Garrett.Grigsby@hhs.gov>; Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Abram, Anna (FDA/OC) <Anna.Abram@fda.hhs.gov>; Steele, Danielle (HHS/IOS) <Danielle.Steele@hhs.gov>; Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>; Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>; Brennan, Patrick (OS/ASPA) <Patrick.Brennan@hhs.gov>; Schmoyer, Michael (OS/ONS) <Michael.Schmoyer@hhs.gov>; Harrison, Brian (HHS/IOS) <Brian.Harrison@hhs.gov>; Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov>; Mango, Paul (HHS/IOS) <Paul.Mango@hhs.gov>
Cc: Moughalian, Jen (HHS/ASFR) <Jen.Moughalian@hhs.gov>; Shuy, Caitrin (HHS/ASFR) <Caitrin.Shuy@hhs.gov>; Hittle, Taylor (HHS/ASFR) <Taylor.Hittle@hhs.gov>; Pence, Laura (HHS/ASL) <Laura.Pence@hhs.gov>; Morse, Sara (HHS/ASL) <Sara.Morse@hhs.gov>; Arbes, Sarah (HHS/ASL) <Sarah.Arbes@hhs.gov>; Dareshori, Zack (HHS/IOS) <Zachary.Dareshori@hhs.gov>; Bradway, Courtney (HHS/ASL) <Courtney.Bradway@hhs.gov>
Subject: DUE 11:30 AM TODAY - AMA nCoV Tear Sheets for budget hearing
Importance: High

All,

Attached are the draft tear sheets and table of contents for the Secretary's nCoV section of his budget briefing book. Please review the tear sheets which are relevant to you and submit any edits to Courtney.Bradway@hhs.gov and myself by **11:30 AM today**.

Please loop in relevant staff who I may have left off. I know there is a lot on this groups plate and this time frame is very tight. The Secretary is well prepared to discuss this topic but we want to be sure these tear sheets are tight as we expect him to get a lot of questions on this topic.

Thank you,

<< File: FINAL CoV for Clearance 2.12.docx >> << File: 2.12.20 nCoV TOC.docx >>

John Twomey

Chief of Staff
Office of the Assistant Secretary for Legislation
U.S. Department of Health & Human Services
Cell: **(b)(6)**
Desk

From: McWilliams, Carly [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B68C7458214244D08424FD441FEA4FDA-CARLYLE.MCW]
Sent: 2/12/2020 11:34:10 AM
To: Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Roth, Lauren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52bfd08572694f269a20c508f3c04a03-Lauren.Roth]; Anderson, Erika (CFSAN, ISS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7500800153174d93bf8d69a0261d77da-Erika.Ander]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Helms Williams, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=873be46f1b1a4d2b8df3fe67137cbdc8-HELMSWILLIA]
Subject: SG Testimony at Roundtalbe
Attachments: Gottlieb-Senate-Statement-Homeland-Security-Governmental-Affairs-1.pdf

Testimony

Are We Prepared? Protecting the U.S. from Global Pandemics: Statement before the Senate Committee on Homeland Security and Governmental Affairs

HEALTH CARE

February 12, 2020

The epidemic spread of coronavirus in China — along with community transmission in Singapore, Hong Kong, and Japan – sharply increase the chance that we endure pandemic spread. Worse still, the novel coronavirus may become endemic. It could take a new position as a more sinister member of the seasonal pathogens that circulate each year and infect humans.

The next month is critical. We must prepare for the prospect that the virus evaded our border protections and was already introduced into the U.S. in late December or early January – when it first appears to have become epidemic in China's Hubei province. Those index cases could have seeded community spread, and eventually, outbreaks could emerge in America. We have the capacity to contain small outbreaks. But we need to be vigilant and ready.

Models suggest that from the time of first introduction of the virus into China – which we now suspect occurred sometime in November – to the time of epidemic spread in China, was about 10 weeks.[i] The experience in the U.S. is likely to be different, not least because our awareness of this risk is prompting collective action that can limit spread. But China's experience shows that if cases were imported into the U.S. in early January and remain undetected, then we could still be early in our own evolution toward broader outbreaks. Right now, we're depending largely on clinical surveillance as our primary tool for identifying potential outbreaks since we're just now deploying diagnostic tools to the Laboratory Response Network. Moreover, we still haven't broadened our screening criteria to include patients who don't have a connection to recent travel to China. This limits our ability to identify secondary spread. So, we may know we're experiencing outbreaks of this disease only when a cluster of cases of atypical pneumonia present to a hospital and trigger closer scrutiny by health officials. By that time, there could be dozens or even hundreds of cases in a local community. Controlling broader spread could become a challenge.

Full Testimony

I want to focus my observations on the vulnerability of our supply chain for drugs and medical devices. Some shortages or near shortages may be inevitable in U.S. as a result of crisis in China. Our drug and medical device supply chain is pointedly and precariously dependent on production in China for our finished goods. In many cases it isn't the finished drugs or medical devices that are being manufactured largely or exclusively in China. Nor is it the intermediate products like the active pharmaceutical ingredients (API). It is lower margin, low technology starting materials and components that – over time – have become sole sourced in China.

Securing alternative supply in the setting of a crisis takes time. But here are steps U.S. regulators can take in the near term, working with Congress and other partners, to lessen the potential impact of supply disruptions on Americans by identifying vulnerabilities and bringing substitute supply online. There are also longer-term policy steps that we could take to reduce the vulnerabilities created by these choke points in the supply of critical public health goods.
I want to address in greater detail these issues as they relate to drugs and production in China.
About 40 percent of generic drugs sold in the U.S. have only a single manufacturer. A significant supply chain disruption could cause shortages for some of many of these products.[ii]

Last year, manufacturing of intermediate or finished goods in China, as well as pharmaceutical source material, accounted for 95 percent of U.S. imports of ibuprofen, 91 percent of U.S. imports of hydrocortisone, 70 percent of U.S. imports of acetaminophen, 40 to 45 percent of U.S. imports of penicillin, and 40 percent of U.S. imports of heparin, according to the Commerce Department. In total, 80 percent of the U.S. supply of antibiotics are made in China.[iii]

While much of the fill finishing work (the actual formulation of finished drug capsules and tablets) is done outside China (and often in India) the starting and intermediate chemicals are often sourced in China. Moreover, the U.S. generic drug industry can no longer produce certain critical medicines such as penicillin and doxycycline without these chemical components.[iv]

According to a report from the US-China Economic and Security Review Commission, China's chemical industry, which accounts for 40 percent of global chemical industry revenue, provides

a large number of ingredients for drug products.v, vi It's these source materials --- where in many cases China is the exclusive source of the chemical ingredients used for the manufacture of a drug product -- that create choke points in the global supply chain for critical medicines.

Moreover, when it comes to starting material for the manufacture of pharmaceutical ingredients, a lot of this production is centered in China's Hubei Provence, the epicenter of coronavirus. Most drug makers have a one to three-months of inventory of drug ingredients on hand. But these supplies are already being drawn down. Among big API makers in Wuhan are Wuhan Shiji Pharmaceutical, Chemwerth, Hubei Biocause, Wuhan Calmland Pharmaceuticals.vii

There are steps that we can take – both in the short term as well as the long run – to expand our supply chain for making these raw and intermediate components of drug production and mitigate risks to our supply chain. In the setting of the current public health crisis related to the novel coronavirus, I want to focus my remarks today on some of these potential actions.

We're facing the potential for unprecedented supply chain disruptions. You can't easily switch component part suppliers — either starter material for the manufacture of drugs or components for device devices. You have to qualify those alternative sources, make sure they meet regulatory standards for Good Manufacturing Practices (GMPs), and meet the conditions set by those incorporating these materials into their finished goods. Even if FDA is able to offer manufacturers flexibility in making these component changes, substitutions are often complex.

Right now, we may not even be aware of the full scope of these vulnerabilities. In many cases, we don't have established systems for tracking down to the level of these components, to easily identify the choke points. This is true even when it comes to where API is sourced. We rely on our ability to track the finished products. This isn't just a coronavirus challenge. An earthquake or political unrest in a major manufacturing region could present the same problems.
How can we take steps to try and address some of these significant challenges?

First, we can work to bring on alternate supply. After Hurricane Maria devastated Puerto Rico, and took offline fully 10 percent of the manufacturing capacity for drugs intended for the U.S. market, the FDA took proactive steps to restart facilities that manufactured key products, and identify alternative suppliers for some products where significant and potentially harmful disruptions were believed to be unavoidable owing to the damage.viii There's idle manufacturing capacity that can be developed to address some of the immediate needs. India, for example, has about 1,500 plants that manufacture APIs and are running at 40 percent capacity.ix

Second, we also need a better system for identifying these supply chain choke points.
When it comes to the kinds of starting materials that may have been disrupted by the crisis in China, FDA would be dependent on manufacturers to identify these supply choke points. This is challenged by the current shortage framework. It relies on a passive reporting system from manufacturers, where we might find out too late of impending shortage. It may not work in a crisis situation like this where information and reporting are imperfect.

In the near term, FDA can issue a solicitation for such information. U.S. officials should already have some awareness of the key components that are manufactured in China, and in the Hubei Province particular. But in the longer term, we need a more systematic process for collecting this information. This is where Congress can help, by giving the FDA authority to look not only at the supply of finished products but to also identify circumstances where key components may have only a single source across an entire category of products. This may take the form of a requirement that manufacturers develop risk management plans that explicitly surface critical supply chain choke points. In turn, we could require companies to take steps to identify alternative sources in the event of a major disruption. It isn't just supply disruptions we need to

be fearful of. In the setting of a public health crisis in a country that hosts the manufacture of critical components, a government may seek to withhold supply or even nationalize key facilities if the components are essential to their own relief efforts. A nation could seek to satisfy its in country needs before they ship outside their borders. Such a circumstance arose with respect to the manufacture of flu vaccine after the H1N1 pandemic.x

Standing up new sources of supply is not as complex as creating new facilities for manufacturing intermediate and final drug products. That's because these starting components and ingredients fall under the GMP requirements of the finished manufacturer's supplier controls. This means that the ingredients and parts are not independently subject to GMP requirements if they're not themselves the drug product or finished device. So, this flexibility can make it easier to more quickly establish alternative manufacturing sites for the production of source material and other inputs. It doesn't require that these new facilities undergo all of the more time consuming GMP requirements as the finished drug. Only finished products need to meet these standards.
It's clear now that we are also going to have significant delays in FDA inspections of facilities in China, and maybe in other foreign locations. This could make efforts to identify new manufacturing sites more challenging if those facilities are required to be inspected by the agency. The falloff in inspectional capabilities could also create some immediate consumer risks.

There are steps we can take to offset these challenges. For example, Congress can support efforts by FDA to increase import sampling and testing of regulated goods coming from China, since the agency will be hard pressed to make up for the lost inspectional activity, even after the current crisis has subsided. This will require additional resources for FDA's inspectional program.
The FDA could also consider revising its risk-based inspection model and plan for 2020. Based on the shutdown in Chinese manufacturing and the need for alternate supplies, the agency might need to redefine the highest risk facilities and shift some of the focus of its inspection resources once facilities are brought back online. These efforts can be supported by Congress. The FDA's inspectional activities and its field force are on the front lines of the agency's historic consumer protection mission. The agency has the expertise to adapt to these challenges, but it can benefit from focused resources and authorities that support these efforts in both the near and long term.
It's not just generic drugs that could fall into shortage. Brand drugs use contract research organizations like WuXi in China for development work, and global clinical trials enroll patients China.xi There are 16,490 studies registered on Clinicaltrials.gov in China and 5,086 studies are currently recruiting. This is about 10 percent of all of the actively recruiting studies. The clinical trial work, as well as the work conducted by China CROs has -- in many cases -- has stopped.xii

As a consequence, some new drug programs could be delayed as innovators are forced to change clinical trial enrollment plans, amend protocols, or shift certain critical development activities to other CROs located in other regions. This could delay regulatory filings on new drugs.
We also must address potential device shortages. Medical devices operate under different framework than drugs. It may be harder to identify and mitigate potential shortages. We should adopt the same practices we've implemented for drugs – which requires manufactures to give FDA early notification of potential shortage situations. More than a year ago, FDA first put forward such a proposal. That proposal was incorporated into the President's current budget.
Finally, we should also contemplate for medical devices a similar framework to the one I believe we need for drugs. It would require manufacturers to report to FDA when there is a key component that is sole sourced and where alternate supply cannot be easily obtained.

While we hope no shortages will result from the tragic epidemic, given the concentration of production work in Wuhan, the risk is real. Those risks can be reduced through careful planning.
In the long run, there are structural changes we can make to reduce these risks for when next global crisis arises. It starts with shifting our emphasis. We've been focused on the risk that finished goods can fall into shortage owing to a supply disruption. In a world where the

manufacture of components and source material has become highly centralized around a small number of regions and facilities, we need to pay equal attention to identifying these other choke points and taking steps to make sure that critical production doesn't hinge on a single location.

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 2/12/2020 4:25:17 PM
To: Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]
Subject: FW: Public health labs report problems with coronavirus test

What is our response here? We will get some news around this since we approved it.

From: POLITICO Pro Health Care <politicoemail@politicopro.com>
Sent: Wednesday, February 12, 2020 4:23 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: Public health labs report problems with coronavirus test

Public health labs report problems with coronavirus test

By David Lim

02/12/2020 04:21 PM EST

At least 25 public health laboratories around the country say they're unable to test for cases of the coronavirus originating in Wuhan because a test kit distributed by the CDC is delivering inconclusive results.

Some labs that began doing quality checks on the test last weekend found one of three reagents in the kit was ineffective, according to Kelly Wroblewski, director of infectious diseases at the Association of Public Health Laboratories. More labs started reporting similar issues on Monday and Tuesday. None of the diagnostic kits were used to test actual clinical specimens.

The kits allow states and localities to test patients, eliminating the need to confirm cases by sending samples to the CDC's headquarters in Atlanta. CDC is developing replacement tests it can send to the labs.

“Some of the states identified some inconclusive laboratory results, but we’re working closely with them to correct the issues,” Nancy Messonnier, director of the CDC’s Center for the National Center for Immunization and Respiratory Diseases, said Wednesday.

There are 13 confirmed cases of coronavirus in the United States with 60 other people under investigation whose samples are waiting to be tested, according to CDC. More than 44,500 cases and 1,100 deaths are confirmed in China, according to the World Health Organization.

CDC initially made 200 of the diagnostic kits available to U.S. labs last week after receiving emergency use authorization from the FDA on Feb. 4.

“Of course I hoped that this week every state would be up and running,” Messonnier said. “How long will that take? I can’t tell you that for sure.”

A “very small number of labs” in the U.S. have successfully verified the diagnostic test, according to Wroblewski. But states will continue to send all clinical specimens to CDC headquarters in Atlanta as a “backstopping” measure, according to Messonnier.

“Although this is sort of an unfortunate development and nobody wanted to see this happen, this is why there are quality control steps in place,” Wroblewski said.

To view online:
https://subscriber.politicopro.com/health-care/article/2020/02/public-health-labs-report-problems-with-coronavirus-test-1879161

From: McSeveney, Megan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0D4B7FC0CFED46C7B1BFCDDD41F240D7-MEGAN.MCSEV]
Sent: 2/14/2020 10:04:21 AM
To: Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]
CC: Janik, Heather [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbebeee5ffeeb7f3d-Heather.Jan]; Stark, Angela [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d04b10a5e0ec40ffa2ebfedd711e83af-Angela.Star]; Leggin, Brooke [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c876a439c57d4d0abaa3c8898c803db3-Brooke.Legg]; Finnen, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]
Subject: Latest version of the statement attached - still needs final AA review and reconciling with HHS
Attachments: CLEANDRFTStatement 0957SHAAOCETORAOCC.docx; Draft Statement 0957SHAAOCETORAOCC.docx

Good morning – here is an internally reconcile version of the statement. Anna, I believe you are in the Schif now but, want to note here that she will review this version or if I am able to get back any edits from HHS before 10:30 – I will send the latest version. I'll ping HHS after I send this email and ask where edits are and see if they are not ready- can we get a sense of timing. I will also run the language highlighted in green in these documents by the fraud task force for review. Please let me know if you have any questions. Thank you!

Megan McSeveney
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-4514/Cell: **(b)(6)**
Megan.McSeveney@fda.hhs.gov

FDA U.S. FOOD & DRUG ADMINISTRATION

From: Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]
Sent: 2/14/2020 12:24:23 PM
To: Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]
Subject: Fwd: NEW - Latest version COVID19 statement - Commissioner's statement re: FDA outbreak coronavirus response efforts
Attachments: image001.png; ATT00001.htm; image002.jpg; ATT00002.htm; image003.jpg; ATT00003.htm; image004.jpg; ATT00004.htm; image005.jpg; ATT00005.htm; image026.png; ATT00006.htm; image027.jpg; ATT00007.htm; image028.jpg; ATT00008.htm; image029.jpg; ATT00009.htm; image030.jpg; ATT00010.htm; CLEANDRFTStatement 0957SHAAOCETORAOCCAA 1205pm.docx; ATT00011.htm

Can you make sure there is a good grammatical scrub on this?

Sent from my iPhone

Begin forwarded message:

From: "McSeveney, Megan" <Megan.McSeveney@fda.hhs.gov>
Date: February 14, 2020 at 12:23:15 PM EST
To: "Thomson, Kyle" <Kyle.Thomson@fda.hhs.gov>, "Raza, Mark" <Mark.Raza@fda.hhs.gov>, "Kumar, Dinesh" <Dinesh.Kumar@fda.hhs.gov>, "Abram, Anna" <Anna.Abram@fda.hhs.gov>, "Cave, Carol" <Carol.Cave@fda.hhs.gov>, "Rogers, Michael" <Michael.Rogers@fda.hhs.gov>, "McMeekin, Judith" <Judith.McMeekin@fda.hhs.gov>, "Laska, Susan F" <Susan.Laska@fda.hhs.gov>, "Hinton, Denise" <Denise.Hinton@fda.hhs.gov>, "Mair, Michael" <Michael.Mair@fda.hhs.gov>, "Courtney, Brooke" <Brooke.Courtney@fda.hhs.gov>, "Sadove, Elizabeth" <Elizabeth.Sadove@fda.hhs.gov>, "Beers, Donald" <Donald.Beers@fda.hhs.gov>, "Humbert, Jason" <Jason.Humbert@fda.hhs.gov>
Cc: "Burgess, Shelly" <Shelly.Burgess@fda.hhs.gov>, "Windt, David" <David.Windt@fda.hhs.gov>, "Caliguiri, Laura" <Laura.Caliguiri@fda.hhs.gov>, "Rebello, Heidi" <Heidi.Rebello@fda.hhs.gov>, "Janik, Heather" <Heather.Janik@fda.hhs.gov>, "Gross, Karas" <Karas.Gross@fda.hhs.gov>, "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>, "Anderson, Erika" <Erika.Anderson@fda.hhs.gov>, "Lynch, Kara P" <Kara.Lynch@fda.hhs.gov>, "Franz, Lauren" <Lauren.Franz@fda.hhs.gov>, "Rath, Prakash (FDA)" <Prakash.Rath@fda.hhs.gov>, "Stark, Angela" <Angela.Stark@fda.hhs.gov>
Subject: NEW - Latest version COVID19 statement - Commissioner's statement re: FDA outbreak coronavirus response efforts

Hi all – attached is the latest version of this statement with final input from the Commissioner and Anna that went to HHS for final clearance through HHS and the interagency. While this will get a final proof, I hope that I won't need to run any more edits by you all. I greatly appreciate all the help. Thank you again!

Megan McSeveney
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-4514/Cell: [redacted] **(b)(6)**
Megan.McSeveney@fda.hhs.gov

From: Janik, Heather [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=117BC4D27D7B47DDBEBEEE5FFEEB7F3D-HEATHER.JAN]
Sent: 2/14/2020 6:30:24 PM
To: McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Finnen, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Stark, Angela [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d04b10a5e0ec40ffa2ebfedd711e83af-Angela.Star]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Finnen, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]; Leggin, Brooke [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c876a439c57d4d0abaa3c8898c803db3-Brooke.Legg]; Kimberly, Brad [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08bc909ed76d49868a5ff92c3c70fb72-Bradley.Kim]
CC: Barber, Daniel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0a326d10d4c5483f843dbb9d59bf1e5d-Daniel.Barb]
Subject: RE: Anything else needed from me tonight?
Attachments: Additional TPs.docx

I think I might, apologies. I see the attached in my inbox, but it says additional. I think there was another document. Nothing immediate, but if you could possibly get me the most recent version of any talking points by Tuesday for a commissioner briefer, that would be great. Thank you!!

From: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
Sent: Friday, February 14, 2020 6:15 PM
To: Janik, Heather <Heather.Janik@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Stark, Angela <Angela.Stark@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Leggin, Brooke <Brooke.Leggin@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>
Cc: Barber, Daniel <Daniel.Barber@fda.hhs.gov>
Subject: RE: Anything else needed from me tonight?

Sorry - do you mean the OL talking points? I wasn't drafting any talking points. I can do that if needed – just let me know what you need – but, if new material it might take a bit to clear. Thanks

Megan McSeveney
Press Officer

Office of Media Affairs
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Megan.McSeveney@fda.hhs.gov

From: Janik, Heather <Heather.Janik@fda.hhs.gov>
Sent: Friday, February 14, 2020 5:56 PM
To: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Stark, Angela <Angela.Stark@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Leggin, Brooke <Brooke.Leggin@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>
Cc: Barber, Daniel <Daniel.Barber@fda.hhs.gov>
Subject: RE: Anything else needed from me tonight?

If the talking points are approved could you please share? Thank you!

From: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
Sent: Friday, February 14, 2020 5:38 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Stark, Angela <Angela.Stark@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Leggin, Brooke <Brooke.Leggin@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>
Cc: Barber, Daniel <Daniel.Barber@fda.hhs.gov>
Subject: Anything else needed from me tonight?

Hi all – checking in to make sure nothing else is needed from me tonight? I'll keep an eye out this weekend but, I think on the media front we should be good with the statement. Thank you!

Megan McSeveney
Press Officer
Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-4514/Cell: (b)(6)
Megan.McSeveney@fda.hhs.gov

From: Abram, Anna [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FB77660891384232A7CD9086FCBB1A3B-ANNA.ABRAM]
Sent: 2/17/2020 5:07:52 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: Re: CDC 2019-nCoV Test Update

Thanks, Keagan. Sounds good.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Date: February 17, 2020 at 5:06:02 PM EST
To: Abram, Anna <Anna.Abram@fda.hhs.gov>
Subject: Re: CDC 2019-nCoV Test Update

There was no noon. Doesn't appear on my calendar. No idea what Laura is doing. Let's just have him give update on the AEG call. If we need a comms call after we can do that at 5:45.

Sent from my iPhone

On Feb 17, 2020, at 4:58 PM, Abram, Anna <Anna.Abram@fda.hhs.gov> wrote:

I'm confused. Do you have a noon mtg? I don't see... what do you want to do with Jeff's request to check in?

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Date: February 17, 2020 at 4:50:53 PM EST
To: Abram, Anna <Anna.Abram@fda.hhs.gov>, Janik, Heather <Heather.Janik@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: CDC 2019-nCoV Test Update

We actually moved it to the daily noon, which we did not have today because of the holiday but I can re-up for this small group.

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Sent: Monday, February 17, 2020 4:36 PM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: CDC 2019-nCoV Test Update

Taking Dr. Hahn off – the 5:45 appears as cancelled on calendars. Are we still touching base then in addition to the 5:15?

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Sent: Monday, February 17, 2020 4:35 PM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Shuren, Jeff

<Jeff.Shuren@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: CDC 2019-nCoV Test Update

Can do then or we also have the comms call at 5:45. LMK your preference.

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Sent: Monday, February 17, 2020 3:41 PM
To: Janik, Heather <Heather.Janik@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Subject: RE: CDC 2019-nCoV Test Update

We have a 5:15 call that also includes some CDER colleagues for a check in (thanks Denise), do you want this group to touch base before then or cover during 5:15? Happy to do whatever works best for others.

From: Janik, Heather <Heather.Janik@fda.hhs.gov>
Sent: Monday, February 17, 2020 3:39 PM
To: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Subject: RE: CDC 2019-nCoV Test Update

Thanks, Jeff. I can be available.

From: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Date: February 17, 2020 at 3:37:49 PM EST
To: Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Janik, Heather <Heather.Janik@fda.hhs.gov>
Subject: RE: CDC 2019-nCoV Test Update

I have an update. It might be better to discuss by phone if folks are available.

Also, below I'm sharing for your awareness an email sent to CDC/FDA/NIH from Rosemary Humes at BARDA regarding interest in point-of-care testing and the development of a one-pager and slides.

Jeff

Internal confidential

From: Humes, Rosemary (OS/ASPR/BARDA) <Rosemary.Humes@hhs.gov>
Sent: Monday, February 17, 2020 2:04 PM
To: Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Carroll, Darin S (CDC) <zuz4@cdc.gov>; Beanan, Maureen J (NIH) <beananm@mail.nih.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Opdyke, Jason A CIV USARMY (USA <jason.a.opdyke.civ@mail.mil>; Wallace, Rodney (OS) <Rodney.Wallace@hhs.gov>; Faison, Tremel (OS) <Tremel.Faison@hhs.gov>; Marston, Hilary D (NIH) <hilary.marston@nih.gov>; Schoske, Richard CIV DTRA J9 (USA) <richard.schoske.civ@mail.mil>
Subject: Dx development status and RNA prioritization

Dear Dx WG members,
Thanks to all who participated in the call on Friday. I know that everyone is swamped.
A couple of follow up items:

(b)(5)

(b)(5)

Rosemary Humes MS, MT(ASCP) SM
HHS/ASPR/BARDA
202-205-8238
Cell (b)(6)

From: Shuren, Jeff
Sent: Sunday, February 16, 2020 11:05 PM
To: Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>
Subject: CDC 2019-nCoV Test Update

CDC submitted their request for a new cut-off this evening. The CDRH team finished their review. (b)(5)

(b)(5)

Jeff

Internal confidential

From: Janik, Heather [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=117BC4D27D7B47DDBEBEEE5FFEEB7F3D-HEATHER.JAN]
Sent: 2/17/2020 5:10:36 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: Re: CDC 2019-nCoV Test Update

I'm not part of the AEG call- let me know if you need me. Thanks!

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Date: February 17, 2020 at 5:09:04 PM EST
To: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Cc: Hahn, Stephen <SH1@fda.hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Janik, Heather <Heather.Janik@fda.hhs.gov>
Subject: Re: CDC 2019-nCoV Test Update

Thanks Jeff. Let's do your readout in the AEG call and if we need to have a comms call after we will add.

Sent from my iPhone

On Feb 17, 2020, at 3:37 PM, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov> wrote:

I have an update. It might be better to discuss by phone if folks are available.

Also, below I'm sharing for your awareness an email sent to CDC/FDA/NIH from Rosemary Humes at BARDA regarding interest in point-of-care testing and the development of a one-pager and slides.

Jeff

Internal confidential

From: Humes, Rosemary (OS/ASPR/BARDA) <Rosemary.Humes@hhs.gov>
Sent: Monday, February 17, 2020 2:04 PM
To: Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Carroll, Darin S (CDC) <zuz4@cdc.gov>; Beanan, Maureen J (NIH) <beananm@mail.nih.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Opdyke, Jason A CIV USARMY (USA <jason.a.opdyke.civ@mail.mil>; Wallace, Rodney (OS) <Rodney.Wallace@hhs.gov>; Faison, Tremel (OS) <Tremel.Faison@hhs.gov>; Marston, Hilary D (NIH) <hilary.marston@nih.gov>; Schoske, Richard CIV DTRA J9 (USA) <richard.schoske.civ@mail.mil>
Subject: Dx development status and RNA prioritization

Dear Dx WG members,
Thanks to all who participated in the call on Friday. I know that everyone is swamped.
A couple of follow up items:

(b)(5)

(b)(5)

Rosemary Humes MS, MT(ASCP) SM
HHS/ASPR/BARDA
202-205-8238
Cell: (b)(6)

From: Shuren, Jeff
Sent: Sunday, February 16, 2020 11:05 PM
To: Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>
Subject: CDC 2019-nCoV Test Update

CDC submitted their request for a new cut-off this evening. The CDRH team finished their review. **(b)(5)**

(b)(5)

Jeff

Internal confidential

From: Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]
Sent: 2/18/2020 1:43:12 PM
To: Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]
Subject: Fwd: BARDA Coronavirus support

(b)(5)

Sent from my iPhone

Begin forwarded message:

From: "Shuren, Jeff" <Jeff.Shuren@fda.hhs.gov>
Date: February 18, 2020 at 10:00:34 AM EST
To: "Stenzel, Timothy" <Timothy.Stenzel@fda.hhs.gov>, "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>, "Abram, Anna" <Anna.Abram@fda.hhs.gov>, "Hinton, Denise" <Denise.Hinton@fda.hhs.gov>
Cc: "Scherf, Uwe" <Uwe.Scherf@fda.hhs.gov>
Subject: Re: BARDA Coronavirus support

What support are they seeking from FDA?

Adding Keagan, Anna, and Denise for awareness.

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Date: February 18, 2020 at 9:08:13 AM EST
To: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Cc: Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
Subject: BARDA Coronavirus support

Hi Jeff,

Rosemary Humes from BARDA has reached out to Uwe and me and asked for support in their plans to (b)(5)

(b)(5)

I am in the process of generating text language for this support to send you this morning. She is wondering if we can get FDA support up through the Commissioner and on up to the Department as needed. She is asking for CDC support too and if there is a CDC call today, I am going to jump on that. She asked me if CMS and/or CLIA could also support but I was unsure of who and how strong their knowledge would be and if they could add something.

Thanks!

Best,
Tim

Timothy T. Stenzel, MD, PhD
Director, OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality

Center for Devices and Radiological Health
U.S. Food and Drug Administration
Timothy.Stenzel@fda.hhs.gov
Jennifer Campbell
Administrative Assistant

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

From: Caccomo, Stephanie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=950C32CEBC4B4F80B302C50CF31C8524-STEPHANIE.C]
Sent: 2/20/2020 11:06:50 AM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Janik, Heather [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbebeee5ffeeb7f3d-Heather.Jan]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Stark, Angela [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d04b10a5e0ec40ffa2ebfedd711e83af-Angela.Star]
Subject: Flagging: Budget/Leg Proposal Q from Politico

Hi all—
Flagging an inquiry we got from David Lim at Politico on this request in our budget proposal: "Expanding Temporary Access to Diagnostic Testing During Certain Emergencies"

CDRH, JIC and OCC cleared below. I'm going to send to him this afternoon, please flag any concerns soon. Thanks!

Inquiry: What examples of products would fall under this category and how much time would it save potentially in an emergency situation? I wanted to ask for an example of a situation where, if implemented, this proposal would result in an improvement over the current EUA process.

Proposed Response:

(b)(5)

Thanks!

Stephanie Caccomo
Press Officer

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

From: Tobias, Lindsay [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A4766773C717470BBC55D204B5F067B2-LINDSAY.STO]
Sent: 2/20/2020 4:34:45 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]
Subject: Letter from CSPI re product claiming to prevent COVID-19
Attachments: CSPI_Letter_to_FTC_FDA_re_Silver_Solution_2-20-2020.pdf

FYI, attached is letter from CSPI to Dr. Hahn and FTC Chairman Simons regarding a televangelist who is claiming that colloidal silver (specifically Silver Solution products) can prevent and treat COVID-19. I've sent this to OES to be logged and assigned to CFSAN. Please let me know if there is anything else you'd like me to do.

Lindsay R. Tobias
Special Assistant to the Chief of Staff

Office of the Commissioner
Office of the Chief of Staff
U.S. Food and Drug Administration
Tel: 301-796-6743
Cell: **(b)(6)**
Lindsay.Tobias@fda.hhs.gov
U.S. FOOD & DRUG ADMINISTRATION

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 2/21/2020 3:18:22 PM
To: Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]
Subject: FW: For urgent review: coronavirus, statement on inspections
Attachments: Statement draft 2.21.20_230pm.docx

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Friday, February 21, 2020 2:31 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>
Subject: For urgent review: coronavirus, statement on inspections

Keagan, Denise, Erika-
For your urgent review, the draft statement on inspections. This has been JIC and OCC cleared. I am waiting to clear one point from ORA, which is noted in the statement. Following your review, we can get to Dr. Hahn.

I'll concurrently flag for ASPA.

Let me know if you have any questions, thanks!

Stephanie Caccomo
Press Officer

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

From: Gross, Karas [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0B6D3DC4EE4B415D86EC634C536453B6-KARA.GROSS]
Sent: 2/21/2020 5:03:09 PM
To: Twomey, John K (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dabd734e611a472d826cd89d9bc4a352-HHS-John.Tw]; Pence, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3f21407a02d44cd4901bcce26f9b3074-HHS-Laura.P]
CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Steele, Danielle (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=634b96dc13cf48f3971ce676b65e952f-HHS-Daniell]; Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Morse, Sara N (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4080ee237c084683ae674366e5cde21d-HHS-Sara.Mo]; Bradway, Courtney B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=efbbfe51847c4c9c931699126d2b78f4-HHS-Courtne]
Subject: RE: coronavirus tear sheets
Attachments: CoV for Clearance 2.21 256PM (002)FDA.docx

Made some edits **(b)(5)** . If there is something else you're looking for, let me know.

CoV for Clearance 2.21 256PM (002...

From: Twomey, John K. (HHS/ASL) <John.Twomey@HHS.GOV>
Sent: Friday, February 21, 2020 3:09 PM
To: Pence, Laura (OS) <Laura.Pence@hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Steele, Danielle (OS) <Danielle.Steele@hhs.gov>; Arbes, Sarah C (OS) <Sarah.Arbes@hhs.gov>; Morse, Sara N (OS) <Sara.Morse@hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Bradway, Courtney B (OS) <Courtney.Bradway@hhs.gov>
Subject: RE: coronavirus tear sheets

Attached is the most up to date version. This has updates that Laura provided yesterday for the ***China Inspection*** tear sheet.

On a separate note there are more updates that need to be made across the board on repatriation, congressional interactions, etc. Laura we can chat offline on how you'd like to handle these other edits before AMA testifies on Tuesday.

<< File: CoV for Clearance 2.21 256PM.docx >>

From: Pence, Laura (HHS/ASL) <Laura.Pence@hhs.gov>
Sent: Friday, February 21, 2020 2:30 PM
To: Twomey, John K. (HHS/ASL) <John.Twomey@HHS.GOV>
Cc: Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Steele, Danielle (HHS/IOS) <Danielle.Steele@hhs.gov>;

Arbes, Sarah (HHS/ASL) <Sarah.Arbes@hhs.gov>; Morse, Sara (HHS/ASL) <Sara.Morse@hhs.gov>; Gross, Karas (FDA/OC) <Karas.Gross@fda.hhs.gov>
Subject: coronavirus tear sheets

Hi Twomey, can you send this group the latest coronavirus tear sheets related to drug supply chain? We need to beef them up some more.

From: Christ, Katelyn E. EOP/NSC (b)(6)
Sent: 2/24/2020 9:23:38 AM
To: Christ, Katelyn E. EOP/NSC (b)(6); Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Brand, Anstice M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4769e643239444161a994c2086b645f4c-HHS-atb6-cd]; Pence, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3f21407a02d44cd4901bcce26f9b3074-HHS-Laura.P]; FAULKNER, CHARLES (b)(6); uyen.dinh (b)(6); Kennedy, Wendy (b)(6); Lange, John (b)(6); Ciccone, Christine (b)(6); Kaldahl, Ryan M (b)(6)]; Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Giannangeli, Giulia R (b)(6); McMillin, Virginia D. EOP/WHO (b)(6); Planning, David M. EO P/WHO (b)(6); Telle, Adam R. EOP/WHO (b)(6); Kelly, Alison (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=881a7b1c2b714af78194995c288bea95-HHS-ayk7-cd]; Killion, William (b)(6); Nichols, Jennifer L (b)(6); Yaworske, Jason A. EOP/OMB (b)(6)]; Tourk, Nancy R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdb086e24ad14975bcc32097b68271fb-HHS-wxk8-cd]; McKenna, Michael A. EOP/WHO (b)(6); Boney, Virginia M. EOP/WHO (b)(6); Swonger, Amy H. EOP/WHO (b)(6); Sugarman, AJ J. EOP/WHO (b)(6); Hodgson, Christopher M. EOP/OVP (b)(6); KWESKIN, BENJAMIN (b)(6); Moore, Jessica L (b)(6); Cantrell, Benjamin B. EOP/OVP (b)(6); Wolfe, William E (b)(6); credmon@usaid.gov; ccole@usaid.gov; Rose, Jay E. EOP/NSC (b)(6); Serna, Christina (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4da9a12770147b1a2967a9a9e7884f3-HHS-yyh9-cd]; Bulgrin, Julie K. EOP/NSC (b)(6); Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Bradsher, Kris (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=945a2ca6355b43059a6dc1cf522f70e9-HHS-Kris.Br]; Kehoe, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e89758c5888c4d3986fdf1a861aff27b-HHS-Brian.K]; Delaney, William (USMS) (b)(6); Rault, Nick M. EOP/NSC (b)(6); KASPER, JOSEPH (b)(6); Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Messonnier, Nancy E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3db273e5a524ff690738a633d2c15de-HHS-nar5-cd]; DL NSC Legislative (b)(6); Shwedo, Eric P COL USARMY OSD OASD LA (USA) (b)(6); skorde@usaid.gov; Leong, Rachel M. EOP/WHO (b)(6); Braid, James C. EOP/OMB (b)(6); Greaser, Jennifer L (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6007c3bba4a1420bb704298c5e49f29b-HHS-cbx5-cd]; ryan.crumpler (b)(6); dino.carluccio (b)(6); MOTBOW (b)(6)
CC: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]

Subject: (FYI ONLY) All Senators briefing
Location: SVC-217

Start: 2/25/2020 8:00:00 AM
End: 2/25/2020 9:00:00 AM
Show Time As: Free

Recurrence: (none)

From: Christ, Katelyn E. EOP/NSC (b)(6)
Date: February 24, 2020 at 9:19:06 AM EST
To: Brand, Anstice M (CDC) <atb6@cdc.gov>, Pence, Laura (OS) <Laura.Pence@hhs.gov>, FAULKNER, CHARLES (b)(6) uyen.dinh@hq.dhs.gov (b)(6), Kennedy, Wendy (b)(6), Lange, John (b)(6), Ciccone, Christine (b)(6), Kaldahl, Ryan M (b)(6), Arbes, Sarah C (OS) (b)(6) Giannangeli, Giulia R (b)(6) McMillin, Virginia D. EOP/WHO (b)(6), Planning, David M. EOP/WHO (b)(6) Telle, Adam R. EOP/WHO (b)(6) Kelly, Alison (CDC) <ayk7@cdc.gov>, Killion, William (b)(6), Nichols, Jennifer L (b)(6) Yaworske, Jason A. EOP/OMB (b)(6), Tourk, Nancy R (CDC) (b)(6), McKenna, Michael A. EOP/WHO (b)(6), Boney, Virginia M. EOP/WHO (b)(6), Swonger, Amy H. EOP/WHO (b)(6) Sugarman, AJ J. EOP/WHO (b)(6), Hodgson, Christopher M. EOP/OVP (b)(6) KWESKIN, BENJAMIN (b)(6) Moore, Jessica L (b)(6) Cantrell, Benjamin B. EOP/OVP (b)(6), Wolfe, William E (b)(6) credmon@usaid.gov <credmon@usaid.gov>, ccole@usaid.gov <ccole@usaid.gov>, Rose, Jay E. EOP/NSC (b)(6) Serna, Christina (CDC) <yyh9@cdc.gov>, Bulgrin, Julie K. EOP/NSC (b)(6), Gross, Karas <Karas.Gross@fda.hhs.gov>, Bradsher, Kris (OS) <Kris.Bradsher@hhs.gov>, Kehoe, Brian (OS) <Brian.Kehoe@hhs.gov>, Delaney, William (USMS) <William.Delaney@usdoj.gov>, Rault, Nick M. EOP/NSC (b)(6), KASPER, JOSEPH (b)(6), Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>, Messonnier, Nancy E (CDC) <nar5@cdc.gov>, DL NSC Legislative (b)(6) Shwedo, Eric P COL USARMY OSD OASD LA (USA) (b)(6), skorde@usaid.gov <skorde@usaid.gov>, Leong, Rachel M. EOP/WHO <Rachel.M.Leong2@who.eop.gov>, Braid, James C. EOP/OMB (b)(6) Greaser, Jennifer L (CDC) <cbx5@cdc.gov>, ryan.crumpler (b)(6) <ryan.crumpler (b)(6) dino.carluccio (b)(6) <dino.carluccio (b)(6), MOTBOW (b)(6)
Cc: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: All Senators briefing

As you know, HELP Chairman Alexander and Ranking Member Murray have been hosting regular briefings on the novel Coronavirus. The Administration will be providing another briefing on this subject on **Tuesday, February 25 at 8:00 am.** (b)(5)
(b)(5)

From: Christ, Katelyn E. EOP/NSC (b)(6)
Sent: 2/24/2020 9:23:38 AM
To: Christ, Katelyn E. EOP/NSC (b)(6) Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Brand, Anstice M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4769e643239441 61a994c2086b645f4c-HHS-atb6-cd]; Pence, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3f21407a02d44cd4901bcce26f9b3074-HHS-Laura.P]; FAULKNER, CHARLES (b)(6) ; uyen.dinh (b)(6) Kennedy, Wendy (b)(6) ; Lange, John (b)(6) Ciccone, Christine [(b)(6) Kaldahl, Ryan M (b)(6)]; Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Giannangeli, Giulia R (b)(6) ; McMillin, Virginia D. EOP/WHO (b)(6) Planning, David M. EOP/WHO (b)(6) Telle, Adam R. EOP/WHO (b)(6) ; Kelly, Alison (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=881a7b1c2b714af78194995c288bea95-HHS-ayk7-cd]; Killion, William (b)(6) ; Nichols, Jennifer L (b)(6) ; Yaworske, Jason A. EOP/OMB (b)(6) Tourk, Nancy R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdb086e24ad14975bcc32097b68271fb-HHS-wxk8-cd]; McKenna, Michael A. EOP/WHO (b)(6) Boney, Virginia M. EOP/WHO (b)(6) Swonger, Amy H. EOP/WHO (b)(6) ; Sugarman, AJ J. EOP/WHO (b)(6) ; Hodgson, Christopher M. EOP/OVP (b)(6) KWESKIN, BENJAMIN (b)(6) ; Moore, Jessica L (b)(6) Cantrell, Benjamin B. EOP/OVP (b)(6) Wolfe, William E (b)(6) credmon@usaid.gov; ccole@usaid.gov; Rose, Jay E. EOP/NSC (b)(6) Serna, Christina (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4da9a12770147b1a2967a9a9e7884f3-HHS-yyh9-cd]; Bulgrin, Julie K. EOP/NSC (b)(6) Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Bradsher, Kris (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=945a2ca6355b43059a6dc1cf522f70e9-HHS-Kris.Br]; Kehoe, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e89758c5888c4d3986fdf1a861aff27b-HHS-Brian.K]; Delaney, William (USMS) [William.Delaney@usdoj.gov]; Rault, Nick M. EOP/NSC (b)(6) KASPER, JOSEPH (b)(6) Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Messonnier, Nancy E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3db273e5a524ff690738a633d2c15de-HHS-nar5-cd]; DL NSC Legislative (b)(6) ; Shwedo, Eric P COL USARMY OSD OASD LA (USA) (b)(6) skorde@usaid.gov; Leong, Rachel M. EOP/WHC (b)(6) Braid, James C. EOP/OMB (b)(6) ; Greaser, Jennifer L (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6007c3bba4a1420bb704298c5e49f29b-HHS-cbx5-cd]; ryan.crumpler (b)(6) dino.carluccio (b)(6) MOTBOW (b)(6)
CC: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]

Subject: All Senators briefing
Location: SVC-217

Start: 2/25/2020 8:00:00 AM
End: 2/25/2020 9:00:00 AM
Show Time As: Tentative

Recurrence: (none)

From: Christ, Katelyn E. EOP/NSC <(b)(6)
Date: February 24, 2020 at 9:19:06 AM EST
To: Brand, Anstice M (CDC) <atb6@cdc.gov>, Pence, Laura (OS) <Laura.Pence@hhs.gov>, FAULKNER, CHARLES (b)(6), uyen.dinh (b)(6) <uyen.dinh (b)(6), Kennedy, Wendy (b)(6), Lange, John (b)(6), Ciccone, Christine (b)(6), Kaldahl, Ryan M (b)(6), Arbes, Sarah C (OS) <Sarah.Arbes@hhs.gov>, Giannangeli, Giulia R <(b)(6), McMillin, Virginia D. EOP/WHO (b)(6), Planning, David M. EOP/WHO <(b)(6), Telle, Adam R. EOP/WHO <(b)(6) Kelly, Alison (CDC) <ayk7@cdc.gov>, Killion, William (b)(6), Nichols, Jennifer L (b)(6), Yaworske, Jason A. EOP/OMB <(b)(6) Tourk, Nancy R (CDC) <wxk8@cdc.gov>, McKenna, Michael A. EOP/WHO (b)(6), Boney, Virginia M. EOP/WHO (b)(6), Swonger, Amy H. EOP/WHO (b)(6), Sugarman, AJ J. EOP/WHO <(b)(6) Hodgson, Christopher M. EOP/OVP <(b)(6) KWESKIN, BENJAMIN (b)(6) Moore, Jessica L (b)(6) Cantrell, Benjamin B. EOP/OVP (b)(6) Wolfe, William E <(b)(6) credmon@usaid.gov <credmon@usaid.gov>, ccole@usaid.gov <ccole@usaid.gov>, Rose, Jay E. EOP/NSC (b)(6) Serna, Christina (CDC) <yyh9@cdc.gov>, Bulgrin, Julie K. EOP/NSC (b)(6) Gross, Karas <Karas.Gross@fda.hhs.gov>, Bradsher, Kris (OS) <Kris.Bradsher@hhs.gov>, Kehoe, Brian (OS) <Brian.Kehoe@hhs.gov>, Delaney, William (USMS) <William.Delaney@usdoj.gov>, Rault, Nick M. EOP/NSC (b)(6) KASPER, JOSEPH (b)(6), Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>, Messonnier, Nancy E (CDC) <nar5@cdc.gov>, DL NSC Legislative (b)(6) Shwedo, Eric P COL USARMY OSD OASD LA (USA) (b)(6), skorde@usaid.gov <skorde@usaid.gov>, Leong, Rachel M. EOP/WHO (b)(6) Braid, James C. EOP/OMB (b)(6) Greaser, Jennifer L (CDC) <cbx5@cdc.gov>, ryan.crumpler (b)(6) <ryan.crumple (b)(6) dino.carluccio (b)(6) <dino.carluccio (b)(6), MOTBOW (b)(6)
Cc: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: All Senators briefing

As you know, HELP Chairman Alexander and Ranking Member Murray have been hosting regular briefings on the novel Coronavirus. The Administration will be providing another briefing on this subject on **Tuesday, February 25 at 8:00 am.** (b)(5)
(b)(5)

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 2/24/2020 9:58:01 AM
To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Caliguiri, Laura (Laura.Caliguiri@fda.hhs.gov) [Laura.Caliguiri@fda.hhs.gov]
Subject: FW: COV inspections communication
Attachments: Statement draft 2.21.20_430pm.docx sca.docx

Did you receive her edits?

From: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Sent: Sunday, February 23, 2020 8:32 PM
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: RE: COV inspections communication

This version is redlined.

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Sunday, February 23, 2020 4:46 PM
To: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: Re: COV inspections communication

Thanks, Stacy. Do you have a redline version?
S

Sent from my iPad

On Feb 23, 2020, at 3:36 PM, Amin, Stacy <Stacy.Amin@fda.hhs.gov> wrote:

Commissioner, this is in your homework, so I'm sending my comments so you can see where I thought the messaging could be clearer, stronger, or more effective. Hope this is helpful, but if you think I'm off base with any of these comments, they are not legal so ultimately it's up to you.

I will send a copy to Heather and Stephanie as well.

****

Stacy Cline Amin
Chief Counsel
Food and Drug Administration
Deputy General Counsel
Department of Health and Human Services

<Statement draft 2.21.20_430pm.docx sca.docx>

From: McGowan, Robert (Kyle) (CDC/OD/OCS) [omc2@cdc.gov]
Sent: 2/24/2020 1:40:11 PM
To: Moughalian, Jen C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1227fced76ad4092bb5f1395d24c0d74-HHS-Jen.Mou]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Zebley, Kyle (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d79ac6af2e1b49089fca453b39ebddde-HHS-Kyle.Ze]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]
CC: Cochran, Norris (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=996319874d544434b96eef30e8232610-HHS-norris.]; Cabezas, Miriam (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45d63ce4e7414998aeb2c55ef0e4a5-HHS-Miriam.]; Hittle, Taylor (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12b1c0c5b2344e6080a6a0b06b214482-HHS-Taylor.]
Subject: RE: Close Hold Review - Send comments by 1:40 pm

We can actually say "COVID-19 related deaths is now over 2,500 people, the majority from China."

From: Moughalian, Jen (HHS/ASFR) <Jen.Moughalian@hhs.gov>
Sent: Monday, February 24, 2020 1:37 PM
To: McGowan, Robert (Kyle) (CDC/OD/OCS) <omc2@cdc.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Grigsby, Garrett (HHS/OS/OGA) <Garrett.Grigsby@hhs.gov>; Zebley, Kyle (HHS/OS/OGA) <Kyle.Zebley@hhs.gov>; Fauci, Anthony (NIH/NIAID) [E] <AFAUCI@niaid.nih.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>
Cc: Cochran, Norris (HHS/ASFR) <norris.cochran@hhs.gov>; Cabezas, Miriam (HHS/ASFR) <Miriam.Cabezas@hhs.gov>; Hittle, Taylor (HHS/ASFR) <Taylor.Hittle@hhs.gov>
Subject: RE: Close Hold Review - Send comments by 1:40 pm

Thank you Kyle, really appreciate the quick review! I noticed you updated the cases; is data still as of Feb 23? Thanks!

From: McGowan, Robert (Kyle) (CDC/OD/OCS) <omc2@cdc.gov>
Sent: Monday, February 24, 2020 1:34 PM
To: Moughalian, Jen (HHS/ASFR) <Jen.Moughalian@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Grigsby, Garrett (HHS/OS/OGA) <Garrett.Grigsby@hhs.gov>; Zebley, Kyle (HHS/OS/OGA) <Kyle.Zebley@hhs.gov>; Fauci, Anthony (NIH/NIAID) [E] <afauci@niaid.nih.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>
Cc: Cochran, Norris (HHS/ASFR) <norris.cochran@hhs.gov>; Cabezas, Miriam (HHS/ASFR) <Miriam.Cabezas@hhs.gov>; Hittle, Taylor (HHS/ASFR) <Taylor.Hittle@hhs.gov>
Subject: RE: Close Hold Review - Send comments by 1:40 pm

Few minor edits below.

In late December 2019, China identified a novel coronavirus which has subsequently been named SARS-CoV-2. On January 30, 2020, the World Health Organization declared a public health emergency of international concern due to the virus. As of February 23, 2020, there are 78,811 confirmed cases of coronavirus disease 2019 (COVID-19) in approximately 30 locations worldwide and the number of COVID-19 related deaths is nearing 2,500 people, the majority of which are from China. To this point the effects of the virus have been limited in the U.S., including 14 confirmed cases of COVID-19 presenting in seven states (not including ~~21~~ 39 persons repatriated to the United States who have tested positive).

The President's priority is protecting the homeland and the Administration is working aggressively to minimize the risk of the spread of the virus in the United States. The President launched a Coronavirus Task Force to direct the United States' response. This Task Force is led by the Secretary of Health and Human Services (HHS) and is composed of subject matter experts from across government, including some of the Nation's foremost experts on infectious diseases. On January 31, 2020, the Secretary of HHS declared a public health emergency and HHS has tapped into the Centers for Disease Control and Prevention's Infectious Diseases Rapid Response Reserve Fund to help combat the virus. ~~Across HHS, FY 2020 funds are being re-prioritized as necessary to address the virus.~~ In addition, FY 2020 funds are being re-prioritized across HHS as necessary to address the virus.

The Government has taken unprecedented steps to minimize the risk of travelers spreading the SARS-CoV-2 to the United States. The President suspended entry into America of certain foreign nationals who have recently traveled to China and who pose a risk of transmitting the virus and directed inbound China flights to 11 airports where enhanced screening now takes place.
The Government has conducted numerous charter flights to evacuate American citizens from Wuhan, China and the cruise ship *Diamond Princess* back to the United States. All passengers were screened for symptoms before the flights, and medical professionals continue to monitor the health of all returning passengers.

At the direction of the President and under the auspices of the Task Force, several Federal agencies are contributing significant resources and personnel to support the domestic and international response to the epidemic. To this point, no agency has been inhibited in response efforts due to resources or authorities. However, much is still unknown about this virus and the disease it causes. The Administration believes additional Federal resources are necessary to take steps to prepare for a potential worsening of the situation in the US, and requests an appropriation of $xx billion in the Public Health and Social Services Emergency Fund at HHS to continue to support critical response and preparedness activities.

From: Moughalian, Jen (HHS/ASFR) <Jen.Moughalian@hhs.gov>
Sent: Monday, February 24, 2020 1:18 PM
To: McGowan, Robert (Kyle) (CDC/OD/OCS) <omc2@cdc.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Grigsby, Garrett (HHS/OS/OGA) <Garrett.Grigsby@hhs.gov>; Zebley, Kyle (HHS/OS/OGA) <Kyle.Zebley@hhs.gov>; Fauci, Anthony (NIH/NIAID) [E] <AFAUCI@niaid.nih.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>
Cc: Cochran, Norris (HHS/ASFR) <norris.cochran@hhs.gov>; Cabezas, Miriam (HHS/ASFR) <Miriam.Cabezas@hhs.gov>; Hittle, Taylor (HHS/ASFR) <Taylor.Hittle@hhs.gov>
Subject: Close Hold Review - Send comments by 1:40 pm
Importance: High

Close hold. Please see below draft OMB language for a possible emergency supplemental request. Due to the fast moving nature of this process, please send comments by 1:40 PM. Numbers are still under discussion, and we will share more info in the daily update.

(b)(5)

(b)(5)

Jen Moughalian
Assistant Secretary for Financial Resources (ASFR)
US Department of Health and Human Services
(b)(6) Office)
Cell)

From: Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]
Sent: 2/24/2020 1:53:25 PM
To: Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]
CC: Moughalian, Jen C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1227fced76ad4092bb5f1395d24c0d74-HHS-Jen.Mou]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS (b)(6)]; McGowan, Robert K (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e6175b088b1d49a4bfa2de3862800d4a-HHS-omc2-cd]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Zebley, Kyle (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d79ac6af2e1b49089fca453b39ebddde-HHS-Kyle.Ze]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Cochran, Norris (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=996319874d544434b96eef30e8232610-HHS-norris.]; Cabezas, Miriam (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45d63ce4e7414998aeb2c55ef0e4a5-HHS-Miriam.]; Hittle, Taylor (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12b1c0c5b2344e6080a6a0b06b214482-HHS-Taylor.]
Subject: Re: Close Hold Review - Send comments by 1:40 pm

No additional edits. Thanks.

Sent from my iPhone

On Feb 24, 2020, at 1:50 PM, Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov> wrote:

Concur with edits offered.

(b)(5)

Sent from my iPhone

On Feb 24, 2020, at 1:43 PM, Moughalian, Jen (HHS/ASFR) <Jen.Moughalian@hhs.gov> wrote:

Thanks for the quick response!

From: Fauci, Anthony (NIH/NIAID) [E] **(b)(6)**
Sent: Monday, February 24, 2020 1:42 PM
To: Moughalian, Jen (HHS/ASFR) <Jen.Moughalian@hhs.gov>; McGowan, Robert (Kyle) (CDC/OD/OCS) <omc2@cdc.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Grigsby, Garrett (HHS/OS/OGA) <Garrett.Grigsby@hhs.gov>; Zebley, Kyle (HHS/OS/OGA) <Kyle.Zebley@hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>
Cc: Cochran, Norris (HHS/ASFR) <norris.cochran@hhs.gov>; Cabezas, Miriam (HHS/ASFR) <Miriam.Cabezas@hhs.gov>; Hittle, Taylor (HHS/ASFR) <Taylor.Hittle@hhs.gov>
Subject: RE: Close Hold Review - Send comments by 1:40 pm

Jen:

See my suggested edits in **red.**

Thanks,

Tony

Anthony S. Fauci, MD
Director
National Institute of Allergy and Infectious Diseases
(b)(6)
National Institutes of Health
Bethesda, MD 20892-2520
Phone (b)(6)
FAX: (301) 496-4409
E-mail: (b)(6)

From: Moughalian, Jen (HHS/ASFR) <Jen.Moughalian@hhs.gov>
Sent: Monday, February 24, 2020 1:18 PM
To: McGowan, Robert (Kyle) (CDC/OD/OCS) <omc2@cdc.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Grigsby, Garrett (HHS/OS/OGA) <Garrett.Grigsby@hhs.gov>; Zebley, Kyle (HHS/OS/OGA) <Kyle.Zebley@hhs.gov>; Fauci, Anthony (NIH/NIAID) [E (b)(6) Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>
Cc: Cochran, Norris (HHS/ASFR) <Norris.Cochran@HHS.GOV>; Cabezas, Miriam (HHS/ASFR) <Miriam.Cabezas@hhs.gov>; Hittle, Taylor (HHS/ASFR) <Taylor.Hittle@hhs.gov>
Subject: Close Hold Review - Send comments by 1:40 pm
Importance: High

Close hold. Please see below draft OMB language for a possible emergency supplemental request. Due to the fast moving nature of this process, please send comments by 1:40 PM. Numbers are still under discussion, and we will share more info in the daily update.

(b)(5)

(b)(5)

activities.

Jen Moughalian
Assistant Secretary for Financial Resources (ASFR)
US Department of Health and Human Services
(b)(6) (Office)
(Cell)

From: Tyler, James [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DDB047FF73E640B29259D7CA22611E67-JAMES.TYLER]
Sent: 2/24/2020 2:52:34 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: RE: Close Hold Review - Send comments by 1:40 pm

Keagan,

Was in meetings. Just seeing this. I have no comments. **(b)(5)**

(b)(5)

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Monday, February 24, 2020 1:48 PM
To: Tyler, James <James.Tyler@fda.hhs.gov>
Subject: Fwd: Close Hold Review - Send comments by 1:40 pm

Any quick edits?

Sent from my iPhone

Begin forwarded message:

From: "McGowan, Robert (Kyle) (CDC/OD/OCS)" <●mc2@cdc.g●v>
Date: February 24, 2020 at 1:35:07 PM EST
To: "Moughalian, Jen C (OS)" <Jen.M●ughalian@hhs.g●v>, "Shuy, Bryan (OS)" <Bryan.Shuy@hhs.g●v>, "Kadlec, Robert P (OS)" <R●bert.Kadlec@hhs.g●v>, "Grigsby, Garrett G (OS)" <Garrett.Grigsby@hhs.g●v>, "Zebley, Kyle (OS)" <Kyle.Zebley@hhs.g●v>, "Fauci, Anthony S (NIH)" <afauci@niaid.nih.g●v>, "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.g●v>, "Redfield, Robert R (CDC)" <●lx1@cdc.g●v>
Cc: "Cochran, Norris (OS)" <n●rris.c●chran@hhs.g●v>, "Cabezas, Miriam (OS)" <Miriam.Cabezas@hhs.g●v>, "Hittle, Taylor (OS)" <Tayl●r.Hittle@hhs.g●v>
Subject: RE: Close Hold Review - Send comments by 1:40 pm

Few minor edits below.

In late December 2019, China identified a novel coronavirus which has subsequently been named SARS-CoV-2. On January 30, 2020, the World Health Organization declared a public health emergency of international concern due to the virus. As of February 23, 2020, there are 78,811 confirmed cases of coronavirus disease 2019 (COVID-19) in approximately 30 locations worldwide and the number of COVID-19 related deaths is nearing 2,500 people, the majority of which are from China. To this point the effects of the virus have been limited in the U.S., including 14 confirmed cases of COVID-19 presenting in seven states (not including ~~21~~ 39 persons repatriated to the United States who have tested positive).

The President's priority is protecting the homeland and the Administration is working aggressively to minimize the risk of the spread of the virus in the United States. The President launched a Coronavirus Task Force to direct the United States' response. This Task Force is led by the Secretary of Health and Human Services (HHS) and is composed of subject matter experts from across government, including some of the Nation's foremost experts on infectious diseases. On January 31, 2020, the Secretary of HHS declared a public health emergency and HHS has tapped into the Centers for Disease Control and Prevention's Infectious Diseases Rapid Response Reserve Fund to help combat the virus. ~~Across HHS, FY 2020 funds~~

~~are being re-prioritized as necessary to address the virus.~~ In addition, FY 2020 funds are being re-prioritized across HHS as necessary to address the virus.

The Government has taken unprecedented steps to minimize the risk of travelers spreading the SARS-CoV-2 to the United States. The President suspended entry into America of certain foreign nationals who have recently traveled to China and who pose a risk of transmitting the virus and directed inbound China flights to 11 airports where enhanced screening now takes place.
The Government has conducted numerous charter flights to evacuate American citizens from Wuhan, China and the cruise ship *Diamond Princess* back to the United States. All passengers were screened for symptoms before the flights, and medical professionals continue to monitor the health of all returning passengers.

At the direction of the President and under the auspices of the Task Force, several Federal agencies are contributing significant resources and personnel to support the domestic and international response to the epidemic. To this point, no agency has been inhibited in response efforts due to resources or authorities. However, much is still unknown about this virus and the disease it causes. The Administration believes additional Federal resources are necessary to take steps to prepare for a potential worsening of the situation in the US, and requests an appropriation of $xx billion in the Public Health and Social Services Emergency Fund at HHS to continue to support critical response and preparedness activities.

From: Moughalian, Jen (HHS/ASFR) <Jen.Moughalian@hhs.gov>
Sent: Monday, February 24, 2020 1:18 PM
To: McGowan, Robert (Kyle) (CDC/OD/OCS) <omc2@cdc.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Grigsby, Garrett (HHS/OS/OGA) <Garrett.Grigsby@hhs.gov>; Zebley, Kyle (HHS/OS/OGA) <Kyle.Zebley@hhs.gov>; Fauci, Anthony (NIH/NIAID) [E] <AFAUCI@niaid.nih.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>
Cc: Cochran, Norris (HHS/ASFR) <norris.cochran@hhs.gov>; Cabezas, Miriam (HHS/ASFR) <Miriam.Cabezas@hhs.gov>; Hittle, Taylor (HHS/ASFR) <Taylor.Hittle@hhs.gov>
Subject: Close Hold Review - Send comments by 1:40 pm
Importance: High

Close hold. Please see below draft OMB language for a possible emergency supplemental request. Due to the fast moving nature of this process, please send comments by 1:40 PM. Numbers are still under discussion, and we will share more info in the daily update.

(b)(5)

(b)(5)

Jen Moughalian
Assistant Secretary for Financial Resources (ASFR)
US Department of Health and Human Services
(b)(6) Office)
Cell)

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 2/24/2020 3:54:41 PM
To: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
Subject: FW: COVID-19 PMO Call Follow-Up 24Feb20
Attachments: Proposed Outbreak Scenarios COVID 19_Release20200220.pdf; DRAFT HHS COVID-19 CIRs and EEIs 23FEB20 1000ET.docx; HHS COVID-19 PMO Description_FINAL.pdf; HHS COVID-19 PMO - Info Sharing and Decison Making Cycle_FINAL.pptx

Did you manage this call? And are you on top of how we are supporting this work?

From: Imbriale, Samuel (OS/ASPR/SIIM) <Samuel.Imbriale@hhs.gov>
Sent: Monday, February 24, 2020 11:55 AM
To: Mango, Paul (OS) <Paul.Mango@hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Pollard, Ashton (OS) <Ashton.Pollard@hhs.gov>; Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>; Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>; McGowan, Robert K (CDC) <omc2@cdc.gov>; Mccreary, Kenneth (OS) <Kenneth.Mccreary@hhs.gov>; Perdue, Christopher (OS) <Christopher.Perdue@hhs.gov>; DeBord, Kristin (OS) <Kristin.DeBord@hhs.gov>; Phillips, Sally (OS) <Sally.Phillips@hhs.gov>; Pratt, Michael (OS) <Michael.Pratt@hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Johnston, Darcie (OS) <Darcie.Johnston@hhs.gov>; Zebley, Kyle (OS) <Kyle.Zebley@hhs.gov>; Chang, William (OS) <William.Chang@hhs.gov>; Trueman, Laura (OS) <Laura.Trueman@hhs.gov>; Marston, Hilary D (NIH) <hilary.marston@nih.gov>; Kerr, Lawrence (OS) <Lawrence.Kerr@hhs.gov>; Fernandez, Jose A (OS) <Jose.Fernandez@hhs.gov>; Elvander, Erika (OS) <Erika.Elvander@hhs.gov>; Valentine, Steven (OS) <Steven.Valentine@hhs.gov>; Schwartz, Erica (OS) <Erica.Schwartz@hhs.gov>; Grigsby, Garrett G (OS) <Garrett.Grigsby@hhs.gov>; Aviles, Natalie (OS) <Natalie.Aviles@hhs.gov>; Knutson, Donna B (CDC) <dbk2@cdc.gov>; Austin, Meredith (uscg.mil) <Meredith.L.Austin@uscg.mil>; Yeskey, Kevin (OS) <Kevin.Yeskey@hhs.gov>; Lee, Scott (OS) <Scott.Lee@hhs.gov>; Greene, Jonathan (OS) <Jonathan.Greene@hhs.gov>; Holland, Tara (OS) <Tara.Holland@hhs.gov>; Maples, David L (CDC) <idr0@cdc.gov>; Bermingham, John (CDC) <uvk7@cdc.gov>; Keane, George (OS) <George.Keane@hhs.gov>; Dreyzehner, John J (CDC) <pwn3@cdc.gov>; Grigsby, Garrett G (OS) <Garrett.Grigsby@hhs.gov>; Schwartz, Erica (OS) <Erica.Schwartz@hhs.gov>; Maples, David L (CDC) <idr0@cdc.gov>; Berger, Sherri (CDC) <sob8@cdc.gov>; Harrison, Brian (OS) <Brian.Harrison@hhs.gov>
Cc: SOC Information Management Section Chief (OS/ASPR) <SOC.IM@hhs.gov>; OS Secretarys Operations Center <hhs.soc@hhs.gov>; EOC Report (CDC) <eocreport@cdc.gov>
Subject: COVID-19 PMO Call Follow-Up 24Feb20

All, please see below actions items and updates from today's PMO call.

Additionally, attached are a series of documents discussed during the today's meeting. Every single document is open to comment, feedback and edit, though the collection plan is the priority.

(b)(5)

General guidance & updates

(b)(5)

PMO Meeting Due-Outs

(b)(5)

- Label all documents as 'PRE-DECISIONAL'

V/r,

Samuel Imbriale, MPH
Director, Information Management Division
Director (Acting), Secretary's Operations Center
Office of Security, Intelligence & Information Management
Assistant Secretary for Preparedness & Response
Office: (202) 205-2843
Cell: (b)(6)
Email: Samuel.Imbriale@hhs.gov
HSDN: Samuel.m.imbriale@dhs.sgov.gov

HHS SOC (24/7): hhs.soc@hhs.gov // (202) 619-7800

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 2/24/2020 6:32:10 PM
To: Lutter, Randall [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=868b21db20e3456ab4e1b3109b56c23f-Randall.Lut]
Subject: RE: New CEA query on Foreign Drug Manufacturing

Check with Karas to see if she has anything useful, they have been trying to get a lot of numbers for Hill events this week.

From: Lutter, Randall <Randall.Lutter@fda.hhs.gov>
Sent: Monday, February 24, 2020 5:05 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: New CEA query on Foreign Drug Manufacturing

HI Keagan:

Eric Sun a PhD MD who works for Tomas Phillipson asks for analysis that would further swamp Andreas's team.

Should I just respond with the following?

(b)(5)

As an aside, JW's testimony **(b)(5)** I think that is what Eric wants.

-rl

(b)(6)

From: Sun, Eric C. EOP/CEA **(b)(6)**
Sent: Monday, February 24, 2020 4:44 PM
To: Lutter, Randall <Randall.Lutter@fda.hhs.gov>
Subject: Foreign Drug Manufacturing

Hey Randy,

I hope this email finds you well!

As you might imagine, coronavirus has led to concerns about the extent to which drug manufacturing is vulnerable. I see that as recently as last October FDA presented some testimony on this subject.

(b)(5)

Thanks!

Eric Sun, MD/PhD

Senior Economist
Council of Economic Advisers
Executive Office of the President
Office: 202-456-3575
Mobile (b)(6)

From: Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]
Sent: 2/24/2020 8:20:12 PM
To: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
Subject: Re: Public health labs press FDA to allow homegrown coronavirus tests

Will have OMA push back. Thanks Jeff.

Sent from my iPhone

On Feb 24, 2020, at 7:52 PM, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov> wrote:

(b)(5)

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Date: February 24, 2020 at 7:37:19 PM EST
To: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: Fwd: Public health labs press FDA to allow homegrown coronavirus tests

Thoughts?

Sent from my iPhone

Begin forwarded message:

From: POLITICO Pro Health Care <politicoemail@politicopro.com>
Date: February 24, 2020 at 7:16:33 PM EST
To: "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>
Subject: Public health labs press FDA to allow homegrown coronavirus tests
Reply-To: "POLITICO subscriptions" <reply-fe971c727160017c75-553241_HTML-924728035-1376319-258397@politicoemail.com>

Public health labs press FDA to allow homegrown coronavirus tests

By David Lim

02/24/2020 07:15 PM EST

Public health laboratories urged the FDA on Monday to permit them to create their own tests for the coronavirus, after problems with a diagnostic developed by CDC prevented its widespread rollout.

FDA typically allows "laboratory developed tests" — which are designed, manufactured and used within a single lab — to be used without close regulatory scrutiny. But the agency requires labs to submit such tests for review during health emergencies to prevent harm from false or misleading results from compounding a crisis. The coronavirus does not appear to be an exception.

"No test should be used without being validated," FDA spokesperson Stephanie Caccomo said. "In the context of a public health emergency, false results can lead to significant adverse public health consequences."

The FDA has traditionally shied away from allowing the use of LDTs in emergency situations. In 2016, the agency sent a letter to two Houston hospitals that created an LDT to rapidly detect the Zika virus, expressing concern that the agency had not reviewed the "high-risk" test.

But Association of Public Health Laboratories Executive Director Scott Becker said that the coronavirus requires a different approach. The virus is spreading in multiple countries, and the CDC's efforts to expand testing capability beyond its labs have run into trouble.

Only five state and local public health labs — in California, Nebraska, Illinois, Nevada and Tennessee — have verified the CDC diagnostic for use since the FDA approved it on an emergency basis on Feb. 4, he said.

APHL hopes to work with FDA to develop a policy that allows some labs to market a LDT without submitting it for FDA review, Becker told POLITICO — adding that it doesn't make sense for more than 100 labs to file individual emergency use authority applications.

"We believe a more expeditious route is needed at this time," Becker and Grace Kubin, director of the Laboratory Services Section at the Texas Department of State Health Services, wrote to FDA Commissioner Stephen Hahn on Monday.

" What we're suggesting is that public health labs be viewed as a group to do this," Becker told POLITICO. "It isn't every lab on their own — we would want to do this in a network sort of fashion. We could also enable confirmation at another public health laboratory to ensure confidence."

The letter says that labs could work together towards a standard protocol, purchase reagents and supplies from a common source and recommend a minimum standard approach for validating test results.

Caccomo says that the FDA is working with more than 70 test developers on products for the virus. The agency can complete reviews for such tests in as little as one day, she added — ensuring that it is effective and meets the minimum standards for emergency use.

Some major hospitals are also starting to develop LDTs for coronavirus screening, but are concerned that FDA rules do not permit them to actually start testing patients, according to Michael Mina, associate medical director of molecular diagnostics at Brigham and Women's Hospital.

"We're actually trying to get our test up and running, even though we don't know if we'll be able to use it," Mina said. "I know that Mass General Hospital is also thinking about doing something very similar. I presume all the major academic hospitals are at least considering it."

The American Clinical Laboratory Association, which represents large commercial labs like LabCorp and Quest Diagnostics, declined to comment on whether LDTs should be used to help increase the country's capacity to screen for the coronavirus. Historically, the lab industry trade lobby has maintained LDTs are not medical devices and subject to FDA regulation.

To view online:
https://subscriber.politicopro.com/health-care/article/2020/02/public-health-labs-press-fda-to-allow-homegrown-coronavirus-tests-1884096

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From: Caccomo, Stephanie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=950C32CEBC4B4F80B302C50CF31C8524-STEPHANIE.C]
Sent: 2/24/2020 8:40:07 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: RE: Public health labs press FDA to allow homegrown coronavirus tests

Of course, happy to

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Monday, February 24, 2020 8:40 PM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: Re: Public health labs press FDA to allow homegrown coronavirus tests

Appreciate you jumping on this!

Sent from my iPhone

On Feb 24, 2020, at 8:38 PM, Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov> wrote:

Updated story just posted:

Public health laboratories urged the FDA on Monday to permit them to create their own tests for the coronavirus, after problems with a diagnostic developed by CDC prevented its widespread rollout.

FDA typically allows "laboratory developed tests" — which are designed, manufactured and used within a single lab — to be used without close regulatory scrutiny. But the agency requires labs to submit such tests for review during health emergencies to prevent harm from false or misleading results from compounding a crisis. The coronavirus does not appear to be an exception.

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Caccomo says that the FDA is working with more than 70 test developers on products for the virus. The agency can complete reviews for such tests in as little as one day, she added — ensuring that it is effective and meets the minimum standards for emergency use.

The FDA said the statute's emergency provisions "establish a lower bar to market compared to conventional premarket pathways — namely that the test may be effective — but still requires a sufficient level of validation even in the context of the emergency."

Some major hospitals are also starting to develop LDTs for coronavirus screening, but are concerned that FDA rules do not permit them to actually start testing patients, according to Michael Mina, associate medical director of molecular diagnostics at Brigham and Women's Hospital.

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From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Monday, February 24, 2020 8:15 PM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: Re: Public health labs press FDA to allow homegrown coronavirus tests

Thanks.

Sent from my iPhone

On Feb 24, 2020, at 7:57 PM, Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov> wrote:

(b)(5)

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Monday, February 24, 2020 7:37 PM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: Fwd: Public health labs press FDA to allow homegrown coronavirus tests

What is our response here??

Sent from my iPhone

Begin forwarded message:

From: POLITICO Pro Health Care <politicoemail@politicopro.com>
Date: February 24, 2020 at 7:16:33 PM EST
To: "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>

Subject: Public health labs press FDA to allow homegrown coronavirus tests
Reply-To: "POLITICO subscriptions" <reply-fe971c727160017c75-553241 HTML-924728035-1376319-258397@politicoemail.com>

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02/24/2020 07:15 PM EST

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Arlington, VA 22209
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Sent: 2/25/2020 10:27:34 AM
To: Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]
Subject: FW: COVID Data Documents
Attachments: SH Senate Update TPs 2.24.20.528.docx; Response By the Numbers 2.25.20.901am.docx

Response by number is too long. Can

From: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Sent: Tuesday, February 25, 2020 10:19 AM
To: Mair, Michael <Michael.Mair@fda.hhs.gov>; Van Pool, Kendall <Kendall.VanPool@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Mettler, Erik <Erik.Mettler@fda.hhs.gov>; OC OCOD Contacts <OCOCODContacts@fda.hhs.gov>; 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Berkowitz, Lauren <Lauren.Berkowitz@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>; Schipper, Jodi <jodi.schipper@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Lockeed, Matthew <Matthew.Lockeed@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Hodnette, Jonathan <Jonathan.Hodnette@fda.hhs.gov>
Subject: COVID Data Documents

Colleagues- Attached here are the two documents we have been working on. The "Response by the Numbers" document (b)(5)
(b)(5)
(b)(5)

(b)(5)
(b)(5) He is very appreciative and so are we, for all of you hard work!

You will see the "by the numbers" document has some (b)(5) – please feel free to email me updates and I will input them. And (b)(5)
(b)(5)

Thank you again for your efforts on this, which should pay dividends for our response efforts moving forward.

From: Gross, Karas <Karas.Gross@fda.hhs.gov>
Sent: Sunday, February 23, 2020 8:33 PM
To: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Van Pool, Kendall <Kendall.VanPool@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Mettler, Erik <Erik.Mettler@fda.hhs.gov>; OC OCOD Contacts <OCOCODContacts@fda.hhs.gov>; 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Black, Jennifer

<Jennifer.Black@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>; Schipper, Jodi <jodi.schipper@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>
Subject: RE: For Data Population and Review by 1pm Monday

Reminder that the deadline for this is tomorrow at 1pm. And highlighting the information that Michael flagged below should, indeed, be the immediate priority. **(b)(5)** **(b)(5)** Thank you!

Karas

From: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Sent: Saturday, February 22, 2020 10:28 AM
To: Mair, Michael <Michael.Mair@fda.hhs.gov>; Van Pool, Kendall <Kendall.VanPool@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Mettler, Erik <Erik.Mettler@fda.hhs.gov>; OC OCOD Contacts <OCOCODContacts@fda.hhs.gov>; 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>; Schipper, Jodi <jodi.schipper@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>
Subject: For Data Population and Review by 1pm Monday

Thanks Michael! And I'm sorry to do this, but since the Commissioner needs this for an 8am Tuesday morning, the paper will have to be populated by **1pm Monday** so that we can **(b)(5)** **(b)(5)**

(b)(5)

Thank you again.

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Saturday, February 22, 2020 8:46 AM
To: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Van Pool, Kendall <Kendall.VanPool@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Mettler, Erik <Erik.Mettler@fda.hhs.gov>; OC OCOD Contacts <OCOCODContacts@fda.hhs.gov>; 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>; Schipper, Jodi <jodi.schipper@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>
Subject: RE: For Data Population and Review by COB Monday

Adding Brooke. While it will be really useful to **(b)(5)**

(b)(5)

From: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Sent: Friday, February 21, 2020 10:03 PM
To: Van Pool, Kendall <Kendall.VanPool@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Tierney,

Julia <Julia.Tierney@fda.hhs.gov>; Mettler, Erik <Erik.Mettler@fda.hhs.gov>; OC OCOD Contacts <OCOCODContacts@fda.hhs.gov>; 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>; Schipper, Jodi <jodi.schipper@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>
Subject: RE: For Data Population and Review by COB Monday

Should also note that if there are other, more preferable ways to quantify or give specifics please feel free to suggest them in the document. That said, **(b)(5)**

(b)(5)

Thank you all!

From: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Sent: Friday, February 21, 2020 9:59 PM
To: Van Pool, Kendall <Kendall.VanPool@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Mettler, Erik <Erik.Mettler@fda.hhs.gov>; OC OCOD Contacts <OCOCODContacts@fda.hhs.gov>; 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>; Schipper, Jodi <jodi.schipper@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>
Subject: For Data Population and Review by COB Monday

IMG, CDER, CBER, CDRH, and ORA:

OL has developed a document to respond to the following directive from Leadership:

(b)(5)

The document is linked below for your respective Centers/Office to populate data and review by **COB Monday, Feb. 24**.

(b)(5)

(b)(5)

Thank you for your efforts on this project. Please let us know if you have any questions or need additional information.

(b)(5)

Andrew Tantillo
Deputy Director

Office of Legislation
U.S. Food and Drug Administration
● 301-796-8919 M **(b)(6)**
andrew.tantillo@fda.hhs.gov

Sent: 2/25/2020 2:45:31 PM
To: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
Subject: FW: COVID-19 Outbreak
Attachments: Letter to FDA Commissioner RE COVID-19.pdf

(b)(5)

From: Brazzell, Sarah E (HEALTH) <sarah.brazzell@health.ny.gov> **On Behalf Of** Zucker, Howard A (HEALTH)
Sent: Tuesday, February 25, 2020 2:16 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: COVID-19 Outbreak

From: Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]
Sent: 2/25/2020 3:03:59 PM
To: Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]
Subject: Fwd: COVID-19 Outbreak
Attachments: Letter to FDA Commissioner RE COVID-19.pdf; ATT00001.htm

For exec sec and CDRH to respond quickly to.

Sent from my iPhone

Begin forwarded message:

From: "Zucker, Howard A (HEALTH)" <howard.zucker@health.ny.gov>
Date: February 25, 2020 at 2:16:33 PM EST
To: "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>
Subject: COVID-19 Outbreak

From: Hall, Bill (HHS/ASPA) [bill.hall@hhs.gov]
Sent: 2/25/2020 4:37:36 PM
To: Oakley, Caitlin B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8feed045e954557aa1e0052f925865f-HHS-Caitlin]; Stecker, Judy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e205440400ab4f629be1faccfe0846fc-HHS-Judy.St]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: RE: FDA chief: 'Very likely' coronavirus impacts medical supply chain
Attachments: RE: URGENT FDA Interview Request--Coronavirus, list of at risk drug products

(b)(5)

From: Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>
Sent: Tuesday, February 25, 2020 4:35 PM
To: Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov>; Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>; Harrison, Brian (HHS/IOS) <Brian.Harrison@hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>
Subject: FW: FDA chief: 'Very likely' coronavirus impacts medical supply chain

From: POLITICO Pro Health Care <politicoemail@politicopro.com>
Sent: Tuesday, February 25, 2020 4:34 PM
To: Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>
Subject: FDA chief: 'Very likely' coronavirus impacts medical supply chain

FDA chief: 'Very likely' coronavirus impacts medical supply chain

By Sarah Owermohle, Brianna Ehley

02/25/2020 04:32 PM EST

U.S. officials are bracing for potential drug and device shortages from the coronavirus outbreak, especially if the situation worsens in China given the country's significant role in drug production.

"FDA is keenly aware that the outbreak will likely effect the medical product supply chain," including critical supplies needed in the U.S., said FDA Commissioner Stephen Hahn at a press briefing this afternoon. While no shortages have been reported so far, he said the agency is monitoring several products that might be at risk and is contacting manufacturers for more information about their supply chains.

Hahn did not say how many products may be at risk, though the agency is eyeing at least 150 medicines, an HHS source said. HHS Secretary Alex Azar earlier today testified that it is challenging to monitor supply chains for medical devices because their manufacturers are not required to report potential shortages the way that drugmakers are.

Tony Fauci, NIH's top infectious disease expert, at the same briefing said his agency's vaccine development effort with Moderna Therapeutics is on track to start human trials within a month and a half, which would be the fastest-ever turnaround on preparing a vaccine for studies. However, he said it would still be months before the product moved to widespread testing and at least a year for it to get close to approval.

The public should not necessarily be discouraged by that timeline, the longtime health official added, saying it's "conceivable that this issue with this coronavirus would go well beyond this season into the next."

To view online:
https://protect2.fireeye.com/url?k=b3e638e8-efb33138-b3e609d7-0cc47a6a52de-18dc4bfb6b6755cc&u=https://subscriber.politicopro.com/health-care/whiteboard/2020/02/fda-chief-very-likely-coronavirus-impacts-medical-supply-chain-3976960

This email was sent to caitlin.oakley@hhs.gov by:
POLITICO, LLC
1000 Wilson Blvd.
Arlington, VA 22209
USA

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 2/25/2020 5:51:45 PM
To: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; 'Hahn, Stephen' [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
Subject: FW: Reply to Dr. Peter Navarro regarding Supply Situation for "List of Essential Medications for Severe CVD Infection"
Attachments: Supply Situation for Essential Medications for Severe CVD_to KL_02252020.docx; WH List of Essential Medications_FDA cover memo_to KL_02252020.docx

Let me know how you all want to handle this?

From: Bernstein, Jessica <Jessica.Bernstein@fda.hhs.gov>
Sent: Tuesday, February 25, 2020 4:44 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: McLatchy, Johanna <Johanna.McLatchy@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Throckmorton, Douglas C <Douglas.Throckmorton@fda.hhs.gov>; Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>
Subject: Reply to Dr. Peter Navarro regarding Supply Situation for "List of Essential Medications for Severe CVD Infection"

Good Afternoon Keagan,

I am attaching the CDER-cleared response to Dr. Navarro's request for information on the supply of products on the "List of Essential Medications for Severe CVD Infection." I'm also attaching a suggested cover memo. Please let me know if you have any questions or need additional information.

Thank you,
Jessica

Jessica Bernstein, MPH
Office of Executive Programs, CDER
Office phone: 240-402-0524

From: McWilliams, Carly [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B68C7458214244D08424FD441FEA4FDA-CARLYLE.MCW]
Sent: 2/25/2020 6:05:17 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: FW: Examples

FYSA

From: McWilliams, Carly
Sent: Tuesday, February 25, 2020 6:00 PM
To: Pataki, Tim A. EOP/WHO (b)(6)
Subject: Examples

Hi-below are some examples of news stories from the press today. For FDA background, if a company files an IND (application for a vaccine), FDA cannot disclose that publicly because the filing is considered Commercial Confidential Information, however if the company chooses they can announce publicly.

Development partnerships at this stage have been announced by BARDA (article highlighted below) so that's the appropriate place to direct questions. BARDA is part of the Task Force. I know there are a lot of communications streams coming into different parts of hhs so we are trying to give a coordinated response.

GlaxoSmithKline To Provide China's Clover Biopharmaceuticals Adjuvant For Its Coronavirus Vaccine Candidate.

Endpoints News (2/24, Tong) reports that amid the spread of the novel coronavirus, "GlaxoSmithKline has found another pair of trusted hands to place its adjuvant system," in that "China's Clover Biopharmaceuticals will add the adjuvant to its preclinical, protein-based vaccine candidate against SARS-CoV-2." Clover's "candidate, COVID-19 S-Trimer, resembles the viral spike (S)-protein found in the virus." There is "no timeline on when their candidate might be ready for a clinical trial."

FierceBiotech (2/24, Taylor) reports, "Clover is one of a clutch of organizations working to tackle COVID-19 by targeting a protein the novel coronavirus needs to enter host cells." The article adds that animal data from Clover's "earlier work to develop recombinant subunit-trimer vaccines for HIV and other enveloped RNA viruses" gave the company "confidence its platform for producing covalently-trimerized fusion proteins is applicable to COVID-19."

Harvard Medical School, Chinese Partner Collaborating To Develop Therapies Against Novel Coronavirus.

Endpoints News (2/24, Mast) reports that "a new and well-funded collaboration between Harvard and a top Chinese research institute will play the long game" against the novel coronavirus. The "5-year, $115 million initiative, which is being backed by China Evergrande Group," will see researchers from the Harvard Medical School, Harvard T.H. Chan School of Public Health and Guangzhou Institute for Respiratory Health "study the virus in an effort to develop therapies against infections by the novel coronavirus, known as SARS–CoV-2, and to prevent new ones." For the Chinese side of the initiative, Zhong Nanshan, "head of the Chinese 2019n-CoV Expert Taskforce and the scientist who isolated the SARS virus in 2003," will lead the effort.

HHS partners with drug makers on COVID-19 vaccine, drugs

Filed Under:
COVID-19
Stephanie Soucheray | News Reporter | CIDRAP News
|

Feb 18, 2020

The US Department of Health and Human Services (HHS) is partnering with Sanofi Pasteur and Johnson & Johnson to develop vaccines and therapeutics to use against COVID-19, according to press releases from the drug makers and HHS today.

Sanofi announced it will be revisiting previous development work for a SARS (severe acute respiratory syndrome) vaccine to examine a path for COVID-19 vaccine development. Both SARS and COVID-19 are coronaviruses that originated in China, with SARS appearing in 2002 and largely disappearing by 2004.

The work will be done through a collaboration with the Biomedical Advanced Research and Development Authority (BARDA).

Sanofi said its vaccine will use a recombinant DNA platform to produce an exact genetic match to proteins found on the surface of the virus. According to Sanofi, the previous work on a SARS vaccine gives them a head start, as that vaccine candidate performed well in non-clinical studies and animal challenge models.

Johnson & Johnson said it will also expand existing an partnership with BARDA via its Janssen Pharmaceutical Companies to develop therapeutics for COVID-19.

"This is the third coronavirus to emerge and cause severe respiratory disease in humans within 18 years, and there are still no proven therapies to treat this disease," said BARDA Director Rick A. Bright, PhD, in an HHS press release. "In partnering with Janssen, BARDA is breaking this barrier to protect against this, as well as the next, coronavirus outbreak. This partnership may accelerate discovery and development of a new potentially lifesaving medicines for people with coronavirus infections."

According to the press release, Janssen and BARDA will share the research and development costs and mobilize resources to screen a library of antiviral molecules for activity against the novel coronavirus.

The work will begin by screening a library of approved therapeutics as well as investigational therapeutics that have completed some clinical trials, HHS said. Promising candidates will be assessed for further development.

Biocontainment system used on evacuees

In other US news, the Kansas City, Missouri, company MRIGlobal said its biocontainment units that roll on and off airplanes were used to evacuate 14 Americans who tested positive for COVID-19 on the Diamond Princess cruise ship off the coast of Japan on Monday.

The units were developed during the 2014 Ebola outbreak, and, according to a company news release, they can contain highly contagious pathogens while protecting those outside the units. The units are durable and provide a safe flight.

Evacuating the Americans allowed them to return to the United States for monitoring and treatment.

From: Tootle, William [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0900DA296E4A474DA740EF1C47E6F1BD-WILLIAM.TOO]
Sent: 2/25/2020 6:58:46 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Tyler, James [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddb047ff73e640b29259d7ca22611e67-James.Tyler]; Sigg, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=37695069dc214f5cb20e6056dd4d7cf7-sigg]
CC: Wong, Eric [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d297edf2c28b4219a30b385f8dd3ab37-Eric.Wong]
Subject: FW: FDA - COVID Supplemental Narrative Justification
Attachments: COVID Agency Narrative Justification - FDA.docx

Hi,

I wanted to share with you the descriptions we were able to collect from the centers/offices **(b)(5)** **(b)(5)** It has been share with ASFR to meet today's deadline.

Let me know if you have any questions.

Bill Tootle

Director, Office of Budget
U.S. Food and Drug Administration
4041 Powder Mill Road,
Beltsville, MD 20705

Phone: 301-796-4710/4579

From: Tootle, William
Sent: Tuesday, February 25, 2020 6:57 PM
To: Cabezas, Miriam (HHS/ASFR) <Miriam.Cabezas@hhs.gov>; Wong, Eric <Eric.Wong@fda.hhs.gov>
Cc: Claude, Rachel (OS) <Rachel.Claude@hhs.gov>; Cormier, Justin P (OS) <Justin.Cormier@hhs.gov>; Willis, Ken <Ken.Willis@fda.hhs.gov>; Tsai, Chen-Tin <Chen-Tin.Tsai@fda.hhs.gov>
Subject: RE: FDA - COVID Supplemental Narrative Justification

Here is FDA's submission. Let us know if you have any questions.

Bill Tootle

Director, Office of Budget
U.S. Food and Drug Administration
4041 Powder Mill Road,
Beltsville, MD 20705

Phone: 301-796-4710/4579

From: Cabezas, Miriam (HHS/ASFR) <Miriam.Cabezas@hhs.gov>
Sent: Tuesday, February 25, 2020 3:21 PM
To: Tootle, William <William.Tootle@fda.hhs.gov>; Wong, Eric <Eric.Wong@fda.hhs.gov>
Cc: Claude, Rachel (OS) <Rachel.Claude@hhs.gov>; Cormier, Justin P (OS) <Justin.Cormier@hhs.gov>
Subject: RE: FDA - COVID Supplemental Narrative Justification

Hi Bill – Once HHS cleared we would share with the appropriations committees. In addition, the Secretary may want to use the information during his hearing tomorrow.

From: Tootle, William <William.Tootle@fda.hhs.gov>
Sent: Tuesday, February 25, 2020 1:38 PM
To: Cabezas, Miriam (HHS/ASFR) <Miriam.Cabezas@hhs.gov>; Wong, Eric (FDA/OC) <Eric.Wong@fda.hhs.gov>
Cc: Claude, Rachel (HHS/ASFR) <Rachel.Claude@hhs.gov>; Cormier, Justin (HHS/ASFR) <Justin.Cormier@hhs.gov>
Subject: RE: FDA - COVID Supplemental Narrative Justification

Can you tell me how this information will be used? Will HHS just use it to answer potential questions or will you actually provide more detail to Congress?

Bill Tootle

Director, Office of Budget
U.S. Food and Drug Administration
4041 Powder Mill Road,
Beltsville, MD 20705

Phone: 301-796-4710/4579

From: Cabezas, Miriam (HHS/ASFR) <Miriam.Cabezas@hhs.gov>
Sent: Tuesday, February 25, 2020 1:24 PM
To: Tootle, William <William.Tootle@fda.hhs.gov>; Wong, Eric <Eric.Wong@fda.hhs.gov>
Cc: Claude, Rachel (OS) <Rachel.Claude@hhs.gov>; Cormier, Justin P (OS) <Justin.Cormier@hhs.gov>
Subject: RE: FDA - COVID Supplemental Narrative Justification

Great, thank you.

From: Tootle, William <William.Tootle@fda.hhs.gov>
Sent: Tuesday, February 25, 2020 1:20 PM
To: Cabezas, Miriam (HHS/ASFR) <Miriam.Cabezas@hhs.gov>; Wong, Eric (FDA/OC) <Eric.Wong@fda.hhs.gov>
Cc: Claude, Rachel (HHS/ASFR) <Rachel.Claude@hhs.gov>; Cormier, Justin (HHS/ASFR) <Justin.Cormier@hhs.gov>
Subject: RE: FDA - COVID Supplemental Narrative Justification

You're asking about the attached document, right? If so, yes.

Bill Tootle

Director, Office of Budget
U.S. Food and Drug Administration
4041 Powder Mill Road,
Beltsville, MD 20705

Phone: 301-796-4710/4579

From: Cabezas, Miriam (HHS/ASFR) <Miriam.Cabezas@hhs.gov>
Sent: Tuesday, February 25, 2020 1:13 PM
To: Tootle, William <William.Tootle@fda.hhs.gov>; Wong, Eric <Eric.Wong@fda.hhs.gov>
Cc: Claude, Rachel (OS) <Rachel.Claude@hhs.gov>; Cormier, Justin P (OS) <Justin.Cormier@hhs.gov>
Subject: RE: FDA - COVID Supplemental Narrative Justification

Hi Bill – I am just checking in to confirm whether FDA will be able to send us a spend plan by COB today.

Thank you

Miriam

From: Cabezas, Miriam (HHS/ASFR)
Sent: Monday, February 24, 2020 7:50 PM
To: Tootle, William (FDA/OC) (William.Tootle@fda.hhs.gov) <William.Tootle@fda.hhs.gov>; Wong, Eric (FDA/OC) <Eric.Wong@fda.hhs.gov>
Cc: Claude, Rachel (HHS/ASFR) <Rachel.Claude@hhs.gov>; Cormier, Justin (HHS/ASFR) <Justin.Cormier@hhs.gov>
Subject: FDA - COVID Supplemental Narrative Justification

Good evening –

As discussed earlier today, we are providing a table with the funding included in the supplemental for FDA. This table reflects the source of funding and footnotes that provide context on the overall request. For FDA, funding would be provided through an enhanced transfer authority. In addition, we are providing a template that can be used to developed narrative justification. Please provide narrative by COB tomorrow. If you anticipate any challenges with that timeline, please let us know so we can discuss in the morning.

Miriam

From: Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]
Sent: 2/25/2020 8:59:13 PM
To: Robert Kadlec [bob.kadlec@hhs.gov]; Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]
CC: Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Steele, Danielle (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=634b96dc13cf48f3971ce676b65e952f-HHS-Daniell]
Subject: Fwd: Reply to Dr. Peter Navarro regarding Supply Situation for "List of Essential Medications for Severe CVD Infection"
Attachments: Supply Situation for Essential Medications for Severe CVD_to KL_02252020.docx; ATT00001.htm; WH List of Essential Medications_FDA cover memo_to KL_02252020.docx; ATT00002.htm

FYI- Navarro asked us to provide more info on a list of drugs. Attached is the cover memo and the response from CDER.

Sent from my iPhone

Begin forwarded message:

From: "Bernstein, Jessica" <Jessica.Bernstein@fda.hhs.gov>
Date: February 25, 2020 at 4:44:21 PM EST
To: "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>
Cc: "McLatchy, Johanna" <Johanna.McLatchy@fda.hhs.gov>, "Woodcock, Janet" <Janet.Woodcock@fda.hhs.gov>, "Cavazzoni, Patrizia" <Patrizia.Cavazzoni@fda.hhs.gov>, "Throckmorton, Douglas C" <Douglas.Throckmorton@fda.hhs.gov>, "Clarke, Mary Beth" <Marybeth.Clarke@fda.hhs.gov>
Subject: Reply to Dr. Peter Navarro regarding Supply Situation for "List of Essential Medications for Severe CVD Infection"

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Thank you,
Jessica

Jessica Bernstein, MPH
Office of Executive Programs, CDER
Office phone: 240-402-0524

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 2/25/2020 8:59:18 PM
To: Robert Kadlec [bob.kadlec@hhs.gov]; Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]
CC: Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Steele, Danielle (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=634b96dc13cf48f3971ce676b65e952f-HHS-Daniell]
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Office of Executive Programs, CDER
Office phone: 240-402-0524

From: Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]
Sent: 2/25/2020 9:00:38 PM
To: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: Fwd: Reply to Dr. Peter Navarro regarding Supply Situation for "List of Essential Medications for Severe CVD Infection"
Attachments: Supply Situation for Essential Medications for Severe CVD_to KL_02252020.docx; ATT00001.htm; WH List of Essential Medications_FDA cover memo_to KL_02252020.docx; ATT00002.htm

Can you send both of these docs to Navarro staff? Let them know this is the list data, but the EO asks are coming soon.

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Office phone: 240-402-0524

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Sent: 2/25/2020 9:00:43 PM
To: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: Fwd: Reply to Dr. Peter Navarro regarding Supply Situation for "List of Essential Medications for Severe CVD Infection"
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Cc: "McLatchy, Johanna" <Johanna.McLatchy@fda.hhs.gov>, "Woodcock, Janet" <Janet.Woodcock@fda.hhs.gov>, "Cavazzoni, Patrizia" <Patrizia.Cavazzoni@fda.hhs.gov>, "Throckmorton, Douglas C" <Douglas.Throckmorton@fda.hhs.gov>, "Clarke, Mary Beth" <Marybeth.Clarke@fda.hhs.gov>
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Jessica Bernstein, MPH
Office of Executive Programs, CDER
Office phone: 240-402-0524

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 2/26/2020 12:21:20 PM
To: Harrison, Brian (HHS/IOS) [Brian.Harrison@hhs.gov]
CC: Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Steele, Danielle (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=634b96dc13cf48f3971ce676b65e952f-HHS-Daniell]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Zebley, Kyle (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d79ac6af2e1b49089fca453b39ebddde-HHS-Kyle.Ze]
Subject: RE: Reply to Dr. Peter Navarro regarding Supply Situation for "List of Essential Medications for Severe CVD Infection"
Attachments: WH List of Essential Medications_FDA cover memo_to KL_02252020.docx; Supply Situation for Essential Medications for Severe CVD_to KL_02252020.docx

Documents attached.

Navarro asked for us to get back answers on his list of drugs.

From: Harrison, Brian (HHS/IOS) <Brian.Harrison@hhs.gov>
Sent: Wednesday, February 26, 2020 12:18 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>; Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>; Steele, Danielle (OS) <Danielle.Steele@hhs.gov>; Grigsby, Garrett G (OS) <Garrett.Grigsby@hhs.gov>; Zebley, Kyle (OS) <Kyle.Zebley@hhs.gov>
Subject: RE: Reply to Dr. Peter Navarro regarding Supply Situation for "List of Essential Medications for Severe CVD Infection"

(b)(5)

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, February 26, 2020 12:16 PM
To: Harrison, Brian (HHS/IOS) <Brian.Harrison@hhs.gov>
Cc: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Steele, Danielle (HHS/IOS) <Danielle.Steele@hhs.gov>; Grigsby, Garrett (HHS/OS/OGA) <Garrett.Grigsby@hhs.gov>; Zebley, Kyle (HHS/OS/OGA) <Kyle.Zebley@hhs.gov>
Subject: RE: Reply to Dr. Peter Navarro regarding Supply Situation for "List of Essential Medications for Severe CVD Infection"

How do you want to handle?

From: Harrison, Brian (HHS/IOS) <Brian.Harrison@hhs.gov>
Sent: Tuesday, February 25, 2020 9:04 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>; Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>; Steele, Danielle (OS) <Danielle.Steele@hhs.gov>; Grigsby, Garrett G (OS) <Garrett.Grigsby@hhs.gov>; Zebley, Kyle (OS) <Kyle.Zebley@hhs.gov>
Subject: Re: Reply to Dr. Peter Navarro regarding Supply Situation for "List of Essential Medications for Severe CVD Infection"

Can we discuss in the morning? Thx

Brian Harrison
Chief of Staff
U.S. Department of Health and Human Services
202.690.7000
brian.harrison@hhs.gov

On Feb 25, 2020, at 8:59 PM, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov> wrote:

FYI- Navarro asked us to provide more info on a list of drugs. Attached is the cover memo and the response from CDER.

Sent from my iPhone

Begin forwarded message:

From: "Bernstein, Jessica" <Jessica.Bernstein@fda.hhs.gov>
Date: February 25, 2020 at 4:44:21 PM EST
To: "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>
Cc: "McLatchy, Johanna" <Johanna.McLatchy@fda.hhs.gov>, "Woodcock, Janet" <Janet.Woodcock@fda.hhs.gov>, "Cavazzoni, Patrizia" <Patrizia.Cavazzoni@fda.hhs.gov>, "Throckmorton, Douglas C" <Douglas.Throckmorton@fda.hhs.gov>, "Clarke, Mary Beth" <Marybeth.Clarke@fda.hhs.gov>
Subject: Reply to Dr. Peter Navarro regarding Supply Situation for "List of Essential Medications for Severe CVD Infection"

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Thank you,
Jessica

Jessica Bernstein, MPH
Office of Executive Programs, CDER
Office phone: 240-402-0524

<Supply Situation for Essential Medications for Severe CVD_to KL_02252020.docx>
<WH List of Essential Medications_FDA cover memo_to KL_02252020.docx>

From: Tyler, James [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DDB047FF73E640B29259D7CA22611E67-JAMES.TYLER]
Sent: 2/26/2020 1:22:44 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Sigg, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=37695069dc214f5cb20e6056dd4d7cf7-sigg]; Klimczak, Katherine [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01a6c20534774be590c50f0d455c81de-Katherine.K]; McBride, Maren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]
Subject: FW: CoV dollars
Attachments: FDA COVID Response Activities for TA.docx

Importance: High

(b)(5)

From: Tootle, William <William.Tootle@fda.hhs.gov>
Sent: Wednesday, February 26, 2020 1:21 PM
To: Tyler, James <James.Tyler@fda.hhs.gov>; Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>
Cc: Sigg, Jim <Jim.Sigg@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: CoV dollars

Please see the attached narrative. Let us know if you have any questions.

Bill Tootle

Director, Office of Budget
U.S. Food and Drug Administration
4041 Powder Mill Road,
Beltsville, MD 20705

Phone: 301-796-4710/4579

From: Tyler, James <James.Tyler@fda.hhs.gov>
Sent: Wednesday, February 26, 2020 1:05 PM
To: Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Tootle, William <William.Tootle@fda.hhs.gov>
Cc: Sigg, Jim <Jim.Sigg@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: CoV dollars

momentarily

From: Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>
Sent: Wednesday, February 26, 2020 12:38 PM
To: Tyler, James <James.Tyler@fda.hhs.gov>; Tootle, William <William.Tootle@fda.hhs.gov>
Cc: Sigg, Jim <Jim.Sigg@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: CoV dollars

Hi all—just wanted to check in on the request. Will we have something to share with Hill soon?

Thank you!
Kate

From: McBride, Maren <Maren.McBride@fda.hhs.gov>
Sent: Wednesday, February 26, 2020 8:52 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Tyler, James <James.Tyler@fda.hhs.gov>
Cc: Tootle, William <William.Tootle@fda.hhs.gov>; Sigg, Jim <Jim.Sigg@fda.hhs.gov>; Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>
Subject: Re: CoV dollars

Pls keep Kate looped in this as well (cced her here). I have several hill meetings this am so she will be tracking/working on it during that period so we can meet the hills deadline

---

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Date: February 26, 2020 at 8:49:52 AM EST
To: Tyler, James <James.Tyler@fda.hhs.gov>
Cc: Tootle, William <William.Tootle@fda.hhs.gov>, McBride, Maren <Maren.McBride@fda.hhs.gov>, Sigg, Jim <Jim.Sigg@fda.hhs.gov>
Subject: Re: CoV dollars

Happy to discuss on the 9am

Sent from my iPhone

On Feb 26, 2020, at 6:03 AM, Tyler, James <James.Tyler@fda.hhs.gov> wrote:

(b)(5)

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Date: February 25, 2020 at 9:52:18 PM EST
To: Tyler, James <James.Tyler@fda.hhs.gov>, Tootle, William <William.Tootle@fda.hhs.gov>
Cc: McBride, Maren <Maren.McBride@fda.hhs.gov>
Subject: CoV dollars

(b)(5)

Thanks!
Keagan

Internal, Deliberative, Confidential

Sent from my iPhone

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 2/26/2020 1:23:07 PM
To: Moughalian, Jen C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1227fced76ad4092bb5f1395d24c0d74-HHS-Jen.Mou]
Subject: FDA Request
Attachments: FDA COVID Response Activities for TA.docx

How is this? Can we pls push this?

From: Caccomo, Stephanie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=950C32CEBC4B4F80B302C50CF31C8524-STEPHANIE.C]
Sent: 2/26/2020 3:22:56 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]
Subject: RE: peter

(b)(5)

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, February 26, 2020 3:07 PM
To: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Subject: RE: peter

(b)(5)

From: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Sent: Wednesday, February 26, 2020 3:02 PM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: peter

(b)(5)

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Wednesday, February 26, 2020 3:00 PM
To: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Subject: peter

(b)(5)

Coronavirus vaccines are far off, FDA official says, but drugs to treat patients could come sooner
STAT
Matthew Herper, Damian Garde
February 26, 2020

New drugs to treat patients already infected with the novel coronavirus, which has sparked outbreaks across multiple continents, will emerge much more quickly than vaccines to prevent infection, a top Food and Drug Administration official said Wednesday.

"The development of a vaccine is not going to prevent a pandemic here," Peter Marks, the director of the FDA's Center for Biologics Evaluation and Research, told STAT at the SVB Leerink Global Healthcare Conference, ahead of a keynote presentation there. And getting a vaccine ready for pivotal testing is going to take more than just a few months, he said.

Marks' words stand in contrast to recent comments from the White House. Larry Kudlow, President Trump's director of the National Economic Council, said Tuesday that drug companies are "probably coming up with a vaccine in much shorter time than people realize," adding that the U.S.'s containment effort is "pretty close to airtight."

Marks said the FDA is on an "even higher level of alert," noting that the number of cases has jumped dramatically in South Korea and Italy.

"The fundamental difference over the past several days is the extent of the spread and the speed of the spread," he said.

To date, there have been more than 80,000 cases of Covid-19, the disease caused by the novel coronavirus, and 2,700 deaths, mostly in China.

"I'm not the one to decide when you declare a pandemic," Marks said. "I'm just the one who stays awake at night worrying about it now."

The FDA's major job in an outbreak is to speed the development of diagnostics for detecting the infectious agent, vaccines to prevent people from catching it, and drugs to treat those who fall ill. Diagnostic tests are handled by the agency's devices center, which is not under Marks' purview but which he said is working "very actively."

On the potential for vaccines and drugs, Marks said Gilead Sciences' remdesivir has shown promise against other coronaviruses, and may be beneficial in this current outbreak. Gilead's drug is now being tested in China and the U.S. Marks also said convalescent plasma, a blood product taken from people who have already fallen ill, may have potential.

Multiple companies are advancing vaccines toward human trials, led by Moderna Therapeutics, whose National Institutes of Health-partnered product is expected to enter clinical study in April.

But crafting a vaccine for healthy people presents greater challenges than developing a treatment for those already infected with the virus, Marks said.

"I do have to be honest that for the vaccines, the idea that there's going to be a vaccine that will really be able to be used in a large patient population and a large clinical trial, in the very near future, as in the next few months, I think that's just not likely," Marks said.

Marks said a real late-stage trial to test a vaccine is likely "months away." One concern is that some previous coronavirus vaccines have caused worsening of the disease, not improvement.

"We have to make sure that as we proceed with development, we're not creating problems," Marks said. It might be realistic, he said, for studies of vaccines to begin by the summer, although that timeline is still aggressive.

Another risk related to the coronavirus, Marks said, is a disruption to the global pharmaceutical supply chain, because many of the basic chemicals used to make new medicines come from China. Marks said that with vaccines and other products his center oversees, much of the manufacturing is not in China. But he acknowledged that the FDA is closely monitoring the potential for drug shortages. "We have to be careful, and to try to understand that," he said.

Marks also spoke in his keynote about the FDA's position on sometimes risky stem cell therapies, an area in which the agency will stop exercising "enforcement discretion" — meaning that it's choosing not to enforce rules — in November 2020. That could mean that the FDA's actions in the area could step up.

And he spoke about the potential for gene therapy, telling the story of a girl who, he said, would not be alive were it not for Novartis' Zolgensma, a one-time treatment for spinal muscular atrophy.

"She was running around Capitol Hill making senators have tears come to their eyes, which is a really hard thing to make happen," Marks said.

Marks said the FDA is looking to take new steps to make it easier to develop gene therapy products for rare diseases. The idea would be that for diseases that affect small populations, a drug developer would be able to leverage results from other, similar therapies, in order to get trials done more quickly.

"We're excited at where cell and gene therapy is headed," Marks said.

Stephanie Caccomo
Press Officer

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

From: Caccomo, Stephanie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=950C32CEBC4B4F80B302C50CF31C8524-STEPHANIE.C]
Sent: 2/26/2020 5:38:02 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
Subject: Re: COVID-19 Talking Points

Great. Thx. I will plan to use below as basis for media responses. Will prep reactive tonight.

Stephanie Caccomo
Press Officer

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

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Date: February 26, 2020 at 5:35:29 PM EST
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: FW: COVID-19 Talking Points

FYI

From: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Sent: Wednesday, February 26, 2020 5:03 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: COVID-19 Talking Points

Here's what I have from Tim

Updates:

(b)(5)

Best,
Tim

Timothy T. Stenzel, MD, PhD
Director, OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality

Center for Devices and Radiological Health
U.S. Food and Drug Administration
Timothy.Stenzel@fda.hhs.gov
Jennifer Campbell
Administrative Assistant

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

From: Julie Khani [jkhani@acla.com]
Sent: 2/26/2020 8:10:31 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: Re: ACLA Annual Meeting, Role of Commercial Labs in Coronavirus Testing

Wonderful. Thank you so much.

Sent from my iPhone

On Feb 26, 2020, at 8:09 PM, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov> wrote:

Ok, let me see if we can get the FDA/CDC team to partner here on that.

Yes, she passed along thanks.

Sent from my iPhone

On Feb 26, 2020, at 7:16 PM, Julie Khani <jkhani@acla.com> wrote:

It's a hotel ballroom. I could look into videoconferencing?

Also, just FYI, I reached out to Danielle Steele on this as well, re both FDA and CDC participation.

Sent from my iPhone

On Feb 26, 2020, at 5:41 PM, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov> wrote:

Not sure we could get anyone to do it in person. Could the FDA person participate by phone?

From: Julie Khani <jkhani@acla.com>
Sent: Wednesday, February 26, 2020 2:52 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: ACLA Annual Meeting, Role of Commercial Labs in Coronavirus Testing

Hi Keagan. As you may be aware, next week Commissioner Hahn has graciously agreed to speak at the ACLA annual meeting. The meeting is on March 4th at the Grand Hyatt in DC and he is scheduled to speak from 9:00-9:15. Elizabeth Hillebrenner is also speaking on a panel at 11:00am to discuss diagnostics generally. Meeting agenda available here.

I am reaching out because in addition to Commissioner Hahn's remarks, I think the ACLA meeting would provide an excellent opportunity for the FDA to address the diagnostics community about the Coronavirus. I've extended the same invitation to the CDC. There will be approximately 200 people in attendance at the meeting, including CEOs and senior leadership from companies such as LabCorp, Quest, Mayo Clinic Laboratories, Hologic, and Siemens. ACLA and several member companies have a weekly call with the CDC, and the FDA has participated on some of the calls. We have shared information with the CDC about lab capacity and other information, in the event that public health labs are unable to handle testing needs, and surge capacity is necessary.

While these calls have been helpful, numerous questions remain about the availability of the CDC assay to commercial labs, the FDA EUA process, and other issues. I'd be happy to modify the agenda to allow time for a representative from the FDA, CDC, or both, to provide an update an answer questions.

I know the situation is changing quickly, and I can only imagine how busy it is at the FDA. But, as a lot of the key players in the diagnostics community will be together at our meeting next week, I wanted to extend the opportunity.

My office and mobile numbers are below if you have questions or if you would like to discuss.

Thanks.

Julie

Julie Khani \ President \ ACLA \ jkhani@acla.com \ 202-637-9466 (o) \ (b)(6) (m)

From: Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]
Sent: 2/26/2020 8:21:50 PM
To: McGowan, Robert K (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e6175b088b1d49a4bfa2de3862800d4a-HHS-omc2-cd]
Subject: Re: ACLA Annual Meeting, Role of Commercial Labs in Coronavirus Testing

Thanks.

Sent from my iPhone

On Feb 26, 2020, at 8:16 PM, McGowan, Robert (Kyle) (CDC/OD/OCS) <omc2@cdc.gov> wrote:

I was going to as (b)(5) tomorrow if he'd be available.

Get Outlook for iOS

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, February 26, 2020 8:07:35 PM
To: McGowan, Robert (Kyle) (CDC/OD/OCS) <omc2@cdc.gov>
Subject: Re: ACLA Annual Meeting, Role of Commercial Labs in Coronavirus Testing

(b)(5)

Sent from my iPhone

On Feb 26, 2020, at 7:51 PM, McGowan, Robert (Kyle) (CDC/OD/OCS) <omc2@cdc.gov> wrote:

Yeah. That could work.

Get Outlook for iOS

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, February 26, 2020 7:32:02 PM
To: McGowan, Robert (Kyle) (CDC/OD/OCS) <omc2@cdc.gov>
Subject: Fwd: ACLA Annual Meeting, Role of Commercial Labs in Coronavirus Testing

Maybe we can have **(b)(5)**

Sent from my iPhone

Begin forwarded message:

From: Julie Khani <jkhani@acla.com>
Date: February 26, 2020 at 2:52:40 PM EST
To: "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>
Subject: ACLA Annual Meeting, Role of Commercial Labs in Coronavirus Testing

Hi Keagan. As you may be aware, next week Commissioner Hahn has graciously agreed to speak at the ACLA annual meeting. The meeting is on March 4th at the Grand Hyatt in DC and he is scheduled to speak from 9:00-9:15. Elizabeth Hillebrenner is also speaking on a panel at 11:00am to discuss diagnostics generally. Meeting agenda available here.

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Thanks.

Julie

Julie Khani \ President \ ACLA \ jkhani@acla.com \ 202-637-9466 (o) \ (b)(6) (m)

From: Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]
Sent: 2/27/2020 10:41:32 AM
To: McGowan, Robert K (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e6175b088b1d49a4bfa2de3862800d4a-HHS-omc2-cd]
Subject: Re: ACLA Annual Meeting, Role of Commercial Labs in Coronavirus Testing

Sorry, meant to send this to Jeff. Ignore.

Sent from my iPhone

On Feb 27, 2020, at 10:40 AM, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov> wrote:

CDC will commit to someone on videoconference **(b)(5)** Will he be down there next week?

Sent from my iPhone

On Feb 26, 2020, at 8:16 PM, McGowan, Robert (Kyle) (CDC/OD/OCS) <omc2@cdc.gov> wrote:

I was going to ask **(b)(5)** tomorrow if he'd be available.

Get Outlook for iOS

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Sent: Wednesday, February 26, 2020 8:07:35 PM
To: McGowan, Robert (Kyle) (CDC/OD/OCS) <omc2@cdc.gov>
Subject: Re: ACLA Annual Meeting, Role of Commercial Labs in Coronavirus Testing

(b)(5)

Sent from my iPhone

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From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, February 26, 2020 7:32:02 PM
To: McGowan, Robert (Kyle) (CDC/OD/OCS) <omc2@cdc.gov>
Subject: Fwd: ACLA Annual Meeting, Role of Commercial Labs in Coronavirus Testing

Maybe we can have **(b)(5)**

Sent from my iPhone

Begin forwarded message:

From: Julie Khani <jkhani@acla.com>
Date: February 26, 2020 at 2:52:40 PM EST
To: "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>
Subject: ACLA Annual Meeting, Role of Commercial Labs in Coronavirus Testing

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Thanks.

Julie

Julie Khani \ President \ ACLA \ jkhani@acla.com \ 202-637-9466 (o) (b)(6)

From: Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]
Sent: 2/27/2020 10:15:05 PM
To: Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]
Subject: Fwd: Pre-EUA IVD template request
Attachments: image002.png; ATT00001.htm; image003.jpg; ATT00002.htm; image013.jpg; ATT00003.htm; image005.jpg; ATT00004.htm; image006.jpg; ATT00005.htm; image007.jpg; ATT00006.htm; image002.png; ATT00007.htm; image003.jpg; ATT00008.htm; image004.jpg; ATT00009.htm; image005.jpg; ATT00010.htm; image006.jpg; ATT00011.htm; image007.jpg; ATT00012.htm; image008.png; ATT00013.htm; Draft cover letter for Sponsor 01212020.docx; ATT00014.htm; EUA Review Template_NAT_Novel Coronavirus 1.19.2020.doc; ATT00015.htm

Sent from my iPhone

Begin forwarded message:

From: "Shuren, Jeff" <Jeff.Shuren@fda.hhs.gov>
Date: February 27, 2020 at 10:03:14 PM EST
To: "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>
Subject: FW: Pre-EUA IVD template request

Additional communication — as of February 25th **(b)(4) (b)(5)**

From: Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
Date: February 27, 2020 at 10:01:33 PM EST
To: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: FW: Pre-EUA IVD template request

FYI

From: CDRH-EUA-Templates <CDRH-EUA-Templates@fda.hhs.gov>
Sent: Tuesday, February 25, 2020 4:03 PM
To: Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
Subject: FW: Pre-EUA IVD template request

FYI – see information in red in the email below and:

(b)(4) (b)(5)

Best regards
Kim

Kim Sapsford-Medintz, Ph.D.
MCM EUA Team Lead

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov

From: Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]
Sent: 2/28/2020 11:25:09 AM
To: Robert Kadlec [bob.kadlec@hhs.gov]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]
Subject: Fwd: Today's Secretary Briefing
Attachments: image013.png; ATT00001.htm; image014.jpg; ATT00002.htm; image015.jpg; ATT00003.htm; image016.jpg; ATT00004.htm; image017.jpg; ATT00005.htm; image018.jpg; ATT00006.htm; Plan to Increase COVID-19 Testing in the US 2-28-20 FINAL.docx; ATT00007.htm

Sent from my iPhone

Begin forwarded message:

From: "Shuren, Jeff" <Jeff.Shuren@fda.hhs.gov>
Date: February 28, 2020 at 8:37:40 AM EST
To: "Hahn, Stephen" <SH1@fda.hhs.gov>, "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>
Subject: Today's Secretary Briefing

Attached is the final draft proposal for increasing COVID-19 testing in the U.S. for the Secretary and for briefing the Secretary today at 10:45 AM.

Jeff

Jeffrey Shuren, MD, JD
Director

Center for Devices and Radiological Health
U.S. Food and Drug Administration
Tel: 301-796-5900
Email: jeff.shuren@fda.hhs.gov

From: Varnado, Martina [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AD1D1BC50F7941718B0FEEB194CBAFF1-MARTINA.VAR]
Sent: 2/28/2020 11:29:21 AM
To: Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Roth, Lauren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52bfd08572694f269a20c508f3c04a03-Lauren.Roth]; Tobias, Lindsay [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a4766773c717470bbc55d204b5f067b2-Lindsay.Sto]
CC: O'Neill, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9a75446cda1244b3aa59af3b53cc2d4d-ONEILLJ]; Russ, Wanda [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2900752acf81445785fb0f5b23c728c8-WRuss]; Kotler, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=13024875752041d9b6883ad277902181-Sarah.Kotle]
Subject: OES Reports
Attachments: Exec Sec and OMA.pdf; Commissioner Sig-Priority Dir Reply Rpt Week of 2-24-2020.doc

Attached are the OES reports for this week. Have a great weekend.

Thank you,

Martina

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 2/28/2020 11:42:43 AM
To: Ashley, Donald [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40241a76230349cbb195ab1721092196-Donald.Ashl]
Subject: RE: OUDLC COVID-19 WLs

Thank you!

From: Ashley, Donald <Donald.Ashley@fda.hhs.gov>
Sent: Friday, February 28, 2020 11:21 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: FW: OUDLC COVID-19 WLs
Importance: High

Keagan: We will soon be issuing 5 COVID-19 WLs. We just sent them to OCC for review and clearance. I understand that COMMS are being prepared. There is a brief description of each letter below. I can send you the drafts as well, but they are not yet OCC cleared. Thanks, Don

---

From: Ashley, Donald
Sent: Friday, February 28, 2020 11:16 AM
To: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Cc: Beshara, Nicholas <Nicholas.Beshara@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>
Subject: FW: OUDLC COVID-19 WLs
Importance: High

Hello Stacy,

(b)(5)

(b)(5)

Please let me know if you have any questions or need further additional information. As always, thanks very much for your partnership and assistance in these important public health matters.

Don

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 2/28/2020 11:57:45 AM
To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
Subject: RE: OUDLC COVID-19 WLs

Thanks.

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Friday, February 28, 2020 11:57 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: OUDLC COVID-19 WLs

Yes, OMA is working on press release right now

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Friday, February 28, 2020 11:43 AM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: FW: OUDLC COVID-19 WLs
Importance: High

(b)(5)

From: Ashley, Donald <Donald.Ashley@fda.hhs.gov>
Sent: Friday, February 28, 2020 11:21 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
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From: Ashley, Donald
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To: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Cc: Beshara, Nicholas <Nicholas.Beshara@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>
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(b)(5)

(b)(5)

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Don

From: Caccomo, Stephanie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=950C32CEBC4B4F80B302C50CF31C8524-STEPHANIE.C]
Sent: 2/28/2020 12:15:08 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: RE: How are we doing on talkers?

No--are they sending us comms?

(b)(5)

-----Original Message-----
From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Friday, February 28, 2020 12:14 PM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: Re: How are we doing on talkers?

Seen anything from CDC?

Sent from my iPhone

> On Feb 28, 2020, at 12:07 PM, Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov> wrote:
>
> Working it to make it more high-level and newsy
>
> -----Original Message-----
> From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
> Sent: Friday, February 28, 2020 12:07 PM
> To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
> Subject: How are we doing on talkers?
>
>
>
> Sent from my iPhone

From: Roth, Lauren [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=52BFD08572694F269A20C508F3C04A03-LAUREN.ROTH]
Sent: 2/28/2020 12:54:24 PM
To: Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Schiller, Lowell [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77949b06919e4f91aa788e9a616c50c7-Lowell.Schi]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: RE: CDRH's covid-19 guidance

Stacy/Keagan,

For your reference: Below is a short set of explanatory points about exceptions from OIRA review of guidances **(b)(5)**

(b)(5)

For your consideration: Given my read of the documents, as a belt-and-suspenders move, **(b)(5)**

(b)(5)

Here are relevant points related to EO 13981 and the CRA:

- **OIRA Review under EO 13981**
  - There is no explicit exception from the entirety of the EO for circumstances involving public health and safety. (By contrast, there is such an exception for national security.)
  - But, notice and comment requirements don't apply under the EO, unless the guidance is "significant."
  - And, if a guidance is "significant", there is an exception in cases when "the agency and the Administrator agree that exigency, safety, health, or other compelling cause warrants an exemption from some or all requirements." *See* EO section 4(iii).
  - Finally, OIRA's implementing memo states (at Q33): "Agencies may request that the significance determination or review be waived due to exigency, safety, or other compelling cause."

- **OIRA Review under the CRA**
  - CRA section 808(2) states: "any rule which an agency for good cause finds (and incorporates such finding and a statement of reasons therefor in the rule issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest, shall take effect at such time as the agency promulgating the rule determines."

If you have any questions, let me know.

Lauren

From: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Sent: Friday, February 28, 2020 9:52 AM
To: Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Schiller, Lowell <Lowell.Schiller@fda.hhs.gov>; Anderson, Erika

<Erika.Anderson@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: CDRH's covid-19 guidance

(b)(5) Thank you, Lauren.

Keagan, do you want me to flag this for Bob (b)(5)

From: Roth, Lauren <Lauren.Roth@fda.hhs.gov>
Sent: Friday, February 28, 2020 9:46 AM
To: Schiller, Lowell <Lowell.Schiller@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: CDRH's covid-19 guidance

All,

I spoke to Jeff Shuren this morning about the guidance that CDRH/OCC are preparing to address (b)(5) (b)(5). I am confirming my understanding of timing and process for this group, so we are all on the same page. No need to reply, unless there is something I'm missing.

(b)(5)

At this point, Office of Policy is not planning to run a process related to clearance/heads up to HHS or OIRA, given that this guidance is being handled through HHS's COVID-19 response efforts. If the HHS process does not specifically include a heads-up to OIRA, however, I would just flag for consideration whether Stacy, Keagan, Lowell or someone at the Department (Bob, Danielle) give a heads-up to Paul Ray, so that OIRA leadership is not surprised.

Thanks,
Lauren

From: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]
Sent: 2/28/2020 1:07:39 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Wallace, Rodney (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2814cd3aa9043f8bf8f8c4490b6b98a-HHS-Rodney.]
Subject: Fwd: DIAGNOSTIC TESTING DOCUMENT
Attachments: Plan to Increase COVID-19 Testing in the US 2-28-20 FINAL JVL_JB.docx; ATT00001.htm; UNMC CLEAN - Plan to Increase COVID-19 Testing in the US 2-28-20 FINAL JVL_JB.docx; ATT00002.htm

Comments and suggested edits from UNMC. I have not reviewed personally
Sent from my iPhone

Begin forwarded message:

From: "Lawler, James V" <james.lawler@unmc.edu>
Date: February 28, 2020 at 1:04:43 PM EST
To: "Kadlec, Robert (OS/ASPR/IO)" <Robert.Kadlec@hhs.gov>
Cc: "Hinrichs, Steven H" <shinrich@unmc.edu>, "Iwen, Peter C" <piwen@unmc.edu>, "Kratochvil, Christopher J" <ckratoch@unmc.edu>, "Broadhurst, Mara J" <jana.broadhurst@unmc.edu>
Subject: DIAGNOSTIC TESTING DOCUMENT

Bob,
Please find attached tracked and clean versions of our edits on FDA document on rapid test network.
james

James Lawler, MD, MPH, FIDSA
Executive Director, International Programs & Innovation
Global Center for Health Security, and
Associate Professor of Medicine
Division of Infectious Diseases
University of Nebraska Medical Center
m (b)(6)
james.lawler@unmc.edu

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 2/28/2020 1:48:21 PM
To: Meyer, Lyndsay [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00176f0991c84d34b3927bfb410d5483-Lyndsay.Mey]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]
CC: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
Subject: RE: Secty TPs

Thank you!

From: Meyer, Lyndsay <Lyndsay.Meyer@fda.hhs.gov>
Sent: Friday, February 28, 2020 1:47 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Cc: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: RE: Secty TPs

For the record, cleared by OCC as-is below. Thanks!

From: Meyer, Lyndsay
Sent: Friday, February 28, 2020 1:45 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Cc: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: RE: Secty TPs

Ah, good point. Made a few small tweaks to that point. I sent to OCC just in case, but in the interest of time it's below. I'll follow if Marcy has more feedback.

(b)(5)

(b)(5)

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Friday, February 28, 2020 1:41 PM
To: Meyer, Lyndsay <Lyndsay.Meyer@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Cc: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: RE: Secty TPs

Looks good, **(b)(5)**

From: Meyer, Lyndsay <Lyndsay.Meyer@fda.hhs.gov>
Sent: Friday, February 28, 2020 1:33 PM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: Secty TPs

Hi there – OCC cleared below. Do these work? Edits in different colors; clean below. Thanks!

(b)(5)

(b)(5)

Lyndsay Meyer
Media Relations Director (Acting)

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-5345 / Cell: (b)(6)
lyndsay.meyer@fda.hhs.gov

From: Stecker, Judy (OS/IOS) [Judy.Stecker@hhs.gov]
Sent: 2/28/2020 2:02:50 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Oakley, Caitlin B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8feed045e954557aa1e0052f925865f-HHS-Caitlin]
Subject: Re: FDA talkers

Okay so how should we say it?

Sent from my iPhone

On Feb 28, 2020, at 2:01 PM, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov> wrote:

I don't think the guidance is combined. FDA will write and post on our website.

From: Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>
Sent: Friday, February 28, 2020 1:54 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Stecker, Judy (OS) <Judy.Stecker@hhs.gov>
Cc: Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>
Subject: Re: FDA talkers

Yes thank you. FYI - based on Mango readout - here's what AMA has for right now:

(b)(5)

On Feb 28, 2020, at 1:48 PM, Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov> wrote:

Thx

Sent from my iPhone

On Feb 28, 2020, at 1:48 PM, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov> wrote:

(b)(5)

(b)(5)

From: Murphy, Ryan (OS/ASPA) [Ryan.Murphy1@hhs.gov]
Sent: 2/28/2020 2:13:23 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Stecker, Judy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e205440400ab4f629be1faccfe0846fc-HHS-Judy.St]; Oakley, Caitlin B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8feed045e954557aa1e0052f925865f-HHS-Caitlin]
Subject: Re: FDA talkers

Copy. Thx.

On Feb 28, 2020, at 2:12 PM, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov> wrote:

It is fine. We can explain later we worked in collaboration with.

From: Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>
Sent: Friday, February 28, 2020 2:07 PM
To: Stecker, Judy (OS) <Judy.Stecker@hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>
Subject: Re: FDA talkers

Not easily no. They are sitting on a stage.

On Feb 28, 2020, at 2:04 PM, Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov> wrote:

Can we pass a note or is it not that big a deal?

Sent from my iPhone

On Feb 28, 2020, at 2:03 PM, Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov> wrote:

Well that's what was told and they've started. Hmmm

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From: Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>
Sent: Friday, February 28, 2020 1:54 PM

To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Stecker, Judy (OS) <Judy.Stecker@hhs.gov>
Cc: Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>
Subject: Re: FDA talkers

Yes thank you. FYI - based on Mango readout - here's what AMA has for right now:

(b)(5)

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Thx

Sent from my iPhone

On Feb 28, 2020, at 1:48 PM, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov> wrote:

(b)(5)

From: Hall, Bill (HHS/ASPA) [bill.hall@hhs.gov]
Sent: 2/28/2020 3:06:43 PM
To: Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Stecker, Judy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e205440400ab4f629be1faccfe0846fc-HHS-Judy.St]; Oakley, Caitlin B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8feed045e954557aa1e0052f925865f-HHS-Caitlin]
Subject: RE: FDA talkers

Judy and I spoke. Press release is all that's needed

From: Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>
Sent: Friday, February 28, 2020 3:03 PM
To: Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>
Cc: Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov>; Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>; Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>
Subject: Re: FDA talkers

Just spoke to Bill on this and Judy he'll call you. I wasn't aware the plan was to spin up a whole rollout. If that's the plan we need to flag this further. I wasn't tracking that level of announcement.

On Feb 28, 2020, at 2:59 PM, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov> wrote:

Guys -we are drafting the guidance for this proposal, if we get FDA clearance it will come to HHS quickly and OIRA for 1 hour review. It is possible we get it up today. If so, we will need to do outreach on it. Media, Hill, Stakeholder – how do you want us to manage?

We can coordinate CDC and FDA doing that together.

From: Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov>
Sent: Friday, February 28, 2020 2:04 PM
To: Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>
Subject: Re: FDA talkers

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Sent from my iPhone

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From: Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>
Sent: Friday, February 28, 2020 1:54 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Stecker, Judy (OS) <Judy.Stecker@hhs.gov>
Cc: Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>
Subject: Re: FDA talkers

Yes thank you. FYI - based on Mango readout - here's what AMA has for right now:

(b)(5)

On Feb 28, 2020, at 1:48 PM, Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov> wrote:

Thx

Sent from my iPhone

On Feb 28, 2020, at 1:48 PM, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov> wrote:

(b)(5)

From: Arbes, Sarah (HHS/ASL) [Sarah.Arbes@hhs.gov]
Sent: 2/28/2020 4:41:34 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Stecker, Judy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e205440400ab4f629be1faccfe0846fc-HHS-Judy.St]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]
CC: Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Oakley, Caitlin B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8feed045e954557aa1e0052f925865f-HHS-Caitlin]; Hall, Bill (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e56218361cd4ffbacdd06ac2d7b809d-HHS-bill.ha]; Pence, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3f21407a02d44cd4901bcce26f9b3074-HHS-Laura.P]; Morse, Sara N (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4080ee237c084683ae674366e5cde21d-HHS-Sara.Mo]
Subject: RE: FDA talkers

(b)(5)

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Friday, February 28, 2020 4:40 PM
To: Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov>; Gross, Karas (FDA/OC) <Karas.Gross@fda.hhs.gov>; Caliguiri, Laura (FDA/OC) <Laura.Caliguiri@fda.hhs.gov>
Cc: Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>; Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>; Arbes, Sarah (HHS/ASL) <Sarah.Arbes@hhs.gov>
Subject: Re: FDA talkers

+ Laura and Karas to help on our end.

FYI- guidance will likely come to HHS for review in next hour.

Sent from my iPhone

On Feb 28, 2020, at 4:23 PM, Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov> wrote:

Just need to coordinate leg with asl and ovp/WH leg

Sent from my iPhone

On Feb 28, 2020, at 3:33 PM, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov> wrote:

(b)(5) Fine with press release for reporters though.

From: Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov>
Sent: Friday, February 28, 2020 3:08 PM
To: Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>; Hall, Bill (OS) <bill.hall@hhs.gov>
Subject: Re: FDA talkers

I thought he mentioned at pen and pad. Then we just need to do what we usually do for guidance. If hill needs to have notification ahead of time (I'm sure ASFR will want to)

Sent from my iPhone

On Feb 28, 2020, at 3:03 PM, Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov> wrote:

Just spoke to Bill on this and Judy he'll call you. I wasn't aware the plar **(b)(5)** **(b)(5)**

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Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>
Subject: Re: FDA talkers

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Sent from my iPhone

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To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Stecker, Judy (OS) <Judy.Stecker@hhs.gov>
Cc: Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>
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Yes thank you. FYI - based on Mango readout - here's what AMA has for right now:

(b)(5)

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Thx

Sent from my iPhone

On Feb 28, 2020, at 1:48 PM, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov> wrote:

(b)(5)

From: Murphy, Ryan (OS/ASPA) [Ryan.Murphy1@hhs.gov]
Sent: 2/28/2020 7:03:45 PM
To: Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Stecker, Judy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e205440400ab4f629be1faccfe0846fc-HHS-Judy.St]; Oakley, Caitlin B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8feed045e954557aa1e0052f925865f-HHS-Caitlin]; Hall, Bill (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e562183611cd4ffbacdd06ac2d7b809d-HHS-bill.ha]; Pence, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3f21407a02d44cd4901bcce26f9b3074-HHS-Laura.P]; Morse, Sara N (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4080ee237c084683ae674366e5cde21d-HHS-Sara.Mo]
Subject: RE: FDA talkers

Got it. Thanks.

From: Gross, Karas <Karas.Gross@fda.hhs.gov>
Sent: Friday, February 28, 2020 7:02 PM
To: Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>
Cc: Arbes, Sarah (HHS/ASL) <Sarah.Arbes@hhs.gov>; Caliguiri, Laura (FDA/OC) <Laura.Caliguiri@fda.hhs.gov>; Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov>; Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>; Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>; Pence, Laura (HHS/ASL) <Laura.Pence@hhs.gov>; Morse, Sara (HHS/ASL) <Sara.Morse@hhs.gov>
Subject: Re: FDA talkers

I emailed this before I knew there was a snag.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Date: February 28, 2020 at 6:59:16 PM EST
To: Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>
Cc: Gross, Karas <Karas.Gross@fda.hhs.gov>, Arbes, Sarah C (OS) <Sarah.Arbes@hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Stecker, Judy (OS) <Judy.Stecker@hhs.gov>, Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>, Hall, Bill (OS) <bill.hall@hhs.gov>, Pence, Laura (OS) <Laura.Pence@hhs.gov>, Morse, Sara N (OS) <Sara.Morse@hhs.gov>
Subject: Re: FDA talkers

Guidance still at FDA. Nothing to Hill. Maybe press release, just coming through FDA for clearance.

Sent from my iPhone

On Feb 28, 2020, at 6:57 PM, Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov> wrote:

What's going to the Hill tonight? I thought the policy was still being worked on. Media statement I don't think has come up for clearance yet either. Sorry – catching up on emails so if I'm just behind the times let me know.

From: Gross, Karas <Karas.Gross@fda.hhs.gov>
Sent: Friday, February 28, 2020 6:16 PM
To: Arbes, Sarah (HHS/ASL) <Sarah.Arbes@hhs.gov>; Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>
Cc: Caliguiri, Laura (FDA/OC) <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov>; Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>; Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>; Pence, Laura (HHS/ASL) <Laura.Pence@hhs.gov>; Morse, Sara (HHS/ASL) <Sara.Morse@hhs.gov>
Subject: RE: FDA talkers

Confirming here that I connected with Laura P and we'll push press tonight to the hill and flag for key staff. We're discussing a potential call for Monday but we're still working out the details so that likely won't be communicated to the hill tonight.

From: Arbes, Sarah (HHS/ASL) <Sarah.Arbes@hhs.gov>
Sent: Friday, February 28, 2020 6:08 PM
To: Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Stecker, Judy (OS) <Judy.Stecker@hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>; Hall, Bill (OS) <bill.hall@hhs.gov>; Pence, Laura (OS) <Laura.Pence@hhs.gov>; Morse, Sara N (OS) <Sara.Morse@hhs.gov>
Subject: Re: FDA talkers

+ Pence and Morse

On Feb 28, 2020, at 5:52 PM, Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov> wrote:

Has the PR gone into clearance?

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Sent: Friday, February 28, 2020 4:45 PM
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Cc: Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>; Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>; Arbes, Sarah (HHS/ASL) <Sarah.Arbes@hhs.gov>
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(b)(5)

- This action today reflects our ability to adapt to this rapidly evolving situation and address critical public health needs.

From: Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]
Sent: 2/28/2020 7:10:25 PM
To: Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]
CC: Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Stecker, Judy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e205440400ab4f629be1faccfe0846fc-HHS-Judy.St]; Oakley, Caitlin B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8feed045e954557aa1e0052f925865f-HHS-Caitlin]; Hall, Bill (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e56218361cd4ffbacdd06ac2d7b809d-HHS-bill.ha]; Pence, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3f21407a02d44cd4901bcce26f9b3074-HHS-Laura.P]; Morse, Sara N (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4080ee237c084683ae674366e5cde21d-HHS-Sara.Mo]
Subject: Re: FDA talkers

Back on track. Sending to department for review.

Sent from my iPhone

On Feb 28, 2020, at 7:01 PM, Gross, Karas <Karas.Gross@fda.hhs.gov> wrote:

I emailed this before I knew there was a snag.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Date: February 28, 2020 at 6:59:16 PM EST
To: Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>
Cc: Gross, Karas <Karas.Gross@fda.hhs.gov>, Arbes, Sarah C (OS) <Sarah.Arbes@hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Stecker, Judy (OS) <Judy.Stecker@hhs.gov>, Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>, Hall, Bill (OS) <bill.hall@hhs.gov>, Pence, Laura (OS) <Laura.Pence@hhs.gov>, Morse, Sara N (OS) <Sara.Morse@hhs.gov>
Subject: Re: FDA talkers

Guidance still at FDA. Nothing to Hill. Maybe press release, just coming through FDA for clearance.

Sent from my iPhone

On Feb 28, 2020, at 6:57 PM, Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov> wrote:

What's going to the Hill tonight? I thought the policy was still being worked on. Media statement I don't think has come up for clearance yet either. Sorry – catching up on emails so if I'm just behind the times let me know.

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Sent: Friday, February 28, 2020 6:16 PM
To: Arbes, Sarah (HHS/ASL) <Sarah.Arbes@hhs.gov>; Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>
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Sent: 2/28/2020 7:26:04 PM
To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
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Subject: Re: FDA talkers

Let's push to tomorrow am. Pls have guidance post in am, assuming we get back from WH tonight.

Sent from my iPhone

On Feb 28, 2020, at 7:23 PM, Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov> wrote:

I'm fine with whatever—but we need to tell cdrh asap b/c everyone is planning for super late release. Keagan—push to tomorrow 10am?

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Sent: Friday, February 28, 2020 7:22 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: RE: FDA talkers

Are we agree to hold til am or stick to 9pm deadline?

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Friday, February 28, 2020 7:17 PM
To: Stecker, Judy (OS) <Judy.Stecker@hhs.gov>
Cc: Gross, Karas <Karas.Gross@fda.hhs.gov>; Arbes, Sarah C (OS) <Sarah.Arbes@hhs.gov>; Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>; Hall, Bill (OS) <bill.hall@hhs.gov>; Pence, Laura (OS) <Laura.Pence@hhs.gov>; Morse, Sara N (OS) <Sara.Morse@hhs.gov>
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Yes.

Sent from my iPhone

On Feb 28, 2020, at 7:15 PM, Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov> wrote:

I don't want us to bury this on a Friday it's good news. Can we get done for sharing tomorrow at 10am so VP can use for hits

Sent from my iPhone

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Guidance needs significant revisions. Not going to HHS for a while hopefully tonight, but not in the near term.

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Subject: Fwd: FDA commissioner joins coronavirus task force at Pence request

(b)(5)

Sent from my iPhone

Begin forwarded message:

From: POLITICO Pro Health Care <politicoemail@politicopro.com>
Date: February 28, 2020 at 8:11:44 PM EST
To: "Stecker, Judy (OS/IOS)" <Judy.Stecker@hhs.gov>
Subject: FDA commissioner joins coronavirus task force at Pence request
Reply-To: "POLITICO subscriptions" <reply-fe971c727160017c75-553241_HTML-880489367-1376319-270759@politicoemail.com>

FDA commissioner joins coronavirus task force at Pence request

By Sarah Karlin-Smith

02/28/2020 08:10 PM EST

Vice President Mike Pence added FDA commissioner Stephen Hahn to the White House's coronavirus task force this afternoon, according to a senior HHS official familiar with the decision.

Trump on Wednesday put Pence in charge of the government's response to the outbreak, taking over the supervisory role from HHS Secretary Alex Azar, who is still chairing the task force. Azar had not initially included Hahn or any FDA staff on the task force, despite the agency's numerous responsibilities related to the outbreak.

FDA is monitoring the supply chain for shortages of drugs and medical devices, given China's significant role in manufacturing. It announced the first drug shortage due to the outbreak Thursday.

FDA has also been coordinating closely with CDC and other diagnostic developers who are working on coronavirus tests. FDA is in charge of approving diagnostics and plays a role in overseeing clinical trials of potential coronavirus vaccines and treatments.

HHS declined to comment on why Hahn was not initially a member of the task force. Pence's office declined to comment.

To view online:
https://protect2.fireeye.com/url?k=1e7b5a0b-422e5318-1e7b6b34-0cc47adb5650-e8c6f628692eaca1&u=https://subscriber.politicopro.com/health-care/whiteboard/2020/02/fda-commissioner-joins-coronavirus-task-force-at-pence-request-3977142

You received this POLITICO Pro content because your customized settings include: Alex Azar. To

change your alert settings, please go to https://protect2.fireeye.com/url?k=88a9f4ac-d4fcfdbf-88a9c593-0cc47adb5650-81874751624d5e01&u=https://subscriber.politicopro.com/settings.

This email was sent to judy.stecker@hhs.gov by:
POLITICO, LLC
1000 Wilson Blvd.
Arlington, VA 22209
USA .

From: Roth, Lauren [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=52BFD08572694F269A20C508F3C04A03-LAUREN.ROTH]
Sent: 2/28/2020 8:29:43 PM
To: Malliou, Ekaterini (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c57996fad6db44ecba5ab5c1dacf7e0a-HHS-Ekateri]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: RE: OMB COMMENTS on the PLAN, ATTACHED: Heads up: FDA guidance on clinical laboratories

Here is the information that we have currently in response to that question:

(b)(5)

From: Malliou, Ekaterini (OS/IOS) <Ekaterini.Malliou@hhs.gov>
Sent: Friday, February 28, 2020 8:21 PM
To: Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: OMB COMMENTS on the PLAN, ATTACHED: Heads up: FDA guidance on clinical laboratories

Lauren, do we have an answer to **(b)(5)**

(b)(5)

I do not want them to ask it again when I send them the guidance for OMB review.

Thank you

From: Malliou, Ekaterini (OS/IOS)
Sent: Friday, February 28, 2020 2:08 PM
To: Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Roth, Lauren (FDA/OC) <Lauren.Roth@fda.hhs.gov>; Schiller, Lowell (FDA/OC) <Lowell.Schiller@fda.hhs.gov>; Steele, Danielle (HHS/IOS) <Danielle.Steele@hhs.gov>
Subject: OMB COMMENTS on the PLAN, ATTACHED: Heads up: FDA guidance on clinical laboratories

Please find attached OMB edits on the plan.

OMB want to know **(b)(5)**

(b)(5)

May I please ask whether it is possible to email me the guidance by 3pm?

Thank you.

****

Lowell and Lauren, update on the process, below for your information:

(b)(5)

From: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Sent: Friday, February 28, 2020 1:03 PM
To: Roth, Lauren (FDA/OC) <Lauren.Roth@fda.hhs.gov>; Malliou, Ekaterini (OS/IOS) <Ekaterini.Malliou@hhs.gov>; Schiller, Lowell (FDA/OC) <Lowell.Schiller@fda.hhs.gov>; Steele, Danielle (HHS/IOS) <Danielle.Steele@hhs.gov>
Subject: RE: Heads up: FDA guidance on clinical laboratories

Kat can you give me a call? I can explain. I just spoke to Judy. **(b)(6)**

From: Roth, Lauren <Lauren.Roth@fda.hhs.gov>
Sent: Friday, February 28, 2020 1:01 PM
To: Malliou, Ekaterini (OS) <Ekaterini.Malliou@hhs.gov>; Schiller, Lowell <Lowell.Schiller@fda.hhs.gov>; Steele, Danielle (OS) <Danielle.Steele@hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: RE: Heads up: FDA guidance on clinical laboratories

Adding Stacy, deleting RPMS.

From: Malliou, Ekaterini (OS/IOS) <Ekaterini.Malliou@hhs.gov>
Sent: Friday, February 28, 2020 12:58 PM
To: Schiller, Lowell <Lowell.Schiller@fda.hhs.gov>; Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Cohen, Kenneth <Kenneth.Cohen@fda.hhs.gov>; OC OPPB OP RPMS <OCOPPBOPRPMS@fda.hhs.gov>; Steele, Danielle (OS) <Danielle.Steele@hhs.gov>
Subject: RE: Heads up: FDA guidance on clinical laboratories

Including Danielle.

Thank you

From: Malliou, Ekaterini (OS/IOS)
Sent: Friday, February 28, 2020 12:54 PM
To: Schiller, Lowell (FDA/OC) <Lowell.Schiller@fda.hhs.gov>; Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Cohen, Kenneth (FDA/OC) <Kenneth.Cohen@fda.hhs.gov>; FDA Regs Box <OCOPPBOPRPMS@fda.hhs.gov>
Subject: FW: Heads up: FDA guidance on clinical laboratories

Hi, I am not aware of this one. **(b)(5)** Thank you

From: Hirsch, Quinn N. EOP/OMB **(b)(6)**
Sent: Friday, February 28, 2020 12:19 PM
To: Malliou, Ekaterini (OS/IOS) <Ekaterini.Malliou@hhs.gov>
Cc: Hawkins, Jamar (HHS/OS) <jamar.hawkins@hhs.gov>
Subject: FW: Heads up: FDA guidance on clinical laboratories

Hi Kat,
Please see below – are you aware of this guidance? Please give me a call as soon as feasible - (b)(6)
I am the contact for OIRA's coronavirus response, and am in close touch with my colleagues who cover interagency equities.

Thanks,
Q

(b)(5)

Stacy said she would send the summary description to us shortly, and the draft when it's done but that may be right up against when they intend to post.

From: Rebello, Heidi [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2834CE193CA949799EF063E34A2CFA0B-HEIDI.REBEL]
Sent: 2/28/2020 9:13:35 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Finnen, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
Subject: Re: FDA commissioner joins coronavirus task force at Pence request

Sounds like ASPA according to bottom of article?

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Date: February 28, 2020 at 8:40:11 PM EST
To: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Finnen, April <April.Finnen@fda.hhs.gov>, Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: Re: FDA commissioner joins coronavirus task force at Pence request

(b)(5) Who confirmed this!!

Sent from my iPhone

On Feb 28, 2020, at 8:18 PM, Rebello, Heidi <Heidi.Rebello@fda.hhs.gov> wrote:

(b)(5)

From: POLITICO Pro Health Care <politicoemail@politicopro.com>
Date: February 28, 2020 at 8:12:13 PM EST
To: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: FDA commissioner joins coronavirus task force at Pence request

FDA commissioner joins coronavirus task force at Pence request

By Sarah Karlin-Smith

02/28/2020 08:10 PM EST

Vice President Mike Pence added FDA commissioner Stephen Hahn to the White House's coronavirus task force this afternoon, according to a senior HHS official familiar with the decision.

Trump on Wednesday put Pence in charge of the government's response to the outbreak, taking over the supervisory role from HHS Secretary Alex Azar, who is still chairing the task force. Azar had not initially

included Hahn or any FDA staff on the task force, despite the agency's numerous responsibilities related to the outbreak.

FDA is monitoring the supply chain for shortages of drugs and medical devices, given China's significant role in manufacturing. It announced the first drug shortage due to the outbreak Thursday.

FDA has also been coordinating closely with CDC and other diagnostic developers who are working on coronavirus tests. FDA is in charge of approving diagnostics and plays a role in overseeing clinical trials of potential coronavirus vaccines and treatments.

HHS declined to comment on why Hahn was not initially a member of the task force. Pence's office declined to comment.

To view online:
https://subscriber.politicopro.com/health-care/whiteboard/2020/02/fda-commissioner-joins-coronavirus-task-force-at-pence-request-3977142

From: Julie Khani [jkhani@acla.com]
Sent: 2/29/2020 9:40:25 AM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: Commercial Labs/Coronavirus Testing

Good morning, Keagan. There is growing confusion about the current role of commercial laboratories in testing for the coronavirus. Given the steady stream of media inquiries ACLA has received, we issued a statement last night. It focused on the primary role of the CDC and public health labs in testing, commercial lab commitment to supporting these labs in the event additional capacity is needed, but that "Currently, the CDC and other public health labs are the only entities authorized to provide testing for COVID-19 in the United States. At this time, commercial laboratories are not collecting, processing or transporting specimens for COVID-19 testing from patients suspected of having, or confirmed to have, COVID-19."

We've seen press articles and social media posts that imply high complexity labs, hospital labs, and/or academic medical center labs are approved or about to be approved to test for the coronavirus. I'd appreciate any updates or clarifications you could provide. ACLA members want to continue to be supportive of the CDC and public health labs, and we also want to avoid public confusion, patients arriving at commercial lab patient service centers requesting testing, coronavirus specimens arriving at commercial labs, etc.

Thanks so much for any clarification.

Julie

Julie Khani \ President \ ACLA \ jkhani@acla.com \ 202-637-9466 (o) \ (b)(6) (m)

From: Caccomo, Stephanie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=950C32CEBC4B4F80B302C50CF31C8524-STEPHANIE.C]
Sent: 2/29/2020 9:53:20 AM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: Diagnostic guidance_PR final 935am.docx
Attachments: Diagnostic guidance_PR final 935am.docx

Doing one final proof

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 3/1/2020 12:46:24 PM
To: Oakley, Caitlin B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8feed045e954557aa1e0052f925865f-HHS-Caitlin]
Subject: FW: Need help asap--test kits

From: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Sent: Sunday, March 1, 2020 12:34 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: Need help asap--test kits

Those numbers are not from us. They came from the CDC.

There is an issue with semantics which can be confusing. A test kit contains many tests, e.g., 500 tests, 1,000 tests. Each test can run one patient specimen. Each specimen could be from a different patient. Therefore, for example, 500 test kits that each have 500 tests can be used to test specimens from up to 250,000 patients.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Sunday, March 1, 2020 12:08 PM
To: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: FW: Need help asap--test kits
Importance: High

Can you pls help with the numbers?

From: Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>
Sent: Sunday, March 1, 2020 12:01 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Bonds, Michelle E (CDC) <meb0@cdc.gov>; Galatas, Kate (CDC) <kkg2@cdc.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>
Cc: Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>; Hall, Bill (OS) <bill.hall@hhs.gov>; McKeogh, Katherine (OS) <Katherine.McKeogh@hhs.gov>; Stecker, Judy (OS) <Judy.Stecker@hhs.gov>
Subject: Need help asap--test kits
Importance: High

CDC/FDA---see below. Could you please help provide clarity on the numbers below?

Have a few of these pending, so need help asap. Thanks!

DRAFT PRE-DECISIONAL DELIBERATIVE

From: Westwood, Sarah <Sarah.Westwood@turner.com>
Sent: Sunday, March 1, 2020 11:03 AM
To: Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>
Subject: Quick question

Hi Caitlin! Hope you're doing well. This is possibly a dumb question but we just wanted to touch base to understand the correct number of available or soon-to-be-available coronavirus test kits out there so we don't say the wrong number…

VP Pence said this morning that 15,000 test kits had been released and the administration is working with a commercial provider to get 50,000 more distributed.

Secretary Azar said we have the ability to test 75,000 people in the field right now and that will increase.

So I just wanted to check for clarification – is it the case that each kit can test more than one person? Or that there was already 10,000 kits in the field before the 15k and 50k that the VP mentioned? Sorry if this betrays my ignorance of how testing kits work, we just wanted to see if the number is 65k or 75k. Thank you!

Sarah

Sarah Westwood
CNN White House Reporter
(202) (b)(6)
(770)

From: Ross, Jennifer [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44AE562EA1D840A3ACA172D0CC23F368-ROSSJ]
Sent: 3/1/2020 1:06:57 PM
To: Busch, Marcy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec4ef9f06a684cafbe4307486233609e-Marcy.Busch]; Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Courtney, Brooke [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=261a2a3791e24e19b095ac0172485ebd-Brooke.Cour]; Paulos, Lauren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5dfb1daac9c14aab8649e6c66087f956-AubrieLaure]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Tomasello, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5aa45d669024d87a822c2a7b33f652b-Jennifer.To]; Ross, Aftin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=340198e1a213488b81fa54f942ae430e-Aftin.Ross]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Dennis, Claire [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2f0121bf65bf48adb8077a2c49324223-Claire.Denn]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]
Subject: RE: COVID-19 supplemental -- PREP Act - N95 Masks

Thanks!

From: Busch, Marcy <Marcy.Busch@fda.hhs.gov>
Date: March 1, 2020 at 1:06:28 PM EST
To: Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>, Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>, Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>, Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>, Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>, Ross, Aftin <Aftin.Ross@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>, Gross, Karas <Karas.Gross@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Dennis, Claire <Claire.Dennis@fda.hhs.gov>, Raza, Mark <Mark.Raza@fda.hhs.gov>, Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: RE: COVID-19 supplemental -- PREP Act - N95 Masks

Thanks all! I've sent this revised (b)(5) on to HHS.

From: Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
Sent: Sunday, March 1, 2020 12:36 PM
To: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Ross, Aftin <Aftin.Ross@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: RE: COVID-19 supplemental -- PREP Act - N95 Masks

Recommend going with **(b)(5)**. This is how CDC uses the terminology and how it appears in their EUA letter of request to FDA.

I know this is fairly obvious, but just to state so that we are all in agreement: **(b)(5)**
(b)(5)

Suzanne B. Schwartz, MD, MBA
Deputy Director (& Acting Office Director) Office of Strategic Partnerships & Technology Innovation
Center for Devices and Radiological Health (CDRH)
Office of Strategic Partnerships and Technology Innovation (OST)
U.S. Food and Drug Administration
WO66, Room 5410
Tel: 301-796-6937
Cell:202-841-9996
Suzanne.Schwartz@fda.hhs.gov

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

From: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Sent: Sunday, March 1, 2020 12:22 PM
To: Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Ross, Aftin <Aftin.Ross@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: RE: COVID-19 supplemental -- PREP Act - N95 Masks

(b)(5)

From: Busch, Marcy <Marcy.Busch@fda.hhs.gov>
Sent: Sunday, March 01, 2020 12:19 PM
To: Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Ross, Aftin <Aftin.Ross@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Cc: Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: RE: COVID-19 supplemental -- PREP Act - N95 Masks

Thanks Suzanne. I'll plan on sending the revised language below forward by **(b)(5)** unless I hear from others.

From: Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
Sent: Sunday, March 1, 2020 12:14 PM
To: Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Ross, Aftin <Aftin.Ross@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: RE: COVID-19 supplemental -- PREP Act - N95 Masks

Thanks Marcy.
I have one suggested edit (highlighted) see below.

Suzanne B. Schwartz, MD, MBA
Deputy Director (& Acting Office Director) Office of Strategic Partnerships & Technology Innovation
Center for Devices and Radiological Health (CDRH)
Office of Strategic Partnerships and Technology Innovation (OST)
U.S. Food and Drug Administration
WO66, Room 5410
Tel: 301-796-6937
Cell:202-841-9996
Suzanne.Schwartz@fda.hhs.gov

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

From: Busch, Marcy <Marcy.Busch@fda.hhs.gov>
Sent: Sunday, March 1, 2020 11:58 AM
To: Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Ross, Aftin <Aftin.Ross@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: RE: COVID-19 supplemental -- PREP Act - N95 Masks

(b)(5)

(b)(5)

From: Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>
Sent: Sunday, March 1, 2020 11:40 AM
To: Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Ross, Aftin <Aftin.Ross@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: RE: COVID-19 supplemental -- PREP Act - N95 Masks

Per Michael yesterday, attached is **(b)(5)** I have incorporated Ellen's edit. **(b)(5)** **(b)(5)**

From: Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
Sent: Sunday, March 1, 2020 11:35 AM
To: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Ross, Aftin <Aftin.Ross@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: RE: COVID-19 supplemental -- PREP Act - N95 Masks

Thanks Brooke. And the EUA language is presently scoped to **(b)(4)** **(b)(4)**. This goes beyond the N95 for requesting PREP Act coverage.

Suzanne B. Schwartz, MD, MBA
Deputy Director (& Acting Office Director) Office of Strategic Partnerships & Technology Innovation
Center for Devices and Radiological Health (CDRH)
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Tel: 301-796-6937
Cell:202-841-9996
Suzanne.Schwartz@fda.hhs.gov

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

From: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Sent: Sunday, March 1, 2020 11:32 AM
To: Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Ross, Aftin <Aftin.Ross@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: RE: COVID-19 supplemental -- PREP Act - N95 Masks

(b)(5)

From: Busch, Marcy <Marcy.Busch@fda.hhs.gov>
Sent: Sunday, March 01, 2020 11:27 AM
To: Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Ross, Aftin <Aftin.Ross@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: RE: COVID-19 supplemental -- PREP Act - N95 Masks

Would someone mind including the latest FDA agreed on language on this email thread?

From: Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
Sent: Sunday, March 1, 2020 11:25 AM
To: Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Ross, Aftin <Aftin.Ross@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Cc: Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Subject: RE: COVID-19 supplemental -- PREP Act - N95 Masks

(b)(5)

From: Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
Date: March 1, 2020 at 11:18:40 AM EST
To: Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>, Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>, Busch, Marcy <Marcy.Busch@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>, Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>, Ross, Aftin <Aftin.Ross@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>, Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>, Gross, Karas <Karas.Gross@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Dennis, Claire <Claire.Dennis@fda.hhs.gov>, Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
Subject: RE: COVID-19 supplemental -- PREP Act - N95 Masks
Importance: High

+ Jennifer Ross from OCET who has been preparing the declaration language needed for the EUA and PREP Act coverage.

Suzanne B. Schwartz, MD, MBA
Deputy Director (& Acting Office Director) Office of Strategic Partnerships & Technology Innovation
Center for Devices and Radiological Health (CDRH)
Office of Strategic Partnerships and Technology Innovation (OST)
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WO66, Room 5410
Tel: 301-796-6937
Cell:202-841-9996
Suzanne.Schwartz@fda.hhs.gov

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

From: Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>
Sent: Sunday, March 1, 2020 11:15 AM
To: Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Ross, Aftin <Aftin.Ross@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Dennis, Claire <Claire.Dennis@fda.hhs.gov>
Subject: RE: COVID-19 supplemental -- PREP Act - N95 Masks

Adding Karas and Keagan for awareness. I'm not sure HHS is aware of all of this.

From: Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>

Date: March 1, 2020 at 11:11:28 AM EST
To: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>, Busch, Marcy <Marcy.Busch@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>, Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>, Ross, Aftin <Aftin.Ross@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>, Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>, Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>
Cc: Dennis, Claire <Claire.Dennis@fda.hhs.gov>
Subject: RE: COVID-19 supplemental -- PREP Act - N95 Masks

I'm concerned that the declaration needed now is going to be broader than for use of N95s requiring PREP Act coverage. So I am asking to make sure these are not in conflict with one another.

Suzanne B. Schwartz, MD, MBA
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Cell:202-841-9996
Suzanne.Schwartz@fda.hhs.gov

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

From: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Sent: Sunday, March 1, 2020 11:08 AM
To: Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Ross, Aftin <Aftin.Ross@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>
Cc: Dennis, Claire <Claire.Dennis@fda.hhs.gov>
Subject: RE: COVID-19 supplemental -- PREP Act - N95 Masks

(b)(5)

From: Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
Sent: Sunday, March 1, 2020 10:48 AM
To: Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Ross, Aftin <Aftin.Ross@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Paulos, Lauren

<Lauren.Paulos@fda.hhs.gov>
Cc: Dennis, Claire <Claire.Dennis@fda.hhs.gov>
Subject: RE: COVID-19 supplemental -- PREP Act - N95 Masks
Importance: High

Question for clarification:

I don't want to mix apples and oranges….

(b)(5)

For the latter, this needs to be broader than N95s…it should be **(b)(5)**
That is the language OCET sent up to ASPR for tomorrow's declaration

Suzanne B. Schwartz, MD, MBA
Deputy Director (& Acting Office Director) Office of Strategic Partnerships & Technology Innovation
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Tel: 301-796-6937
Cell:202-841-9996
Suzanne.Schwartz@fda.hhs.gov

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

From: Busch, Marcy <Marcy.Busch@fda.hhs.gov>
Sent: Sunday, March 1, 2020 10:09 AM
To: Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Ross, Aftin <Aftin.Ross@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>
Cc: Dennis, Claire <Claire.Dennis@fda.hhs.gov>
Subject: FW: COVID-19 supplemental -- PREP Act - N95 Masks

FYI – below is the proposed statutory language that HHS has prepared re: amendments to the PREP Act **(b)(5)**

(b)(5)

Thanks all!

From: Moughalian, Jen (HHS/ASFR)
Sent: Sunday, March 01, 2020 8:32 AM
To: Friedman, Richard (HHS/OGC); Amin, Stacy (FDA/OC); Charrow, Robert (HHS/OGC); Shuy, Bryan (OS/ASPR/IO); Cash, Lester (HHS/ASFR); Johnson-Weider, Michelle (HHS/OGC); Sherman, Susan (HHS/OGC); Ray Gorrie, Jennifer (HHS/OGC); Benor, David E. (HHS/OGC)
Cc: Busch, Marcy (FDA/OC); Dennis, Claire (FDA/OC); Raza, Mark (FDA/OC)
Subject: RE: COVID-19 supplemental -- PREP Act - N95 Masks

Thank you Richard for the quick turn! Please send comments or edits by 10:30 am. We need to move this forward to OMB in support of today's negotiations.

From: Friedman, Richard (HHS/OGC) <Richard.Friedman@HHS.GOV>
Sent: Sunday, March 1, 2020 3:18 AM
To: Amin, Stacy (FDA/OC) <Stacy.Amin@fda.hhs.gov>; Charrow, Robert (HHS/OGC) <Robert.Charrow@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Cash, Lester (HHS/ASFR) <Lester.Cash@HHS.GOV>; Moughalian, Jen (HHS/ASFR) <Jen.Moughalian@hhs.gov>; Johnson-Weider, Michelle (HHS/OGC) <Michelle.Johnson-weider@hhs.gov>; Sherman, Susan (HHS/OGC) <Susan.Sherman@HHS.GOV>; Ray Gorrie, Jennifer (HHS/OGC) <Jennifer.Ray-Gorrie@hhs.gov>; Benor, David E. (HHS/OGC) <david.benor@hhs.gov>
Cc: Busch, Marcy (FDA/OC) <Marcy.Busch@fda.hhs.gov>; Dennis, Claire (FDA/OC) <Claire.Dennis@fda.hhs.gov>; Raza, Mark (FDA/OC) <Mark.Raza@fda.hhs.gov>
Subject: RE: COVID-19 supplemental -- PREP Act - N95 Masks

Adding Susan, Jenn, and Dave. Apologies for the initial omission.

Richard Friedman
(cell) **(b)(6)**

From: Friedman, Richard (HHS/OGC)
Sent: Sunday, March 01, 2020 1:42 AM
To: Amin, Stacy (FDA/OC) (Stacy.Amin@fda.hhs.gov); Charrow, Robert (HHS/OGC) (Robert.Charrow@hhs.gov); Shuy, Bryan (OS/ASPR/IO); Cash, Lester (HHS/ASFR); Moughalian, Jen (HHS/ASFR) (Jen.Moughalian@hhs.gov); Johnson-Weider, Michelle (HHS/OGC)
Cc: Busch, Marcy (FDA/OC); Dennis, Claire (FDA/OC); Raza, Mark (FDA/OC)
Subject: COVID-19 supplemental -- PREP Act - N95 Masks

Here is a draft of a bill provision to make N95 respirators eligible for PREP Act coverage. The declaration to be issued by the Secretary under the PREP Act could cover all N95 respirators, a specific brand and model of such a respirator, or some category of such respirators. The declaration would have to comply with section 319F-3(b) of the PHS Act, and the declaration would have to be issued by the end of FY24.

(b)(5)

If anyone has any questions, please email me, or call me.

Richard Friedman

(cell) 240-618-0675

*****

(b)(5)

From: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Sent: Saturday, February 29, 2020 3:28 PM
To: Charrow, Robert (HHS/OGC) <Robert.Charrow@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>
Cc: Busch, Marcy (FDA/OC) <Marcy.Busch@fda.hhs.gov>; Dennis, Claire (FDA/OC) <Claire.Dennis@fda.hhs.gov>; Raza, Mark (FDA/OC) <Mark.Raza@fda.hhs.gov>
Subject: RE: PREP Act - N95 Masks

(b)(5)

Marcy/Claire/Mark – anything to add?

From: Charrow, Robert (HHS/OGC) <Robert.Charrow@hhs.gov>
Sent: Saturday, February 29, 2020 3:20 PM
To: Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>
Cc: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: RE: PREP Act - N95 Masks

It is (b)(5)
(b)(5)
(b)(5) B

From: Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>
Sent: Saturday, February 29, 2020 3:14 PM
To: Moughalian, Jen (HHS/ASFR) <Jen.Moughalian@hhs.gov>
Cc: McMillin, Virginia D. EOP/WHO (b)(6) Arbes, Sarah (HHS/ASL) <Sarah.Arbes@hhs.gov>; Pence, Laura (HHS/ASL) <Laura.Pence@hhs.gov>; Steele, Danielle (HHS/IOS) <Danielle.Steele@hhs.gov>; Shuy, Caitrin (HHS/ASFR) <Caitrin.Shuy@hhs.gov>; Yaworske, Jason A. EOP/OMB (b)(6) D'Angelo, Gregory B. EOP/OMB <Gregory.B.D'Angelo@omb.eop.gov>; Planning, David M. EOP/WHO (b)(6) Hodgson, Christopher M. EOP/OVP (b)(6) Charrow, Robert (HHS/OGC) <Robert.Charrow@hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>
Subject: Re: PREP Act - N95 Masks

Hi All,

Per my boss (Dr. Kadlec-HHS/ASPR), my understanding was this was decided at the TF meeting that HHS would issue a Prep Act declaration for the N95 respirators. Therefore no additional action is necessary in the Supplemental. Hopefully this helps to answer these questions.

Best,
Bryan

Sent from my iPhone

On Feb 29, 2020, at 3:05 PM, Moughalian, Jen (HHS/ASFR) <Jen.Moughalian@hhs.gov> wrote:

Adding Bob Charrow, HHS GC, who will advise on what can be done under current authority.

From: McMillin, Virginia D. EOP/WHO [(b)(6)]
Sent: Saturday, February 29, 2020 2:50 PM
To: Moughalian, Jen (HHS/ASFR) <Jen.Moughalian@hhs.gov>; Arbes, Sarah (HHS/ASL) <Sarah.Arbes@hhs.gov>
Cc: Pence, Laura (HHS/ASL) <Laura.Pence@hhs.gov>; Steele, Danielle (HHS/IOS) <Danielle.Steele@hhs.gov>; Shuy, Caitrin (HHS/ASFR) <Caitrin.Shuy@hhs.gov>; Yaworske, Jason A. EOP/OMB [(b)(6)]
D'Angelo, Gregory B. EOP/OMB [(b)(6)] Planning, David M. EOP/WHO
[(b)(6)]; Hodgson, Christopher M. EOP/OVP [(b)(6)]
Subject: RE: PREP Act - N95 Masks

Thank you!

In addition to the concerns, Burr and Alexander staff have also asked me why we don't just issue a PREP Act declaration using our current authorities. I assume that would be market moving information that I couldn't share with them, but do think [(b)(5)]

From: Moughalian, Jen (HHS/ASFR) <Jen.Moughalian@hhs.gov>
Sent: Saturday, February 29, 2020 2:31 PM
To: Arbes Sarah (HHS/ASL) <Sarah.Arbes@hhs.gov>; McMillin, Virginia D. EOP/WHO
[(b)(6)]
Cc: Pence, Laura (HHS/ASL) <Laura.Pence@hhs.gov>; Steele, Danielle (HHS/IOS) <Danielle.Steele@hhs.gov>; Shuy, Caitrin (HHS/ASFR) <Caitrin.Shuy@hhs.gov>; Yaworske, Jason A. EOP/OMB [(b)(6)]
D'Angelo, Gregory B. EOP/OMB [(b)(6)]
Subject: RE: PREP Act - N95 Masks

Premature send! I am chasing this down now.

From: Moughalian, Jen (HHS/ASFR)
Sent: Saturday, February 29, 2020 2:30 PM
To: Arbes, Sarah (HHS/ASL) <Sarah.Arbes@hhs.gov>; McMillin, Virginia D. EOP/WHO
[(b)(6)]
Cc: Pence, Laura (HHS/ASL) <Laura.Pence@hhs.gov>; Steele, Danielle (HHS/IOS) <Danielle.Steele@hhs.gov>; Shuy, Caitrin (HHS/ASFR) <Caitrin.Shuy@hhs.gov>
Subject: RE: PREP Act - N95 Masks

From: Arbes, Sarah (HHS/ASL) <Sarah.Arbes@hhs.gov>
Sent: Saturday, February 29, 2020 2:19 PM
To: McMillin, Virginia D. EOP/WHO <(b)(6)
Cc: Pence, Laura (HHS/ASL) <Laura.Pence@hhs.gov>; Steele, Danielle (HHS/IOS) <Danielle.Steele@hhs.gov>; Moughalian, Jen (HHS/ASFR) <Jen.Moughalian@hhs.gov>
Subject: Re: PREP Act - N95 Masks

+ Jen who is the HHS lead on supp negotiations

On Feb 29, 2020, at 2:05 PM, McMillin, Virginia D. EOP/WHO (b)(6) wrote:

+Arbes — need to sort this out in the next couple of hours as the supplemental is actively being negotiated. It sounds like ASPR is advocating for something that is FDA/NIOSH jurisdiction and that I understand both FDA and the hill to have concerns with.

On Feb 29, 2020, at 1:53 PM, McMillin, Virginia D. EOP/WHO (b)(6) wrote:

Hey, just us. Apparently Kadlec brought this up at the Task Force and said we need it in the supplemental and Hahn didn't speak up. Can you all flag up and elevate your concerns with this ASAP? I'm going to forward the concerns that Angela flagged for me in case it is helpful

Virginia Heppner McMillin
Special Assistant to the President
Office of Legislative Affairs
(202) 881-6454

From: Stannard, Paula (HHS/IOS) <Paula.Stannard@hhs.gov>
Sent: Friday, February 28, 2020 8:32 AM
To: Baehr, James S. EOP/WHO (b)(6)
Cc: Pence, Laura (HHS/ASL) <Laura.Pence@hhs.gov>; McMillin, Virginia D. EOP/WHO (b)(6); Bonner, Maria K. EOP/WHO <Maria.K.Bonner@who.eop.gov>; Heilig, Rebecca B. EOP/WHO (b)(6); Daravi, Kamran S. EOP/WHO (b)(6); Steele, Danielle (HHS/IOS) <Danielle.Steele@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>
Subject: Re: PREP Act - N95 Masks

+ Danielle Steele, Brian Shuy

Sent from my iPhone

On Feb 28, 2020, at 3:53 AM, Baehr, James S. EOP/WHO (b)(6) wrote:

Paula, Laura,

Do you have a few minutes to walk me through HHS' vision on this N95 PREP Act issue (inclusion in items protected from punitive trial lawyer litigation) today (Friday)?

We spoke with industry reps on this issue and, on first blush, I found their points compelling, but I understand there may be different views out there.

Best,

James S. C. Baehr
Special Assistant to the President
Domestic Policy Council
C
C (b)(6)

From: Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]
Sent: 3/2/2020 10:50:49 AM
To: Flowers, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9418b62ec07642d7bc53c564e008f5ce-Susan.Flowe]
Subject: Fwd: opening remarks, TPs
Attachments: CDC telebriefing Hahn remarks_3.2.20.docx; ATT00001.htm

Pls print this for me.

Sent from my iPhone

Begin forwarded message:

From: "Caccomo, Stephanie" <Stephanie.Caccomo@fda.hhs.gov>
Date: March 2, 2020 at 10:48:35 AM EST
To: "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>, "Caliguiri, Laura" <Laura.Caliguiri@fda.hhs.gov>
Subject: opening remarks, TPs

Opener, plus responsive content

From: Robinson, Michael J (HHS/ASPA) [michael.robinson@hhs.gov]
Sent: 3/2/2020 10:56:14 AM
To: Hall, Bill (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e56218361cd4ffbacdd06ac2d7b809d-HHS-bill.ha]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Stecker, Judy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e205440400ab4f629be1faccfe0846fc-HHS-Judy.St]; OS HHSPress (HHS/ASPA) [HHSPress@hhs.gov]; Brennan, Patrick (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e87181146141b1ba0978553d9ff156-HHS-Patrick]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]
Subject: RE: CLEARANCE_0210: FDA "FDA and CDC increase the availability of respirators for health care personnel"
Attachments: FW: CLEARANCE_0210: FDA "FDA and CDC increase the availability of respirators for health care personnel"

Per attached, GC has noted they will need more time with the update

---

From: Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>
Sent: Monday, March 2, 2020 10:55 AM
To: Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; Caccomo, Stephanie (FDA/OC) <Stephanie.Caccomo@fda.hhs.gov>; Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov>; OS HHSPress (HHS/ASPA) <HHSPress@hhs.gov>; Brennan, Patrick (OS/ASPA) <Patrick.Brennan@hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Caliguiri, Laura (FDA/OC) <Laura.Caliguiri@fda.hhs.gov>
Subject: RE: CLEARANCE_0210: FDA "FDA and CDC increase the availability of respirators for health care personnel"

Would Hahn be able to announce this on the noon telebriefing? Or will it not be ready yet?

From: Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>
Sent: Monday, March 2, 2020 8:16 AM
To: Caccomo, Stephanie (FDA/OC) <Stephanie.Caccomo@fda.hhs.gov>; Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov>; OS HHSPress (HHS/ASPA) <HHSPress@hhs.gov>; Brennan, Patrick (OS/ASPA) <Patrick.Brennan@hhs.gov>
Cc: Palczewski, Andrew (HHS/ASPA) <Andrew.Palczewski@hhs.gov>; Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>; OS OGC-IO ControlDesk (HHS/OS/OGC) <ControlDesk.OGCIO@hhs.gov>; Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>; Muhammad, Janell (HHS/ASPA) <Janell.Muhammad@hhs.gov>; Steele, Danielle (HHS/IOS) <Danielle.Steele@hhs.gov>; White, Caroline (HHS/OGC) <Caroline.White@hhs.gov>; Stimson, Brian (HHS/OGC) <Brian.Stimson@hhs.gov>; Charrow, Robert (HHS/OGC) <Robert.Charrow@hhs.gov>; Keveney, Sean (HHS/OGC) <Sean.Keveney@hhs.gov>; Chang, William (HHS/OGC) <William.Chang@hhs.gov>; Barry, Daniel J (HHS/OGC) <daniel.barry@hhs.gov>; CDC OADC ASPA Clearance <OADCASPAClearance@cdc.gov>; Bonds, Michelle E. (CDC/OD/OADC) <meb0@cdc.gov>; Burden, Bernadette (CDC/OD/OADC) <btb8@cdc.gov>; Galatas, Kate (CDC/OD/OADC) <kkg2@cdc.gov>; Haynes, Benjamin (CDC/OD/OADC) <fxq2@cdc.gov>; Heldman, Amy B. (CDC/OD/OADC) <evd4@cdc.gov>; Hoskins, Sharon (K.D.) (CDC/OD/OADC) <sdh4@cdc.gov>; Reed, Jasmine (CDC/OD/OADC) <pvz1@cdc.gov>; Toro, Ana (CDC/OD/OADC) <pvq1@cdc.gov>; Caliguiri, Laura (FDA/OC) <Laura.Caliguiri@fda.hhs.gov>
Subject: RE: CLEARANCE_0210: FDA "FDA and CDC increase the availability of respirators for health care personnel"

+ Patrick for Secretary's quote

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Monday, March 2, 2020 8:03 AM
To: Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov>; OS HHSPress (HHS/ASPA) <HHSPress@hhs.gov>
Cc: Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; Palczewski, Andrew (HHS/ASPA) <Andrew.Palczewski@hhs.gov>; Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>; OS OGC-IO ControlDesk (HHS/OS/OGC) <ControlDesk.OGCIO@hhs.gov>; Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>; Muhammad, Janell (HHS/ASPA) <Janell.Muhammad@hhs.gov>; Steele, Danielle (HHS/IOS) <Danielle.Steele@hhs.gov>; White, Caroline (HHS/OGC) <Caroline.White@hhs.gov>; Stimson, Brian (HHS/OGC) <Brian.Stimson@hhs.gov>; Charrow, Robert (HHS/OGC) <Robert.Charrow@hhs.gov>; Keveney, Sean (HHS/OGC) <Sean.Keveney@hhs.gov>; Chang, William (HHS/OGC) <William.Chang@hhs.gov>; Barry, Daniel J (HHS/OGC) <daniel.barry@hhs.gov>; CDC OADC ASPA Clearance <OADCASPAClearance@cdc.gov>; Bonds, Michelle E. (CDC/OD/OADC) <meb0@cdc.gov>; Burden, Bernadette (CDC/OD/OADC) <btb8@cdc.gov>; Galatas, Kate (CDC/OD/OADC) <kkg2@cdc.gov>; Haynes, Benjamin (CDC/OD/OADC) <fxq2@cdc.gov>; Heldman, Amy B. (CDC/OD/OADC) <evd4@cdc.gov>; Hoskins, Sharon (K.D.) (CDC/OD/OADC) <sdh4@cdc.gov>; Reed, Jasmine (CDC/OD/OADC) <pvz1@cdc.gov>; Toro, Ana (CDC/OD/OADC) <pvq1@cdc.gov>; Caliguiri, Laura (FDA/OC) <Laura.Caliguiri@fda.hhs.gov>
Subject: Re: CLEARANCE_0210: FDA "FDA and CDC increase the availability of respirators for health care personnel"

Hi Jusy-
We can update/address those Qs and resend. Should FDA craft Secretary quote?

Stephanie Caccomo
Press Officer

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

From: Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov>
Date: March 2, 2020 at 7:41:11 AM EST
To: OS HHSPress (HHS/ASPA) <HHSPress@hhs.gov>
Cc: Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>, Palczewski, Andrew (OS) <Andrew.Palczewski@hhs.gov>, Hall, Bill (OS) <bill.hall@hhs.gov>, OS OGC-IO ControlDesk (HHS/OS/OGC) <ControlDesk.OGCIO@hhs.gov>, Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>, Muhammad, Janell M (OS) <Janell.Muhammad@hhs.gov>, Steele, Danielle (OS) <Danielle.Steele@hhs.gov>, White, Caroline (OS) <Caroline.White@hhs.gov>, Stimson, Brian (OS) <Brian.Stimson@hhs.gov>, Charrow, Robert (OS) <Robert.Charrow@hhs.gov>, Keveney, Sean (OS) <Sean.Keveney@hhs.gov>, Chang, William (OS) <William.Chang@hhs.gov>, Barry, Daniel J (OS) <daniel.barry@hhs.gov>, CDC OADC ASPA Clearance <OADCASPAClearance@cdc.gov>, Bonds, Michelle E (CDC) <meb0@cdc.gov>, Burden, Bernadette (CDC) <btb8@cdc.gov>, Galatas, Kate (CDC) <kkg2@cdc.gov>, Haynes, Benjamin (CDC) <fxq2@cdc.gov>, Heldman, Amy B (CDC) <evd4@cdc.gov>, Hoskins, Sharon D (CDC) <sdh4@cdc.gov>, Reed, Jasmine M (CDC) <pvz1@cdc.gov>, Toro, Ana M (CDC) <pvq1@cdc.gov>, Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>,

Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Subject: Re: CLEARANCE_0210: FDA "FDA and CDC increase the availability of respirators for health care personnel"

Pre decisional/deliberative

(b)(5)

Sent from my iPhone

On Mar 2, 2020, at 7:02 AM, OS HHSPress (HHS/ASPA) <HHSPress@hhs.gov> wrote:

Please reply with comments / clearance before 12 (noon), today, Monday, March 2

From: OS HHSPress (HHS/ASPA)
Sent: Monday, March 2, 2020 6:59 AM
Subject: CLEARANCE_0210: FDA "FDA and CDC increase the availability of respirators for health care personnel"

CLOSE-HOLD / URGENT

Agency/Office: FDA

Subject: *FDA and CDC increase the availability of respirators for health care personnel*

Materials: Draft news release (cleared by FDD's Claire Dennis)

Deadline for comments: ~~Before 1 p.m. today, Monday, March 2~~

Planned release date: Monday, March 2

Driving event: Global Coronavirus Outbreak

V/r,

Mike Robinson
Strategic Planning, ASPA

202-690-6885 –desk

(b)(6) mobile

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

<draft_PR_N95s_3.1.20_1025pm.docx>

From: Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]
Sent: 3/2/2020 11:36:17 AM
To: Flowers, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9418b62ec07642d7bc53c564e008f5ce-Susan.Flowe]
Subject: Fwd: CLEARANCE_0210: FDA "FDA and CDC increase the availability of respirators for health care personnel"
Attachments: CDC telebriefing Hahn remarks_3.2.20.docx; ATT00001.htm

Pls print out 2 copies of this attachment.

Sent from my iPhone

Begin forwarded message:

From: "Caccomo, Stephanie" <Stephanie.Caccomo@fda.hhs.gov>
Date: March 2, 2020 at 11:34:21 AM EST
To: "Stecker, Judy (OS)" <Judy.Stecker@hhs.gov>, "Robinson, Michael J (OS)" <michael.robinson@hhs.gov>, "Stimson, Brian (OS)" <Brian.Stimson@hhs.gov>, "Brennan, Patrick (OS)" <Patrick.Brennan@hhs.gov>, "Murphy, Ryan (OS)" <Ryan.Murphy1@hhs.gov>, "OS HHSPress (HHS/ASPA)" <HHSPress@hhs.gov>, "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>
Cc: "Palczewski, Andrew (OS)" <Andrew.Palczewski@hhs.gov>, "Hall, Bill (OS)" <bill.hall@hhs.gov>, "OS OGC-lO ControlDesk (HHS/OS/OGC)" <ControlDesk.OGClO@hhs.gov>, "Oakley, Caitlin B (OS)" <Caitlin.Oakley@HHS.GOV>, "Muhammad, Janell M (OS)" <Janell.Muhammad@hhs.gov>, "Steele, Danielle (OS)" <Danielle.Steele@hhs.gov>, "White, Caroline (OS)" <Caroline.White@hhs.gov>, "Charrow, Robert (OS)" <Robert.Charrow@hhs.gov>, "Keveney, Sean (OS)" <Sean.Keveney@hhs.gov>, "Chang, William (OS)" <William.Chang@hhs.gov>, "Barry, Daniel J (OS)" <daniel.barry@hhs.gov>, CDC OADC ASPA Clearance <OADCASPAClearance@cdc.gov>, "Bonds, Michelle E (CDC)" <meb0@cdc.gov>, "Burden, Bernadette (CDC)" <btb8@cdc.gov>, "Galatas, Kate (CDC)" <kkg2@cdc.gov>, "Haynes, Benjamin (CDC)" <fxq2@cdc.gov>, "Heldman, Amy B (CDC)" <evd4@cdc.gov>, "Hoskins, Sharon D (CDC)" <sdh4@cdc.gov>, "Reed, Jasmine M (CDC)" <pvz1@cdc.gov>, "Toro, Ana M (CDC)" <pvq1@cdc.gov>, "Caliguiri, Laura" <Laura.Caliguiri@fda.hhs.gov>
Subject: RE: CLEARANCE_0210: FDA "FDA and CDC increase the availability of respirators for health care personnel"

Latest draft

From: Stecker, Judy (OS/lOS) <Judy.Stecker@hhs.gov>
Sent: Monday, March 02, 2020 11:33 AM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Robinson, Michael J (OS) <michael.robinson@hhs.gov>; Stimson, Brian (OS) <Brian.Stimson@hhs.gov>; Brennan, Patrick (OS) <Patrick.Brennan@hhs.gov>; Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>; OS HHSPress (HHS/ASPA) <HHSPress@hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Palczewski, Andrew (OS) <Andrew.Palczewski@hhs.gov>; Hall, Bill (OS) <bill.hall@hhs.gov>; OS OGC-lO ControlDesk (HHS/OS/OGC) <ControlDesk.OGClO@hhs.gov>; Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>; Muhammad, Janell M (OS) <Janell.Muhammad@hhs.gov>; Steele, Danielle (OS) <Danielle.Steele@hhs.gov>; White, Caroline (OS) <Caroline.White@hhs.gov>; Charrow, Robert (OS) <Robert.Charrow@hhs.gov>; Keveney, Sean (OS) <Sean.Keveney@hhs.gov>; Chang, William (OS) <William.Chang@hhs.gov>; Barry, Daniel J (OS) <daniel.barry@hhs.gov>; CDC OADC ASPA Clearance <OADCASPAClearance@cdc.gov>; Bonds, Michelle E (CDC) <meb0@cdc.gov>; Burden, Bernadette (CDC) <btb8@cdc.gov>; Galatas, Kate (CDC) <kkg2@cdc.gov>; Haynes, Benjamin (CDC) <fxq2@cdc.gov>; Heldman, Amy B (CDC) <evd4@cdc.gov>; Hoskins, Sharon D (CDC) <sdh4@cdc.gov>; Reed, Jasmine M (CDC)

<pvz1@cdc.gov>; Toro, Ana M (CDC) <pvq1@cdc.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Subject: RE: CLEARANCE_0210: FDA "FDA and CDC increase the availability of respirators for health care personnel"

Were the preview points in what was sent over to OVP for clearance? Want to make sure OVP knows we might preview. Thx

---

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Monday, March 2, 2020 11:31 AM
To: Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov>; Robinson, Michael J (HHS/ASPA) <michael.robinson@hhs.gov>; Stimson, Brian (HHS/OGC) <Brian.Stimson@hhs.gov>; Brennan, Patrick (OS/ASPA) <Patrick.Brennan@hhs.gov>; Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; OS HHSPress (HHS/ASPA) <HHSPress@hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>
Cc: Palczewski, Andrew (HHS/ASPA) <Andrew.Palczewski@hhs.gov>; Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>; OS OGC-IO ControlDesk (HHS/OS/OGC) <ControlDesk.OGCIO@hhs.gov>; Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>; Muhammad, Janell (HHS/ASPA) <Janell.Muhammad@hhs.gov>; Steele, Danielle (HHS/IOS) <Danielle.Steele@hhs.gov>; White, Caroline (HHS/OGC) <Caroline.White@hhs.gov>; Charrow, Robert (HHS/OGC) <Robert.Charrow@hhs.gov>; Keveney, Sean (HHS/OGC) <Sean.Keveney@hhs.gov>; Chang, William (HHS/OGC) <William.Chang@hhs.gov>; Barry, Daniel J (HHS/OGC) <daniel.barry@hhs.gov>; CDC OADC ASPA Clearance <OADCASPAClearance@cdc.gov>; Bonds, Michelle E. (CDC/OD/OADC) <meb0@cdc.gov>; Burden, Bernadette (CDC/OD/OADC) <btb8@cdc.gov>; Galatas, Kate (CDC/OD/OADC) <kkg2@cdc.gov>; Haynes, Benjamin (CDC/OD/OADC) <fxq2@cdc.gov>; Heldman, Amy B. (CDC/OD/OADC) <evd4@cdc.gov>; Hoskins, Sharon (K.D.) (CDC/OD/OADC) <sdh4@cdc.gov>; Reed, Jasmine (CDC/OD/OADC) <pvz1@cdc.gov>; Toro, Ana (CDC/OD/OADC) <pvq1@cdc.gov>; Caliguiri, Laura (FDA/OC) <Laura.Caliguiri@fda.hhs.gov>
Subject: RE: CLEARANCE_0210: FDA "FDA and CDC increase the availability of respirators for health care personnel"

Just heard from our team that rollout might be a bit delayed, for an hour or so. We are still planning to preview on telebriefing

---

From: Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov>
Sent: Monday, March 02, 2020 11:30 AM
To: Robinson, Michael J (OS) <michael.robinson@hhs.gov>; Stimson, Brian (OS) <Brian.Stimson@hhs.gov>; Brennan, Patrick (OS) <Patrick.Brennan@hhs.gov>; Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; OS HHSPress (HHS/ASPA) <HHSPress@hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Palczewski, Andrew (OS) <Andrew.Palczewski@hhs.gov>; Hall, Bill (OS) <bill.hall@hhs.gov>; OS OGC-IO ControlDesk (HHS/OS/OGC) <ControlDesk.OGCIO@hhs.gov>; Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>; Muhammad, Janell M (OS) <Janell.Muhammad@hhs.gov>; Steele, Danielle (OS) <Danielle.Steele@hhs.gov>; White, Caroline (OS) <Caroline.White@hhs.gov>; Charrow, Robert (OS) <Robert.Charrow@hhs.gov>; Keveney, Sean (OS) <Sean.Keveney@hhs.gov>; Chang, William (OS) <William.Chang@hhs.gov>; Barry, Daniel J (OS) <daniel.barry@hhs.gov>; CDC OADC ASPA Clearance <OADCASPAClearance@cdc.gov>; Bonds, Michelle E (CDC) <meb0@cdc.gov>; Burden, Bernadette (CDC) <btb8@cdc.gov>; Galatas, Kate (CDC) <kkg2@cdc.gov>; Haynes, Benjamin (CDC) <fxq2@cdc.gov>; Heldman, Amy B (CDC) <evd4@cdc.gov>; Hoskins, Sharon D (CDC) <sdh4@cdc.gov>; Reed, Jasmine M (CDC) <pvz1@cdc.gov>; Toro, Ana M (CDC) <pvq1@cdc.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Subject: RE: CLEARANCE_0210: FDA "FDA and CDC increase the availability of respirators for health care personnel"

One nit b/c it's kind of a run on. Can we get this ready by noon call?

(b)(5)

From: Robinson, Michael J (HHS/ASPA) <michael.robinson@hhs.gov>
Sent: Monday, March 2, 2020 11:25 AM
To: Stimson, Brian (HHS/OGC) <Brian.Stimson@hhs.gov>; Brennan, Patrick (OS/ASPA) <Patrick.Brennan@hhs.gov>; Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; Caccomo, Stephanie (FDA/OC) <Stephanie.Caccomo@fda.hhs.gov>; Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov>; OS HHSPress (HHS/ASPA) <HHSPress@hhs.gov>
Cc: Palczewski, Andrew (HHS/ASPA) <Andrew.Palczewski@hhs.gov>; Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>; OS OGC-IO ControlDesk (HHS/OS/OGC) <ControlDesk.OGCIO@hhs.gov>; Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>; Muhammad, Janell (HHS/ASPA) <Janell.Muhammad@hhs.gov>; Steele, Danielle (HHS/IOS) <Danielle.Steele@hhs.gov>; White, Caroline (HHS/OGC) <Caroline.White@hhs.gov>; Charrow, Robert (HHS/OGC) <Robert.Charrow@hhs.gov>; Keveney, Sean (HHS/OGC) <Sean.Keveney@hhs.gov>; Chang, William (HHS/OGC) <William.Chang@hhs.gov>; Barry, Daniel J (HHS/OGC) <daniel.barry@hhs.gov>; CDC OADC ASPA Clearance <OADCASPAClearance@cdc.gov>; Bonds, Michelle E. (CDC/OD/OADC) <meb0@cdc.gov>; Burden, Bernadette (CDC/OD/OADC) <btb8@cdc.gov>; Galatas, Kate (CDC/OD/OADC) <kkg2@cdc.gov>; Haynes, Benjamin (CDC/OD/OADC) <fxq2@cdc.gov>; Heldman, Amy B. (CDC/OD/OADC) <evd4@cdc.gov>; Hoskins, Sharon (K.D.) (CDC/OD/OADC) <sdh4@cdc.gov>; Reed, Jasmine (CDC/OD/OADC) <pvz1@cdc.gov>; Toro, Ana (CDC/OD/OADC) <pvq1@cdc.gov>; Caliguiri, Laura (FDA/OC) <Laura.Caliguiri@fda.hhs.gov>
Subject: RE: CLEARANCE_0210: FDA "FDA and CDC increase the availability of respirators for health care personnel"

And the most current Secretary quote is:

(b)(5)

I've updated it in attached

From: Stimson, Brian (HHS/OGC) <Brian.Stimson@hhs.gov>
Sent: Monday, March 2, 2020 11:23 AM
To: Brennan, Patrick (OS/ASPA) <Patrick.Brennan@hhs.gov>; Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; Caccomo, Stephanie (FDA/OC) <Stephanie.Caccomo@fda.hhs.gov>; Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov>; OS HHSPress (HHS/ASPA) <HHSPress@hhs.gov>
Cc: Palczewski, Andrew (HHS/ASPA) <Andrew.Palczewski@hhs.gov>; Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>; OS OGC-

IO ControlDesk (HHS/OS/OGC) <ControlDesk.OGCIO@hhs.gov>; Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>; Muhammad, Janell (HHS/ASPA) <Janell.Muhammad@hhs.gov>; Steele, Danielle (HHS/IOS) <Danielle.Steele@hhs.gov>; White, Caroline (HHS/OGC) <Caroline.White@hhs.gov>; Charrow, Robert (HHS/OGC) <Robert.Charrow@hhs.gov>; Keveney, Sean (HHS/OGC) <Sean.Keveney@hhs.gov>; Chang, William (HHS/OGC) <William.Chang@hhs.gov>; Barry, Daniel J (HHS/OGC) <daniel.barry@hhs.gov>; CDC OADC ASPA Clearance <OADCASPAClearance@cdc.gov>; Bonds, Michelle E. (CDC/OD/OADC) <meb0@cdc.gov>; Burden, Bernadette (CDC/OD/OADC) <btb8@cdc.gov>; Galatas, Kate (CDC/OD/OADC) <kkg2@cdc.gov>; Haynes, Benjamin (CDC/OD/OADC) <fxq2@cdc.gov>; Heldman, Amy B. (CDC/OD/OADC) <evd4@cdc.gov>; Hoskins, Sharon (K.D.) (CDC/OD/OADC) <sdh4@cdc.gov>; Reed, Jasmine (CDC/OD/OADC) <pvz1@cdc.gov>; Toro, Ana (CDC/OD/OADC) <pvq1@cdc.gov>; Caliguiri, Laura (FDA/OC) <Laura.Caliguiri@fda.hhs.gov>
Subject: RE: CLEARANCE_0210: FDA "FDA and CDC increase the availability of respirators for health care personnel"

Reviewing

From: Brennan, Patrick (OS/ASPA) <Patrick.Brennan@hhs.gov>
Sent: Monday, March 2, 2020 10:58 AM
To: Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; Caccomo, Stephanie (FDA/OC) <Stephanie.Caccomo@fda.hhs.gov>; Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov>; OS HHSPress (HHS/ASPA) <HHSPress@hhs.gov>
Cc: Palczewski, Andrew (HHS/ASPA) <Andrew.Palczewski@hhs.gov>; Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>; OS OGC-IO ControlDesk (HHS/OS/OGC) <ControlDesk.OGCIO@hhs.gov>; Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>; Muhammad, Janell (HHS/ASPA) <Janell.Muhammad@hhs.gov>; Steele, Danielle (HHS/IOS) <Danielle.Steele@hhs.gov>; White, Caroline (HHS/OGC) <Caroline.White@hhs.gov>; Stimson, Brian (HHS/OGC) <Brian.Stimson@hhs.gov>; Charrow, Robert (HHS/OGC) <Robert.Charrow@hhs.gov>; Keveney, Sean (HHS/OGC) <Sean.Keveney@hhs.gov>; Chang, William (HHS/OGC) <William.Chang@hhs.gov>; Barry, Daniel J (HHS/OGC) <daniel.barry@hhs.gov>; CDC OADC ASPA Clearance <OADCASPAClearance@cdc.gov>; Bonds, Michelle E. (CDC/OD/OADC) <meb0@cdc.gov>; Burden, Bernadette (CDC/OD/OADC) <btb8@cdc.gov>; Galatas, Kate (CDC/OD/OADC) <kkg2@cdc.gov>; Haynes, Benjamin (CDC/OD/OADC) <fxq2@cdc.gov>; Heldman, Amy B. (CDC/OD/OADC) <evd4@cdc.gov>; Hoskins, Sharon (K.D.) (CDC/OD/OADC) <sdh4@cdc.gov>; Reed, Jasmine (CDC/OD/OADC) <pvz1@cdc.gov>; Toro, Ana (CDC/OD/OADC) <pvq1@cdc.gov>; Caliguiri, Laura (FDA/OC) <Laura.Caliguiri@fda.hhs.gov>
Subject: RE: CLEARANCE_0210: FDA "FDA and CDC increase the availability of respirators for health care personnel"

Please see attached and below for draft AMA quote – can FDA, CDC, and OGC let me know if this is OK? Thank you!

(b)(5)

From: Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>
Sent: Monday, March 2, 2020 8:16 AM
To: Caccomo, Stephanie (FDA/OC) <Stephanie.Caccomo@fda.hhs.gov>; Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov>; OS HHSPress (HHS/ASPA) <HHSPress@hhs.gov>; Brennan, Patrick (OS/ASPA) <Patrick.Brennan@hhs.gov>

Cc: Palczewski, Andrew (HHS/ASPA) <Andrew.Palczewski@hhs.gov>; Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>; OS OGC-IO ControlDesk (HHS/OS/OGC) <ControlDesk.OGCIO@hhs.gov>; Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>; Muhammad, Janell (HHS/ASPA) <Janell.Muhammad@hhs.gov>; Steele, Danielle (HHS/IOS) <Danielle.Steele@hhs.gov>; White, Caroline (HHS/OGC) <Caroline.White@hhs.gov>; Stimson, Brian (HHS/OGC) <Brian.Stimson@hhs.gov>; Charrow, Robert (HHS/OGC) <Robert.Charrow@hhs.gov>; Keveney, Sean (HHS/OGC) <Sean.Keveney@hhs.gov>; Chang, William (HHS/OGC) <William.Chang@hhs.gov>; Barry, Daniel J (HHS/OGC) <daniel.barry@hhs.gov>; CDC OADC ASPA Clearance <OADCASPAClearance@cdc.gov>; Bonds, Michelle E. (CDC/OD/OADC) <meb0@cdc.gov>; Burden, Bernadette (CDC/OD/OADC) <btb8@cdc.gov>; Galatas, Kate (CDC/OD/OADC) <kkg2@cdc.gov>; Haynes, Benjamin (CDC/OD/OADC) <fxg2@cdc.gov>; Heldman, Amy B. (CDC/OD/OADC) <evd4@cdc.gov>; Hoskins, Sharon (K.D.) (CDC/OD/OADC) <sdh4@cdc.gov>; Reed, Jasmine (CDC/OD/OADC) <pvz1@cdc.gov>; Toro, Ana (CDC/OD/OADC) <pvq1@cdc.gov>; Caliguiri, Laura (FDA/OC) <Laura.Caliguiri@fda.hhs.gov>
Subject: RE: CLEARANCE_0210: FDA "FDA and CDC increase the availability of respirators for health care personnel"

+ Patrick for Secretary's quote

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Monday, March 2, 2020 8:03 AM
To: Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov>; OS HHSPress (HHS/ASPA) <HHSPress@hhs.gov>
Cc: Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; Palczewski, Andrew (HHS/ASPA) <Andrew.Palczewski@hhs.gov>; Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>; OS OGC-IO ControlDesk (HHS/OS/OGC) <ControlDesk.OGCIO@hhs.gov>; Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>; Muhammad, Janell (HHS/ASPA) <Janell.Muhammad@hhs.gov>; Steele, Danielle (HHS/IOS) <Danielle.Steele@hhs.gov>; White, Caroline (HHS/OGC) <Caroline.White@hhs.gov>; Stimson, Brian (HHS/OGC) <Brian.Stimson@hhs.gov>; Charrow, Robert (HHS/OGC) <Robert.Charrow@hhs.gov>; Keveney, Sean (HHS/OGC) <Sean.Keveney@hhs.gov>; Chang, William (HHS/OGC) <William.Chang@hhs.gov>; Barry, Daniel J (HHS/OGC) <daniel.barry@hhs.gov>; CDC OADC ASPA Clearance <OADCASPAClearance@cdc.gov>; Bonds, Michelle E. (CDC/OD/OADC) <meb0@cdc.gov>; Burden, Bernadette (CDC/OD/OADC) <btb8@cdc.gov>; Galatas, Kate (CDC/OD/OADC) <kkg2@cdc.gov>; Haynes, Benjamin (CDC/OD/OADC) <fxg2@cdc.gov>; Heldman, Amy B. (CDC/OD/OADC) <evd4@cdc.gov>; Hoskins, Sharon (K.D.) (CDC/OD/OADC) <sdh4@cdc.gov>; Reed, Jasmine (CDC/OD/OADC) <pvz1@cdc.gov>; Toro, Ana (CDC/OD/OADC) <pvq1@cdc.gov>; Caliguiri, Laura (FDA/OC) <Laura.Caliguiri@fda.hhs.gov>
Subject: Re: CLEARANCE_0210: FDA "FDA and CDC increase the availability of respirators for health care personnel"

Hi Jusy-
We can update/address those Qs and resend. Should FDA craft Secretary quote?

Stephanie Caccomo
Press Officer

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

From: Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov>
Date: March 2, 2020 at 7:41:11 AM EST
To: OS HHSPress (HHS/ASPA) <HHSPress@hhs.gov>
Cc: Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>, Palczewski, Andrew (OS) <Andrew.Palczewski@hhs.gov>, Hall, Bill (OS) <bill.hall@hhs.gov>, OS OGC-IO ControlDesk (HHS/OS/OGC) <ControlDesk.OGCIO@hhs.gov>, Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>, Muhammad, Janell M (OS) <Janell.Muhammad@hhs.gov>, Steele, Danielle (OS) <Danielle.Steele@hhs.gov>, White, Caroline (OS) <Caroline.White@hhs.gov>, Stimson, Brian (OS) <Brian.Stimson@hhs.gov>, Charrow, Robert (OS) <Robert.Charrow@hhs.gov>, Keveney, Sean (OS) <Sean.Keveney@hhs.gov>, Chang, William (OS) <William.Chang@hhs.gov>, Barry, Daniel J (OS) <daniel.barry@hhs.gov>, CDC OADC ASPA Clearance <OADCASPAClearance@cdc.gov>, Bonds, Michelle E (CDC) <meb0@cdc.gov>, Burden, Bernadette (CDC) <btb8@cdc.gov>, Galatas, Kate (CDC) <kkg2@cdc.gov>, Haynes, Benjamin (CDC) <fxq2@cdc.gov>, Heldman, Amy B (CDC) <evd4@cdc.gov>, Hoskins, Sharon D (CDC) <sdh4@cdc.gov>, Reed, Jasmine M (CDC) <pvz1@cdc.gov>, Toro, Ana M (CDC) <pvq1@cdc.gov>, Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Subject: Re: CLEARANCE_0210: FDA "FDA and CDC increase the availability of respirators for health care personnel"

Pre decisional/deliberative

(b)(5)

Sent from my iPhone

On Mar 2, 2020, at 7:02 AM, OS HHSPress (HHS/ASPA) <HHSPress@hhs.gov> wrote:

Please reply with comments / clearance before 12 (noon), today, Monday, March 2

From: OS HHSPress (HHS/ASPA)
Sent: Monday, March 2, 2020 6:59 AM
Subject: CLEARANCE_0210: FDA "FDA and CDC increase the availability of respirators for health care personnel"

CLOSE-HOLD / URGENT

Agency/Office: FDA

Subject: *FDA and CDC increase the availability of respirators for health care personnel*

Materials: Draft news release (cleared by FDD's Claire Dennis)

Deadline for comments: ~~Before 1 p.m. today, Monday, March 2~~

Planned release date: Monday, March 2

Driving event: Global Coronavirus Outbreak

V/r,

Mike Robinson
Strategic Planning, ASPA

(b)(6) desk
mobile

<draft_PR_N95s_3.1.20_1025pm.docx>

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 3/2/2020 12:30:30 PM
To: 'Hahn, Stephen' [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
Subject: RE: CDC lab standards

Will ask Heidi to chase down.

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Monday, March 2, 2020 12:24 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: Re: CDC lab standards

Thanks. Can someone provide assistance for my response?
S

Sent from my iPad

On Mar 2, 2020, at 12:16 PM, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov> wrote:

FYI – I will send him your correct email address.

From: Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>
Sent: Monday, March 2, 2020 12:14 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: FW: CDC lab standards

This came to the FDA main box on Friday.

From: Redfield, Robert R (CDC) <olx1@cdc.gov>
Sent: Friday, February 28, 2020 12:47 PM
To: FDA Commissioner <Stephen.Hahn@fda.hhs.gov>
Cc: Berger, Sherri (CDC) <sob8@cdc.gov>; Campbell, Amanda (CDC) <ons3@cdc.gov>; McGowan, Robert K (CDC) <omc2@cdc.gov>
Subject: CDC lab standards

Dear Steve,

Below are CDC standards on laboratory safety.

CDC recommendations and specific guidance for handling clinical and laboratory specimens can be found at: https://www.cdc.gov/coronavirus/2019-nCoV/lab/lab-biosafety-guidelines.html

In summary:

- The routine processing of clinical diagnostic specimens may be performed in BSL-2 facilities using standard BSL-2 work practices (directional airflow in the room is not a requirement for BSL2).
  - This work should be performed in a certified Class II Biological Safety Cabinet (BSC).

- Virus propagation and manipulation of virus cultures requires BSL-3 conditions require a room with directional airflow.
  - Specifically: Virus isolation in cell culture and initial characterization of viral agents recovered in cultures of SARS-CoV-2 specimens are not recommended at this time, except in a BSL3 laboratory using BSL3 work practices.
- Site specific risk assessments may indicate additional precautions be applied.

Peace,

R3

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 3/2/2020 12:39:36 PM
To: Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]
Subject: RE: CDC lab standards

thx

From: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Sent: Monday, March 2, 2020 12:39 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: CDC lab standards

Ah. Will send suggestion to him.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Monday, March 2, 2020 12:36 PM
To: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: RE: CDC lab standards

He wants a response to Redfield, does he need to say anything?

From: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Sent: Monday, March 2, 2020 12:34 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: CDC lab standards

Already spoke to Lindsay about it. We are contacting their EAs to give them updated address and talking with Exec Sec how best to get anything from head of op-div directly to SH.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Monday, March 2, 2020 12:31 PM
To: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: FW: CDC lab standards

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Monday, March 2, 2020 12:24 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: Re: CDC lab standards

Thanks. Can someone provide assistance for my response?
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Sent from my iPad

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Sent: Monday, March 2, 2020 12:14 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
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To: FDA Commissioner <Stephen.Hahn@fda.hhs.gov>
Cc: Berger, Sherri (CDC) <sob8@cdc.gov>; Campbell, Amanda (CDC) <ons3@cdc.gov>; McGowan, Robert K (CDC) <omc2@cdc.gov>
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  - Specifically: Virus isolation in cell culture and initial characterization of viral agents recovered in cultures of SARS-CoV-2 specimens are not recommended at this time, except in a BSL3 laboratory using BSL3 work practices.
- Site specific risk assessments may indicate additional precautions be applied.

Peace,

R3

From: Pence, Laura (OS) [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3F21407A02D44CD4901BCCE26F9B3074-HHS-LAURA.P]
Sent: 3/2/2020 1:22:45 PM
To: Pence, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3f21407a02d44cd4901bcce26f9b3074-HHS-Laura.P]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Oxner, Julie (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08b67fbda196471fa5ab3b113e264438-HHS-Julie.O]; Rybak, Bailey (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43b2c40b61a84ceb8dcda589e07d8cef-HHS-Bailey.]; Bigham, Jane E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58d05801bf1d46d883ff225114683c3a-HHS-vsy0-cd]; Tourk, Nancy R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdb086e24ad14975bcc32097b68271fb-HHS-wxk8-cd]; Greaser, Jennifer L (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6007c3bba4a1420bb704298c5e49f29b-HHS-cbx5-cd]; Brand, Anstice M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4769e64323944161a994c2086b645f4c-HHS-atb6-cd]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Tatem, Anne (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5222c26605ef4894a8d237d82fd1ba6f-HHS-Anne.Ta]; Bradsher, Kris (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=945a2ca6355b43059a6dc1cf522f70e9-HHS-Kris.Br]; Kehoe, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e89758c5888c4d3986fdf1a861aff27b-HHS-Brian.K]; Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; LaMontagne, Karen A (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=556f3d319c9c4a3e8c0cb28ba4529cb0-HHS-karen.l]

Subject: HELP hearing on coronavirus (w/CDC, ASPR, NIAID, FDA)
Location: SD430

Start: 3/3/2020 9:30:00 AM
End: 3/3/2020 12:30:00 PM
Show Time As: Busy

-----Original Appointment-----
From: Pence, Laura (HHS/ASL) <Laura.Pence@hhs.gov>
Sent: Wednesday, February 19, 2020 12:21 PM
To: Pence, Laura (OS); Shuy, Bryan (OS); Oxner, Julie (OS); Rybak, Bailey (OS); Bigham, Jane E (CDC); Tourk, Nancy R (CDC); Greaser, Jennifer L (CDC); Brand, Anstice M (CDC); Gross, Karas; Tatem, Anne (OS); Bradsher, Kris (OS); Kehoe, Brian (OS); Arbes, Sarah C (OS); LaMontagne, Karen A (NIH)
Subject: HELP hearing on coronavirus (w/CDC, ASPR, NIAID, FDA)
When: Tuesday, March 3, 2020 9:30 AM-12:30 PM (UTC-05:00) Eastern Time (US & Canada).
Where: SD430

SENATE COMMITTEE ON
HEALTH, EDUCATION, LABOR AND PENSIONS

Hearing Notice

To: **All Committee Members**

Title: **An Emerging Disease Threat: How the U.S. Is Responding to COVID-19, the Novel Coronavirus**

Date: **Tuesday, March 3, 2020**

Time: **10:00 AM**

Place: **430 Dirksen Senate Office Building**

Chung Shek
Chief Clerk

February 19, 2020

From: Pence, Laura (OS) [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3F21407A02D44CD4901BCCE26F9B3074-HHS-LAURA.P]
Sent: 3/2/2020 1:22:45 PM
To: Pence, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3f21407a02d44cd4901bcce26f9b3074-HHS-Laura.P]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Oxner, Julie (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08b67fbda196471fa5ab3b113e264438-HHS-Julie.O]; Rybak, Bailey (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43b2c40b61a84ceb8dcda589e07d8cef-HHS-Bailey.]; Bigham, Jane E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58d05801bf1d46d883ff225114683c3a-HHS-vsy0-cd]; Tourk, Nancy R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdb086e24ad14975bcc32097b68271fb-HHS-wxk8-cd]; Greaser, Jennifer L (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6007c3bba4a1420bb704298c5e49f29b-HHS-cbx5-cd]; Brand, Anstice M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4769e64323944161a994c2086b645f4c-HHS-atb6-cd]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Tatem, Anne (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5222c26605ef4894a8d237d82fd1ba6f-HHS-Anne.Ta]; Bradsher, Kris (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=945a2ca6355b43059a6dc1cf522f70e9-HHS-Kris.Br]; Kehoe, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e89758c5888c4d3986fdf1a861aff27b-HHS-Brian.K]; Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; LaMontagne, Karen A (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=556f3d319c9c4a3e8c0cb28ba4529cb0-HHS-karen.l]
Subject: HELP hearing on coronavirus (w/CDC, ASPR, NIAID, FDA)
Location: SD430

Start: 3/3/2020 9:30:00 AM
End: 3/3/2020 12:30:00 PM
Show Time As: Tentative

-----Original Appointment-----
From: Pence, Laura (HHS/ASL) <Laura.Pence@hhs.gov>
Sent: Wednesday, February 19, 2020 12:21 PM
To: Pence, Laura (OS); Shuy, Bryan (OS); Oxner, Julie (OS); Rybak, Bailey (OS); Bigham, Jane E (CDC); Tourk, Nancy R (CDC); Greaser, Jennifer L (CDC); Brand, Anstice M (CDC); Gross, Karas; Tatem, Anne (OS); Bradsher, Kris (OS); Kehoe, Brian (OS); Arbes, Sarah C (OS); LaMontagne, Karen A (NIH)
Subject: HELP hearing on coronavirus (w/CDC, ASPR, NIAID, FDA)
When: Tuesday, March 3, 2020 9:30 AM-12:30 PM (UTC-05:00) Eastern Time (US & Canada).
Where: SD430

SENATE COMMITTEE ON
HEALTH, EDUCATION, LABOR AND PENSIONS

Hearing Notice

To: **All Committee Members**

Title: **An Emerging Disease Threat: How the U.S. Is Responding to COVID-19, the Novel Coronavirus**

Date: **Tuesday, March 3, 2020**

Time: **10:00 AM**

Place: **430 Dirksen Senate Office Building**

Chung Shek
Chief Clerk

February 19, 2020

From: Sheehy, Janice [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F45A6C96F5274724A1BE5970EB648FF7-JSHEEHY]
Sent: 3/2/2020 2:03:16 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]
CC: Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]
Subject: FW: Coronavirus Docs
Attachments: NYS Wadsworth Center COVID-19; RE: NYS Wadsworth Center COVID-19; RE: NYS Wadsworth Center COVID-19; CDC Agrees to QC Lot Testing for IDT and Biosearch; Laboratory Diagnostic Test Timeline; CDC contact information, re: Laboratory activities

Importance: High

Hi, the attached emails came in for SH over the weekend in to the public email box (FDA Commissioner). I don't know if he ended up receiving these emails or not. **(b)(5)** **(b)(5)** Right now, the only extensions that are autoforwarded are from the White House and HHS only. Thanks!

From: Russ, Wanda <Wanda.Russ@fda.hhs.gov>
Sent: Monday, March 2, 2020 1:23 PM
To: Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Cc: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>
Subject: Coronavirus Docs
Importance: High

Attached are emails that came to the Commissioner's public mailbox on coronavirus from CDC folks and FDA folks.

Thank you,

Wanda

From: Mango, Paul (HHS/IOS) [Paul.Mango@hhs.gov]
Sent: 3/2/2020 3:35:27 PM
To: Mango, Paul (HHS/IOS) [Paul.Mango@hhs.gov]; Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]; Marston, Hilary D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; Johnson, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c7eb3a419464ea2917f9d1e3f6e57a4-HHS-Robert.]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Berger, Sherri (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b1ac8b1b9ba4abe8ef7b1d7abcd8d71-HHS-sob8-cd]; Tabak, Lawrence A (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0037b2fbba164f33a24944311b80393e-HHS-Lawrenc]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]
CC: Pollard, Ashton (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0eba064633c94d69ac56385c0972e3da-HHS-Ashton.]

Subject: DOE Scanning of Potential COVID Therapies
Attachments: DOE coronavirus.pdf
Location: Dial In Below

Start: 3/3/2020 9:30:00 AM
End: 3/3/2020 10:00:00 AM
Show Time As: Tentative

Required Attendees: Farley, John (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Johnson, Robert (OS/ASPR/BARDA); Lenihan, Keagan (FDA/OC); Berger, Sherri (CDC/OCOO/OD); Tabak, Lawrence (NIH/OD) [E]; Shuy, Bryan (OS/ASPR/IO)

DIAL IN INFORMATION
(b)(6)

From: Mango, Paul (HHS/IOS) <Paul.Mango@hhs.gov>
Sent: Monday, March 2, 2020 2:47 PM
To: Farley, John (FDA/CDER) <John.Farley@fda.hhs.gov>; Marston, Hilary (NIH/NIAID) [E] <hilary.marston@nih.gov>; Johnson, Robert (OS/ASPR/BARDA) <Robert.Johnson@hhs.gov>
Cc: Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>; Tabak, Lawrence (NIH/OD) [E] <lawrence.tabak@nih.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Pollard, Ashton (OS/IOS) <Ashton.Pollard@hhs.gov>
Subject: Phone call on DOE Scanning of potential COVID therapies

Folks- we would like to convene this group by phone possibly along with the a couple folks at DOE to discuss the attached (which I believe most of you have read). We are shooting for 930am tomorrow. Ashton will send invite. Please be prepared to give your reaction to this as well as outstanding questions you may have. Many thanks.

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 3/2/2020 3:38:43 PM
To: Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]
Subject: FW: Phone call on DOE Scanning of potential COVID therapies
Attachments: DOE coronavirus.pdf

Can you do this tomorrow? Anyone else from FDA join you? I will be stuck at the hearing with Hahn tomorrow, apologies.

From: Mango, Paul (HHS/IOS) <Paul.Mango@hhs.gov>
Sent: Monday, March 2, 2020 2:47 PM
To: Farley, John <John.Farley@fda.hhs.gov>; Marston, Hilary D (NIH) <hilary.marston@nih.gov>; Johnson, Robert (OS) <Robert.Johnson@hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) <sob8@cdc.gov>; Tabak, Lawrence A (NIH) <lawrence.tabak@nih.gov>; Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>; Pollard, Ashton (OS) <Ashton.Pollard@hhs.gov>
Subject: Phone call on DOE Scanning of potential COVID therapies

Folks- we would like to convene this group by phone possibly along with the a couple folks at DOE to discuss the attached (which I believe most of you have read). We are shooting for 930am tomorrow. Ashton will send invite. Please be prepared to give your reaction to this as well as outstanding questions you may have. Many thanks.

DOE coronavirus.pdf

From: Caccomo, Stephanie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=950C32CEBC4B4F80B302C50CF31C8524-STEPHANIE.C]
Sent: 3/2/2020 3:40:28 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]
Subject: RE: Coronavirus testing

Thanks—can correct folks

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Monday, March 02, 2020 3:30 PM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>
Subject: FW: Coronavirus testing

FYI

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Monday, March 2, 2020 3:27 PM
To: Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: FW: Coronavirus testing

Dear Commissioner Hahn and Keagan,

Please see the response below. Emer is double checking, but in short, it seems like there is not a WHO developed or sponsored test at this point.

Please let me know if you have any questions.

Best Regards,
Peter

From: COOKE, Emer <cookee@who.int>
Sent: Monday, March 2, 2020 3:15 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Raychaudhuri, Gopa <Gopa.Raychaudhuri@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: Re: Coronavirus testing

Dear Peter,
Do you know where this information is coming from? We certainly haven't developed a test, and, as far as I am aware, we haven't listed one either. We did announce Friday that the Emergency Use Listing procédure would be open to candidate IVDs to detect SARS-CoV-2 Nucleic acid.
I am enquiring with other colleagues just in case I missed something in another part of the organisation.
Best wishes,
Emer

Emer Cooke
Director Regulation and Prequalification Department (RPQ) WHO
(b)(6)

Sent from my mobile device, please excuse brevity and typos

On 2 Mar 2020, at 20:39, Marks, Peter <Peter.Marks@fda.hhs.gov> wrote:

Dear Emer,

My apologies if this is a duplicate email. I was having some connectivity issues on my phone and am now on my laptop.

There has been some confusion here regarding WHO and coronavirus testing. Is there an actual WHO developed test, or is WHO simply endorsing or listing the use of other tests? I suspect the latter, but Jeff Shuren, the head of devices at FDA an I would like to confirm. Thanks so much for your help clarifying this. (Also, so sorry that the predictions that we spoke of seem to be coming true.)

Best Regards,
Peter

From: Stecker, Judy (OS/IOS) [Judy.Stecker@hhs.gov]
Sent: 3/2/2020 4:03:26 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: Fwd: [EXTERNAL] WSJ request for comment on coronavirus testing

Sent from my iPhone

Begin forwarded message:

From: "Miller, Katie R. EOP/OVP" <Katie.R.Miller@ovp.eop.gov>
Date: March 2, 2020 at 3:53:58 PM EST
To: "Stecker, Judy (OS/IOS)" <Judy.Stecker@hhs.gov>, "Harrison, Brian (HHS/IOS)" <Brian.Harrison@hhs.gov>, "Oakley, Caitlin B. (OS/ASPA)" <Caitlin.Oakley@HHS.GOV>, "Murphy, Ryan (OS/ASPA)" <Ryan.Murphy1@hhs.gov>
Cc: "Devin.O'Malley@treasury.gov" <Devin.O'Malley@treasury.gov>
Subject: Fwd: [EXTERNAL] WSJ request for comment on coronavirus testing

I have no background on this - **(b)(5)**

Sent from my iPhone

Begin forwarded message:

From: "Restuccia, Andrew" <andrew.restuccia@wsj.com>
Date: March 2, 2020 at 3:13:48 PM EST
To: "Deere, Judd P. EOP/WHO" <Judson.P.Deere@who.eop.gov>, "Miller, Katie R. EOP/OVP" <Katie.R.Miller@ovp.eop.gov>, "Devin.omalley@treasury.gov" <Devin.omalley@treasury.gov>, "Grisham, Stephanie A. EOP/WHO" **(b)(6)** Gidley, Hogan H. EOP/WHO" **(b)(6)**
Subject: [EXTERNAL] WSJ request for comment on coronavirus testing

Hi everybody.

We're writing a story about the backstory on the decision to send the initial defective coronavirus tests to states and public health labs. My colleagues have been digging into this, and they've been told there was a conference call earlier this month with senior administration officials, including Azar, his chief of staff, Brian Harrison, Stephan Hahn, Anthony Fauci, Jeffrey Shuren, Robert Redfield and Anand Shah.

On the call, Harrison and Azar were warned that the tests were potentially compromised, and Harrison ordered them to be shipped anyway.

We're told that Hahn, Fauci, Shuren and Shah all raised concerns about the tests on the call. Harrison decided to move forward with shipping the tests even after Shuren gave a 20-minute argument about the seriousness of the contamination.

We're already talking to HHS, but we wanted to reach out to the White House about this as well to see if you have any comment, and to check in to see if the president still has confidence in Mr. Azar.

We've been told this story is competitive, so we're hoping to publish later today.

Andrew Restuccia
WHITE HOUSE REPORTER, WASHINGTON BUREAU

M: (b)(6)
E: andrew.restuccia@wsj.com | T: @andrewrestuccia
A: 1025 Connecticut Ave. NW, Suite 800 | Washington, D.C. 20036

From: Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]
Sent: 3/2/2020 9:11:20 PM
To: McWilliams, Carly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]
Subject: Re: Science Magazine Article + UPDATE + TOMORROW's Plan

Would like to see anything before it goes to SH. Thanks.

Sent from my iPhone

On Mar 2, 2020, at 9:07 PM, McWilliams, Carly <Carly.McWilliams@fda.hhs.gov> wrote:

Thank you all for your attention on this. I am also going to be helping coordinate on this outbreak from the commissioners office. Trying to loop the two groups together for tomorrow's deliverables based on the WHTF meeting this afternoon.

The VP has asked Dr. Hahn to address two things at the press conference in the afternoon 1. CDC lab contamination and 2. Clarification that the WHO is not actually manufacturing/developing tests. So, we do not need to do press outreach as he is going to proactively discuss at press conference and this could also potentially be brought up at hearing for tomorrow **(b)(5)**

(b)(5)

Dr. Marks, please let us know what you learn from WHO on testing.

Stephanie and I developed talking points for the press conference. We are going to send to Denise and Michael first this evening and then it will go through the clearance process which needs to be done by 1PM TOMORROW.

Separately, I will also be pulling together his background for his briefing at WHTF tomorrow on any updates, which will also be due at 1pm tomorrow. I will be pulling that from this evenings sit rep.

Thank you in advance for your help and please let me know if you have questions.

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Sent: Monday, March 2, 2020 7:25 PM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Lutter, Randall <Randall.Lutter@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Subject: RE: Science Magazine Article

Sidenote, there is another chain on this and Peter has been running to ground with WHO.

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Monday, March 2, 2020 7:21 PM
To: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Lutter, Randall <Randall.Lutter@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Subject: RE: Science Magazine Article

Yes, there are several publications that I'll be reaching out to, thanks for following up.

From: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Sent: Monday, March 02, 2020 7:13 PM
To: Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Cc: Lutter, Randall <Randall.Lutter@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Subject: RE: Science Magazine Article

Extremely helpful. I neglected to include Stephanie on this chain. Stephanie and Laura **(b)(5)** **(b)(5)**

From: Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
Date: March 2, 2020 at 7:06:18 PM EST
To: Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>, Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>, McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>, Janik, Heather <Heather.Janik@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Lutter, Randall <Randall.Lutter@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>, Gross, Karas <Karas.Gross@fda.hhs.gov>, Black, Jennifer <Jennifer.Black@fda.hhs.gov>, Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Subject: RE: Science Magazine Article

Thanks again all.

Jeff said WHO confirmed that they have not made a test, shipped a test, or listed a test. The news stories are not accurate, so we should be clear about it.

Best,

Jennifer
Jennifer Brown Tomasello, MPA
Senior Policy Advisor

Center for Devices and Radiological Health
Office of Policy
U.S. Food and Drug Administration
Tel 301-796-8924 (b)(6)
jennifer.tomasello@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=5000&S=E

From: Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>
Sent: Monday, March 2, 2020 6:20 PM
To: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Lutter, Randall <Randall.Lutter@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
Subject: Re: Science Magazine Article

Looping in Tim and Jennifer.

From: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>
Date: March 2, 2020 at 6:12:00 PM EST
To: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>, Janik, Heather <Heather.Janik@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Lutter, Randall <Randall.Lutter@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>, Gross, Karas <Karas.Gross@fda.hhs.gov>, Black, Jennifer <Jennifer.Black@fda.hhs.gov>, Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>, Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>
Subject: Re: Science Magazine Article

+ Lauren

From: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Date: March 2, 2020 at 5:54:45 PM EST

To: Janik, Heather <Heather.Janik@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Lutter, Randall <Randall.Lutter@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>, Gross, Karas <Karas.Gross@fda.hhs.gov>, Black, Jennifer <Jennifer.Black@fda.hhs.gov>, Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>, Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>
Subject: Science Magazine Article

Hi, I was sent this article by Randy. Based on the talking points I have seen though, **(b)(5)**
(b)(5)
Were they coordinating distribution of tests? Fortunately, it does note that things will get better. Could we **(b)(5)**

(b)(5)

The United States badly bungled coronavirus testing—but things may soon improve

By Jon CohenFeb. 28, 2020 , 5:45 PM

Speed is critical in the response to COVID-19. So why has the United States been so slow in its attempt to develop reliable diagnostic tests and use them widely?

The World Health Organization (WHO) has shipped testing kits to 57 countries. China had five commercial tests on the market 1 month ago and can now do up to 1.6 million tests a week; South Korea has tested 65,000 people so far. The U. S. Centers for Disease Control and Prevention (CDC), in contrast, has done only 459 tests since the epidemic began. The rollout of a CDC-designed test kit to state and local labs has become a fiasco because it contained a faulty reagent. Labs around the country eager to test more suspected cases—and test them faster—have been unable to do so. No commercial or state labs have the approval to use their own tests.

In what is already an infamous snafu, CDC initially refused a request to test a patient in Northern California who turned out to be the first probable COVID19 case without known links to an infected person.

The problems have led many to doubt that the official tally of 60 confirmed cases in the United States is accurate. the official tally of 60 confirmed cases in the United States is accurate. “There have been blunders, and there could be an underlying catastrophe that we don’t know about,” says epidemiologist Michael Mina, who helps run a microbiology testing lab at Brigham and Women’s Hospital. “It’s been very complicated and confusing for everyone with almost no clarity being provided by the CDC.”

The situation may soon improve. State labs and commercial diagnostic developers hope to win approval from the Food and Drug Administration (FDA) for their own tests, and FDA and CDC on Wednesday agreed on a workaround for the faulty CDC kit—which has a problem that is not essential to its proper functioning—so that it can now be used by at least some of the state labs that have it.

But there’s widespread discontent with the way the system has worked. “The U.S. government has not appropriately prioritized diagnostic tests and supported the laboratory response network to the degree they should have been supported over the years,” says Luciana Borio, who in previous jobs had lead roles in responding to emerging threats at the National Security Council and FDA.

If a new disease emerges, CDC normally "gets the ball rolling" with diagnostics because it has the expertise and the biosafety laboratories to handle dangerous novel pathogens, says Borio, who now works for In-Q-Tel, a not-for-profit venture capital firm. Typically, there are few confirmed viral samples from patients at the outset, which researchers need to validate their tests, and CDC has the capability to grow the virus for this critical quality assurance step. Once the agency has a working test, that goes out to state labs. Then, in a third phase, commercial labs take over and either produce their own tests or scale-up the CDC one. "I would have hoped to see that third phase by now," Borio says.

In the case of SARS-CoV-2, as the virus causing COVID-19 is officially known, CDC's sluggishness was apparent 1 month ago. On 26 January, the agency held an unusual Sunday teleconference for the media to provide an update about the rapidly growing outbreak. There were then five cases in the United States, but the CDC lab in Atlanta was still the only one in the country able to test for the virus, and it repeatedly had backlogs. Asked why more labs weren't able to do the tests, Nancy Messonnier, who then was leading CDC's response, said it was a quality issue. "We hold ourselves to an incredibly high standard of precision in terms of laboratory testing," Messonnier said. "We wouldn't want to inadvertently make a mistake in patient care."

CDC finally started to send kits to state and local health labs on 5 February. But on 12 February, it revealed that several labs had difficulty validating the test because of a problem with one of the reagents.

The key problem with the kits is what's known as a negative control, says Kelly Wroblewski, director of infectious diseases at the Association of Public Health Laboratories (APHL). CDC's test uses the polymerase chain reaction (PCR) assay to find tiny amounts of the SARS-CoV-2 genome in, say, a nose swab. To make sure a test is working properly, kits also include DNA unrelated to SARS-CoV-2. The assay should not react to this negative control, but the CDC reagents did at many, but not all, state labs. The labs where the negative control failed were not allowed to use the test; they have to continue to send their samples to Atlanta.

The declaration of a public health emergency ... limited the diagnostic capacity of this country. It's insane.

Michael Mina, Brigham and Women's Hospital

In principle, many hospital and academic labs around the country have the capability to carry out tests themselves. The PCR reaction uses so-called primers, short stretches of DNA, to find viral sequences. The CDC website posts the primers used in its test, and WHO publicly catalogs other primers and protocols, too. Well-equipped state or local labs can use these—or come up with their own—to produce what are known as a "laboratory-developed tests" for in-house use.

But at the moment, they're not allowed to do that without FDA approval. When the United States declared the outbreak a public health emergency on 31 January, a bureaucratic process kicked in that requires FDA's "emergency use approval" for any tests. "The declaration of a public health emergency did exactly what it shouldn't have. It limited the diagnostic capacity of this country," Mina says. "It's insane."

On 24 February, APHL asked FDA Commissioner Stephen Hahn for "enforcement discretion" to sidestep the emergency process and allow APHL members labs to use their own tests. On 26 February, Hahn replied that the CDC test could be modified to use just the primers that specifically detect SARS-CoV-2, essentially ignoring the faulty portion of the kits. FDA, in other words, would look the other way to make more widespread testing possible.

CDC has notified labs of FDA's decision in a letter, but the agency must still file an emergency use authorization with FDA for the protocol change. Once it does, it won't take long, Hahn promised in his letter to APHL: "FDA has been able to authorize tests for public health emergencies within as little as 1 day upon receipt of the complete validation."

In New York, the State Department of Health has designed its own test based on the CDC protocol and plans to seek emergency use authorization.

CDC provided an update about the situation in an email but did not respond to *Science*'s request for an interview with a scientist to discuss the details of the problem. Mina stresses he has great respect for CDC's competence overall, but says, "There's no good explanation for what's going on here."

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Sent: 3/2/2020 9:12:01 PM
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Dr. Marks, please let us know what you learn from WHO on testing.

Stephanie and I developed talking points for the press conference. We are going to send to Denise and Michael first this evening and then it will go through the clearance process which needs to be done by 1PM TOMORROW.

Separately, I will also be pulling together his background for his briefing at WHTF tomorrow on any updates, which will also be due at 1pm tomorrow. I will be pulling that from this evenings sit rep.

Thank you in advance for your help and please let me know if you have questions.

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Thanks again all.

Jeff said WHO confirmed that they have not made a test, shipped a test, or listed a test. The news stories are not accurate, so we should be clear about it.

Best,

Jennifer
Jennifer Brown Tomasello, MPA
Senior Policy Adviser

Center for Devices and Radiological Health
Office of Policy
U.S. Food and Drug Administration
Tel: 301-796-8924 **(b)(6)**
jennifer.tomasello@fda.hhs.gov

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Hi, I was sent this article by Randy. Based on the talking points I have seen though, **(b)(5)**
(b)(5)
Were they coordinating distribution of tests? Fortunately, it does note that things will get better. Could we t **(b)(5)**

(b)(5)

The United States badly bungled coronavirus testing—but things may soon improve

By Jon CohenFeb. 28, 2020 , 5:45 PM

Speed is critical in the response to COVID-19. So why has the United States been so slow in its attempt to develop reliable diagnostic tests and use them widely?

The World Health Organization (WHO) has shipped testing kits to 57 countries. China had five commercial tests on the market 1 month ago and can now do up to 1.6 million tests a week; South Korea has tested 65,000 people so far. The U. S. Centers for Disease Control and Prevention (CDC), in contrast, has done only 459 tests since the epidemic began. The rollout of a CDC-designed test kit to state and local labs has become a fiasco because it contained a faulty reagent. Labs around the country eager to test more suspected cases—and test them faster—have been unable to do so. No commercial or state labs have the approval to use their own tests.

In what is already an infamous snafu, CDC initially refused a request to test a patient in Northern California who turned out to be the first probable COVID19 case without known links to an infected person.

The problems have led many to doubt that the official tally of 60 confirmed cases in the United States is accurate. the official tally of 60 confirmed cases in the United States is accurate. “There have been blunders, and there could be an underlying catastrophe that we don’t know about,” says epidemiologist Michael Mina, who helps run a microbiology testing lab at Brigham and Women’s Hospital. “It’s been very complicated and confusing for everyone with almost no clarity being provided by the CDC.”

The situation may soon improve. State labs and commercial diagnostic developers hope to win approval from the Food and Drug Administration (FDA) for their own tests, and FDA and CDC on

Wednesday agreed on a workaround for the faulty CDC kit—which has a problem that is not essential to its proper functioning—so that it can now be used by at least some of the state labs that have it.

But there's widespread discontent with the way the system has worked. "The U.S. government has not appropriately prioritized diagnostic tests and supported the laboratory response network to the degree they should have been supported over the years," says Luciana Borio, who in previous jobs had lead roles in responding to emerging threats at the National Security Council and FDA.

If a new disease emerges, CDC normally "gets the ball rolling" with diagnostics because it has the expertise and the biosafety laboratories to handle dangerous novel pathogens, says Borio, who now works for In-Q-Tel, a not-for-profit venture capital firm. Typically, there are few confirmed viral samples from patients at the outset, which researchers need to validate their tests, and CDC has the capability to grow the virus for this critical quality assurance step. Once the agency has a working test, that goes out to state labs. Then, in a third phase, commercial labs take over and either produce their own tests or scale-up the CDC one. "I would have hoped to see that third phase by now," Borio says.

In the case of SARS-CoV-2, as the virus causing COVID-19 is officially known, CDC's sluggishness was apparent 1 month ago. On 26 January, the agency held an unusual Sunday teleconference for the media to provide an update about the rapidly growing outbreak. There were then five cases in the United States, but the CDC lab in Atlanta was still the only one in the country able to test for the virus, and it repeatedly had backlogs. Asked why more labs weren't able to do the tests, Nancy Messonnier, who then was leading CDC's response, said it was a quality issue. "We hold ourselves to an incredibly high standard of precision in terms of laboratory testing," Messonnier said. "We wouldn't want to inadvertently make a mistake in patient care."

CDC finally started to send kits to state and local health labs on 5 February. But on 12 February, it revealed that several labs had difficulty validating the test because of a problem with one of the reagents.

The key problem with the kits is what's known as a negative control, says Kelly Wroblewski, director of infectious diseases at the Association of Public Health Laboratories (APHL). CDC's test uses the polymerase chain reaction (PCR) assay to find tiny amounts of the SARS-CoV-2 genome in, say, a nose swab. To make sure a test is working properly, kits also include DNA unrelated to SARS-CoV-2. The assay should not react to this negative control, but the CDC reagents did at many, but not all, state labs. The labs where the negative control failed were not allowed to use the test; they have to continue to send their samples to Atlanta.

The declaration of a public health emergency … limited the diagnostic capacity of this country. It's insane.

Michael Mina, Brigham and Women's Hospital

In principle, many hospital and academic labs around the country have the capability to carry out tests themselves. The PCR reaction uses so-called primers, short stretches of DNA, to find viral sequences. The CDC website posts the primers used in its test, and WHO publicly catalogs other primers and protocols, too. Well-equipped state or local labs can use these—or come up with their own—to produce what are known as a "laboratory-developed tests" for in-house use.

But at the moment, they're not allowed to do that without FDA approval. When the United States declared the outbreak a public health emergency on 31 January, a bureaucratic process kicked in that requires FDA's "emergency use approval" for any tests. "The declaration of a public health emergency did exactly what it shouldn't have. It limited the diagnostic capacity of this country," Mina says. "It's insane."

On 24 February, APHL asked FDA Commissioner Stephen Hahn for "enforcement discretion" to sidestep the emergency process and allow APHL members labs to use their own tests. On 26 February, Hahn replied that the CDC test could be modified to use just the primers that specifically

detect SARS-CoV-2, essentially ignoring the faulty portion of the kits. FDA, in other words, would look the other way to make more widespread testing possible.

CDC has notified labs of FDA's decision in a letter, but the agency must still file an emergency use authorization with FDA for the protocol change. Once it does, it won't take long, Hahn promised in his letter to APHL: "FDA has been able to authorize tests for public health emergencies within as little as 1 day upon receipt of the complete validation."

In New York, the State Department of Health has designed its own test based on the CDC protocol and plans to seek emergency use authorization.

CDC provided an update about the situation in an email but did not respond to *Science*'s request for an interview with a scientist to discuss the details of the problem. Mina stresses he has great respect for CDC's competence overall, but says, "There's no good explanation for what's going on here."

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From: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Date: March 2, 2020 at 5:54:45 PM EST
To: Janik, Heather <Heather.Janik@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Lutter, Randall <Randall.Lutter@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>, Gross, Karas <Karas.Gross@fda.hhs.gov>, Black, Jennifer <Jennifer.Black@fda.hhs.gov>, Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>, Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>
Subject: Science Magazine Article

Hi, I was sent this article by Randy. Based on the talking points I have seen though, **(b)(5)**
(b)(5)
Were they coordinating distribution of tests? Fortunately, it does note that things will get better. Could we 1. **(b)(5)**

(b)(5)

The United States badly bungled coronavirus testing—but things may soon improve

By Jon CohenFeb. 28, 2020 , 5:45 PM

Speed is critical in the response to COVID-19. So why has the United States been so slow in its attempt to develop reliable diagnostic tests and use them widely?

The World Health Organization (WHO) has shipped testing kits to 57 countries. China had five commercial tests on the market 1 month ago and can now do up to 1.6 million tests a week; South Korea has tested 65,000 people so far. The U. S. Centers for Disease Control and Prevention (CDC), in contrast, has done only 459 tests since the epidemic began. The rollout of a CDC-designed test kit to state and local labs has become a fiasco because it contained a faulty reagent. Labs around the country eager to test more suspected cases—and test them faster—have been unable to do so. No commercial or state labs have the approval to use their own tests.

In what is already an infamous snafu, CDC initially refused a request to test a patient in Northern California who turned out to be the first probable COVID19 case without known links to an infected person.

The problems have led many to doubt that the official tally of 60 confirmed cases in the United States is accurate. the official tally of 60 confirmed cases in the United States is accurate. "There have been blunders, and there could be an underlying catastrophe that we don't know about," says epidemiologist Michael Mina, who helps run a microbiology testing lab at Brigham and Women's Hospital. "It's been very complicated and confusing for everyone with almost no clarity being provided by the CDC."

The situation may soon improve. State labs and commercial diagnostic developers hope to win approval from the Food and Drug Administration (FDA) for their own tests, and FDA and CDC on Wednesday agreed on a workaround for the faulty CDC kit—which has a problem that is not essential to its proper functioning—so that it can now be used by at least some of the state labs that have it.

But there's widespread discontent with the way the system has worked. "The U.S. government has not appropriately prioritized diagnostic tests and supported the laboratory response network to the degree they should have been supported over the years," says Luciana Borio, who in previous jobs had lead roles in responding to emerging threats at the National Security Council and FDA.

If a new disease emerges, CDC normally "gets the ball rolling" with diagnostics because it has the expertise and the biosafety laboratories to handle dangerous novel pathogens, says Borio, who now works for In-Q-Tel, a not-for-profit venture capital firm. Typically, there are few confirmed viral samples from patients at the outset, which researchers need to validate their tests, and CDC has the capability to grow the virus for this critical quality assurance step. Once the agency has a working test, that goes out to state labs. Then, in a third phase, commercial labs take over and either produce their own tests or scale-up the CDC one. "I would have hoped to see that third phase by now," Borio says.

In the case of SARS-CoV-2, as the virus causing COVID-19 is officially known, CDC's sluggishness was apparent 1 month ago. On 26 January, the agency held an unusual Sunday teleconference for the media to provide an update about the rapidly growing outbreak. There were then five cases in the United States, but the CDC lab in Atlanta was still the only one in the country able to test for the virus, and it repeatedly had backlogs. Asked why more labs weren't able to do the tests, Nancy Messonnier, who then was leading CDC's response, said it was a quality issue. "We hold ourselves to an incredibly high standard of precision in terms of laboratory testing," Messonnier said. "We wouldn't want to inadvertently make a mistake in patient care."

CDC finally started to send kits to state and local health labs on 5 February. But on 12 February, it revealed that several labs had difficulty validating the test because of a problem with one of the reagents.

The key problem with the kits is what's known as a negative control, says Kelly Wroblewski, director of infectious diseases at the Association of Public Health Laboratories (APHL). CDC's test uses the polymerase chain reaction (PCR) assay to find tiny amounts of the SARS-CoV-2 genome in, say, a nose swab. To make sure a test is working properly, kits also include DNA unrelated to SARS-CoV-2. The assay should not react to this negative control, but the CDC reagents did at many, but not all, state labs. The labs where the negative control failed were not allowed to use the test; they have to continue to send their samples to Atlanta.

The declaration of a public health emergency … limited the diagnostic capacity of this country. It's insane.

Michael Mina, Brigham and Women's Hospital

In principle, many hospital and academic labs around the country have the capability to carry out tests themselves. The PCR reaction uses so-called primers, short stretches of DNA, to find viral sequences. The CDC website posts the primers used in its test, and WHO publicly catalogs other primers and protocols, too.

Well-equipped state or local labs can use these—or come up with their own—to produce what are known as a "laboratory-developed tests" for in-house use.

But at the moment, they're not allowed to do that without FDA approval. When the United States declared the outbreak a public health emergency on 31 January, a bureaucratic process kicked in that requires FDA's "emergency use approval" for any tests. "The declaration of a public health emergency did exactly what it shouldn't have. It limited the diagnostic capacity of this country," Mina says. "It's insane."

On 24 February, APHL asked FDA Commissioner Stephen Hahn for "enforcement discretion" to sidestep the emergency process and allow APHL members labs to use their own tests. On 26 February, Hahn replied that the CDC test could be modified to use just the primers that specifically detect SARS-CoV-2, essentially ignoring the faulty portion of the kits. FDA, in other words, would look the other way to make more widespread testing possible.

CDC has notified labs of FDA's decision in a letter, but the agency must still file an emergency use authorization with FDA for the protocol change. Once it does, it won't take long, Hahn promised in his letter to APHL: "FDA has been able to authorize tests for public health emergencies within as little as 1 day upon receipt of the complete validation."

In New York, the State Department of Health has designed its own test based on the CDC protocol and plans to seek emergency use authorization.

CDC provided an update about the situation in an email but did not respond to *Science*'s request for an interview with a scientist to discuss the details of the problem. Mina stresses he has great respect for CDC's competence overall, but says, "There's no good explanation for what's going on here."

From: Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]
Sent: 3/2/2020 10:13:57 PM
To: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
Subject: Re: FDA chief's claim of 1M coronavirus tests by end of week stirs controversy

Thanks.

Sent from my iPhone

On Mar 2, 2020, at 10:09 PM, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov> wrote:

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Date: March 2, 2020 at 7:52:42 PM EST
To: Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>, Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Cc: Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>
Subject: RE: FDA chief's claim of 1M coronavirus tests by end of week stirs controversy

I called David and he should be updating the story with the commercial manufacturing context.

From: Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
Sent: Monday, March 02, 2020 7:50 PM
To: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Cc: Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>
Subject: Fwd: FDA chief's claim of 1M coronavirus tests by end of week stirs controversy
Importance: High

FYI - APHL is pushing back on the Commissioner's estimates for testing capacity.

Brigham and Women's is saying it will take from 2 to 3 weeks to get running and even that i **(b)(5)** **(b)(5)**

From: POLITICO Pro Health Care <politicoemail@politicopro.com>
Date: March 2, 2020 at 7:37:08 PM EST

To: Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
Subject: FDA chief's claim of 1M coronavirus tests by end of week stirs controversy

FDA chief's claim of 1M coronavirus tests by end of week stirs controversy

By David Lim

03/02/2020 07:35 PM EST

U.S. labs will have enough materials on hand by the end of this week to perform "close to 1 million" coronavirus tests, FDA Commissioner Stephen Hahn said at a White House briefing Monday evening.

But that estimate far exceeds the number of tests that several labs told POLITICO they will actually be able to run each day. Under ideal conditions, the nation's public health labs could run up to 10,000 tests per day by the end of the week, according to figures provided by the Association of Public Health Laboratories.

The announcement by Hahn comes amid intense scrutiny of the technical troubles that have slowed labs' adoption of the CDC diagnostic, with many public health officials and politicians blaming HHS Secretary Alex Azar for the delay.

FDA issued regulations over the weekend that allow some high-complexity labs to create and use their own coronavirus tests before seeking an emergency use authorization from the agency — a move aimed at closing the testing gap.

"With this new policy, we have heard from multiple companies and multiple academic centers, and we expect to have a substantial increase in the number of tests this week, next week and throughout the month," Hahn told reporters.

But as of Sunday night, only 36 of roughly 100 public health laboratories had successfully verified a diagnostic developed by the CDC, and 10 more are in the process of doing so, according to APHL CEO Scott Becker.

With CDC distributing more test kits to public health labs, Becker expects all of APHL's member labs to be in "various stages of verification" by the end of the week. At normal capacity, each lab can run 100 samples per day, with each patient requiring at least two samples to be tested, APHL estimates.

Former FDA Commissioner Scott Gottlieb said Sunday on Face the Nation that the U.S. would be able to test 10,000 people a day by the end of the week if all 100 public health labs were up and running. As academic labs begin performing the tests, the country's total capacity could increase by an additional 10,000 tests per day within two weeks, Gottlieb added.

Michael Mina, associate medical director of molecular diagnostics at Brigham and Women's Hospital, told POLITICO that Gottlieb's estimate is accurate. Under FDA's new guidelines, Mina's hospital is creating its own in-house test, but he cautions it will take time for it to become operational.

"We will have something up and running within a matter of two or three weeks, that's the hope," Mina said. "And this is an extraordinarily fast timeline for a laboratory even like ours."

To view online:
https://subscriber.politicopro.com/health-care/article/2020/03/fda-chiefs-claim-of-1m-coronavirus-tests-by-end-of-week-stirs-controversy-1887338

From: Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]
Sent: 3/3/2020 7:15:33 AM
To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
Subject: Re: FDA chief's claim of 1M coronavirus tests by end of week stirs controversy

Thanks.

Sent from my iPhone

On Mar 3, 2020, at 5:52 AM, Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov> wrote:

No updates. Just adding context that this is commercial manufacturing. I don't believe he said "commercial" at WH briefing and reporters were confused about 1 mil number **(b)(5)**

Stephanie Caccomo
Press Officer

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

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Date: March 2, 2020 at 10:46:47 PM EST
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: Re: FDA chief's claim of 1M coronavirus tests by end of week stirs controversy

If there are updates we need them for me to go over with him in am. I will be at HHS with him.

Sent from my iPhone

On Mar 2, 2020, at 10:19 PM, Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov> wrote:

Yes. I've been on the phone with several Reporters explaining context—NPR, WaPo, NYT and David at politico.

(b)(5)

Stephanie Caccomo
Press Officer

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

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Date: March 2, 2020 at 10:14:33 PM EST
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: Fwd: FDA chief's claim of 1M coronavirus tests by end of week stirs controversy

You pushing back on these stories? Thanks.

Sent from my iPhone

Begin forwarded message:

From: "Shuren, Jeff" <Jeff.Shuren@fda.hhs.gov>
Date: March 2, 2020 at 10:09:41 PM EST
To: "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>
Subject: Fwd: FDA chief's claim of 1M coronavirus tests by end of week stirs controversy

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From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Date: March 2, 2020 at 7:52:42 PM EST
To: Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>, Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
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Sent: Monday, March 02, 2020 7:50 PM
To: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
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Subject: Fwd: FDA chief's claim of 1M coronavirus tests by end of week stirs controversy
Importance: High

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Brigham and Women's is saying it will take from 2 to 3 weeks to get running and even that (b)(5) (b)(5)

From: POLITICO Pro Health Care <politicoemail@politicopro.com>
Date: March 2, 2020 at 7:37:08 PM EST
To: Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
Subject: FDA chief's claim of 1M coronavirus tests by end of week stirs controversy

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To view online:
https://subscriber.politicopro.com/health-care/article/2020/03/fda-chiefs-claim-of-1m-coronavirus-tests-by-end-of-week-stirs-controversy-1887338

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From: Rice, Crystal [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=79DC1E87F3874BBE8200F684FD8963A6-RICEC]
Sent: 3/3/2020 8:14:04 AM
To: Ashcraft, Charlotte [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3defaed236074242aced487d77b09b47-Cmashcraft]; Burgess, Shelly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5beb691d4bac4848945f6039974b29fa-Shelly.Burg]; Burrows, Vanessa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d1f3cb2e6b30473a81c857c14e99cf4a-Vanessa.Bur]; CDRH Info Sender [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7975e25340144033a6b11e32f24e8df2-INFO]; Davis, Sharon M (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4d7fc7ee069b462badaabec29c892d7b-SYD]; DeLancey, Siobhan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a414ba562dcd4c8284b1120074969b9a-SDELANCE]; Dewitt, Susan J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eb6df6a470314db388c55ffe16308efe-SDEWITT]; Duckhorn, Jodi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b850290f254071b056886642cc8b43-Jodi.Duckho]; Dunham, Chanell [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3062b88d6ac64890b58de52196bb0d1d-Chanell.Dun]; Flahive, James [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=570655c122f24177ba6e9ac768a6f731-James.Flahi]; Henriques, Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc46749df13d4d62addf0b0c02f6e6e0-Maria.Henri]; Imlay, Bonnie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8d6864e106ef46f5a434ff051b1c5187-Bonnie.Imla]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; McNeill, Lorrie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77b0b352c9c24851bf0c7330f53e00d9-McNeill]; Meadows, Michelle [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=88c8fb162d204889b22d9cfce0f5d6be-MEADOWSM]; Mendrick, Donna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4a2be78d4cfe4c8fa2685b38cbdd6e25-DMendrick]; Naum, Marianna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=64ee210fc44b461682ff3f344e507d22-Marianna.Na]; OC OEA IO [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58663b06ac5747a89bd6887583023718-OC OEA IO]; OC OEA OMA-Press [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0300b0a1ab1147298784b94e4a5ed928-OC OEA OMA-]; OC OL CDER Team [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17ec643a2d7045a19a409d16edbb97d2-OC OL CDER]; Rice, Crystal [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79dc1e87f3874bbe8200f684fd8963a6-RICEC]; Riley, Karen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9941d592a1354b74be835c6288542ed5-Karen.Riley]; Shapinsky, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3df7a6c8631b47ddb0f11f3ad7e45309-David.Shapi]; Staples, Necola [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f96113ad51d34dc09c0e438989ac77ae-Necola.Stap]; Swann, John P [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8de1de74f22a48e5a8474a77f37d2088-JSWANN]; Vyas, Tonya J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2470693cf04a4b08ac91afa828f7e187-TVyas]; Witters, Alicia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5901a9f9d0c34942bea0bd09734e732b-ALW]

Subject: FW: Commissioner Stephen Hahn to Testify on Coronavirus, Today at 10:00 a.m. -- See Webcast Link

Good morning,

FYI to below.

Best,
Crystal

Crystal Rice
Internal Communications Program
Division of Public Education and Outreach
Office of Communications
U.S. FDA's Center for Drug Evaluation and Research
10001 New Hampshire Avenue, Rm 4166
Silver Spring, MD 20993
301-796-3111 Crystal.Rice@fda.hhs.gov

From: CDER OCOMM <Cder.Ocomm@fda.hhs.gov>
Sent: Tuesday, March 03, 2020 8:03 AM
To: FDA-CDER-wide <FDA-CDER-wide@fda.hhs.gov>
Subject: Commissioner Stephen Hahn to Testify on Coronavirus, Today at 10:00 a.m. -- See Webcast Link

FDA Commissioner Stephen M. Hahn, M.D., will testify at a hearing, "An Emerging Disease Threat: How the U.S. Is Responding to COVID-19, the Novel Coronavirus."

U.S. Senate Committee on Health, Education, Labor & Pensions

Today: Tuesday, March 3, 2020 at 10:00 a.m.

Watch via webcast:

https://www.help.senate.gov/hearings/an-emerging-disease-threat-how-the-us-is-responding-to-covid-19-the-novel-coronavirus

Note: If your browser does not support the video, copy and paste the video link URL, and try opening it in another browser, such as Mozilla Firefox.

From: Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]
Sent: 3/3/2020 9:20:21 AM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; McWilliams, Carly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]
Subject: RE: SARS-CoV-2 Diagnosric

This is good – thank you

Carly, please fit this into the bullets I sent over. Let's think through the types of questions that would be asked by media.

(b)(5)

Thank you

PRE-DECISIONAL, CONFIDENTIAL

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Tuesday, March 3, 2020 9:17 AM
To: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: FW: SARS-CoV-2 Diagnosric

See below

From: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Sent: Tuesday, March 3, 2020 9:15 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: SARS-CoV-2 Diagnosric

(b)(5) Alternative below.

(b)(5)

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Tuesday, March 3, 2020 9:05 AM

To: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: RE: SARS-CoV-2 Diagnosric

Is this correct??

(b)(5)

From: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Sent: Tuesday, March 3, 2020 8:42 AM
To: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Cc: Shah, Anand <Anand.Shah@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: SARS-CoV-2 Diagnosric

Correct. You can't use their or any of the other two labs' names.

From: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Sent: Tuesday, March 3, 2020 8:35 AM
To: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Cc: Shah, Anand <Anand.Shah@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: FW: SARS-CoV-2 Diagnosric

Good Morning-thanks for updating **(b)(5)** **(b)(5)**

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Tuesday, March 3, 2020 8:00 AM
To: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: RE: SARS-CoV-2 Diagnosric

(b)(5)

From: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Sent: Tuesday, March 3, 2020 7:57 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: Re: SARS-CoV-2 Diagnosric

Thank you. Will update **(b)(5)**

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Date: March 3, 2020 at 7:46:34 AM EST
To: Shah, Anand <Anand.Shah@fda.hhs.gov>, McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Subject: FW: SARS-CoV-2 Diagnosric

(b)(5)

From: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Sent: Monday, March 2, 2020 8:45 PM
To: Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: SARS-CoV-2 Diagnosric

FYI — Stanford Healthcare Clinical Laboratory submitted a notification under our new policy today at 6:54 PM. That is

(b)(5)

Jeff

From: Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]
Sent: 3/3/2020 10:43:40 AM
To: Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]
Subject: Fwd: 3M urgent concerns regarding EUA on respirators
Attachments: image001.gif; ATT00001.htm; image002.png; ATT00002.htm; image003.png; ATT00003.htm; image004.png; ATT00004.htm; image005.png; ATT00005.htm; image006.gif; ATT00006.htm; image007.png; ATT00007.htm; CDC-EUA-FFR-Letter.pdf; ATT00008.htm; respirators.pdf; ATT00009.htm

Here are the concerns.

Sent from my iPhone

Begin forwarded message:

From: "Arbes, Sarah (HHS/ASL)" <Sarah.Arbes@hhs.gov>
Date: March 3, 2020 at 10:39:37 AM EST
To: "Amin, Stacy" <Stacy.Amin@fda.hhs.gov>, "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>, "Steele, Danielle (OS)" <Danielle.Steele@hhs.gov>, "Moughalian, Jen C (OS)" <Jen.Moughalian@hhs.gov>
Cc: "Chris Hodgson (Christopher.M.Hodgson@ovp.eop.gov)" <Christopher.M.Hodgson@ovp.eop.gov>
Subject: FW: 3M urgent concerns regarding EUA on respirators

Stacy, Keagan, Danielle –

See the urgent note below from Chris in VP's office **(b)(5)**

(b)(5)

VP will be at both GOP and Dem policy lunches today starting at 1:00pm.

Sarah

From: Hodgson, Christopher M. EOP/OVP **(b)(6)**
Sent: Tuesday, March 3, 2020 10:17 AM
To: Arbes, Sarah (HHS/ASL) <Sarah.Arbes@hhs.gov>
Subject: FW: 3M urgent concerns regarding EUA on respirators

(b)(5)

(b)(5) Thanks!

Steve—

I wanted to update you on something that is urgent given the VP's presence at Senate lunch today.

It's our understanding some in the White House may be under the impression that the liability concerns we had are now solved under the most recent EUA that was published yesterday by FDA.

Let me be very clear in saying that is not the case. We have serious concerns with this EUA that was published on FDA's website yesterday and it does not align with the signed Azar document.

(b)(4)

There is significant confusion both in the House and Senate regarding which EUA folks are referring to. I am flagging because we would appreciate if VP Pence would discuss this with Sen. Fischer and Sen. Rounds at lunch.

From: McWilliams, Carly [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B68C7458214244D08424FD441FEA4FDA-CARLYLE.MCW]
Sent: 3/3/2020 2:54:46 PM
To: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
CC: Copeland, Jakea [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7fe05ed233c42b68be990b12ae2c8c8-Jakea.Copel]
Subject: MATERIALS FOR COVID
Attachments: WHTF Briefing 03.03.2020 COMPILED.docx; 20200303HahnTPsforWHTF_OCCcleared_clean no background.docx; 20200303HahnTPsforWHTF_OCCcleared_clean.docx

I am not familiar with font and size preferences so please adjust accordingly. I went over with Anand the differences in the press conference talking points—it's his preference, whichever one he prefers, the other just remove from his materials. Please let me know that this is meets our needs.

Highlights=new information since yesterday and red=cci

Talking Points for Press Conference **(b)(5)**
Clean Version

20200303HahnT...
no background.d...

One with comment that includes context:

20200303HahnT...

Briefing Background Materials

WHTF Briefing
03.03.2020 COM..

From: Rebello, Heidi [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2834CE193CA949799EF063E34A2CFA0B-HEIDI.REBEL]
Sent: 3/3/2020 4:17:24 PM
To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; McWilliams, Carly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]
Subject: Re: CDC blocked FDA official from premises

Steph, will call you to find out how to support incoming.

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Date: March 3, 2020 at 3:49:01 PM EST
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>, McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Subject: FW: CDC blocked FDA official from premises

From: POLITICO Pro Health Care <politicoemail@politicopro.com>
Sent: Tuesday, March 3, 2020 3:33 PM
To: Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
Subject: CDC blocked FDA official from premises

CDC blocked FDA official from premises

By Dan Diamond

03/03/2020 03:32 PM EST

In a sign of growing tension among the Trump administration's health agencies, officials are expressing frustration that a top scientist was initially rebuffed when attempting to visit the CDC in Atlanta last month to help coordinate the government's stalled response to coronavirus testing, two individuals with knowledge of the episode told POLITICO.

Timothy Stenzel, who is the director of the FDA's Office of In Vitro Diagnostics and Radiological Health, was made to wait overnight on the weekend of Feb. 22 — as senior health department officials negotiated his access in a series of calls — before CDC granted him permission to be on campus. Stenzel's visit had been expected, the individuals said.

The FDA had dispatched Stenzel to the CDC in an effort to expedite the development of lab tests for the novel coronavirus outbreak. Problems with the CDC-developed test delayed the Trump administration's plan to expand screening for weeks, POLITICO first reported on Feb. 20. A senior HHS official confirmed the episode.

A CDC spokesperson said the delay was because of a scheduling misunderstanding.

"On Saturday, February 22, at about 7 p.m., an FDA employee arrived at CDC Roybal campus in Atlanta, a day before what CDC understood to be his scheduled arrival time. Due to CDC security requirements, he was not allowed on campus that night," the spokesperson said. "On Sunday morning, February 23, as scheduled, CDC staff met the FDA employee and escorted him on campus, in full compliance with standard security processes

required for all individuals whether they are federal employees or other visitors."

Stenzel later found evidence of lab contamination , which he reported to HHS officials and may have contributed to the coronavirus lab test delays and other problems.

The CDC had spent days reassuring HHS leaders that the lab tests were imminent, even as delays prevented their delivery. The delays prevented many Americans, who didn't fit the CDC's strict criteria, from being tested for coronavirus. CDC initially limited testing to people who had recently traveled to China or had close contact with a confirmed case and were also symptomatic.

Health officials have reported more than 100 cases of coronavirus across the United States, with increasing evidence that the virus has been spreading undetected for weeks.

CDC officials have acknowledged the agency's lab tests were suffering flaws that prevented the health department from executing its plan to expand testing across the nation.

"Contamination is one possible explanation but there are others, and I can't comment on what is an ongoing investigation," Nancy Messonnier, director of the CDC's National Center for Immunization and Respiratory Diseases, told reporters on a Tuesday conference call.

HHS has begun an investigation into the possible contamination of coronavirus tests and is asking a team of non-CDC scientists to probe the lab test defect.

Brianna Ehley contributed to this report.

To view online:
https://subscriber.politicopro.com/health-care/article/2020/03/cdc-blocked-fda-official-from-premises-1887592

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 3/3/2020 4:40:38 PM
To: Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]
Subject: RE: Remdesivir -- Proposed NIH and FDA Actions for 6:30pm Lawyer's Call

Thanks for being on top of this!

From: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Sent: Tuesday, March 3, 2020 4:39 PM
To: Stimson, Brian (OS) <Brian.Stimson@hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Giroir, Brett (OS) <Brett.Giroir@hhs.gov>; Valentine, Steven (OS) <Steven.Valentine@hhs.gov>; Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>
Cc: Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>; Mango, Paul (OS) <Paul.Mango@hhs.gov>; Charrow, Robert (OS) <Robert.Charrow@hhs.gov>; Stannard, Paula (OS) <Paula.Stannard@hhs.gov>; Chang, William (OS) <William.Chang@hhs.gov>; Barry, Daniel J (OS) <daniel.barry@hhs.gov>; Strom, John (OS) <John.Strom@hhs.gov>
Subject: RE: Remdesivir -- Proposed NIH and FDA Actions for 6:30pm Lawyer's Call

(b)(5)

From: Stimson, Brian (HHS/OGC) <Brian.Stimson@hhs.gov>
Sent: Tuesday, March 3, 2020 4:31 PM
To: Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Giroir, Brett (OS) <Brett.Giroir@hhs.gov>; Valentine, Steven (OS) <Steven.Valentine@hhs.gov>; Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>
Cc: Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>; Mango, Paul (OS) <Paul.Mango@hhs.gov>; Charrow, Robert (OS) <Robert.Charrow@hhs.gov>; Stannard, Paula (OS) <Paula.Stannard@hhs.gov>; Chang, William (OS) <William.Chang@hhs.gov>; Barry, Daniel J (OS) <daniel.barry@hhs.gov>; Strom, John (OS) <John.Strom@hhs.gov>
Subject: Remdesivir -- Proposed NIH and FDA Actions for 6:30pm Lawyer's Call
Importance: High

All,

(b)(5)

Thanks,

Brian

Principal Deputy General Counsel
U.S. Department of Health and Human Services
200 Independence Ave., SW
Humphrey Bldg., Room 713F
Washington, DC 20201
(O) (202) 690-7741

(C) (b)(6)
Email: Brian.Stimson@hhs.gov

From: Davis, May M. EOP/WHO (b)(6)
Sent: Tuesday, March 3, 2020 12:29 PM
To: Davis, May M. EOP/WHO (b)(6) Hart, Rosemary <rosemary.hart@usdoj.gov>; Charles.Steele2@treasury.gov; Gannon, Curtis E. (OLC) <Curtis.E.Gannon@usdoj.gov>; MWalsh@doc.gov; DeBacker, Devin A. EOP/WHO (b)(6) Heather.Trew@treasury.gov; Allen, Charles A SES OSD OGC (USA) (b)(6); Palomino, Jeffrey G (Jeff) Col USAF OSD OGC (USA) (b)(6); Amin, Stacy (FDA/OC) <Stacy.Amin@fda.hhs.gov>; Moore, Douglas W LTC USARMY OSD OGC (USA) (b)(6); Mirasola, Christopher A (Chris) CIV DLSA (USA) (b)(6); Stimson, Brian (HHS/OGC) <Brian.Stimson@hhs.gov>; Barry, Daniel J (HHS/OGC) <daniel.barry@hhs.gov>; Chang, William (HHS/OGC) <William.Chang@hhs.gov>; Stannard, Paula (HHS/IOS) <Paula.Stannard@hhs.gov>; John.Geresk (b)(6) John.Havranek (b)(6) Brian.Puchalsky (b)(6) Lauren.Sun@treasury.gov; Andrea.Delisi@treasury.gov; Eisenberg, John A. EOP/WHO (b)(6); kyle.r.jacobson.civ (b)(6); DCurtis@doc.gov; JJEST@doc.gov; Whitaker, Henry C. (OLC) <Henry.Whitaker2@usdoj.gov>; BREKKE, IAN (b)(6); Suska, David (OLC) <David.Suska@usdoj.gov>; Parker, Robert (b)(6) Brian.Callanan@treasury.gov; Joseph.Clark2@treasury.gov; Philbin, Patrick F. EOP/WHO (b)(6)
Subject: Lawyers Call: Remdesivir

DRAFT // DELIBERATIVE

(b)(5)

Thanks,

May

May Davis
Associate Counsel to the President
Office of White House Counsel

(b)(6)

From: McWilliams, Carly [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B68C7458214244D08424FD441FEA4FDA-CARLYLE.MCW]
Sent: 3/3/2020 5:05:15 PM
To: Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: hhs request--too late?
Attachments: coronavirus.pdf

I think hhs wanted feedback on this (b)(5) today. Is it too late to have people review? (b)(5)

(b)(5)

Due: ASAP

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 3/3/2020 5:41:25 PM
To: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: FW: UPDATED TP FOR WH PRESS CONFERENCE URGENT REVIEW
Attachments: 20200303HahnTPsforWHTF_OCCcleared_clean no background KL (002) (003)_CD MB 002.docx

Can you pls get these printed for SH?

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Tuesday, March 3, 2020 5:37 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>
Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: RE: UPDATED TP FOR WH PRESS CONFERENCE URGENT REVIEW

Keagan, Anand, Colin—

Cleaned up TPs, with 18ft and page breaks. Thanks

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Tuesday, March 03, 2020 5:31 PM
To: Dennis, Claire <Claire.Dennis@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>
Cc: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: RE: UPDATED TP FOR WH PRESS CONFERENCE URGENT REVIEW

Carly, can you pls clean up and send back? Thanks.

From: Dennis, Claire <Claire.Dennis@fda.hhs.gov>
Sent: Tuesday, March 3, 2020 5:28 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>
Cc: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: RE: UPDATED TP FOR WH PRESS CONFERENCE URGENT REVIEW

OCC's revisions are attached. Please reach out if there are any questions. Thanks!

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Tuesday, March 3, 2020 4:43 PM
To: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; Dennis, Claire

<Claire.Dennis@fda.hhs.gov>; Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
Cc: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: UPDATED TP FOR WH PRESS CONFERENCE URGENT REVIEW

Sorry – need you all to clear again, **(b)(5)** He is giving this at press conference at 6. I need to get it printed and to him? Any problems?

From: Lenihan, Keagan
Sent: Tuesday, March 3, 2020 4:02 PM
To: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
Cc: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: UPDATED TP FOR WH PRESS CONFERENCE URGENT REVIEW

Here you go.

From: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Sent: Tuesday, March 3, 2020 3:39 PM
To: Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
Cc: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: UPDATED TP FOR WH PRESS CONFERENCE URGENT REVIEW

Sorry updated again!!!

From: McWilliams, Carly
Sent: Tuesday, March 3, 2020 3:37 PM
To: Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
Cc: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Lenihan, Keagan (Keagan.Lenihan@fda.hhs.gov); Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: UPDATED TP FOR WH PRESS CONFERENCE URGENT REVIEW
Importance: High

So sorry, but we have some additions to the talking points that need to be re-cleared. Can occ review ASAP?

Sent: 3/3/2020 6:03:17 PM
To: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
CC: Beers, Donald [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d079bf15a01744bd94687d6718ca4c42-Donald.Beer]; Busch, Marcy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec4ef9f06a684cafbe4307486233609e-Marcy.Busch]; Dennis, Claire [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2f0121bf65bf48adb8077a2c49324223-Claire.Denn]
Subject: RE: At Novel Coronavirus Briefing, Governor Cuomo Announces State is Partnering with Hospitals to Expand Novel Coronavirus Testing Capacity in New York

(b)(5)

From: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Sent: Tuesday, March 3, 2020 6:01 PM
To: Raza, Mark <Mark.Raza@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
Cc: Beers, Donald <Donald.Beers@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>
Subject: RE: At Novel Coronavirus Briefing, Governor Cuomo Announces State is Partnering with Hospitals to Expand Novel Coronavirus Testing Capacity in New York

Adding Ellen.

(b)(5)

From: Raza, Mark <Mark.Raza@fda.hhs.gov>
Date: March 3, 2020 at 5:56:40 PM EST
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Amin, Stacy <Stacy.Amin@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Cc: Beers, Donald <Donald.Beers@fda.hhs.gov>, Busch, Marcy <Marcy.Busch@fda.hhs.gov>, Dennis, Claire <Claire.Dennis@fda.hhs.gov>
Subject: RE: At Novel Coronavirus Briefing, Governor Cuomo Announces State is Partnering with Hospitals to Expand Novel Coronavirus Testing Capacity in New York

(b)(5)

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Tuesday, March 3, 2020 5:40 PM
To: Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Cc: Raza, Mark <Mark.Raza@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>

Subject: FW: At Novel Coronavirus Briefing, Governor Cuomo Announces State is Partnering with Hospitals to Expand Novel Coronavirus Testing Capacity in New York

Here is the email chain. Hahn has a call with him at 7:10, would appreciate CDRH and OCCs thoughts beforehand.

From: Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
Sent: Tuesday, March 3, 2020 11:44 AM
To: Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Roth, Kristian <Kristian.Roth@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
Subject: RE: At Novel Coronavirus Briefing, Governor Cuomo Announces State is Partnering with Hospitals to Expand Novel Coronavirus Testing Capacity in New York

We will have to discuss within CDRH

Kim Sapsford-Medintz, Ph.D.
MCM EUA Team Lead

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov

From: Busch, Marcy <Marcy.Busch@fda.hhs.gov>
Sent: Tuesday, March 03, 2020 10:48 AM
To: Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Roth, Kristian <Kristian.Roth@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
Subject: RE: At Novel Coronavirus Briefing, Governor Cuomo Announces State is Partnering with Hospitals to Expand Novel Coronavirus Testing Capacity in New York

(b)(5)

From: Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
Sent: Tuesday, March 3, 2020 10:28 AM
To: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Roth, Kristian <Kristian.Roth@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>
Subject: RE: At Novel Coronavirus Briefing, Governor Cuomo Announces State is Partnering with Hospitals to Expand Novel Coronavirus Testing Capacity in New York

(b)(5)

Thanks,

Jennifer

From: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Sent: Tuesday, March 03, 2020 10:15 AM
To: Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Roth, Kristian <Kristian.Roth@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
Subject: RE: At Novel Coronavirus Briefing, Governor Cuomo Announces State is Partnering with Hospitals to Expand Novel Coronavirus Testing Capacity in New York

Adding Jennifer… **(b)(5)**
(b)(5)

From: Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
Sent: Tuesday, March 3, 2020 10:08 AM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Roth, Kristian <Kristian.Roth@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
Subject: RE: At Novel Coronavirus Briefing, Governor Cuomo Announces State is Partnering with Hospitals to Expand Novel Coronavirus Testing Capacity in New York

Marcy or Liz? – in the letter **(b)(5)**

(b)(5)

Kim Sapsford-Medintz, Ph.D.
MCM EUA Team Lead

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Tuesday, March 03, 2020 10:07 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Roth, Kristian <Kristian.Roth@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
Subject: RE: At Novel Coronavirus Briefing, Governor Cuomo Announces State is Partnering with Hospitals to Expand Novel Coronavirus Testing Capacity in New York

Adding Liz for engagement – thanks.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Tuesday, March 3, 2020 10:05 AM
To: Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Roth, Kristian <Kristian.Roth@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: Re: At Novel Coronavirus Briefing, Governor Cuomo Announces State is Partnering with Hospitals to Expand Novel Coronavirus Testing Capacity in New York

Let me know pls.

Sent from my iPhone

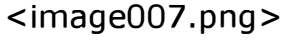
On Mar 3, 2020, at 9:45 AM, Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov> wrote:

(b)(5)

Kim Sapsford-Medintz, Ph.D.
MCM EUA Team Lead

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov



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<image010.jpg>

<image011.jpg>

<image012.jpg>

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Tuesday, March 03, 2020 9:37 AM
To: Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Roth, Kristian <Kristian.Roth@fda.hhs.gov>
Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: At Novel Coronavirus Briefing, Governor Cuomo Announces State is Partnering with Hospitals to Expand Novel Coronavirus Testing Capacity in New York

https://www.governor.ny.gov/news/novel-coronavirus-briefing-governor-cuomo-announces-state-partnering-hospitals-expand-novel

During a briefing on the novel Coronavirus at his office in midtown Manhattan, Governor Andrew M. Cuomo today announced the world-renowned Wadsworth Center — the research-intensive public health laboratory housed within the State Department of Health — is partnering with hospitals to expand surge testing capacity to 1,000 tests per day statewide for the novel coronavirus. The Wadsworth Center will provide these hospitals with instructions on how to replicate the State's test, as well as help them purchase some of the equipment necessary to develop and validate the test.

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 3/3/2020 6:59:02 PM
To: McGowan, Robert K (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e6175b088b1d49a4bfa2de3862800d4a-HHS-omc2-cd]
CC: Campbell, Amanda (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a88bfd63aaaf4a5398fddd4e28849e43-HHS-ons3-cd]
Subject: FW: Inovalon **(b)(4)**
Attachments: INOV **(b)(4)** v1.0.0 (PDF).pdf

Below are the folks I told you about this weekend. They are eager to speak to you.

(b)(5)

Thanks!

From: Matt Brow <mbrow@inovalon.com>
Sent: Tuesday, March 3, 2020 6:51 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: Inovalon **(b)(4)**

Keagan,

Thanks for your time and effort to connect our CE Keith D urdavy ,MD **(b)(6)** **(b)(6)** with someone senior at CDC regarding our ability **(b)(4)**

Attached is a deck to support the discussion. I can only imagine how busy everyone there is at present, so please know that the key slides are numbers 3, 4, and 5. The remaining slides are for more detail and background. If they are interested, we would love to help.

Thanks,

Matt

(b)(4)

(b)(4)

Matt Brow | President & General Manager - Pharmacy, Life Sciences & Advisory
Inovalon

4321 Collington Road | Bowie, MD 20716
P. (301) 809-4000 **ext.** (b)(6) | **E.** mbrow@inovalon.com

Healthcare Empowered® / Learn more.

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From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 3/3/2020 7:18:29 PM
To: Matt Brow [mbrow@inovalon.com]
Subject: RE: Inovalon (b)(4)

Forwarded it to them!

From: Matt Brow <mbrow@inovalon.com>
Sent: Tuesday, March 3, 2020 6:51 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: Inovalon National COVID-19 Data Lake

Keagan,

Thanks for your time and effort to connect our CEO Keith Dunleavy, MD (b)(6) (b)(6) with someone senior at CDC regarding our ability (b)(4)

Attached is a deck to support the discussion. I can only imagine how busy everyone there is at present, so please know that the key slides are numbers 3, 4, and 5. The remaining slides are for more detail and background. If they are interested, we would love to help.

Thanks,

Matt

(b)(4)

Matt Brow | President & General Manager - Pharmacy, Life Sciences & Advisory
Inovalon

4321 Collington Road | Bowie, MD 20716
P. (301) 809-4000 **ext.** (b)(6) | **E.** mbrow@inovalon.com

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www.inovalon.com

Sent: 3/3/2020 7:44:24 PM
To: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]
Subject: RE: QC IDT test update

Thanks.

-----Original Message-----
From: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Sent: Tuesday, March 3, 2020 7:43 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: RE: QC IDT test update

In speaking with Ellen Flannery after she spoke with Mark, the agreement may be okay but the FDA wouldn't be a signatory to it. (b)(5) (b)(5) (b)(5) That said, Ellen and Mark are continuing to discuss.

-----Original Message-----
From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Tuesday, March 3, 2020 7:27 PM
To: Hahn, Stephen <SH1@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: FW: QC IDT test update

FYI team, (b)(5)

-----Original Message-----
From: Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>
Sent: Tuesday, March 3, 2020 6:42 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Redfield, Robert R (CDC) <olx1@cdc.gov>; McGowan, Robert K (CDC) <omc2@cdc.gov>; Giroir, Brett (OS) <Brett.Giroir@hhs.gov>
Subject: QC IDT test update

Hi Keagan,

CDC drafted an agreement to be signed by CDC, the commercial manufacturers, and possibly FDA, to allow the commercial companies to use CDC's EUA to manufacture CDC's coronavirus assay reagents/kit and distribute to commercial labs for diagnostic testing. The essential purpose of the agreement is to assure high quality testing happens by among other things having the companies provide training and helpdesk access to the labs. The expectation is that the commercial companies will separately seek their own EUAs which would take the place of this process. In the agreement, CDC would also assist the companies with their EUA applications by allowing right of reference to the CDC EUA request in their own EUA applications. The draft agreement is being reviewed this evening by Mark Raza, Deputy Chief Counsel for FDA's Office of Chief Counsel, and Marcy Busch, FDA attorney who handles EUA matters.

We have completed QC of the first lot we received from IDT and would like to include the agreement when IDT is notified the QC is complete.

Will you provide an update to the Commissioner?

Thank you,
Sherri

-----Original Message-----
From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Tuesday, March 3, 2020 10:50 AM
To: Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>
Subject: Re: QC IDT tests

Thanks Sherri! Appreciate your help.

Sent from my iPhone

> On Mar 3, 2020, at 10:49 AM, Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov> wrote:
>
> Hi Keagan -
> They gave us one lot and we will have it done today.
> They are sending more, arrival tomorrow at the earliest.
> Thank you
>
> -----Original Message-----
> From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
> Sent: Tuesday, March 3, 2020 10:13 AM
> To: Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>
> Subject: QC IDT tests
>
> Hi Sherri - (b)(5) he said to confirm with you. Is that your understanding?
>
> Thanks,
> Keagan
>
> Sent from my iPhone

From: Roth, Lauren [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=52BFD08572694F269A20C508F3C04A03-LAUREN.ROTH]
Sent: 3/3/2020 8:07:59 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: RE: CMS/FDA: Questions regarding FDA plan for COVID-19 Testing

Thanks – will do.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Tuesday, March 3, 2020 7:44 PM
To: Roth, Lauren <Lauren.Roth@fda.hhs.gov>
Subject: RE: CMS/FDA: Questions regarding FDA plan for COVID-19 Testing

Ask Michael Mair and Denise running the IMG to see if they can direct or give you contact?

From: Roth, Lauren <Lauren.Roth@fda.hhs.gov>
Sent: Tuesday, March 3, 2020 7:35 PM
To: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Ross, Aftin <Aftin.Ross@fda.hhs.gov>
Cc: Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: CMS/FDA: Questions regarding FDA plan for COVID-19 Testing

Seems like several questions are best answered by CMS. Trying to think about the best way to get them answered… is there a covid-19 working group at HHS that should help triage? Or a main point of contact at CMS? I don't know if our regular HHS desk officer, Kat, has been plugged into that effort, which is why she sent the questions to us.

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Sent: Tuesday, March 3, 2020 7:22 PM
To: Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Ross, Aftin <Aftin.Ross@fda.hhs.gov>
Cc: Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: CMS/FDA: Questions regarding FDA plan for COVID-19 Testing

My thoughts, see attached.

Best,
Tim

Timothy T. Stenzel, MD, PhD
Director, OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality

Center for Devices and Radiological Health
U.S. Food and Drug Administration
Timothy.Stenzel@fda.hhs.gov

Jennifer Campbell
Administrative Assistant

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

From: Roth, Lauren <Lauren.Roth@fda.hhs.gov>
Sent: Tuesday, March 3, 2020 7:11 PM
To: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Ross, Aftin <Aftin.Ross@fda.hhs.gov>
Cc: Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: FW: CMS/FDA: Questions regarding FDA plan for COVID-19 Testing

All,

We received the following email from OIRA, with questions on our original "plan" document. My best guess is that these questions are stragglers (given that they are reflected on the plan and not the guidance itself), but HHS has asked us to respond by tomorrow.

(b)(5)

Let me know if you would like to discuss.

Thanks,
Lauren

From: Malliou, Ekaterini (OS/IOS) <Ekaterini.Malliou@hhs.gov>
Sent: Tuesday, March 3, 2020 1:06 PM
To: Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Cohen, Kenneth <Kenneth.Cohen@fda.hhs.gov>; OC OPPB OP RPMS <OC●PPB●PRPMS@fda.hhs.gov>
Subject: FW: CMS/FDA: Questions regarding FDA plan for COVID-19 Testing

Hi Lauren,

Please find attached some follow-up questions from the Medicare team of OIRA. If FDA could provide bubble responses on the attached by tomorrow, that would be great.

Thank you

From: Hirsch, Quinn N. EOP/OMB (b)(6)
Sent: Tuesday, March 3, 2020 12:57 PM
To: Malliou, Ekaterini (OS/IOS) <Ekaterini.Malliou@hhs.gov>
Cc: Fischbach, Aaron (OS/IOS) <Aaron.Fischbach@hhs.gov>
Subject: CMS/FDA: Questions regarding FDA plan for COVID-19 Testing

Hi Kat,

(b)(5)

Thanks,
Q

Quinn N. Hirsch, MPH
Office of Information and Regulatory Affairs
(b)(6)
(she/her/hers)

From: Berger, Sherri (CDC/OCOO/OD) [sob8@cdc.gov]
Sent: 3/4/2020 6:00:21 AM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; McGowan, Robert K (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e6175b088b1d49a4bfa2de3862800d4a-HHS-omc2-cd]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]
Subject: RE: QC IDT test update
Attachments: Coronavirus Assay Agreement March 3 2020 final.docx

Morning -
Attached is the final of the agreement to allow commercial use of CDC's EUA-authorized coronavirus assay. FDA's Office of Chief Counsel reviewed it before it was finalized.
Thank you,
Sherri

-----Original Message-----
From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Tuesday, March 3, 2020 7:27 PM
To: Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>
Cc: Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>; McGowan, Robert (Kyle) (CDC/OD/OCS) <omc2@cdc.gov>; Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Subject: RE: (b)(5) update

Thank you Sherri - will send to him now.

-----Original Message-----
From: Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>
Sent: Tuesday, March 3, 2020 6:42 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Redfield, Robert R (CDC) <olx1@cdc.gov>; McGowan, Robert K (CDC) <omc2@cdc.gov>; Giroir, Brett (OS) <Brett.Giroir@hhs.gov>
Subject: (b)(5) update

Hi Keagan,

(b)(5)

Will you provide an update to the Commissioner?

Thank you,
Sherri

-----Original Message-----
From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Tuesday, March 3, 2020 10:50 AM
To: Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>
Subject: Re: (b)(5)

Thanks Sherri! Appreciate your help.

Sent from my iPhone

> On Mar 3, 2020, at 10:49 AM, Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov> wrote:
>
> Hi Keagan -

(b)(5)

> Thank you
>
> -----Original Message-----
> From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
> Sent: Tuesday, March 3, 2020 10:13 AM
> To: Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>
> Subject: (b)(5)
>
> Hi Sherri - Dr Redfield just let me know CDC would (b)(5) y, he said to confirm with you. Is that your understanding?
>
> Thanks,
> Keagan
>
> Sent from my iPhone

From: Berger, Sherri (CDC/OCOO/OD) [sob8@cdc.gov]
Sent: 3/4/2020 9:21:26 AM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; McGowan, Robert K (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e6175b088b1d49a4bfa2de3862800d4a-HHS-omc2-cd]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]
Subject: RE: (b)(5) update

Update: (b)(5)
(b)(5)

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, March 4, 2020 7:41 AM
To: Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>
Cc: Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>; McGowan, Robert (Kyle) (CDC/OD/OCS) <omc2@cdc.gov>; Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Subject: Re: (b)(5) update

Correct. Thanks Sherri. Appreciate your help!

Sent from my iPhone

On Mar 4, 2020, at 7:35 AM, Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov> wrote:

Good morning (b)(5)
(b)(5) Thanks

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, March 4, 2020 7:22:38 AM
To: Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>
Cc: Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>; McGowan, Robert (Kyle) (CDC/OD/OCS) <omc2@cdc.gov>; Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Subject: Re: (b)(5) update

Thanks. (b)(5)

Sent from my iPhone

> On Mar 4, 2020, at 6:00 AM, Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov> wrote:
>
> Morning -
> Attached is the final of the agreement to allow commercial use of CDC's EUA-authorized coronavirus assay. FDA's Office of Chief Counsel reviewed it before it was finalized.
> Thank you,
> Sherri
>

> -----Original Message-----
> From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
> Sent: Tuesday, March 3, 2020 7:27 PM
> To: Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>
> Cc: Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>; McGowan, Robert (Kyle) (CDC/OD/OCS) <omc2@cdc.gov>; Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
> Subject: RE: (b)(5) update
>
> Thank you Sherri - will send to him now.
>
> -----Original Message-----
> From: Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>
> Sent: Tuesday, March 3, 2020 6:42 PM
> To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
> Cc: Redfield, Robert R (CDC) <olx1@cdc.gov>; McGowan, Robert K (CDC) <omc2@cdc.gov>; Giroir, Brett (OS) <Brett.Giroir@hhs.gov>
> Subject: (b)(5) update
>
> Hi Keagan,
>

(b)(5)

>
> Will you provide an update to the Commissioner?
>
> Thank you,
> Sherri
>
> -----Original Message-----
> From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
> Sent: Tuesday, March 3, 2020 10:50 AM
> To: Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>
> Subject: Re: (b)(5)
>
> Thanks Sherri! Appreciate your help.
>
> Sent from my iPhone
>
>> On Mar 3, 2020, at 10:49 AM, Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov> wrote:
>>
>> Hi Keagan -

(b)(5)

>> Thank you

>>
>> -----Original Message-----
>> From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
>> Sent: Tuesday, March 3, 2020 10:13 AM
>> To: Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>
>> Subject: (b)(5)
>>
>> Hi Sherri - Dr Redfield just let me know CDC would (b)(5) he said to confirm with you. Is that your understanding?
>>
>> Thanks,
>> Keagan
>>
>> Sent from my iPhone
> <Coronavirus Assay Agreement March 3 2020 final.docx>

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 3/4/2020 11:57:43 AM
To: Kimberly, Brad [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08bc909ed76d49868a5ff92c3c70fb72-Bradley.Kim]
CC: Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Lynch, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d24ee4a4fc6241f48110d6b35e6704ed-Sarah.Lynch]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Meyer, Lyndsay [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00176f0991c84d34b3927bfb410d5483-Lyndsay.Mey]; Stark, Angela [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d04b10a5e0ec40ffa2ebfedd711e83af-Angela.Star]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]
Subject: RE: KEAGAN:: HELP Testimony

Think it is fine. Thanks.

From: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>
Sent: Wednesday, March 4, 2020 11:48 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Meyer, Lyndsay <Lyndsay.Meyer@fda.hhs.gov>; Stark, Angela <Angela.Stark@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: KEAGAN:: HELP Testimony

Good morning, Keagan. Just following up per Dr. Hahn's note. Is this language below correct on tests?

Brad Kimberly
Director, Social Media

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-1002 | [redacted](b)(6)
brad.kimberly@fda.hhs.gov

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Wednesday, March 4, 2020 8:46 AM
To: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Thorpe, Valarie <Valarie.Thorpe@fda.hhs.gov>; Meyer, Lyndsay <Lyndsay.Meyer@fda.hhs.gov>; Stark, Angela <Angela.Stark@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise

<Denise.Hinton@fda.hhs.gov>
Subject: Re: TWEETS for REVIEW: HELP Testimony // Feed Your Mind

Look good. Keagan, **(b)(5)**
S

Sent from my iPad

On Mar 4, 2020, at 8:25 AM, Kimberly, Brad <Brad.Kimberly@fda.hhs.gov> wrote:

Good morning… two threads for your review this AM. Thanks! --Brad

===

HELP Testimony

1. Yesterday, I had the opportunity to update the senate HELP committee about FDA's latest actions addressing #COVID19 outbreak, including the availability of diagnostics as industry ramps up production. **[VIDEO CLIP]**

2. In addition to CDC continuing distribution of their test, we have heard from a commercial manufacturer that they will be ramping up production of CDC's authorized test & produce more than 1 million tests by the end of this week. https://www.fda.gov/news-events/congressional-testimony/hearing-emerging-disease-threat-how-us-responding-covid-19-novel-coronavirus-03032020

3. Going forward, this manufacturer expects to produce significantly more tests.

Feed Your Mind

1. Excited to launch #FeedYourMind today with @USDA & @EPA, to help you better understand everyday foods created with genetic engineering (also called GMOs). **[hyperlink][image]**

2. Genetic engineering has created new plants that are resistant to insects and diseases, led to products with improved nutritional profiles & certain produce that don't brown/bruise as easily.

Brad Kimberly
Director, Social Media

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-1002 | **(b)(6)**
brad.kimberly@fda.hhs.gov

<image001.png>

<image002.jpg>

<image003.jpg>

<image004.jpg>

<image005.jpg>

<image006.jpg>

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 3/4/2020 4:06:21 PM
To: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: FW: WHTF BRIEFING MATERIALS-INTERNAL CONFIDENTIAL DELIBERATIVE
Attachments: WHTF Briefing 03.04.2020 COMPILED.docx

I am not comfortable sending this to Ian for him to print with all the CCI. Thoughts?

From: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Sent: Wednesday, March 4, 2020 3:28 PM
To: Rom, Colin <Colin.Rom@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>
Subject: WHTF BRIEFING MATERIALS-INTERNAL CONFIDENTIAL DELIBERATIVE

Attached is the latest for Dr. Hahn's briefing. Based on agenda it seems FDA doesn't have anything to present.

Reminder that this does contain CCI that should not be shared. Stephanie is separately working on talking points for the press briefing after and we will send once it is cleared.

From: Helmanis, Lisa M [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4345183932AA42A99C9ADB79DFC1BA4B-LHELMANI]
Sent: 3/4/2020 4:36:42 PM
To: Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Boon, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=11917eb34d5445c3802eef2a3999e2e3-Caitlin.Boo]; Cohen, Kenneth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44f565b739ea4879bdc516caf2e136bc-Kenneth.Coh]; Dickinson, Elizabeth (FDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05cb143d66ed470ebe4dba5c54a88074-EDickins]; Dupont, Jarilyn [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce4025bc43cc4505b2f29f2de33b7b36-JDUPONT]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Roth, Lauren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52bfd08572694f269a20c508f3c04a03-Lauren.Roth]; Schiller, Lowell [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77949b06919e4f91aa788e9a616c50c7-Lowell.Schi]; Tobias, Lindsay [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a4766773c717470bbc55d204b5f067b2-Lindsay.Sto]; McWilliams, Carly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]; O'Neill, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9a75446cda1244b3aa59af3b53cc2d4d-ONEILLJ]; Varnado, Martina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad1d1bc50f7941718b0feeb194cbaff1-Martina.Var]; Wiley, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=db729bc60c0140fd968242e8c817d38c-WILEYE]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Jenkins, Yolanda [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f074311e73aa4061a2dfee3827751964-Yolanda.Jen]; Alexander, Nicholas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08e1fd211c4a4c96be426218bd0711e9-Nicholas.Al]; OC ECON Supervisors [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e72d55228304cc8bf52e3c43ce1ed79-OC OPL ECON]
CC: OC OPPB OP RPMS [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f2e26c08c0a24020b0200a64ba43a096-OC OPPB OP]; Pendleton, Brian L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd2fc0664bb7423da4912e43c0ad3daf-PENDLETONB]; Arellano, Shena [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d53be8e831b43bab84929891f8a1009-Shena.Arell]; Croce, Teresa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3abf9312c3984913bde628d5e6fa48d1-Teresa.Croc]; Finegan, Julie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5cc0c98f656543caa97ab2ca61c98cec-Julie.Fineg]; Hurwitz, Zahava [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4082a16a8a814b7bb489ccf825871a93-Zahava.Hurw]; Flamm, Eric [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=72d91495273741e0ae2b7c6cf01b9e3c-EFLAMM]; Meyer, Raymond [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=09b2e97a15624941aef7b5b4ae5c12de-MEYERR]
Subject: RE: FDA's Week Ahead Report--SENT TO HHS March 5, 2020
Attachments: WAR FINAL 3-5-20.docx

Attached is FDA's WAR for this week. L

Lisa Helmanis
Senior Advisor
Office of Policy
U.S. Food and Drug Administration
301-796-9135
Lisa.Helmanis@fda.hhs.gov

From: Caccomo, Stephanie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=950C32CEBC4B4F80B302C50CF31C8524-STEPHANIE.C]
Sent: 3/4/2020 5:35:02 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: RE: LANGUAGE

I would say the answer is:

(b)(5)

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, March 04, 2020 5:31 PM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: LANGUAGE

(b)(5)

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Wednesday, March 4, 2020 5:29 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>

Cc: Busch, Marcy <Marcy.Busch@fda.hhs.gov>
Subject: LANGUAGE

(b)(5)

(b)(5)

Stephanie Caccomo
Press Officer

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

From: Caccomo, Stephanie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=950C32CEBC4B4F80B302C50CF31C8524-STEPHANIE.C]
Sent: 3/4/2020 6:21:28 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
CC: Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]
Subject: RE: LANGUAGE

Will make sure to note it is to provide clarity.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, March 04, 2020 6:13 PM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Subject: RE: LANGUAGE

(b)(5)

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Wednesday, March 4, 2020 6:11 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Subject: RE: LANGUAGE

Do you mind if I start using part of below for media inquiries, can provide on background? I continue pinged on what VP/Azar said. I can flag for HHS for their concurrence.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, March 04, 2020 5:31 PM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: LANGUAGE

(b)(5)

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Wednesday, March 4, 2020 5:29 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Cc: Busch, Marcy <Marcy.Busch@fda.hhs.gov>
Subject: LANGUAGE

(b)(5)

(b)(5)

(b)(5)

Stephanie Caccomo
Press Officer

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

From: Rebello, Heidi [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2834CE193CA949799EF063E34A2CFA0B-HEIDI.REBEL]
Sent: 3/4/2020 8:02:31 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: RE: proactive inspection statement
Attachments: inspection statemnt 3.4.20 445pm.docx

This needed some work. See attached. Happy to clean up and send to OEA. Let me know what you prefer.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, March 4, 2020 6:23 PM
To: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: FW: proactive inspection statement

Can you review first, pls?

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Wednesday, March 4, 2020 6:20 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Subject: proactive inspection statement

CLOSE HOLD, DRAFT, DELIBERATIVE

Keagan-
For consideration, a draft statement on foreign inspections. I would recommend **(b)(5)**

(b)(5)

Ideally, we would issue this tomorrow.

Let us know if you concur and we can put above into clearance.

From: Caccomo, Stephanie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=950C32CEBC4B4F80B302C50CF31C8524-STEPHANIE.C]
Sent: 3/4/2020 8:33:28 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]
Subject: RE: proactive inspection statement
Attachments: inspection statemnt 3.4.20 445pm.docx

Just putting this at top of your inbox for consideration.

From: Caccomo, Stephanie
Sent: Wednesday, March 04, 2020 6:20 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Subject: proactive inspection statement

CLOSE HOLD, DRAFT, DELIBERATIVE

Keagan-
For consideration, a draft statement on foreign inspections. I would recommend **(b)(5)**

(b)(5)

Ideally, we would issue this tomorrow.

Let us know if you concur and we can put above into clearance.

From: HHS Office of Public Affairs [hhsopa@hhs.gov]
Sent: 3/4/2020 11:16:51 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: HHS to procure N95 respirators to support healthcare workers in COVID-19 outbreaks

News Release

U.S. Department of Health and Human Services

202-205-8117
asprmedia@hhs.gov
www.hhs.gov/news
Twitter @SpoxHHS

FOR IMMEDIATE RELEASE
Wednesday, March 4, 2020

HHS to procure N95 respirators to support healthcare workers in COVID-19 outbreaks

As part of the government-wide efforts to respond to the global outbreak of the 2019 novel coronavirus infection (COVID-19), the U.S. Department of Health and Human Services intends to purchase 500 million N95 respirators over the next 18 months for the Strategic National Stockpile (SNS).

Through guaranteed orders, this acquisition encourages manufacturers to immediately increase production of N95s for use by health care professionals. These guaranteed orders offer reassurance to manufacturers that they will not be left with excess supplies if private sector orders are cancelled once the COVID-19 response subsides. Manufacturers typically avoid ramping up production without such a guarantee.

Private sector orders would be filled before the SNS order. The SNS currently holds millions of N95 respirators that may be used in accordance with the Strategies for Optimizing the Supply of N95 Respirators guidance released by the Centers for Disease Control and Prevention (CDC). In an emergency, the SNS could disperse the existing products as well as any available quantity obtained through future contracts to areas in need as requested by state health officials.

This SNS acquisition of N95 respirators is part of a broader effort to maximize the availability of personal protective equipment for healthcare workers who are on the front lines in mitigating community spread of COVID-19.

In addition, on March 2, the U.S. Food and Drug Administration granted a request from the CDC for an emergency use authorization (EUA) to allow health care personnel to use certain National Institute for Occupational Safety and Health (NIOSH) approved respirators - not currently regulated by the FDA - during the coronavirus (COVID-19) outbreak.

Together, the SNS acquisition and the FDA and CDC action will help maximize the number of respirators available to meet the needs of the U.S. health care system.

No proposals have been received and no contracts have been executed to date. The solicitation for proposals

opened March 4; proposals must be received by March 18, 2020.

N95 respirators are respiratory protective devices designed to achieve a very close facial fit and very efficient filtration of airborne particles. The 'N95' designation means that when subjected to careful testing, the respirator blocks at least 95 percent of very small (0.3 micron) test particles.

The Strategic National Stockpile is the nation's largest supply of life-saving pharmaceuticals and medical supplies for use in a public health emergency severe enough to cause local supplies to run out. When state, local, tribal, and territorial responders request federal assistance to support their response efforts, the stockpile ensures that the right medicines and supplies get to those who need them most during an emergency. Organized for scalable response to a variety of public health threats, this repository contains enough supplies to respond to multiple large-scale emergencies simultaneously.

###

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From: Paulos, Lauren [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5DFB1DAAC9C14AAB8649E6C66087F956-AUBRIELAURE]
Sent: 3/5/2020 10:04:55 AM
To: Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Pence, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3f21407a02d44cd4901bcce26f9b3074-HHS-Laura.P]; Brand, Anstice M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4769e64323944161a994c2086b645f4c-HHS-atb6-cd]; Bigham, Jane E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58d05801bf1d46d883ff225114683c3a-HHS-vsy0-cd]; Tourk, Nancy R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdb086e24ad14975bcc32097b68271fb-HHS-wxk8-cd]; Greaser, Jennifer L (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6007c3bba4a1420bb704298c5e49f29b-HHS-cbx5-cd]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Oxner, Julie (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08b67fbda196471fa5ab3b113e264438-HHS-Julie.O]; Berger, Sherri (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b1ac8b1b9ba4abe8ef7b1d7abcd8d71-HHS-sob8-cd]
CC: Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Morse, Sara N (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4080ee237c084683ae674366e5cde21d-HHS-Sara.Mo]
Subject: RE: It's Grace from Lucas' computer

Including edits here in brackets. On bullet 3 adding information below that we can share:

As of Saturday, February 29th, 102 developers had requested the EUA template (now the template is public, so we do not have a way to track how many more are using it).

- We currently have 22 developers in the door, working with us.
- We had a webinar for developers this past Monday, March 1st, where almost 1200 individuals called in. We will have a follow up to this webinar on Friday (March 6th) to answer additional technical questions from developers.

Bucket 1:

By end of the week, state and local public health labs will have the ability to test up to 75,000 patients for the coronavirus

Bucket 2:

CDC [IDT]is shipping 2,500 lab kits by the end of the week, and each kit can test [approximately] 500 samples, or [200 (2 samples per patient with 20% controls)] patients. These 2,500 kits are being [shipped/sold] to commercial [hospitals] and academic labs [if requested/purchased.] Once these 2,500 kits are in place and validated by the lab running the kit, those kits can test 1,000,000 samples, or [Around 400,000] patients.

Bucket 3:

FDA is working with over 60 commercial and academic labs across the country who want to develop and use their own test to detect coronavirus. FDA issued a press release and guidance Saturday, February 29, announcing that commercial and academic labs can being using their tests once the test is validated by commercial or academic lab running such test, as long as they submit the information to FDA within 15 days of validation.

From: Gross, Karas <Karas.Gross@fda.hhs.gov>
Date: March 5, 2020 at 9:54:00 AM EST
To: Pence, Laura (OS) <Laura.Pence@hhs.gov>, Brand, Anstice M (CDC) <atb6@cdc.gov>, Bigham, Jane E (CDC) <vsy0@cdc.gov>, Tourk, Nancy R (CDC) <wxk8@cdc.gov>, Greaser, Jennifer L (CDC) <cbx5@cdc.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>, Oxner, Julie (OS) <Julie.Oxner@hhs.gov>, Berger, Sherri (CDC) <sob8@cdc.gov>
Cc: Arbes, Sarah C (OS) <Sarah.Arbes@hhs.gov>, Morse, Sara N (OS) <Sara.Morse@hhs.gov>, Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>
Subject: RE: It's Grace from Lucas' computer

Adding Lauren, we're checking our stuff

From: Pence, Laura (HHS/ASL) <Laura.Pence@hhs.gov>
Sent: Thursday, March 5, 2020 9:52 AM
To: Gross, Karas <Karas.Gross@fda.hhs.gov>; Brand, Anstice M (CDC) <atb6@cdc.gov>; Bigham, Jane E (CDC) <vsy0@cdc.gov>; Tourk, Nancy R (CDC) <wxk8@cdc.gov>; Greaser, Jennifer L (CDC) <cbx5@cdc.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>; Oxner, Julie (OS) <Julie.Oxner@hhs.gov>; Berger, Sherri (CDC) <sob8@cdc.gov>
Cc: Arbes, Sarah C (OS) <Sarah.Arbes@hhs.gov>; Morse, Sara N (OS) <Sara.Morse@hhs.gov>
Subject: Fwd: It's Grace from Lucas' computer

Can we get this info checked and filled out this morning? Want to share this info broadly. Mentioned at briefings this morning but would like in writing to be able to get the message out there

Begin forwarded message:

From: "DaPieve, Lucas (Alexander)" <Lucas_DaPieve@alexander.senate.gov>
Date: March 5, 2020 at 9:40:09 AM EST
To: "Pence, Laura (HHS/ASL)" <Laura.Pence@hhs.gov>, "McMillin, Virginia D. EOP/WHO" <Virginia.D.McMillin@who.eop.gov>
Cc: "Pfaff, Melissa (HELP Committee)" <Melissa_Pfaff@help.senate.gov>, "Bell, Kathryn (HELP Committee)" <Kathryn_Bell@help.senate.gov>, "Coulter, Margaret (HELP Committee)" <Margaret_Coulter@help.senate.gov>, "Graham, Grace (HELP Committee)" <Grace_Graham@help.senate.gov>
Subject: It's Grace from Lucas' computer

Hi! Trying to confirm numbers on testing for LA so he can say it right when talking to reporters before votes. Please confirm below is accurate and fill in numbers in brackets if possible. Please get us whatever you can by 11:30.

Thanks!

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By end of the week, state and local public health labs will have the ability to test up to 75,000 patients for the coronavirus

Bucket 2:

CDC is shipping 2,500 lab kits by the end of the week, and each kit can test 500 samples, or [ZYY] patients. These 2,500 kits are being [shipped/made available] to commercial and academic labs [if requested.] Once these 2,500 kits are in place and validated by the lab running the kit, those kits can test 1,000,000 samples, or [ABC] patients.

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From: McWilliams, Carly [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B68C7458214244D08424FD441FEA4FDA-CARLYLE.MCW]
Sent: 3/5/2020 10:42:42 AM
To: Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Kahn, Jeremy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1b98d36d2c1f4ae795140b68de7b37f7-Jeremy.Kahn]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]
Subject: RE: Senate briefing notes

(b)(5)

From: Gross, Karas <Karas.Gross@fda.hhs.gov>
Sent: Thursday, March 5, 2020 10:40 AM
To: Kahn, Jeremy <Jeremy.Kahn@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Subject: RE: Senate briefing notes

House briefing

Walden - need info on diagnostic tests - how many, when available

Azar- 1) CDC shopping capacity to test 7500 people. Those tests do to public health labs for free. 2) IDC selling tests for 400k people to local hospitals etc. ramping up. 3) gigantic commercial lab companies like lab Corp- Saturday we opened door for them to develop tests. They are ramping up. But there will be frustration as this scales up.

Eshoo to Azar - where are diagnostics being shipped to? What is capacity
Giroir- 75k now to public health departments. Then commercial prodiuxtion - IDT - taking orders form hospitals and commercial labs enough for 400k, more so to CA and Wa. By next week there will be millions and will go to normal ordinary ordering for clia highly complex labs.
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How did previous admins refs impact this
Azar - under Obama CDRH put out guidance that they had jurisdiction over lab developed tests as a device. Historically never regulated by FDA. FDA under Obama wanted to. CDRH withdrew G bc outcry, but this is why CDC had to apply to FDA. And why companies found this to be a barrier developing their own. Hahn said they do not have to come in to FDA first.

From: Kahn, Jeremy <Jeremy.Kahn@fda.hhs.gov>
Date: March 5, 2020 at 10:26:06 AM EST
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>, Gross, Karas <Karas.Gross@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Anderson, Erika <Erika.Anderson@fda.hhs.gov>, McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Subject: RE: Senate briefing notes

Also, here is the language DDI is using right now.

Key discussion points:

- Hand sanitizers are marketed under the OTC drug monograph system
- Hand sanitizers marketed under the monograph may include one of 3 active ingredients—ethyl alcohol (alcohol), isopropyl alcohol, or benzalkonium chloride. Additional data are required for all 3 of these active ingredients in order for FDA to make a determination that the active ingredient is Generally Recognized as Safe and Effective (GRASE) under the conditions of the health care antiseptic monograph.
- The indication for these products is for reduction of bacteria on the skin that can potentially cause disease; they are not specifically tested for viruses, and may not make disease specific or antiviral claims
- FDA recommends hand washing with use of hand sanitizer as an alternative when soap and water are not available
- The only NDA approved hand sanitizer is Avagard, which is a combination of chlorhexidine and ethyl alcohol

Jeremy Kahn
Press Officer

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Tel: 301-796-8671
jeremy.kahn@fda.hhs.gov

U.S. FOOD & DRUG ADMINISTRATION

From: Kahn, Jeremy
Sent: Thursday, March 5, 2020 10:02 AM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Subject: RE: Senate briefing notes

Hi all—

Here's some general information on our regulation of hand sanitizers and instructive info for consumers.

FDA works to help ensure that over-the-counter (OTC) hand sanitizers are safe and effective for regular use. Products regulated by FDA must meet the conditions of approval if marketed under a new drug application or, in the case of over-

the-counter (OTC) drugs, such as hand sanitizers, the conditions set forth in relevant FDA regulations. Companies cannot claim on their product labels or promotional materials their products are effective in preventing disease or infection from pathogens such as Coronavirus, Ebola, MRSA, VRE, norovirus, flu, and Candida auris.

Most consumer recommendations come from CDC. Here's the info on our website:
For Consumers: If Soap and Water Are Not Available, Hand Sanitizers May Be a Good Alternative
"Hand sanitizers are an easy, quick alternative when handwashing with plain soap and water isn't convenient or possible. Hand sanitizers often have a form of alcohol, such as ethyl alcohol, as an active ingredient and are used as an antiseptic."

Let me know if you need additional information.

Thanks,
--Jeremy
Jeremy Kahn
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel 301-796-8671
jeremy.kahn@fda.hhs.gov

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Sent: Thursday, March 5, 2020 9:49 AM
To: Gross, Karas <Karas.Gross@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Cc: Kahn, Jeremy <Jeremy.Kahn@fda.hhs.gov>
Subject: RE: Senate briefing notes

Looping in Jeremy to share media responses we've been sharing.

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To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: FW: Senate briefing notes

From: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Sent: Thursday, March 5, 2020 9:24 AM
To: Gross, Karas <Karas.Gross@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Schipper, Jodi <jodi.schipper@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>; Lockeed, Matthew <Matthew.Lockeed@fda.hhs.gov>

Cc: Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>
Subject: Senate briefing notes

Alexander- you should have daily public briefings

Alex- Hahn said 2500 kits w capacity for 1M tests by end of week
shah- idt can send out 2500 kits, each 500, 1M tests AVAILABLE

Alex- be careful, not true that can do 1M tests tomorrow

Shah1 agree, not true

Gillivrand, Murray, a lot of confusion about what patients can expect to access tests

Azar- will be confusing for week for patient experience, will try to put out info on patient physician expectations

Romney - need to be clear on test availability

Murray - schools closing

Portman - **NEEDS PUBLIC INFO ON HAND SANATIZERB- what is fdas position - or he will ask publicly.**

From: McWilliams, Carly [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B68C7458214244D08424FD441FEA4FDA-CARLYLE.MCW]
Sent: 3/5/2020 12:25:30 PM
To: Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Kahn, Jeremy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1b98d36d2c1f4ae795140b68de7b37f7-Jeremy.Kahn]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]
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From: Gross, Karas <Karas.Gross@fda.hhs.gov>
Sent: Thursday, March 05, 2020 9:27 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: FW: Senate briefing notes

From: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Sent: Thursday, March 5, 2020 9:24 AM
To: Gross, Karas <Karas.Gross@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Schipper, Jodi <jodi.schipper@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>; Lockeed, Matthew <Matthew.Lockeed@fda.hhs.gov>

Cc: Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>
Subject: Senate briefing notes

Alexander- you should have daily public briefings

Alex- Hahn said 2500 kits w capacity for 1M tests by end of week
shah- idt can send out 2500 kits, each 500, 1M tests AVAILABLE

Alex- be careful, not true that can do 1M tests tomorrow

Shah1 agree, not true

Gillivrand, Murray, a lot of confusion about what patients can expect to access tests

Azar- will be confusing for week for patient experience, will try to put out info on patient physician expectations

Romney - need to be clear on test availability

Murray - schools closing

Portman - **NEEDS PUBLIC INFO ON HAND SANATIZERB- what is fdas position - or he will ask publicly.**

From: Courtney, Brooke [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=261A2A3791E24E19B095AC0172485EBD-BROOKE.COUR]
Sent: 3/5/2020 12:47:33 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: Re: RFI to ASPR

Yes, I sent you a message explaining it all a little while ago, I'll send to you again.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Date: March 5, 2020 at 12:43:00 PM EST
To: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Subject: FW: RFI to ASPR

Do you know about this?

From: McLatchy, Johanna <Johanna.McLatchy@fda.hhs.gov>
Sent: Thursday, March 5, 2020 10:03 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: FW: RFI to ASPR

Hi Keagan,
Sharing for your awareness. CDER is requesting ASPR to create a list of approved medical drug products being used for the management of COVID-19 patients.

Johanna

From: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Sent: Thursday, March 5, 2020 9:54 AM
To: Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; 2019-nCoV FDA IMG Operations <2019-nCoVFDAIMGOperations@fda.hhs.gov>; 2019-nCoV FDA IMG Planning <2019-nCoVFDAIMGPlanning@fda.hhs.gov>
Cc: CDER-ER-OPS <CDEREROPS@fda.hhs.gov>; CDER COVID-19 Response <CDERCOVID19Response@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Throckmorton, Douglas C <Douglas.Throckmorton@fda.hhs.gov>; Bernstein, Jessica <Jessica.Bernstein@fda.hhs.gov>
Subject: RE: RFI to ASPR

Hi Rosemary,

Before the EOC sends this RFI to ASPR, I just noticed that the memo is from Dr. Hahn. To confirm, has his office reviewed this yet? If not, let's touch base.

Thanks,
Brooke

From: Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>
Sent: Thursday, March 05, 2020 9:51 AM
To: 2019-nCoV FDA IMG Operations <2019-nCoVFDAIMGOperations@fda.hhs.gov>; 2019-nCoV FDA IMG Planning <2019-nCoVFDAIMGPlanning@fda.hhs.gov>
Cc: CDER-ER-OPS <CDEREROPS@fda.hhs.gov>; CDER COVID-19 Response <CDERCOVID19Response@fda.hhs.gov>;

Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Throckmorton, Douglas C <Douglas.Throckmorton@fda.hhs.gov>; Bernstein, Jessica <Jessica.Bernstein@fda.hhs.gov>
Subject: RFI to ASPR

Operations/Planning,

CDER asks that you send the attached memo to Dr. Kadlec at ASPR. CDER is requesting ASPR to create a list of approved drugs and therapeutic biologics that are being used to manage patients with COVID-19.

Let me know if you have questions.

Rosemary Roberts
COVID-19 Outbreak Response, FDA IMG Operations, Drugs Lead

From: Courtney, Brooke [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=261A2A3791E24E19B095AC0172485EBD-BROOKE.COUR]
Sent: 3/5/2020 12:48:55 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: FW: RFI to ASPR
Attachments: Memo from FDA to ASPR re COVID drug sources v2_030520.docx

In follow up to the response I just sent you, I sent the following to you about 2 hours ago.

From: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Date: March 5, 2020 at 10:44:00 AM EST
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: FW: RFI to ASPR

Hi Keagan,

CDER (Johanna McLatchy) might already have contacted you about this. I just spoke with CDER about the attached RFI they've drafted, **(b)(5)**

(b)(5)

Thoughts on how best to proceed?

Thanks so much,
Brooke

From: Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>
Sent: Thursday, March 05, 2020 9:51 AM
To: 2019-nCoV FDA IMG Operations <2019-nCoVFDAIMGOperations@fda.hhs.gov>; 2019-nCoV FDA IMG Planning <2019-nCoVFDAIMGPlanning@fda.hhs.gov>
Cc: CDER-ER-OPS <CDEREROPS@fda.hhs.gov>; CDER COVID-19 Response <CDERCOVID19Response@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Throckmorton, Douglas C <Douglas.Throckmorton@fda.hhs.gov>; Bernstein, Jessica <Jessica.Bernstein@fda.hhs.gov>
Subject: RFI to ASPR

Operations/Planning,

CDER asks that you send the attached memo to Dr. Kadlec at ASPR. CDER is requesting ASPR to create a list of approved drugs and therapeutic biologics that are being used to manage patients with COVID-19.

Let me know if you have questions.

Rosemary Roberts
COVID-19 Outbreak Response, FDA IMG Operations, Drugs Lead

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 3/5/2020 1:43:22 PM
To: Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]
Subject: RE: requests from CDC

Thank you. I will send this email to Anne and The Commissioner and see what they say. Thanks!

From: Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
Sent: Thursday, March 5, 2020 1:42 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
Subject: requests from CDC

Keagan and Stacy,

Below is our list of requests from CDC.

(b)(5)

Thank you for all your help.

Ellen and Elizabeth

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 3/5/2020 1:53:18 PM
To: Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]
Subject: FW: requests from CDC

Is this what we discussed with them? Seems to be more here.

From: Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
Sent: Thursday, March 5, 2020 1:42 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
Subject: requests from CDC

Keagan and Stacy,

Below is our list of requests from CDC.

(b)(5)

Thank you for all your help.

Ellen and Elizabeth

From: Caccomo, Stephanie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=950C32CEBC4B4F80B302C50CF31C8524-STEPHANIE.C]
Sent: 3/5/2020 1:53:42 PM
To: McKeogh, Katherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3facab3fd03480f8553892121fd2009-HHS-Katheri]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Steele, Danielle (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=634b96dc13cf48f3971ce676b65e952f-HHS-Daniell]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; McWilliams, Carly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]
Subject: RE: Question on COVID testing capacity

I am clearing the latest from our attorneys right now and should have updated context for you.

(b)(5)

New language coming shortly.

From: McKeogh, Katherine (OS/ASPA) <Katherine.McKeogh@hhs.gov>
Sent: Thursday, March 05, 2020 1:50 PM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>; Steele, Danielle (OS) <Danielle.Steele@hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Subject: RE: Question on COVID testing capacity

(b)(5)

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Thursday, March 5, 2020 12:45 PM
To: McKeogh, Katherine (OS/ASPA) <Katherine.McKeogh@hhs.gov>; Felberbaum, Michael (FDA/OC) <Michael.Felberbaum@fda.hhs.gov>; Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; Steele, Danielle (HHS/IOS) <Danielle.Steele@hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>
Cc: Rebello, Heidi (FDA/OC) <Heidi.Rebello@fda.hhs.gov>; Caliguiri, Laura (FDA/OC) <Laura.Caliguiri@fda.hhs.gov>;

McWilliams, Carly (FDA/OC) <Carly.McWilliams@fda.hhs.gov>
Subject: RE: Question on COVID testing capacity

Please standby—updated numbers coming asap. The projections by end of week need to be updated.

From: McKeogh, Katherine (OS/ASPA) <Katherine.McKeogh@hhs.gov>
Sent: Thursday, March 05, 2020 12:36 PM
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>; Steele, Danielle (OS) <Danielle.Steele@hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: Question on COVID testing capacity

Hi All – Can you review these points, especially the numbers that are stated below. Thank you!!

(b)(5)

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Sent: Thursday, March 5, 2020 11:28 AM
To: McKeogh, Katherine (OS/ASPA) <Katherine.McKeogh@hhs.gov>
Cc: Caccomo, Stephanie (FDA/OC) <Stephanie.Caccomo@fda.hhs.gov>
Subject: RE: Question on COVID testing capacity

Reporter off.

Katie – I'm looping in Stephanie on this one.

Michael Felberbaum
Senior Advisor

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

FDA U.S. FOOD & DRUG ADMINISTRATION

From: Andrew Siddons <andrewsiddons@cgrollcall.com>
Sent: Thursday, March 05, 2020 11:21 AM
To: McKeogh, Katherine (OS) <Katherine.McKeogh@hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: Question on COVID testing capacity

Hi Katie and Michael -
Sec. Azar and Commissioner Hahn have both been referencing testing capacity and the number of tests that are likely to be available. Could you please clear something up on capacity? I don't need attribution, this is just a fact check.

Sec. Azar today said that public health labs can currently test 15,000 people and would be able to test 75,000 by the end of the week with the additional test kits going out (please correct me if that's wrong). He said with the addition of the 1 million IDT tests going to hospitals, the number would expand to 400,000, etc. Does this mean 15,000 people a day, a week, or what?

Thanks!

Andrew Siddons
Reporter, health care | CQ Roll Call
E: andrewsiddons@cgrollcall.com
P: 202-650-6441 | C (b)(6)

rollcall.com | info.cq.com | fiscalnote.com

From: Flannery, Ellen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F3A88F0EBDF24B898CCD4814707DAEDF-ELLEN.FLANN]
Sent: 3/5/2020 2:09:29 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]
Subject: RE: requests from CDC

Keagan and Stacy,

Below is our list of requests from CDC.

1. Please release QC results for all qualified lots from IDT so that they can distribute the 1200 kits they have ready to go.
2. Please commit to qualifying future lots of kits from both IDT and Biosearch, including N3, so that they can distribute under your EUA. Please plan to do lot release testing rapidly and immediately release results.
3. Please provide in writing an umbrella right of reference to the data and information in the CDC EUA that can be relied upon by any test developer that wants to leverage it for bridging.
4. Please commit to running specimens from high complexity clinical labs for comparative LoD (bridging studies) studies so that they can validate their LDTs.
5. Please commit to confirming the first 5 positive and first 5 negative specimens from labs running LDTs under the new policy until such time as more labs are able to perform the validation testing.
6. Please make positive control for COVID-19 (nCoVPC) available to high complexity clinical labs so that they can validate their tests.
7. Please submit your EUA amendment so that we can officially authorize all of the things for which we have given temporary enforcement discretion.

With respect to kit manufacturers, we understand the biggest hurdle is obtaining the RNA isolates in order to validate. Modifying the guidance to include kit manufacturers will not help this problem, as the policy still requires validation up front. We have just learned that BEI (part of NIH) will review in 12-72 hours the paperwork to provide RNA isolates to labs and manufacturers. This is the most critical piece for enabling labs to validate tests and make them available.

Thank you for all your help.

Ellen and Elizabeth

From: Caccomo, Stephanie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=950C32CEBC4B4F80B302C50CF31C8524-STEPHANIE.C]
Sent: 3/5/2020 2:38:08 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]
Subject: inspection statement
Attachments: draft_inspection_3.4.20_915pm.docx

Per Laura ping, current inspection statement. We need to issue today if ORA employees have already been told inspections postponed. **(b)(5)**

(b)(5)

Stephanie Caccomo
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: 301.348.1956
Cell: **(b)(5)**
stephanie.caccomo@fda.hhs.gov

From: Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]
Sent: 3/5/2020 6:19:51 PM
To: Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]
CC: Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
Subject: Re: COVID-19 Assay Validation

Thanks.

Sent from my iPhone

On Mar 5, 2020, at 6:17 PM, Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov> wrote:

Keagan,
LabCorp notified us at 5:11pm today that they completed validation and will begin testing under the new policy. We have asked for their testing capacity and are awaiting response.
Elizabeth

From: Krueger, Brian <Kruegeb@LabCorp.com>
Date: March 5, 2020 at 5:11:20 PM EST
To: CDRH-EUA-Templates <CDRH-EUA-Templates@fda.hhs.gov>
Cc: Eisenberg, Marcia <Eisenbm@LabCorp.com>, Nye, Mindy <Nyem@LabCorp.com>, Dale, Suzanne <Dales1@LabCorp.com>, Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>, Bisht, Himani <Himani.Bisht@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
Subject: COVID-19 Assay Validation

Dear Dr. Scherf,

We would like to inform you that we have completed the lab validation of our COVID-19 RT PCR test. We will begin sample testing immediately and submit our final EUA validation for your review within the next 15 days.

This test will be run out of the Center for Esoteric Testing, 1447 York Court, Burlington, NC. This lab is directed by Dr. Suzanne Dale (dales1@labcorp.com) who is also copied on this email.

Sincerely,

Brian Krueger, PhD
Associate Vice President
Technical Director, Research and Development

Laboratory Corporation of America

1912 TW Alexander Dr.
Research Triangle Park, NC 27703

Email: Brian.Krueger@LabCorp.com
Office: (919) 224 5714
Cell: (b)(6)

From: Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]
Sent: 3/6/2020 7:28:04 AM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
Subject: Re: LDTs and EUAs -- privileged/deliberative

Sounds good. **(b)(5)** **(b)(5)** Worth a discussion.

Sent from my iPhone

On Mar 6, 2020, at 6:42 AM, Hahn, Stephen <SH1@fda.hhs.gov> wrote:

Let's discuss this morning with Anand
Thanks

Sent from my iPad

Begin forwarded message:

From: "McKeogh, Katherine (OS/ASPA)" <Katherine.McKeogh@hhs.gov>
Date: March 5, 2020 at 11:32:33 PM EST
To: "Stecker, Judy (OS)" <Judy.Stecker@hhs.gov>, "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>, "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

Yes sending now.

From: Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov>
Sent: Thursday, March 5, 2020 11:31 PM
To: Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>
Cc: Amin, Stacy (FDA/OC) <Stacy.Amin@fda.hhs.gov>; McKeogh, Katherine (OS/ASPA) <Katherine.McKeogh@hhs.gov>; Arbes, Sarah (HHS/ASL) <Sarah.Arbes@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

Good points Ryan. Katie can you **(b)(5)**

Sent from my iPhone

On Mar 5, 2020, at 11:30 PM, Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov> wrote:

Kessler: "…there was nothing -- ie, no Obama rule -- that prevented the administration from acting sooner on EUAs."
The Administration's point is not about what prohibited *the administration* from acting sooner but rather what prevented *labs* from acting sooner – namely this reasonable assumption by labs, based on the previous administration's behavior, that they would be met with regulatory action.

Kessler: "I'm glad we've clarified that the LDT draft guidance was not an issue."
Correct me if I'm wrong, but to my knowledge, we've clarified no such conclusion. The draft guidance spoke to the previous administration's regulatory perspective even if it was not finalized. And the previous administration's behavior – as evidenced by the letters below – show that they were willing to act on that perspective absent formal guidance.

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 **(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 10:40 PM, Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov> wrote:

Yes, though (b)(5) The rest is important.

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 <SH1@fda.hhs.gov>; Gross, Karas (FDA/OC) <Karas.Gross@fda.hhs.gov>
Subject: Re: LDTs and EUAs -- privileged/deliberative

To be clear sending this:

(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:

Very fair. (b)(5)
(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

Yes (b)(5)
(b)(5) End of story.

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. As you know but others on the chain here may not, we have an inquiry from Glenn Kessler, the WaPo "fact" checker, on this item. We've provided him today our statement that was cleared yesterday (b)(5)

(b)(5)

Thoughts from you and group on providing this information or a modified version to WaPo?

- 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

I heard the President was asked about this again tonight, and I saw it on the news all day. I've pulled together more information on this in case helpful.

(b)(5)

****

Stacy Cline Amin
Chief Counsel
Food and Drug Administration
Deputy General Counsel
Department of Health and Human Services

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 3/6/2020 9:21:43 AM
To: Monroe, Steve (CDC/DDPHSS/OLSS/OD) [stm2@cdc.gov]
CC: Monroe, Stephan S (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4dd10bb2bc4747788ce38b0e0d6d2f8d-HHS-stm2-cd]
Subject: RE: CDC Right-of-reference language

Thank you!

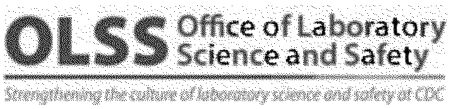
From: Monroe, Steve (CDC/DDPHSS/OLSS/OD) <stm2@cdc.gov>
Sent: Friday, March 6, 2020 8:30 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Monroe, Stephan S (CDC) <stm2@cdc.gov>
Subject: CDC Right-of-reference language

Keagan – here's our proposed language regarding right-of-reference. Please let me know if you need this to be modified. Also, please send your complete contact information in case I need to reach out urgently.

Best,
Steve

+++++
In the interest of facilitating an increase in U.S. diagnostic testing capacity for COVID-19, CDC hereby grants right of reference to the performance data contained in CDC's EUA (FDA submission number EUA200001) to any entity seeking an FDA EUA for a COVID-19 diagnostic device.
+++++

Steve Monroe, PhD
Associate Director for Laboratory Science and Safety
Director, Office of Laboratory Science and Safety
Centers for Disease Control and Prevention (CDC)
+1-404-639-2391 (direct)
(b)(6) (mobile)
smonroe@cdc.gov
EA: Ms. Kimberly Guyton / KGuyton@cdc.gov /+1-404-718-7415
http://www.cdc.gov/labs/



From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Friday, March 6, 2020 7:34 AM
To: Monroe, Steve (CDC/DDPHSS/OLSS/OD) <stm2@cdc.gov>
Subject: Re: FDA Requests for CDC

Thanks Steve- Anne said that you all would send me language on #3 quickly. Any chance we could get that this morning? Would love to get it out to large manufacturers.

Sent from my iPhone

On Mar 6, 2020, at 7:22 AM, Monroe, Steve (CDC/DDPHSS/OLSS/OD) <stm2@cdc.gov> wrote:

Keagan,
Sorry for the delayed response. Complete contact info below. Call my mobil (b)(6) for anything urgent.

Steve Monroe, PhD
Associate Director for Laboratory Science and Safety
Director, Office of Laboratory Science and Safety
Centers for Disease Control and Prevention (CDC)
+1-404-639-2391 (direct)
(b)(6) (mobile)
smonroe@cdc.gov
EA: Ms. Kimberly Guyton / KGuyton@cdc.gov /+1-404-718-7415
http://www.cdc.gov/labs/

<image001.jpg>

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Thursday, March 5, 2020 3:29 PM
To: Schuchat, Anne MD (CDC/OD) <acs1@cdc.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Monroe, Steve (CDC/DDPHSS/OLSS/OD) <stm2@cdc.gov>
Cc: Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>; Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>
Subject: RE: FDA Requests for CDC

Thanks Anne. Steve – what is the best way to connect with you on these? Will get our team to reach out.

From: Schuchat, Anne MD (CDC/OD) <acs1@cdc.gov>
Sent: Thursday, March 5, 2020 2:47 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Monroe, Stephan S (CDC) <stm2@cdc.gov>
Cc: Berger, Sherri (CDC) <sob8@cdc.gov>; Redfield, Robert R (CDC) <olx1@cdc.gov>
Subject: Re: FDA Requests for CDC

Steve Monroe, our associate director for laboratory science, will be our lead in working through this with you all.
Get Outlook for iOS

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Thursday, March 5, 2020 2:17 PM
To: Schuchat, Anne MD (CDC/OD); Hahn, Stephen
Cc: Berger, Sherri (CDC/OCOO/OD)
Subject: RE: FDA Requests for CDC

Thanks Dr. Schuchat,

I asked the team to focus on the maximum steps we could take with you all to make sure we got as many tests out there as we could. That being said, what would get us the most bang would be the below:

(b)(5)

(b)(5)

Can you all help with this? I am including Sherri as well.

Thanks,
Keagan

From: Schuchat, Anne MD (CDC/OD) <acs1@cdc.gov>
Sent: Thursday, March 5, 2020 2:01 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Re: FDA Requests for CDC

This is a bit broader than what I spoke to the commissioner about but we are pulling more expertise so we can respond.

Get Outlook for iOS

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Thursday, March 5, 2020 1:53:14 PM
To: Schuchat, Anne MD (CDC/OD) <acs1@cdc.gov>; Hahn, Stephen <SH1@fda.hhs.gov>
Subject: FDA Requests for CDC

Hi Dr. Schuchat,

Dr. Hahn said that he spoke with you about some ideas that would help get more diagnostic tests to market. Below are some of those suggestions. We would greatly appreciate your approval.

(b)(5)

Let me know if you have questions. We greatly appreciate your help here.

Thanks,
Keagan

From: McWilliams, Carly [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B68C7458214244D08424FD441FEA4FDA-CARLYLE.MCW]
Sent: 3/6/2020 12:30:05 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: WHTF Press Briefing Talking Points 2020.03.06.docx
Attachments: WHTF Press Briefing Talking Points 2020.03.06.docx

From: McWilliams, Carly [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B68C7458214244D08424FD441FEA4FDA-CARLYLE.MCW]
Sent: 3/6/2020 1:53:41 PM
To: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: WHTF Press Briefing Talking Points 2020.03.06.docx
Attachments: WHTF Press Briefing Talking Points 2020.03.06.docx

WE CAUGHT INCONSISITENCIES IN THE NUMBER. PLEASE USE THIS DOCUMENT

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 3/6/2020 2:29:47 PM
To: Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]
Subject: FW: LDTs and EUAs -- privileged/deliberative

Your email to Rachel. **(b)(5)** Sorry, they changed it on me.

From: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Sent: Friday, March 6, 2020 2:28 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: Re: LDTs and EUAs -- privileged/deliberative

I have confirmed the date as January 27 when we first put information on our website regarding contacting us for advice and the template I will send that confirming email to you in a moment.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Date: March 6, 2020 at 2:26:38 PM EST
To: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: FW: LDTs and EUAs -- privileged/deliberative

Is the (b)(5) the date? See below.

From: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Sent: Friday, March 6, 2020 2:26 PM
To: Semmel, Rachel K. EOP/OMB <**(b)(6)**
Cc: Stecker, Judy (OS) <Judy.Stecker@hhs.gov>; Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>; McKeogh, Katherine (OS) <Katherine.McKeogh@hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Arbes, Sarah C (OS) <Sarah.Arbes@hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: RE: LDTs and EUAs -- privileged/deliberative

Time line is filled in on the bottom. Do you want a different timeline? Let me know if anything is missing that you need.

(b)(5)

From: Semmel, Rachel K. EOP/OMB <**(b)(6)**
Sent: Friday, March 6, 2020 2:23 PM
To: Amin, Stacy <Stacy.Amin@fda.hhs.gov>

Cc: Stecker, Judy (OS) <Judy.Stecker@hhs.gov>; Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>; McKeogh, Katherine (OS) <Katherine.McKeogh@hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Arbes, Sarah C (OS) <Sarah.Arbes@hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: Re: LDTs and EUAs -- privileged/deliberative

One more question—sorry if you sent it over already. **(b)(5)**

Rachel Semmel

On Mar 6, 2020, at 2:16 PM, Amin, Stacy <Stacy.Amin@fda.hhs.gov> wrote:

(b)(5)

From: Amin, Stacy
Sent: Friday, March 6, 2020 1:37 PM
To: Semmel, Rachel K. EOP/OMB <Rachel.K.Semmel@omb.eop.gov>
Subject: RE: LDTs and EUAs -- privileged/deliberative

(b)(5)

(b)(5)

From: Semmel, Rachel K. EOP/OMB (b)(6)
Sent: Friday, March 6, 2020 12:53 PM
To: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: RE: LDTs and EUAs -- privileged/deliberative

Thanks! d (b)(5) (b)(5)
Also, can you eyeball these and provide feedback or edit anything that stands out on your end?

(b)(5)

(b)(5)

From: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Sent: Friday, March 6, 2020 12:22 PM
To: Semmel, Rachel K. EOP/OMB (b)(6)
Subject: RE: LDTs and EUAs -- privileged/deliberative

See below on what FDA has done. Pls call with any questions:

(b)(5)

(b)(5)

From: Semmel, Rachel K. EOP/OMB [(b)(6)]
Sent: Friday, March 6, 2020 11:33 AM
To: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: RE: LDTs and EUAs -- privileged/deliberative

Hey, Stacy,

I'm helping Grogan and Maria on some coms, mind giving me a call?

Rachel Semmel
Director of Communications
The White House, Office of Management and Budget
(b)(6) work
(b)(6) cell (Cannot receive text)

Begin forwarded message:

From: "Amin, Stacy" <Stacy.Amin@fda.hhs.gov>
Date: March 5, 2020 at 9:52:47 PM EST
To: "Bonner, Maria K. EOP/WHO" <Maria.K.Bonner@who.eop.gov>
Cc: "Rom, Colin" <Colin.Rom@fda.hhs.gov>, "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>, "Shah, Anand" <Anand.Shah@fda.hhs.gov>
Subject: LDTs and EUAs -- privileged/deliberative

(b)(5)

(b)(5)

****

Stacy Cline Amin
Chief Counsel
Food and Drug Administration
Deputy General Counsel
Department of Health and Human Services

From: Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]
Sent: 3/6/2020 2:55:17 PM
To: Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]
Subject: Re: LDTs and EUAs -- privileged/deliberative

Apologies. That my fault. Driving and not paying attention. I will ping Jeff.

Sent from my iPhone

On Mar 6, 2020, at 2:51 PM, Amin, Stacy <Stacy.Amin@fda.hhs.gov> wrote:

(b)(5)

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Friday, March 6, 2020 2:50 PM
To: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: Fwd: LDTs and EUAs -- privileged/deliberative

Jeff - anything else you can provide?

Sent from my iPhone

Begin forwarded message:

From: "Semmel, Rachel K. EOP/OMB" **(b)(6)**
Date: March 6, 2020 at 2:40:41 PM EST
To: "Amin, Stacy" <Stacy.Amin@fda.hhs.gov>
Cc: "Stecker, Judy (OS)" <Judy.Stecker@hhs.gov>, "Murphy, Ryan (OS)" <Ryan.Murphy1@hhs.gov>, "McKeogh, Katherine (OS)" <Katherine.McKeogh@hhs.gov>, "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>, "Arbes, Sarah C (OS)" <Sarah.Arbes@hhs.gov>, "Rom, Colin" <Colin.Rom@fda.hhs.gov>, "Shah, Anand" <Anand.Shah@fda.hhs.gov>
Subject: Re: LDTs and EUAs -- privileged/deliberative

(b)(6)

Rachel Semmel

On Mar 6, 2020, at 2:26 PM, Amin, Stacy <Stacy.Amin@fda.hhs.gov> wrote:

Time line is filled in on the bottom. Do you want a different timeline? Let me know if anything is missing that you need.

(b)(5)

(b)(5)

From: Semmel, Rachel K. EOP/OMB (b)(6)
Sent: Friday, March 6, 2020 2:23 PM
To: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Cc: Stecker, Judy (OS) <Judy.Stecker@hhs.gov>; Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>; McKeogh, Katherine (OS) <Katherine.McKeogh@hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Arbes, Sarah C (OS) <Sarah.Arbes@hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: Re: LDTs and EUAs -- privileged/deliberative

One more question—sorry if you sent it over already: (b)(5)

Rachel Semmel

On Mar 6, 2020, at 2:16 PM, Amin, Stacy <Stacy.Amin@fda.hhs.gov> wrote:

(b)(5)

From: Amin, Stacy
Sent: Friday, March 6, 2020 1:37 PM
To: Semmel, Rachel K. EOP/OMB < (b)(6)
Subject: RE: LDTs and EUAs -- privileged/deliberative

(b)(5)

(b)(5)

From: Semmel, Rachel K. EOP/OMB [(b)(6)]
Sent: Friday, March 6, 2020 12:53 PM
To: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: RE: LDTs and EUAs -- privileged/deliberative

Thanks! [(b)(5)] [(b)(5)]
Also, can you eyeball these and provide feedback or edit anything that stands out on your end?

(b)(5)

(b)(5)

From: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Sent: Friday, March 6, 2020 12:22 PM
To: Semmel, Rachel K. EOP/OMB (b)(6)
Subject: RE: LDTs and EUAs -- privileged/deliberative

See below on what FDA has done. Pls call with any questions:

(b)(5)

From: Semmel, Rachel K. EOP/OMB (b)(6)
Sent: Friday, March 6, 2020 11:33 AM
To: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: RE: LDTs and EUAs -- privileged/deliberative

Hey, Stacy,

I'm helping Grogan and Maria on some coms, mind giving me a call?

Rachel Semmel
Director of Communications
The White House, Office of Management and Budget
(b)(6) work
(b)(6) cell (Cannot receive text)

Begin forwarded message:

From: "Amin, Stacy" <Stacy.Amin@fda.hhs.gov>
Date: March 5, 2020 at 9:52:47 PM EST
To: "Bonner, Maria K. EOP/WHO" <Maria.K.Bonner@who.eop.gov>
Cc: "Rom, Colin" <Colin.Rom@fda.hhs.gov>, "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>, "Shah, Anand" <Anand.Shah@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

From: Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]
Sent: 3/6/2020 3:51:05 PM
To: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
CC: Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]
Subject: Fwd: For your quick review: quote in COVID health fraud news release for asap today
Attachments: COVID-19 WLs Press Release 3.5.20 OCC Cleared.docx; ATT00001.htm

Pls have him review this before you leave him.

Sent from my iPhone

Begin forwarded message:

From: "Rebello, Heidi" <Heidi.Rebello@fda.hhs.gov>
Date: March 6, 2020 at 3:34:52 PM EST
To: "Hahn, Stephen" <SH1@fda.hhs.gov>
Cc: "Rom, Colin" <Colin.Rom@fda.hhs.gov>, "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>
Subject: For your quick review: quote in COVID health fraud news release for asap today

Sir, attached and below is a quote for your review for today's COVID-19 health fraud action. Release is ready to go and has been fully cleared—please review asap.

(b)(5)

From: HHS Office of Public Affairs [hhsopa@hhs.gov]
Sent: 3/6/2020 4:51:10 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: HHS solicits proposals for development of medical products for novel coronavirus

News Release

U.S. Department of Health and Human Services

202-205-8117
asprmedia@hhs.gov
www.hhs.gov/news
Twitter @SpoxHHS

FOR IMMEDIATE RELEASE
Friday, March 6, 2020

HHS solicits proposals for development of medical products for novel coronavirus

As part of the government-wide effort to mitigate the spread of COVID-19 in U.S. communities, the U.S. Department of Health and Human Services (HHS) has updated a broad agency announcement (BAA) to focus specifically on products to diagnose, prevent or treat coronavirus infections.

The Biomedical Advanced Research and Development Authority (BARDA), part of the HHS Office of the Assistant Secretary for Preparedness and Response (ASPR), issued the BAA, BAA-18-100-SOL-00003-Amendment 13, to solicit proposals for advanced development and licensure of COVID-19 diagnostics, vaccines, or medicines such as therapeutics or antivirals.

"Amid the expanding global outbreak of COVID-19, Americans need diagnostics, vaccines, and medicines to mitigate the potential impact of this virus", said BARDA Director Rick Bright, Ph.D. "To accelerate the availability of these lifesaving tools, BARDA took an important step today to request proposals for development of COVID-19 diagnostics, vaccines, or therapeutics, many of which will be developed using existing platform technologies to permit rapid development."

BARDA will provide funding as well as expertise and core services to support development projects selected through this BAA. These products include diagnostic tests (assays); vaccines; therapeutics; medications to help regulate or normalize the immune system (immunomodulators); therapeutics targeting lung repair; medicines that prevent infections either before or after exposure to the virus (pre-exposure or post-exposure prophylaxis); respiratory protective devices; and ventilators.

There are currently no approved diagnostics, vaccines or treatments for COVID-19 infections. However, the U.S. Food and Drug Administration (FDA) issued two emergency use authorization of diagnostic tests from the Centers for Disease Control and Prevention (CDC) and other authorized public health laboratories, and for use of New York State's Wadsworth diagnostics test. In addition, FDA also issued a new policy Feb. 29 to help expedite the availability of diagnostics.

HHS continues to work across the U.S. government, including with the Department of Defense, to review potential products from public and private sectors to identify promising candidates that could detect or protect against or treat COVID-19 for development and licensure. HHS divisions, including the National Institutes of Health (NIH) and ASPR, have begun supporting development of multiple vaccines and treatments for COVID-19.

To obtain information about any potential products in development in the private sector that could be used in responding to the novel coronavirus outbreak, the U.S. government launched a single point-of-entry website for innovators and product developers to submit brief descriptions of their diagnostics, therapeutics, vaccines, and other products or technologies being developed for COVID-19.

To shorten the time to apply for product licensure and to reduce the spread of COVID-19, federal agencies are particularly interested in identifying products and technologies that have progressed beyond non-clinical studies, have established domestic large-scale commercial Good Manufacturing Practices (cGMP) manufacturing capability, and have utilized a platform used to manufacture a product already approved by the FDA.

In addition, BARDA opened an easy broad agency announcement, an EZ-BAA, seeking diagnostics that utilize platforms already cleared by the FDA, with a viable plan to meet requirements for the FDA to consider emergency use authorization within 12 weeks.

About HHS, ASPR, and BARDA

HHS works to enhance and protect the health and well-being of all Americans, providing for effective health and human services and fostering advances in medicine, public health, and social services. The mission of ASPR is to save lives and protect Americans from 21st century health security threats. Within ASPR, BARDA invests in the innovation, advanced research and development, acquisition, and manufacturing of medical countermeasures – vaccines, drugs, therapeutics, diagnostic tools, and non-pharmaceutical products needed to combat health security threats. To date, 54 BARDA-supported products have achieved regulatory approval, licensure or clearance.

###

Connect with HHS and sign up for HHS email updates

From: Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]
Sent: 3/6/2020 5:01:38 PM
To: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
CC: Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]
Subject: Re: LDTs and EUAs -- privileged/deliberative

Yep. Thanks.

Sent from my iPhone

On Mar 6, 2020, at 4:54 PM, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov> wrote:

And I sent the LDT timeline in a separate email to you, Keagan, and Stacy.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Date: March 6, 2020 at 4:02:04 PM EST
To: Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
Cc: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: Re: LDTs and EUAs -- privileged/deliberative

Thanks for flagging. CDC sent their timeline.

Sent from my iPhone

On Mar 6, 2020, at 4:00 PM, Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov> wrote:

I just wanted to note a couple things for your consideration:

(b)(5)

Elizabeth

From: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Sent: Friday, March 6, 2020 2:59 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
Subject: Re: LDTs and EUAs -- privileged/deliberative

We posted on our website on January 29 that for interested developers they can get advice and ELA templates from us in the mailbox to contact. That is the email I sent you a few minutes ago. We subsequently received requests from Laboratories for the EU a template as well as had pre-Waze with laboratories to provide advice and to receive

information in support of an easy way while they were developing or validating their tests. We have also had ongoing informal discussions and emailsWith laboratories over the past few weeks.

Adding Elizabeth in case you need more or something drafted. Very hard to type with one hand. Trying to dictate Text as much as possible.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Date: March 6, 2020 at 2:49:55 PM EST
To: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: Fwd: LDTs and EUAs -- privileged/deliberative

Jeff - anything else you can provide?

Sent from my iPhone

Begin forwarded message:

From: "Semmel, Rachel K. EOP/OMB" **(b)(6)**
Date: March 6, 2020 at 2:40:41 PM EST
To: "Amin, Stacy" <Stacy.Amin@fda.hhs.gov>
Cc: "Stecker, Judy (OS)" <Judy.Stecker@hhs.gov>, "Murphy, Ryan (OS)" <Ryan.Murphy1@hhs.gov>, "McKeogh, Katherine (OS)" <Katherine.McKeogh@hhs.gov>, "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>, "Arbes, Sarah C (OS)" <Sarah.Arbes@hhs.gov>, "Rom, Colin" <Colin.Rom@fda.hhs.gov>, "Shah, Anand" <Anand.Shah@fda.hhs.gov>
Subject: Re: LDTs and EUAs -- privileged/deliberative

(b)(5)

Rachel Semmel

On Mar 6, 2020, at 2:26 PM, Amin, Stacy <Stacy.Amin@fda.hhs.gov> wrote:

Time line is filled in on the bottom. Do you want a different timeline? Let me know if anything is missing that you need.

(b)(5)

From: Semmel, Rachel K. EOP/OMB **(b)(6)**
Sent: Friday, March 6, 2020 2:23 PM
To: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Cc: Stecker, Judy (OS) <Judy.Stecker@hhs.gov>; Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>; McKeogh, Katherine

(OS) <Katherine.McKeogh@hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Arbes, Sarah C (OS) <Sarah.Arbes@hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: Re: LDTs and EUAs -- privileged/deliberative

One more question—sorry if you sent it over already: **(b)(5)**

Rachel Semmel

On Mar 6, 2020, at 2:16 PM, Amin, Stacy <Stacy.Amin@fda.hhs.gov> wrote:

(b)(5)

From: Amin, Stacy
Sent: Friday, March 6, 2020 1:37 PM
To: Semmel, Rachel K. EOP/OMB **(b)(6)**
Subject: RE: LDTs and EUAs -- privileged/deliberative

(b)(5)

(b)(5)

From: Semmel, Rachel K. EOP/OMB (b)(6)
Sent: Friday, March 6, 2020 12:53 PM
To: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: RE: LDTs and EUAs -- privileged/deliberative

(b)(5)

(b)(5)

From: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Sent: Friday, March 6, 2020 12:22 PM
To: Semmel, Rachel K. EOP/OMB (b)(6)
Subject: RE: LDTs and EUAs -- privileged/deliberative

See below on what FDA has done. Pls call with any questions:

(b)(5)

(b)(5)

From: Semmel, Rachel K. EOP/OMB [(b)(6)]
Sent: Friday, March 6, 2020 11:33 AM
To: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: RE: LDTs and EUAs -- privileged/deliberative

Hey, Stacy,

I'm helping Grogan and Maria on some coms, mind giving me a call?

Rachel Semmel
Director of Communications
The White House, Office of Management and Budget
(b)(6) work
(b)(6) cell (Cannot receive text)

Begin forwarded message:

From: "Amin, Stacy" <Stacy.Amin@fda.hhs.gov>
Date: March 5, 2020 at 9:52:47 PM EST
To: "Bonner, Maria K. EOP/WHO" <Maria.K.Bonner@who.eop.gov>
Cc: "Rom, Colin" <Colin.Rom@fda.hhs.gov>, "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>, "Shah, Anand" <Anand.Shah@fda.hhs.gov>
Subject: LDTs and EUAs -- privileged/deliberative

(b)(5)

(b)(5)

****

Stacy Cline Amin
Chief Counsel
Food and Drug Administration
Deputy General Counsel
Department of Health and Human Services

From: Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]
Sent: 3/6/2020 6:53:29 PM
To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
Subject: Fwd: Talkers on diagnostics
Attachments: Denise 3.6.20 BIPAR Hill Call Update-Clean - LP comments.docx; ATT00001.htm; Reactive Responses for Denise - 3.6.20_.docx; ATT00002.htm

Sent from my iPhone

Begin forwarded message:

From: "Hinton, Denise" <Denise.Hinton@fda.hhs.gov>
Date: March 6, 2020 at 6:50:17 PM EST
To: "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>, "Gross, Karas" <Karas.Gross@fda.hhs.gov>
Subject: RE: Talkers on diagnostics

Yes - please see attachments.

-----Original Message-----
From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Friday, March 6, 2020 6:42 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>
Subject: Talkers on diagnostics

Denise- can I have the talkers you used on the tests today?

Sent from my iPhone

From: Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]
Sent: 3/7/2020 10:50:31 AM
To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
Subject: Fwd: This is cleared as the new guidance
Attachments: PUI Recommendations 3.5.20 FOR CLEARANCE.docx; ATT00001.htm

CDC putting new guidance up on their website on who should get the test.

(b)(5)

Sent from my iPhone

Begin forwarded message:

From: "Giroir, Brett (HHS/OASH)" <Brett.Giroir@hhs.gov>
Date: March 7, 2020 at 10:44:01 AM EST
To: "Hahn, Stephen" <SH1@fda.hhs.gov>
Cc: "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>
Subject: This is cleared as the new guidance

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 3/7/2020 10:50:35 AM
To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
Subject: Fwd: This is cleared as the new guidance
Attachments: PUI Recommendations 3.5.20 FOR CLEARANCE.docx; ATT00001.htm

CDC putting new guidance up on their website on who should get the test.

(b)(5)

Sent from my iPhone

Begin forwarded message:

From: "Giroir, Brett (HHS/OASH)" <Brett.Giroir@hhs.gov>
Date: March 7, 2020 at 10:44:01 AM EST
To: "Hahn, Stephen" <SH1@fda.hhs.gov>
Cc: "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>
Subject: This is cleared as the new guidance

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 3/7/2020 11:09:17 AM
To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
Subject: Hahn's edits attached
Attachments: press briefing talkers_3.7.20 840am_SH updates.docx

Can you pls incorporate and then send us your revised?

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 3/7/2020 11:18:37 AM
To: Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
Attachments: press briefing talkers_3.7.20 840am_SH updates.docx

From: Baum, Kristina R. EOP/OSTP (b)(6)
Sent: 3/7/2020 3:49:14 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: Fwd: [EXTERNAL] FDA Testing During COVID-19 Outbreak
Attachments: FDA EUA feedback from KOLs 030120.pdf; ATT00001.htm; EUA Letter_for_clinical_labs FINAL signatures.pdf; ATT00002.htm

Hi Keagan,

Who at your office is working on this issue?

Hoping to connect Lanier to the appropriate person.

Thank you!

Kristina Baum
Communications Director
Office of Science and Technology Policy
Executive Office of the President
The White House

Begin forwarded message:

From: "Hodgson, Lanier Swann" <Lanier.Hodgson@unchealth.unc.edu>
Date: March 5, 2020 at 6:26:23 PM EST
To: "Baum, Kristina R. EOP/OSTP" (b)(6)
Subject: [EXTERNAL] FDA Testing During COVID-19 Outbreak

Kristina,

Thanks for your willingness to take a peek at this & see if you have any insight on how we might continue the conversation with our colleagues at the FDA.

The short summary is this: Dr. Melissa Miller on my team has an LDT that would help significantly speed up the process of identifying and isolating COVID-19 patients. As you are already well aware, a chief issue here in states with confirmed cases is that it can take up to a day for the state labs to confirm a test. The sooner we can confirm a case, the sooner we can isolate that patient and reduce risk of spread. I will spare you the anecdotes, knowing whomever you share this with is already up to speed on the whys of this need.

That said, relaxing some of the regulations of our EUA would serve our entire state. Because we are a System with hospitals that stretch across the full state of North Carolina, our ability to test within our affiliates will also relieve the backlog of tests pending at the state labs. This decision from the FDA would have an immediate positive ripple effect in a state that truly needs it.

I have attached two documents summarizing the need and some of what has already been shared with leaders on the Hill.

Any conversation I could have with counterparts at the FDA would be greatly appreciated – I simply want to be able to have a dialogue on this. I am keenly aware we are not the only state-wide hospital system making this ask.

Again, my profuse thanks –

Lanier

Lanier Swann Hodgson | Vice President, State & Federal Relations
UNC Health & UNC School of Medicine
4030 Bondurant Hall | Campus Box 7000
Chapel Hill, NC 27599-7000
p (202) 320-7665
lanier.hodgson@unchealth.unc.edu

From: Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]
Sent: 3/8/2020 8:51:13 PM
To: Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]
CC: Monroe, Stephan S (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4dd10bb2bc4747788ce38b0e0d6d2f8d-HHS-stm2-cd]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Berger, Sherri (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b1ac8b1b9ba4abe8ef7b1d7abcd8d71-HHS-sob8-cd]; Wolinetz, Carrie D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4c547ca11976474a8fdcfcc02744b3a6-HHS-carrie.]; Jernigan, Daniel B (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83b3dd3de35d489aa4012b73d93f133f-HHS-dbj0-cd]
Subject: Re: Task Force do out from tonight

Thanks Brett.

If this is already out there can we get the links to share? Thanks.

Sent from my iPhone

On Mar 8, 2020, at 8:42 PM, Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov> wrote:

Copying Steve Monroe and Tim Stenzel

(b)(5)

Brett P. Giroir, MD
ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Sunday, March 8, 2020 8:39 PM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Subject: Task Force do out from tonight

Hey Brett -

VP asked Hahn to help regarding CDC/NIH collaboration on information needed to update the Coronavirus website. VP asked FDA to work w CDC and NIH to provide information for states, labs, etc for what they need to get their tests up and running once they receive them, procedures, process, etc.

Can you help with this? Not exactly sure how to manage this ask, would appreciate your guidance.

Thanks,
Keagan

Sent from my iPhone

From: HHS Office of Public Affairs [hhsopa@hhs.gov]
Sent: 3/9/2020 12:00:36 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: HHS supports development of first high-throughput COVID-19 diagnostic test

News Release

U.S. Department of Health and Human Services

202-205-8117
asprmedia@hhs.gov
www.hhs.gov/news
Twitter @SpoxHHS

FOR IMMEDIATE RELEASE
Monday, March 9, 2020

HHS supports development of first high-throughput COVID-19 diagnostic test

A diagnostic test for coronavirus disease 2019 (COVID-19) - designed for use in a diagnostic system that can process up to 1,000 tests in 24 hours - will receive advanced development support from the U.S. Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response (ASPR).

The molecular diagnostic test from Hologic, Inc. becomes the first COVID-19 product selected for development through ASPR's Biomedical Advanced Research and Development Authority streamlined selection process, called an easy broad agency announcement (EZ-BAA).

"Early, rapid diagnosis is essential for clinicians and their patients to treat infections appropriately and take immediate action to help mitigate the spread of COVID-19," said BARDA Director Rick Bright, Ph.D. "While the Centers for Disease Control and Prevention and our nation's public health laboratories are making valiant efforts in testing and surveillance of coronavirus infections, these labs could become overwhelmed as the number of suspected cases grows. Rapid, high-throughput tests are critical to provide quick results for more Americans and to aid the nationwide public health response."

BARDA will contribute $699,000 to accelerate Hologic's development of a test that detects the genetic material of SARS-CoV-2, the virus that causes COVID-19. Test results could be available to clinicians in less than three hours.

BARDA and Hologic expect that necessary development will be completed in a matter of weeks which then would allow the U.S. Food and Drug Administration (FDA) to consider granting Emergency Use Authorization (EUA) for the diagnostic test. An EUA facilitates the availability and use of medical products needed during public health emergencies.

The test will be designed for use with the company's Panther Fusion system. The system is available today in commercial laboratories in the United States and other parts of the world.

This Panther Fusion system provides complete sample-to-result automation with minimal user interaction and

offers a broad menu of FDA-cleared tests to detect common respiratory infections. This existing infrastructure and supply chain would allow for rapid scale-up of the COVID-19 diagnostic test if the FDA issues an EUA, which would increase access to testing for more U.S. patients and healthcare providers in the fight against COVID-19.

The business-friendly EZ-BAA application process streamlines the way BARDA collaborates with industry and entrepreneurs, enabling awards in as few as 30 days. BARDA recently opened the EZ-BAA for diagnostics that utilize platforms already cleared by the FDA, with a viable plan to meet requirements for the FDA to consider emergency use authorization. In addition to the EZ-BAA, BARDA expanded its standard broad agency announcement to accept proposals for advanced development of diagnostics, vaccines, therapeutics and other medical products for use in the current COVID-19 emergency response and future coronavirus outbreaks.

There are currently no approved diagnostics, vaccines or treatments for COVID-19 infections. However, the FDA issued emergency use authorizations of diagnostic tests from the Centers for Disease Control and Prevention (CDC) and other authorized public health laboratories, and for New York State's Wadsworth diagnostics test. In addition, on February 29, FDA also issued a new policy to help expedite the availability of diagnostics.

HHS continues to work across the U.S. government, including with the Department of Defense, to review potential products from public and private sectors to identify promising candidates that could detect or protect against or treat COVID-19 for development and licensure. HHS divisions, including the National Institutes of Health (NIH) and ASPR, have begun supporting development of multiple vaccines and treatments for COVID-19.

To obtain information about any potential products in development in the private sector that could be used in responding to the COVID-19 outbreak, the U.S. government launched a single point-of-entry website for innovators and product developers to submit brief descriptions of their diagnostics, therapeutics, vaccines, and other products or technologies being developed for COVID-19.

To shorten the time to apply for product licensure and to reduce the spread of COVID-19, federal agencies are particularly interested in identifying products and technologies that have progressed beyond non-clinical studies, have established domestic large-scale commercial Good Manufacturing Practices (cGMP) manufacturing capability, and have utilized a platform used to manufacture a product already approved by the FDA.

About HHS, ASPR, and BARDA

HHS works to enhance and protect the health and well-being of all Americans, providing for effective health and human services and fostering advances in medicine, public health, and social services. The mission of ASPR is to save lives and protect Americans from 21st century health security threats. Within ASPR, BARDA invests in the innovation, advanced research and development, acquisition, and manufacturing of medical countermeasures – vaccines, drugs, therapeutics, diagnostic tools, and non-pharmaceutical products needed to combat health security threats. To date, 54 BARDA-supported products have achieved regulatory approval, licensure or clearance.

###

Connect with HHS and sign up for HHS email updates

From: McWilliams, Carly [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B68C7458214244D08424FD441FEA4FDA-CARLYLE.MCW]
Sent: 3/9/2020 4:48:06 PM
To: Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: RE: COVID-19 Treatments

This was the only thing CDER sent me and I haven't seen anything for **(b)(4)**

From: Shah, Anand
Sent: Monday, March 9, 2020 4:47 PM
To: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: COVID-19 Treatments

I thought we had an internal response prepared specific for those 2 products, but I could be mistaken?

From: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Sent: Monday, March 9, 2020 4:46 PM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: COVID-19 Treatments

Is this what you mean?

Talking points

(b)(5)

From: Shah, Anand
Sent: Monday, March 9, 2020 4:42 PM
To: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: COVID-19 Treatments

Agree with both of you…

Carly, can you send me the language again on **(b)(4)** that was prepared for Hahn?

From: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Sent: Monday, March 9, 2020 4:29 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: COVID-19 Treatments

My understanding is that we cannot confirm or deny the existence of applications but not sure if that applies to this particular situation.

From: Lenihan, Keagan
Sent: Monday, March 9, 2020 3:27 PM
To: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: COVID-19 Treatments

Let him know of the privilege, if we have nothing in house on (b)(4) and the other one he mentions, I think you can tell him that.

From: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Sent: Monday, March 9, 2020 2:08 PM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: COVID-19 Treatments

Removed James, does he not know that we cannot discuss applications if it is not publicly disclosed by company?

From: Shah, Anand
Sent: Monday, March 9, 2020 2:03 PM
To: Williams, James H. EOP/WHO (b)(6)
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: Re: COVID-19 Treatments

Hi James, thanks for your note. We'll huddle on this and be in touch shortly
Anand

From: Williams, James H. EOP/WHO (b)(6)
Date: March 9, 2020 at 1:51:40 PM EDT
To: Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: COVID-19 Treatments

Anand, can you please give DPC a readout on (b)(5) (b)(5) ? In particular, has there been any progress with (b)(4) ? Thanks.

James H. Williams
Special Assistant to the President
Domestic Policy Council

From: McWilliams, Carly [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B68C7458214244D08424FD441FEA4FDA-CARLYLE.MCW]
Sent: 3/9/2020 6:10:46 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
CC: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: RE: COVID-19 Treatments

Just connected with peter. He says we don't say anything about status of any application. The most we will do if pushed is look at what has been publicly announced by a company and point to that.

From: Lenihan, Keagan
Sent: Monday, March 9, 2020 4:58 PM
To: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: COVID-19 Treatments

Check with Peter, I thought we could say we have not interacted with a company?

From: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Sent: Monday, March 9, 2020 4:29 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: COVID-19 Treatments

My understanding is that we cannot confirm or deny the existence of applications but not sure if that applies to this particular situation.

From: Lenihan, Keagan
Sent: Monday, March 9, 2020 3:27 PM
To: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: COVID-19 Treatments

Let him know of the privilege, if we have nothing in house or **(b)(4)** and the other one he mentions, I think you can tell him that.

From: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Sent: Monday, March 9, 2020 2:08 PM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: COVID-19 Treatments

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From: Shah, Anand
Sent: Monday, March 9, 2020 2:03 PM
To: Williams, James H. EOP/WHO **(b)(6)**

Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: Re: COVID-19 Treatments

Hi James, thanks for your note. We'll huddle on this and be in touch shortly
Anand

From: Williams, James H. EOP/WHO (b)(6)
Date: March 9, 2020 at 1:51:40 PM EDT
To: Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: COVID-19 Treatments

Anand, can you please give DPC a readout on (b)(5) (b)(5) In particular, has there been any progress with (b)(4) Thanks.

James H. Williams
Special Assistant to the President
Domestic Policy Council
The White House

From: McWilliams, Carly [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B68C7458214244D08424FD441FEA4FDA-CARLYLE.MCW]
Sent: 3/9/2020 6:41:50 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: RE: CDRH Readout Deliverables from 3/9 Monday

I am working on it with cdrh they are gathering what they have but anticipate that most info will be available tomorrow.

From: Lenihan, Keagan
Sent: Monday, March 9, 2020 6:35 PM
To: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Subject: RE: CDRH Readout Deliverables from 3/9 Monday

What talkers do we have for his 7pm call with Governor Cuomo?? Need some info on status of things asap. Pls.

From: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Sent: Monday, March 9, 2020 6:30 PM
To: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
Cc: O'Callaghan, Kathryn <Kathryn.OCallaghan@fda.hhs.gov>; Kamon-Brancazio, Jamie <Jamie.Kamon-Brancazio@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Ellis, Patricia <Patricia.Ellis@fda.hhs.gov>; Diamond, Matthew <Matthew.Diamond@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: CDRH Readout Deliverables from 3/9 Monday

Hi CDRH, I know there have been a lot of emails today so I have done my best to compile the requests and divided by outstanding and completed (because it's important to note what you accomplished!). Please feel free to loop in those I missed. I am aware you are working on Cuomo info and I believe **(b)(5)**

(b)(5)

To Do list of outstanding items Monday

Commissioner Call with Gov. Cuomo re concerns:

- " Your approval of the EUA amendment to allow us to add any hospital approved by us to do testing. We will have **(b)(4)** and
- We need more nasopharyngeal (NP) and oropharyngeal (OP) and viral transport media (VTM) as our stockpile is getting depleted by the Westchester sampling. Manufacturers are saying these are on backorder until may. (aware you are working on this)
- CDRH update on Wadsworth center's platform
- Status of NY EUA?

Expansion

(b)(4)

Ta-Da List (all of the things accomplished)

Change in swabs/Sample Collection

- FDA supports CDC's move to a single swab for testing, anticipating this change will allow more patients to be tested more quickly without posing any regulatory or supply chain difficulties.
- ACTION/ Follow Up We are finding out from large commercial labs if they have enough supplies for tests and also where they are with swabs to examine if there any critical vulnerabilities that will inhibit their fast ramp up. The team is contact the manufacturers of the swabs and find out about their ability to ramp up supply. **(b)(5)**

(b)(5)

Q: Will the change to a single swab for testing require a new EUA or a supplement to the current EUA? Does it work like a regular application that got cleared/approved and then had a change? The commissioner asked for clarity on regulatory steps. …Same question regarding the use of sputum test…
A: For the use of a single sample, as opposed to using multiple samples, no new EUA or EUA amendment would be necessary.
For use of a nasopharyngeal (NP) swab, an oropharyngeal (OP) swab, or sputum, no new EUA or EUA amendment would be necessary for any currently issued EUAs because the claims made by these organizations in their original EUA submission explicitly included analysis of "upper and lower respiratory specimens," which includes NP or OP swabs and sputum as well as lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate.
If new EUAs are issued to organizations making more limited claims, e.g. only claiming analysis of "upper respiratory specimens," and one wanted to use a lower respiratory specimen such as sputum, then an EUA amendment would normally be necessary, e.g. to add lower respiratory specimens to the test claims.

- Beginning assessment ASAP (today without delay) regarding status of the materials that are needed to perform sample collection for COVID diagnostics testing.
- The below excerpt was received from State of New York a short while ago:
- We need more nasopharyngeal (NP) and oropharyngeal (OP) and viral transport media (VTM) as our stockpile is getting depleted by the Westchester sampling.
- Matthew was tasked earlier today to assess the swab situation and now we have an escalating situation beyond swabs to include the transport medium in which the sample is carried.
- **Action Items**

1. Suzanne S requested 2 staff members from DARSS to help with this immediately to determine commercial labs supply of swabs, any vulnerabilities in the that will inhibit their first ramp up? Finding out ramp up supply? (b)(5) If you can identify right away who those are….I will provide separate guidance but basically we will follow our procedures for assessing product availability.
2. **Hahn Call with Gov Cuomo**

WHO TESTS

- There has been some confusion about whether the World Health Organization developed and distributed a diagnostic test. WHO has not developed an in house test, however, they did support distribution of a test that was developed in Germany. They have facilitated the distribution of hundreds of thousands of

these tests worldwide to more than 100 countries, mostly low- and middle-income countries that did not have their own testing protocols.

- WHO selected this test in mid-January test because (1) it was manufactured according to international standards, (2) it was manufactured using the first validated published protocol for testing, and (3) because they knew about the manufacturing and distribution capabilities of the company producing the test.
- This test was distributed after self-validation of its accuracy. However, in the U.S. we require more validation before such wide spread use.
- CDC, which is a World Health Organization Essential Reference Laboratory also created a test like several other countries were doing. Until issues with the test were detected, which were rapidly resolved, there were no reasons to rely on another country's self-certified test.
- From an earlier exchange with (b)(4)

(b)(4)

(b)(5)

Contact for States

- (FL SG) Matthew Diamond

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 3/9/2020 6:57:29 PM
To: McWilliams, Carly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]
Subject: FW: Quest Diagnostics to being testing for Coronavirus Monday, March 9th

FYI

From: Johnston, Darcie (HHS/IEA) <Darcie.Johnston@hhs.gov>
Sent: Monday, March 9, 2020 6:50 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; McGough, John (OS) <John.Mcgough@hhs.gov>; McGowan, Robert K (CDC) <omc2@cdc.gov>; Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>; Trueman, Laura (OS) <Laura.Trueman@hhs.gov>; Pottebaum, Nicholas (b)(6) Swint, Zachariah D. EOP/WHO (b)(6) Baker, Michael G (OS) <Michael.Baker@hhs.gov>; Giroir, Brett (OS) <Brett.Giroir@hhs.gov>; Butler, Jay C (CDC) <jcb3@cdc.gov>
Subject: FW: Quest Diagnostics to being testing for Coronavirus Monday, March 9th

FYI – good info on Florida

Darcie L. Johnston
Director, Intergovernmental Affairs
U.S. Department of Health and Human Services
Office of the Secretary
202-690-1058 (office)
(b)(6) (cell)

From: (b)(6)
Sent: Monday, March 9, 2020 6:45 PM
To: Johnston, Darcie (HHS/IEA) <Darcie.Johnston@hhs.gov>
Subject: Fwd: Quest Diagnostics to being testing for Coronavirus Monday, March 9th

See attached notice from Quest diagnostics about the delay in testing availability and an inability to test specimens that have already been collected.

(b)(6)

Sent from my iPhone

Begin forwarded message:

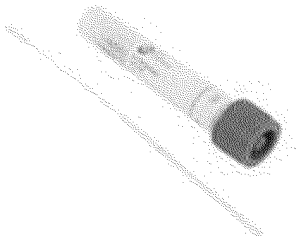
From (b)(4)
Date: March 9, 2020 at 1:57:21 PM EDT
To (b)(6)
Subject: Fw: Quest Diagnostics to being testing for Coronavirus Monday, March 9th

From: Chancey, Matt F <Matt.F.Chancey@questdiagnostics.com>
Sent: Monday, March 9, 2020 1:55 PM
Subject: RE: Quest Diagnostics to being testing for Coronavirus Monday, March 9th

Important update relating to COVID-19 testing from last week's message.

While Quest Diagnostics was successful in launching the COVID-19 test (Coronavirus) on March 9th, this was rolled out to West coast only. We are currently taking every measure necessary to make capacity to perform the test at our East coast specialty lab in Chantilly. We anticipate to have this test available in Chantilly at some point during the week of March 16th. Please **DO NOT** make an attempt to order the COVID-19 test at this time. Due to the logistical restraints and the specimen stability, any test being sent to the west coast will not be performed. If by chance you have already collected a patient for this test and submitted the swab please let me know. I am getting constant updates on the testing and its availability in our area. As soon we have a specific go-live date during the week of the 16th I will share this info with you. At this point, it is best to prepare your offices with the necessary supplies, educate your staff on the proper collection protocol, and be ready for the regional roll out for our area. Below are the details on the preferred specimen for testing, proper collection/processing instructions, as well as other helpful information.

Specimen Requirements-
The media below is the preferred collection media for COVID-19. Please order this device (supply S05) to prepare for any testing. You can order this online in Quanum LSM. If you have any issues ordering this device please let me know and I will get some for you.



S05 – Swab, VCM, Nasal

Transport requirements: Transport refrigerated (cold packs) to local Quest Diagnostics accessioning laboratory. Specimens should not be left in lock boxes, but if you must please include a cold pack.

Other important details:

- When ordering COVID-19 it is important that the test is on its own separate order, not included with any testing
- The swab is only good for a single test. If your provider wants to order COVID-19 and Influenza A/B we will need two separate swabs
- This test will need to be collected at the office. Our Patient Service Centers do not collect nasal swabs.
- Call In – It is preferred, even if you have a daily pickup, to call in on days you have a COVID-19 test. This will allow our logistics operators to notify the courier. We can be on the look-out for this swab to ensure it does not get missed and the integrity of the specimen is not compromised.
- COVID-19 is not yet listed online, in Quanum LSM, or any other Quest maintained website or lab ordering module. Once the test is approved and orderable (which should be sometime the week of 3/16) the test code and name will be #39433 – SARS-CoV-2 RNA, Qualitative Real-Time RT-PCR

If you have any additional questions or concerns please don't hesitate to reach out to me. I will keep you all posted any new progress. Thank You.

Matt F. Chancey
Physician Account Executive

Quest Diagnostics | Action from Insight | 4161 Tamiami Trail, Bldg 6, Suite 601
| Charlotte Harbor, FL 33952 | **phone** 239.633.2460 | **fax** 610.271.6099 | Matt.F.Chancey@QuestDiagnostics.com
| QuestDiagnostics.com

UnitedHealthcare members are getting a stronger network! Beginning January 1, 2019 Quest Diagnostics will be in-network with UnitedHealthcare across all geographies.

From: Chancey, Matt F
Sent: Friday, March 6, 2020 10:38 AM
Subject: Quest Diagnostics to being testing for Coronavirus Monday, March 9th

Hello,

On March 5, Quest Diagnostics announced plans to launch a new test service for the novel Coronavirus. (Official name: COVID-19). We expect to begin collecting specimens and make the tests available to providers on Monday, March 9th, 2020.

I will have more information when we launch the test, once I receive this, I will send out a second correspondence with that information. At this time below are the details that I have. If you have questions please feel free to reach out to me. Thanks

Test code: 39433
CPT code: is 87798

Test name: SARS-CoV-2 RNA, Qualitative Real-Time RT-PCR

Collection: Collect a dedicated nasopharyngeal (NP) from the nose or Oropharyngeal swab for throat. No other test can be performed from these specimens. If other tests are needed, a second NP/OP swab should be collected AND on a separate requisition. *** read this again ***

Specimen requirements: 1 nasopharyngeal or oropharyngeal swab in M4, VCM, or UTM media. Only sterile Dacron or Rayon swabs should be used. Do not use calcium alginate swabs as they may contain substances that inhibit PCR testing. We are being told we have enough supplies.

Transport requirements: Transport refrigerated (cold packs) to local Quest Diagnostics accessioning laboratory. IMPORTANT: If sample is being shipped directly to the performing laboratory facility by an overnight air courier, then transport it frozen on dry ice. Specimens must not be left in lock boxes.

Performed: at San Juan Capistrano lab (soon in Chantilly) - It's a Qualitative molecular assay and the technique is real-time reverse transcription PCR assay

Specimen stability: 72-hour stability when refrigerated.

Turn Around Time: 24 hours once it arrives to the lab

FDA: This test is our own lab-developed test (LDT). This test has not been FDA cleared or approved or authorized. The test has been validated according to CLIA, but FDA's independent review of this validation is pending.

For more information about the company's response to COVID-19, visit:
www.questdiagnostics.com/home/Coronavirus

Thank you.

Matt F. Chancey
Physician Account Executive

Quest Diagnostics | Action from Insight | 4161 Tamiami Trail, Bldg 6, Suite 601
| Charlotte Harbor, FL 33952 | **phone** 239.633.2460 | **fax** 610.271.6099 | Matt.F.Chancey@QuestDiagnostics.com
| QuestDiagnostics.com

UnitedHealthcare members are getting a stronger network! Beginning January 1, 2019 Quest Diagnostics will be in-network with UnitedHealthcare across all geographies.

From: Caccomo, Stephanie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=950C32CEBC4B4F80B302C50CF31C8524-STEPHANIE.C]
Sent: 3/10/2020 1:12:38 PM
To: McKeogh, Katherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3facab3fd03480f8553892121fd2009-HHS-Katheri]; Stecker, Judy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e205440400ab4f629be1faccfe0846fc-HHS-Judy.St]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Steele, Danielle (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=634b96dc13cf48f3971ce676b65e952f-HHS-Daniell]
Subject: RE: AP story-FDA testing guidance

That's works!

Stephanie Caccomo
Press Officer

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

From: McKeogh, Katherine (OS/ASPA) <Katherine.McKeogh@hhs.gov>
Sent: Tuesday, March 10, 2020 1:09 PM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Stecker, Judy (OS) <Judy.Stecker@hhs.gov>; Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Steele, Danielle (OS) <Danielle.Steele@hhs.gov>
Subject: FW: AP story-FDA testing guidance
Importance: High

Hi all – another inquiry on this line of questioning about "delays" to the FDA EUA policy.

Stephanie – do you think it would just work if you provide the FDA spox statement we gave WSJ?

On background from FDA spokesperson: No one at HHS delayed FDA's issuance of the new EUA policy to help expedite the availability of diagnostics. Prior to issuing the new EUA policy, FDA was focused on collaboratively working with the CDC to ensure the efficacy of the CDC diagnostic. FDA felt getting the CDC diagnostic right was a critical step to addressing this outbreak, and HHS was supportive throughout this process.

From: Perrone, Matthew <MPerrone@ap.org>
Sent: Tuesday, March 10, 2020 1:03 PM
To: McKeogh, Katherine (OS/ASPA) <Katherine.McKeogh@hhs.gov>
Cc: Caccomo, Stephanie (FDA/OC) <Stephanie.Caccomo@fda.hhs.gov>
Subject: AP story-FDA testing guidance
Importance: High

Hi Katie,

Matthew Perrone here with the AP, where I cover the FDA. The AP is working on a story about the government's response to the coronavirus and specifically the rollout of increased lab testing for the virus.

Some leaders in Washington, including Sen. Patty Murray, have suggested that the FDA's Feb. 29 guidance broadening testing to private labs may have been delayed by officials at HHS, CDC or other parts of the administration. Is that true? We'll need a response by 4 pm today. Feel free to call me anytime at the number below

Thanks much,

Matthew Perrone
AP Health Writer
(202) 641-9863
mperrone@ap.org
@AP_FDAwriter

From: Berger, Sherri (CDC/OCOO/OD) [sob8@cdc.gov]
Sent: 3/10/2020 4:22:00 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Galatas, Kate (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0a0623b3cb34f86a2f6f9d14afe115e-HHS-kkg2-cd]; Dorigo, Leslie L (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f3532db6f33488ba102962eb3d2623d-HHS-fus3-cd]
Subject: Re: Website

+Comms. Thanks

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Tuesday, March 10, 2020 4:20 PM
To: Berger, Sherri (CDC/OCOO/OD)
Subject: Website

Hi Sherri –

The Commissioner asked me to send CDC some links for you to potentially include on the CoV website.

(b)(5)

If there are other things you think would be helpful for us to put up on the CoV website, please let me know.

Thanks,
KL

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 3/10/2020 4:24:20 PM
To: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
Subject: RE: Lawmakers question COVID-19 testing capabilities

No

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Tuesday, March 10, 2020 4:18 PM
To: 2019-nCoV FDA IMG Leadership <2019-nCoVFDAIMGLeadership@fda.hhs.gov>; Abdoo, Mark <Mark.Abdoo@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Arsenault, Sam <Samuel.Arsenault@fda.hhs.gov>; Beach, Carter <Carter.Beach@fda.hhs.gov>; Branch, Tiffany <Tiffany.Branch@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Carter, Lionel <Lionel.Carter@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Hebert, Angelique A. <Angelique.Hebert@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Keller, Melanie <Melanie.Keller@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Malais, Tanya <Tanya.Malais@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>; Musser, Steven M <Steven.Musser@fda.hhs.gov>; O'Callaghan, Kathryn <Kathryn.OCallaghan@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Rogers, Michael <Michael.Rogers@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Ross, Bruce <Bruce.Ross@fda.hhs.gov>; Russo, Mark <Mark.Russo@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Sigg, Jim <Jim.Sigg@fda.hhs.gov>; Solberg, Tim <Tim.Solberg@fda.hhs.gov>; Solomon, Steven M <Steven.Solomon@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Throckmorton, Douglas C <Douglas.Throckmorton@fda.hhs.gov>; Tootle, William <William.Tootle@fda.hhs.gov>; Torres-Rivera, Sahra <Sahra.Torres-Rivera@fda.hhs.gov>; Tse, Tania <Tania.Tse@fda.hhs.gov>; Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>; Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>
Subject: Lawmakers question COVID-19 testing capabilities

(b)(5)

CQ NEWS
Mar. 10, 2020

Lawmakers question COVID-19 testing capabilities

March 10, 2020 – 2:12 p.m. By Sandhya Raman, CQ

House appropriators from both parties expressed concerns Tuesday about the state of testing capabilities for the new coronavirus in the U.S. and reaffirmed they would not cut funding for the Centers for Disease Control and Prevention.

That comes as the vice president's office is slated to release a mitigation strategy to states later Tuesday on how to address the disease known as COVID-19, according to CDC Director Robert Redfield's testimony before the House Labor-HHS-Education Appropriations Subcommittee.

Support for increasing funding for the CDC has been bipartisan and bicameral, especially as the number of COVID-19 cases continues to rise.

"I hope we have made it very clear not to you but the powers that be that we continue to make these investments on a bipartisan basis," subcommittee ranking member Tom Cole, R-Okla., told Redfield. "There's no sense sending us a budget that cuts things that we're not intending to cut."

Redfield testified that the CDC will follow up with states to tailor the strategy that Vice President Mike Pence's office plans to release, which is a guidance document explaining how states should assess and react to low-risk, moderate-risk and high-risk situations.

"Rather than CDC give a blanket recommendation, since this is community by community, we're working with the local health departments head-on to come up with expressing our technical assistance and recommendations," Redfield said.

The CDC has already sent individuals to provide assistance to local health departments in New York, Washington state, California and Florida. Massachusetts is likely one of the next states.

CDC officials also explained the agency's plans for $8.3 billion in supplemental funding that Congress provided.

"I can assure you we are going get that money out very quickly, and much of that to the state and local health departments to operationalize this," Redfield said.

Sherri A. Berger, CDC chief strategy officer and chief operating officer, added that 90 percent of the congressional preparedness funding is expected to be distributed within the next two weeks.

Testing availability

The key concern from committee leadership was why testing capabilities for the disease lags behind that of other countries.

Subcommittee Chairwoman Rosa DeLauro, D-Conn., raised the issue during opening remarks and again during her questions for Redfield.

"I am very concerned about our nation's testing capabilities for coronavirus," said DeLauro. "The low number of positive tests in the U.S. is likely a by-product of under-testing, as opposed to an accurate count of the prevalence of coronavirus in the U.S."

She and other lawmakers are concerned that the delays in the widespread availability of testing for the disease have set back diagnoses and containment strategies.

Redfield said because active agents in some of the testing kits were initially not working properly, the CDC had to advise labs to hold off on using those tests. They then worked with the Food and Drug Administration to correct that issue and replace those tests.

"CDC's focus was to provide testing for the public health system. There's a whole other system we need testing for and that's clinical medicine," he said.

The CDC director also said with two lab testing corporations now able to test for the virus, individuals should not face roadblocks in getting tested if they exhibit symptoms or have been exposed to infected patients.

"I do believe the availability of testing in the last two days through Quest and LabCorp is getting us to where we need to be," he told Rep. Lois Frankel, D-N.Y.

In response to questions from Rep. Mark Pocan, D-Wis., on whether anyone can now get tested anywhere in the country, Redfield said this was now possible.

"Yes, through their physician," Redfield repeated, in contrast to reports from many patients and facilities.

Full Committee Chairwoman Nita M. Lowey, D-N.Y., spoke out against slow approvals by the Trump administration for laboratories and the delayed distribution of working kits in her home state.

"There are labs in New York awaiting approval that could greatly expand testing capacity by thousands per day — as may be the case throughout the country — if only the federal government would get off the sidelines and approve these facilities," she said.

The CDC director said the government's response is improving.

Redfield said separate, updated guidance is going out later Tuesday on health care workers. Health care workers are not proactively being tested unless they are suspected to be at risk, he said.

From: McWilliams, Carly [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B68C7458214244D08424FD441FEA4FDA-CARLYLE.MCW]
Sent: 3/10/2020 4:38:10 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Margaret Garikes [Margaret.Garikes@ama-assn.org]
CC: Shannon Curtis [Shannon.Curtis@ama-assn.org]
Subject: RE: AMA request --COVID-19

Glad you were able to connect with CDRH and we appreciate your outreach. Please feel free to contact me when issues arise.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Tuesday, March 10, 2020 4:29 PM
To: Margaret Garikes <Margaret.Garikes@ama-assn.org>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Cc: Shannon Curtis <Shannon.Curtis@ama-assn.org>
Subject: RE: AMA request --COVID-19

Appreciate the help.

From: Margaret Garikes <Margaret.Garikes@ama-assn.org>
Sent: Tuesday, March 10, 2020 4:27 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Cc: Shannon Curtis <Shannon.Curtis@ama-assn.org>
Subject: RE: AMA request --COVID-19

Keagan – Thanks so much for the quick response. We literally just got off the phone with some folks from CDRH. We had a good conversation and will make every effort to correct the urban myth. I have learned from experience with past epidemics that such issues/questions periodically arise. Best to try to head these issues off before they take on a life of their own. Carly- great to have your name. Promise not to inundate you unnecessarily, but we may circle back as things arise. Don't hesitate to reach out to Shannon or me if we can help you. Thanks again. Margaret

---

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Tuesday, March 10, 2020 4:20 PM
To: Margaret Garikes <Margaret.Garikes@ama-assn.org>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Cc: Shannon Curtis <Shannon.Curtis@ama-assn.org>
Subject: RE: AMA request --COVID-19

[Warning External Email]
Hi Margaret,

Thanks for reaching out. Carly McWilliams is assisting in the Office of the Commissioner with COVID-19. She can be your point person for questions.

Sounds like you have some misinformation. As you know from the policy, that labs can build, test and verify their tests and start using them immediately after notifying FDA. Then they have 15 days to come in for an EUA. So, there is no delay on the FDA end.

Hopefully this link can help you with any diagnostic questions: https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2

Thanks,
Keagan

From: Margaret Garikes <Margaret.Garikes@ama-assn.org>
Sent: Tuesday, March 10, 2020 3:33 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Shannon Curtis <Sh amon Curtis@ama-assn.org>
Subject: AMA request --COVID-19
Importance: High

Keagan –
I am sorry to bother you. We have identified someone at CMS and CDC who, where possible, can work us to get quick answers to questions regarding COVID-19. First, it would help if you could identify someone at FDA who will be able to respond to periodic questions. Rest assured we would be sensitive to the workload that you guys are under but I think it is in everyone's interest if we can clarify issues as they arise.

Second, I think there is some misinformation circulating and I am reaching out to possibly get some information that will help us in communicating with AMA leadership about COVID-19 diagnostics. In short, our physician leadership is hearing from numerous sources that there are delays at FDA in approving the Emergency Use Authorizations for COVID-19 diagnostics developed by laboratories/academic centers. We are aware of the recent policy on this matter issued by FDA, as well as the two currently issued EUAs (CDC and NY state).

Can you shed any light on whether the agency may be seeing delays in getting these EUAs issued, or if this is simply some misinformation circulating among the medical community? This has obviously become an exceptionally high priority issue for the AMA and its members and an issue we anticipate continuing to be very active on. Any light you may be able to shed on the issue of the pace of authorization for new COVD-19 diagnostics would be very helpful to us as we determine how best to manage this work, communicate with our AMA leadership, and collaborate with FDA where possible.

Thanks in advance for any help you can provide. Thanks, Margaret

AMA

Margaret Garikes
Vice President, Federal Affairs
25 Massachusetts Avenue, NW
Suite 600
Washington, DC 20001-7400

P: (202) 789-7409
M: (b)(6)
margaret.garikes@ama-assn.org

From: McWilliams, Carly [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B68C7458214244D08424FD441FEA4FDA-CARLYLE.MCW]
Sent: 3/10/2020 4:47:59 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: RE: AMA request --COVID-19

Happy to. I will keep you posted when they ping for awareness.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Tuesday, March 10, 2020 4:20 PM
To: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Subject: FW: AMA request --COVID-19
Importance: High

Do you want to be the point of contact for them? **(b)(5)**
(b)(5)

From: Margaret Garikes <Margaret.Garikes@ama-assn.org>
Sent: Tuesday, March 10, 2020 3:33 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Shannon Curtis <Shannon.Curtis@ama-assn.org>
Subject: AMA request --COVID-19
Importance: High

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AMA

Margaret Garikes
Vice President, Federal Affairs
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margaret.garikes@ama-assn.org

From: Short, Marc T. EOP/OVP [Marc.T.Short@ovp.eop.gov]
Sent: 3/10/2020 6:31:31 PM
To: Short, Marc T. EOP/OVP [Marc.T.Short@ovp.eop.gov]; Angela.H.Stubblefield@faa.gov; as2ktc@hq.dhs.gov; Telle, Adam R. EOP/WHO [Adam.R.Telle@who.eop.gov]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS (b)(6)]; Sugarman, AJ J. EOP/WHO (b)(6) ; (b)(6) Hooker, Allison M. EOP/NSC (b)(6) ; amie.kalsbeek@dot.gov; Abrams, Andrew D. EOP/OMB (b)(6) ; Hurst, Natalie R. EOP/OVP (b)(6) ; Ruggiero, Anthony J. EOP/NSC (b)(6) ; Cantrell, Benjamin B. EOP/OVP (b)(6) Hall, Bill (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e56218361cd4ffbacdd06ac2d7b809d-HHS-bill.ha]; Stimson, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=21fcf1b527694276af1ccdb7db495042-HHS-Brian.S]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Cavanaugh, Brian J. EOP/NSC (b)(6) ; Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; BrownleeIG@state.gov; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Shuy, Caitrin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=875ab76b6ae34c4cad510d8e5ceddf9b-HHS-Caitrin]; (b)(6) Schuchat, Anne (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=848b7544f27d4a2a9554a80e78d002fc-HHS-acs1-cd]; Berger, Sherri (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b1ac8b1b9ba4abe8ef7b1d7abcd8d71-HHS-sob8-cd]; (b)(6) ; Hodgson, Christopher M. EOP/OVP (b)(6) ; Liddell, Christopher P. EOP/WHO (b)(6) ; Troye, Olivia EOP/NSC [Olivia.Troye@nsc.eop.gov]; (b)(6) Daniel.Elwell@faa.gov; Johnston, Darcie (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0e6d7dbb72d4d6eb84029c0547f7458-HHS-Darcie.]; (b)(6) Planning, David M. EOP/WHO (b)(6) ; Kan, Derek T. EOP/OMB (b)(6) ; donna.o'berry@dot.gov; Hoelscher, Douglas L. EOP/WHO (b)(6) ; Taylor, Elizabeth A. EOP/WHO (b)(6) Elvander, Erika (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e95f3e9a68a641e7bfd7ba7dae325e8f-HHS-Erika.E]; ADA-DE@faa.gov; (b)(6) Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Bruno, Grace A. EOP/OMB (b)(6) D'Angelo, Gregory B. EOP/OMB (b)(6) ; (b)(6) (b)(6) Watson, Ian D. EOP/OSTP (b)(6) Butler, Jay C (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5889356ccdc748039523698679f9d269-HHS-jcb3-cd]; jcc@usdoj.gov; Rubini, Jeffrey H. EOP/NSC (b)(6) Moughalian, Jen C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1227fced76ad4092bb5f1395d24c0d74-HHS-Jen.Mou]; Adams, Jerome (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=302991451fc341bf9a7ffa53eba3f81c-HHS-Jerome.]; Ditto, Jessica E. EOP/WHO (b)(6) ; Dulaigh, Joel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01f4f5f895214d4f8112c62d40ac50ce-HHS-Joel.Du]; (b)(6) Wilson, John Mark M. EOP/NSC (b)(6) Woolfolk, Jon J. EOP/OVP (b)(6) Greene, Jonathan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a431fbb31b9b4f8fbeb326c5e670d41c-HHS-Jonatha]; Ullyot, John L. EOP/NSC (b)(6) Fernandez, Jose A (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f9ce43e810f43a0b1ff03a6a5d6d542-HHS-Jose.Fe]; (b)(6) Deere, Judd P. EOP/WHO

(b)(6) Stecker, Judy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e205440400ab4f629be1faccfe0846fc-HHS-Judy.St]; Stufft, Julie M. EOP/NSC (b)(6) Christ, Katelyn E. EOP/NSC (b)(6) l; Miller, Kati e R. EOP/OV [Katie.R.Miller@ovp.eop.gov] (b)(6) Chafin, Kelly B. EOP/NSC (b)(6) Yeskey, Kevin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=754752a933bb4079b8e5bec6f74841a9-HHS-Kevin.Y]; Newman, Kim A. EOP/OMB (b)(6) Nevins, Kristan K. EOP/WHO (b)(6) Baum, Kristina R. EOP/OSTP (b)(6) Zebley, Kyle (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d79ac6af2e1b49089fca453b39ebddde-HHS-Kyle.Ze]; Pence, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3f21407a02d44cd4901bcce26f9b3074-HHS-Laura.P]; Trueman, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9385c36713d64340ac51bc3e72864402-HHS-Laura.T]; Fabina, Lauren C. EOP/NSC (b)(6) ; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; (b)(6) Garufi, Marc A. EOP/OMB (b)(6) (b)(6) Lowry, Patrick J. EOP/NSC (b)(6) Mango, Paul (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2fe1932caf0249d2a0c6af5fb82c9ec5-HHS-Paul.Ma]; Stannard, Paula (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=447102489a24495bb9004e524dda1589-HHS-Paula.S]; Ferro, Phil J. EOP/NSC (b)(6) Hudson, Renee R. EOP/WHO (b)(6) Blair, Robert B. EOP/WHO (b)(6) ; Charrow, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12441403d18b42559a072c648988b55a-HHS-Robert.]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; (b)(6) Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; S60.policy@dot.gov; Phillips, Sally (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1cb037be9832427da73afb313d34e243-HHS-Sally.P]; Imbriale, Samuel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8833a4896f4e4d0d86bffec7b280b7bc-HHS-Samuel.]; (b)(6) Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Thallam, Satya P. EOP/OMB (b)(6) Bonyun, Sean C. EOP/OSTP (b)(6) (b)(6) Grisham, Stephanie A. EOP/WHO (b)(6) Steven.Bradbury@dot.gov; (b)(6) Reilly, Tom M. EOP/OMB (b)(6) Pataki, Tim A. EOP/WHO (b)(6) McMillin, Virginia D. EOP/WHO [Virginia.D.McMillin@who.eop.gov]; (b)(6) Chang, William (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306e2f56f7cf45d6afae2d8d4791dadd-HHS-William]; (b)(6) William.C.Hughes@usdoj.gov (b)(6) Zachary.McEntee@treasury.gov; Dareshori, Zachary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3460db40e0d54c918d19bb70b52d8825-HHS-Zachary]; (b)(6) Brian.W.Anderson@usdoj.gov; Philip.C.Ball@usdoj.gov; Boles, Cassie L. EOP/OMB (b)(6) Burton, Nicholas S. EOP/OMB (b)(6) ; Farquharson, Christine E. EOP/OMB (b)(6) ; DL NSC Asia (b)(6) Hallisey, William B. EOP/NSC (b)(6) ; Hanna, Cory M. EOP/NSC (b)(6) Morgan, Jameson A. EOP/NSC (b)(6) Wright, Janet (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=292cd8567b18485682c845385a17b897-HHS-Janet.W]; Rotz, Lisa D (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b77a22d3468c4b46b0ffa72e818e1cb4-HHS-ler8-cd]; (b)(6) (b)(6) Russo, Joseph H. EOP/WHO (b)(6) meredith.bumpus@va.gov; pamela.powers@va.gov; teresa.mock@va.gov; Andrew.Hughes@hud.gov; (b)(6) (b)(6) Martin, Nicole M. EOP/WHO [(b)(6) Campana,

Alexandra D. EOP/WHO [Alexandra.D.Campana2@who.eop.gov]; DeValliere, Ian C. EOP/WHO (b)(6) Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@who.eop.gov]; Jonas, Seth H. EOP/NSC (b)(6); Joyce, Shannon M. EOP/OMB (b)(6); Hirsch, Quinn N. EOP/OMB (b)(6); Uldricks, Nathan R. EOP/OMB (b)(6); Lang, Jon D. EOP/NSC (b)(6); Blackford, Carol W (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7dc338b24154229bd381935f207cb43-HHS-Carol.B]; (b)(6); Bonner, Maria K. EOP/WHO [Maria.K.Bonner@who.eop.gov]; mark.michalic@usdoj.gov; Pottinger, Matthew F. EOP/WHO (b)(6); Davis, May M. EOP/WHO [May.Davis@who.eop.gov]; (b)(6); Lin, Merry S. EOP/WHO (b)(6); McKenna, Michael A. EOP/WHO (b)(6); Sinclair, Michael R. EOP/NSC (b)(6); Williams, Michael B. EOP/WHO (b)(6); Cetron, Martin (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0df896abcded4e5d91d79a34c4b49ce9-HHS-mzc4-cd]; Butterfield, Nicholas W. EOP/WHO [Nicholas.W.Butterfield@who.eop.gov]; Pottebaum, Nic D. EOP/WHO [Nicholas.D.Pottebaum@who.eop.gov]; Theriot, Nicole D. EOP/NSC (b)(6); (b)(6); McGowan, Robert K (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e6175b088b1d49a4bfa2de3862800d4a-HHS-omc2-cd]; Waterman, Paige E. EOP/OSTP (b)(6); brent.mcintosh@treasury.gov; Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Obenshain, Tucker T. EOP/OVP (b)(6); Devin.O'Malley@treasury.gov (b)(6); (b)(6); Gastfriend, Daniel Z. EOP/OMB (b)(6); Theroux, Rich P. EOP/OMB (b)(6); Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; (b)(6); Stephen C. EOP/NSC (b)(6); Joel.Szabat@dot.gov; Evelyn.Lim@hud.gov; Marston, Hilary D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; Sheehan, Matthew J. EOP/OVP (b)(6)

Subject: White House Coronavirus Subtask Force Call
Attachments: Untitled Attachment; White House Coronavirus Subtask Force Call - Agenda
Location: Participant Dial-In: 1(888) 330-1716 | Access Code: (b)(6)

Start: 3/11/2020 9:00:00 AM
End: 3/11/2020 9:30:00 AM
Show Time As: Tentative

Recurrence: (none)

All –

There will be a daily **White House Coronavirus Subtask Force Call** at **9:00 am** Monday-Friday.

Agenda for Wednesday, March 11, will be forthcoming.

Call-In Information:
Participant Dial-In: (888) 330-1716
Access Code (b)(6)

Thank you,

Natalie Hurst

Executive Assistant to the Chief of Staff
The Office of the Vice President
(b)(6)

From: Schwartz, Suzanne [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=60FBAC0E12A24633B1018181711F7849-SUZANNE.SCH]
Sent: 3/10/2020 7:41:47 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
Subject: FW: request for engagement on surgical masks

Just keeping you in the loop....

Suzanne B. Schwartz, MD, MBA
Deputy Director (& Acting Office Director) Office of Strategic Partnerships & Technology Innovation
Center for Devices and Radiological Health (CDRH)
Office of Strategic Partnerships and Technology Innovation (OST)
U.S. Food and Drug Administration
WO66, Room 5410
Tel: 301-796-6937
Cell:202-841-9996
Suzanne.Schwartz@fda.hhs.gov

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

From: Schwartz, Suzanne
Sent: Tuesday, March 10, 2020 7:41 PM
To: (b)(6) CDRH All Hazards Readiness Response and Cybersecurity <cdrharc@fda.hhs.gov>
Cc: Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; O'Callaghan, Kathryn <Kathryn.OCallaghan@fda.hhs.gov>
Subject: request for engagement on surgical masks

Good evening (b)(6),
I just left you a voicemail on your work number. We received through the White House and HHS a message indicating you would like to discuss a matter concerning surgical masks.

My team and I are directly involved in COVID-19 response for medical devices, including supply chain issues. We'd be happy to accommodate a call with you tomorrow (Wednesday) at your convenience. Please advise as to your availability and we can set that up.

Best,
Suzanne

Suzanne B. Schwartz, MD, MBA
Deputy Director (& Acting Office Director) Office of Strategic Partnerships & Technology Innovation
Center for Devices and Radiological Health (CDRH)
Office of Strategic Partnerships and Technology Innovation (OST)
U.S. Food and Drug Administration
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Cell:202-841-9996
Suzanne.Schwartz@fda.hhs.gov

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

From: Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]
Sent: 3/10/2020 8:45:39 PM
To: Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]
Subject: Re: Social monitoring - testing

Just tried you, if you need something pls call my cell.

Sent from my iPhone

On Mar 10, 2020, at 8:28 PM, Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov> wrote:

AGREE:
Guidance on who to test is CDC.

(b)(5)

https://www.cdc.gov/coronavirus/2019-ncov/lab/index.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fguidance-laboratories.html
I just talked to the Commissioner – awesome – and I may want to have a quick talk with Keagan. Call me?

Ryan: If you need to chat, call me.

Brett P. Giroir, MD
ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Tuesday, March 10, 2020 8:24 PM
To: Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>
Cc: Pratt, Michael (OS/ASPA) <Michael.Pratt@hhs.gov>; ASPA-Deputies <ASPA-Deputies@hhs.gov>; Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Bonds, Michelle E. (CDC/OD/OADC) <meb0@cdc.gov>
Subject: Re: Social monitoring - testing

Who should get the test is CDC guidance I believe. I think it is online, but yield to them. How to make a test or the guidance or how to interact with the FDA around tests in posted online.

Sent from my iPhone

On Mar 10, 2020, at 7:37 PM, Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov> wrote:

Isn't the testing guidance online?

On Mar 10, 2020, at 6:34 PM, Pratt, Michael (OS/ASPA) <Michael.Pratt@hhs.gov> wrote:

https://twitter.com/jaketapper/status/1237500452222222336
Jake Tapper
@jaketapper Washington firefighters who responded to nursing home face longer quarantine as bottlenecks delay testing: https://t.co/tmgYJ3ijbv?amp=1

https://twitter.com/jaketapper/status/1237489777118674944
Jake Tapper
@jaketapper
CNN's @OmarJimenez reports that a spokesman for Life Care Center in Kirkland WA says the nursing facility has finally begun testing employees after what many considered a long delay. Test results are not yet available for 30 employees who were tested off site.

1/

https://twitter.com/NitzaSoledad/status/1237502741968191490
Nitza Soledad Perez
@NitzaSoledad
While Germany has drive-in testing facilities, ppl in the US struggle to get screened for coronavirus. Health and Human Services ☐
@SecAzar
☐ just said to the public that there is a surplus of tests. The misinformation from the White House continues. #COVID19 #coronavirus

https://twitter.com/markknoller/status/1237502685839945728
Mark Knoller
@markknoller
Though millions of Coronavirus tests are being produced, @SecAzar says persons who want to be tested need to go through their doctor or hospital and cannot just demand a test. Stresses persons should call their doctor and ask to be considered for a Coronavirus test.

https://twitter.com/chrislhayes/status/1237502187762257931
Chris Hayes
@chrislhayes
Hey doctors: as @SecAzar says there's actually a "surplus" of tests available, I'm curious if this your experience at point of care as of today, March 10th.

https://twitter.com/laallergydoc/status/1237503671534927872
Marc Meth, MD
@chrislhayes The answer is no. I've tried to get swabs to actually perform the testing if needed to give to Quest or Labcorp and there are NONE available.

https://twitter.com/rcbutter1/status/1237502598791512065
RB
@rcbutter1
No! I cant keep hearing these answers. I'm a primary care doctor in Albany, NY. There are no tests unless a patient meets strict criteria which DO NOT include travel to Seattle, Westchester or California!

https://twitter.com/MORDE110/status/1237503914703904768
MORDE1
@MORDE110
Untrue.
Sick patients must meet a critical 3+ level to be tested in California.

https://twitter.com/MollyJongFast/status/1237502769495506946
Molly Jong-Fast
@MollyJongFast
“there are millions of tests out there now,” say @SecAzar but this doesn’t sound right

Michael J. Pratt
Director, Strategic Communications & Campaigns
Office of the Assistant Secretary for Public Affairs
U.S. Department of Health and Human Services
michael.pratt@hhs.gov
202.690.7471 **(b)(6)** (m)

From: Caccomo, Stephanie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=950C32CEBC4B4F80B302C50CF31C8524-STEPHANIE.C]
Sent: 3/10/2020 11:28:48 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]
CC: McWilliams, Carly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]; McBride, Maren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]
Subject: FW: New York Times: 'It's Just Everywhere Already': How Delays in Testing Set Back the U.S. Coronavirus Response

FYI—CDRH is fact checking some of the highlighted info below, flagging for you all for awareness

Of note, here is what we sent to NYT:

On the record, attributable to FDA spokesperson: FDA did participate in calls with the Seattle Flu Study researchers. FDA recommended that the researchers talk with their hospital administrator about what was needed to move forward with clinical research, which has different scientific and regulatory requirements compared to academic research.

We also want to share ways that FDA is supporting all diagnostic developers during this time. FDA received its first request for an EUA template on January 22nd and we sent the template to them the same day. We have since received over 100 requests for the template. Of those, more than 40 have sought our assistance with development and validation of tests they plan to bring through the Emergency Use Authorization process. We are talking to them around the clock, and our door is open for any developers who want to have a test for use in the U.S.

Additionally, we issued a policy last weekend to achieve more rapid testing in the U.S. We have provided regulatory relief and clarity to encourage the development of new diagnostic tests for Americans. Under that new policy, we have heard from 14 labs, 10 of whom already have begun patient testing.

On background, not for quoting: At that time, as shared by the Seattle lab, we understood their IRB had not given them permission to proceed with their work. Hence why we recommended the researchers speak with their hospital administrator about appropriate next steps.

'It's Just Everywhere Already': How Delays in Testing Set Back the U.S. Coronavirus Response
New York Times // Sheri Fink, Mike Baker

A series of missed chances by the federal government to ensure more widespread testing came during the early days of the outbreak, when containment would have been easier.

Dr. Helen Y. Chu, an infectious disease expert in Seattle, knew that the United States did not have much time.

In late January, the first confirmed American case of the coronavirus had landed in her area. Critical questions needed answers: Had the man infected anyone else? Was the deadly virus already lurking in other communities and spreading?

As luck would have it, Dr. Chu had a way to monitor the region. For months, as part of a research project into the flu, she and a team of researchers had been collecting nasal swabs from residents experiencing symptoms throughout the Puget Sound region.

To repurpose the tests for monitoring the coronavirus, they would need the support of state and federal officials. But nearly everywhere Dr. Chu turned, officials repeatedly rejected the idea, interviews and emails show, even as weeks crawled by and outbreaks emerged in countries outside of China, where the infection began.

By Feb. 25, Dr. Chu and her colleagues could not bear to wait any longer. They began performing coronavirus tests, without government approval.

What came back confirmed their worst fear. They quickly had a positive test from a local teenager with no recent travel history. The coronavirus had already established itself on American soil without anybody realizing it.

"It must have been here this entire time," Dr. Chu recalled thinking with dread. "It's just everywhere already."

In fact, officials would later discover through testing, the virus had already contributed to the deaths of two people, and it would go on to kill 20 more in the Seattle region over the following days.

Federal and state officials said the flu study could not be repurposed because it did not have explicit permission from research subjects; the labs were also not certified for clinical work. While acknowledging the ethical questions, Dr. Chu and others argued there should be more flexibility in an emergency during which so many lives could be lost. On Monday night, state regulators told them to stop testing altogether.

The failure to tap into the flu study, detailed here for the first time, was just one in a series of missed chances by the federal government to ensure more widespread testing during the early days of the outbreak, when containment would have been easier. Instead, local officials across the country were left to work blindly as the crisis grew undetected and exponentially.

Even now, after weeks of mounting frustration toward federal agencies over flawed test kits and burdensome rules, states with growing cases such as New York and California are struggling to test widely for the coronavirus. The continued delays have made it impossible for officials to get a true picture of the scale of the growing outbreak, which has now spread to at least 36 states and Washington, D.C.

Dr. Robert R. Redfield, director of the Centers for Disease Control and Prevention, said in an interview on Friday that acting quickly was critical for combating an outbreak. "Time matters," he said.

He insisted that despite the rocky start, there was still time to beat back the coronavirus in the United States. "It's going to take rigorous, aggressive public health — what I like to say, block and tackle, block and tackle, block and tackle, block and tackle," he said. "That means if you find a new case, you isolate it."

But the Seattle Flu Study illustrates how existing regulations and red tape — sometimes designed to protect privacy and health — have impeded the rapid rollout of testing nationally, while other countries ramped up much earlier and faster. Faced with a public health emergency on a scale potentially not seen in a century, the United States has not responded nimbly.

The C.D.C.'s own effort to create a system for monitoring the virus around the country, using established government surveillance networks for the flu, has not yet built steam. And as late as last week, after expanding authorizations for commercial and academic institutions to make tests, administration officials provided conflicting accounts of when a significant increase in tests would be available.

In states like Maine, Missouri and Michigan, where there are few or no known infections, state public health officials say they have more than enough tests to meet demand.

But it remains unclear how many Americans have been tested for the coronavirus. The C.D.C. says approximately 8,500 specimens or nose swabs have been taken since the beginning of the outbreak — a figure that is almost certainly larger than the number of people tested since one person can have multiple swabs. By comparison, South Korea, which discovered its first case around the same time as the United States, has reported having the capacity to test roughly 10,000 people a day since late February.

A prime mission

As soon as the genetic sequence of the coronavirus was published in January, the C.D.C.'s first job was to develop a diagnostic test. "That's our prime mission," Dr. Redfield said, "to get eyes on this thing."

The agency also released criteria for deciding which individuals should be tested for the virus — at first only those who had a fever and respiratory issues and had traveled from the outbreak's origin in Wuhan, China.

The criteria were so strict that the sick man in the Seattle area who had visited Wuhan did not meet it. Still, worried state health officials pushed to get him checked, and the C.D.C. agreed. Local officials sent a sample to Atlanta and the results came backpositive.

Officials monitored 70 people who were in contact with the man, including 50 who consented to getting nose swabs, and none tested positive for the coronavirus. But there was still the possibility that someone had been missed, said Dr. Scott Lindquist, the state epidemiologist for communicable diseases.

Around this time, the Washington State Department of Health began discussions with the Seattle Flu Study already going on in the state.

But there was a hitch: The flu project primarily used research laboratories, not clinical ones, and its coronavirus test was not approved by the Food and Drug Administration. And so the group was not certified to provide test results to anyone outside of their own investigators. They began discussions with state, C.D.C. and F.D.A. officials to figure out a solution, according to emails and interviews.

Dr. Scott F. Dowell, a former high-ranking C.D.C. official and a current deputy director at the Bill & Melinda Gates Foundation, which funds the Seattle Flu Study, asked for help from the leaders of the C.D.C.'s coronavirus response. "Hoping there is a solution," he wrote on Feb. 10.

Later, Dr. Lindquist, the state epidemiologist in Washington, wrote an email to Dr. Alicia Fry, the chief of the C.D.C.'s epidemiology and prevention branch, requesting the study be used to test for the coronavirus.

C.D.C. officials repeatedly said it would not be possible. "If you want to use your test as a screening tool, you would have to check with F.D.A.," Gayle Langley, an officer at the C.D.C.'s National Center for Immunization and Respiratory Disease, wrote back in an email on Feb. 16. But the F.D.A. could not offer the approval because the lab was not certified as a clinical laboratory under regulations established by the Centers for Medicare & Medicaid Services, a process that could take months.

Dr. Chu and Dr. Lindquist tried repeatedly to wrangle approval to use the Seattle Flu Study. The answers were always no.

"We felt like we were sitting, waiting for the pandemic to emerge," Dr. Chu said. "We could help. We couldn't do anything."

Sense of exasperation

As Washington State debated with the federal officials over what to do, the C.D.C. confronted the daunting task of testing more widely for the coronavirus.

The C.D.C. had designed its own test as it typically does during an outbreak. Several other countries also developed their own tests.

But when the C.D.C. shipped test kits to public labs across the country, some local health officials began reporting that the test was producing invalid results.

The C.D.C. promised that replacement kits would be distributed within days, but the problem stretched on for over two weeks. Only five state laboratories were able to test in that period. Washington and New York were not among them.

By Feb. 24, as new cases of the virus began popping up in the United States, the state labs were growing frantic.

The Association of Public Health Laboratories made what it called an "extraordinary and rare request" of Dr. Stephen Hahn, the commissioner of the F.D.A., asking him to use his discretion to allow state and local public health laboratories to create their own tests for the virus.

"We are now many weeks into the response with still no diagnostic or surveillance test available outside of C.D.C. for the vast majority of our member laboratories," Scott Becker, the chief executive of the association, wrote in a letter to Dr. Hahn.

Dr. Hahn responded two days later, saying in a letter that "false diagnostic test results can lead to significant adverse public health consequences" and that the laboratories were welcome to submit their own tests for emergency authorization.

But the approval process for laboratory-developed tests was proving onerous. Private and university clinical laboratories, which typically have the latitude to develop their own tests, were frustrated about the speed of the F.D.A. as they prepared applications for emergency approvals from the agency for their coronavirus tests.

Dr. Alex Greninger, an assistant professor at the University of Washington Medical Center in Seattle, said he became exasperated in mid-February as he communicated with the F.D.A. over getting his application ready to begin testing. "This virus is faster than the F.D.A.," he said, adding that at one point the agency required him to submit materials through the mail in addition to over email.

New tests typically require validation — running the test on known positive samples from a patient or a copy of the virus genome. The F.D.A.'s process called for five. Obtaining such samples has been hard because most hospital labs have not seen coronavirus cases yet, said Dr. Karen Kaul, chair of the department of pathology and laboratory medicine at NorthShore University HealthSystem in Illinois.

She said she had to scramble to obtain virus RNA from a laboratory in Europe. "Everyone is trying to figure out what we can get to help us gather the data that we need," she said.

The F.D.A. has disputed that it moved too slowly, saying that it provided emergency authorization for two laboratory-developed tests within 24 hours of a completed submission — one was the C.D.C.'s test and the other a test developed by New York's Wadsworth laboratory after it had trouble verifying the C.D.C.'s test.

'What do we do?'

On the other side of the country in Seattle, Dr. Chu and her flu study colleagues, unwilling to wait any longer, decided to begin running samples.

A technician in the laboratory of Dr. Lea Starita who was testing samples soon got a hit.

"I'm like, 'Oh my God,"' Dr. Starita said. "I just took off running" to the office of the study's program managers. "We got one," she told them. "What do we do?"

Members of the research group discussed the ethics of what to do next.

"What we were allowed to do was to keep it to ourselves," Dr. Chu said. "But what we felt like we needed to do was to tell public health."

They decided the right thing to do was to inform local health officials.

The case was a teenager, in the same county where the first coronavirus case had surfaced, who had a flu swab just a few days before but had no travel history and no link to any known case.

The state laboratory, finally able to begin testing, confirmed the result the next morning. The teenager, who had recovered from his illness, was located and informed just after he entered his school building. He was sent home and the school was later closed as a precaution.

Later that day, the investigators and Seattle health officials gathered with representatives of the C.D.C. and the F.D.A. to discuss what happened. The message from the federal government was blunt. "What they said on that phone call very clearly was cease and desist to Helen Chu," Dr. Lindquist remembered. "Stop testing."

A silent spread

Still, the troubling finding reshaped how officials understood the outbreak. Seattle Flu Study scientists quickly sequenced the genome of the virus, finding a genetic variation also present in the country's first coronavirus case.

The implications were unnerving. There was a good chance that the virus had been circulating silently in the community for around six weeks, infecting potentially hundreds of people.

On a phone call the day after the C.D.C. and F.D.A. had told Dr. Chu to stop, officials relented, but only partially, the researchers recalled. They would allow the study's laboratories to test cases and report the results only in future samples. They would need to use a new consent form that explicitly mentioned that results of the coronavirus tests might be shared with the local health department.

They were not to test the thousands of samples that had already been collected.

The same day, the F.D.A. said it would relax its rules and allowclinical labs to begin using their own coronavirus tests as long as they submitted evidence that they worked to the agency. Under that new policy, according to an agency representative on Tuesday, it had heard from 14 labs, with 10 already beginning patient testing.

On March 2, the Seattle Flu Study's institutional review board at the University of Washington determined that it would be unethical for the researchers not to test and report the results in a public health emergency, Dr. Starita said. Since then, her laboratory has found and reported numerous additional cases, all of which have been confirmed.

As new samples came in, Dr. Starita's laboratory also worked their way backward through some older samples that had been sitting in the freezers for weeks, finding cases that date back to at least Feb. 20 — seven days before public health officials had any idea the virus was in the community.

The scientists said they believe that they will find evidence that the virus was infecting people even earlier, and that they could have alerted authorities sooner if they had been allowed to test.

But on Monday night, state regulators, enforcing Medicare rules, stepped in and again told them to stop until they could finish getting certified as a clinical laboratory, a process that could take many weeks.

In the days since the teenager's test, the Seattle region has spun into crisis, with dozens of people testing positive and at least 22 dying — many of them infected in a nursing home that had unknowingly been suffering casualties since Feb. 19.

The availability of testing for coronavirus remains uneven, with some people able to easily obtain tests in certain parts of the country while others have been turned away. Some state officials fear that the virus is spreading far faster than the capacity for testing is increasing.

Looking back, Dr. Chu said she understood why the regulations that stymied the flu study's efforts for weeks existed. "Those protections are in place for a reason," she said. "You want to protect human subjects. You want to do things in an ethical way."

The frustration, she said, was how long it took to cut through red tape to try to save lives in an outbreak that had the potential to explode in Washington State and spread in many other regions. "I don't think people knew that back then," she said. "We know it now."

From: Caccomo, Stephanie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=950C32CEBC4B4F80B302C50CF31C8524-STEPHANIE.C]
Sent: 3/11/2020 10:19:10 AM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: Re: Social monitoring - testing

Will do

Stephanie Caccomo
Press Officer

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

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Date: March 11, 2020 at 10:17:41 AM EDT
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: Fwd: Social monitoring - testing

(b)(5)

Sent from my iPhone

Begin forwarded message:

From: "Stecker, Judy (OS/IOS)" <Judy.Stecker@hhs.gov>
Date: March 11, 2020 at 10:01:02 AM EDT
To: "Pratt, Michael (OS)" <Michael.Pratt@hhs.gov>
Cc: "Bonds, Michelle E (CDC)" <meb0@cdc.gov>, "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>, ASPA-Deputies <ASPA-Deputies@hhs.gov>, "Giroir, Brett (OS)" <Brett.Giroir@hhs.gov>, "Caliguiri, Laura" <Laura.Caliguiri@fda.hhs.gov>
Subject: Re: Social monitoring - testing

(b)(5)

Sent from my iPhone

On Mar 11, 2020, at 9:56 AM, Pratt, Michael (OS/ASPA) <Michael.Pratt@hhs.gov> wrote:

As part of what was discussed this morning, (b)(5)

(b)(5)

https://twitter.com/JonVigliotti/status/1237736498390130688
Jonathan Vigliotti @JonVigliotti
@secazar is delivering an alternate reality. Consider this: The US and South Korea discovered their first cases around the same time. SK has capacity to test 10,000 a day. US has administered 8,500 since February.

From: Pratt, Michael (OS/ASPA) <Michael.Pratt@hhs.gov>
Sent: Tuesday, March 10, 2020 10:36 PM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Cc: Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; ASPA-Deputies <ASPA-Deputies@hhs.gov>; Bonds, Michelle E. (CDC/OD/OADC) <meb0@cdc.gov>
Subject: Re: Social monitoring - testing

More:

https://twitter.com/ncdhhs/status/1237408712559669250?s=21

https://twitter.com/billkristol/status/1237566901603065858?s=21

https://twitter.com/jsodonoghue/status/1237562508258340869?s=21

Sent from my iPhone

On Mar 10, 2020, at 8:28 PM, Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov> wrote:

AGREE:

(b)(5)

https://www.cdc.gov/coronavirus/2019-ncov/lab/index.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fguidance-laboratories.html
I just talked to the Commissioner – awesome – and I may want to have a quick talk with Keagan. Call me?

Ryan: If you need to chat, call me.

Brett P. Giroir, MD
ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Tuesday, March 10, 2020 8:24 PM

To: Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>
Cc: Pratt, Michael (OS/ASPA) <Michael.Pratt@hhs.gov>; ASPA-Deputies <ASPA-Deputies@hhs.gov>; Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Bonds, Michelle E. (CDC/OD/OADC) <meb0@cdc.gov>
Subject: Re: Social monitoring - testing

Who should get the test is CDC guidance I believe. I think it is online, but yield to them. How to make a test or the guidance or how to interact with the FDA around tests in posted online.

Sent from my iPhone

On Mar 10, 2020, at 7:37 PM, Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov> wrote:

Isn't the testing guidance online?

On Mar 10, 2020, at 6:34 PM, Pratt, Michael (OS/ASPA) <Michael.Pratt@hhs.gov> wrote:

https://twitter.com/jaketapper/status/1237500452222222336
Jake Tapper
@jaketapper Washington firefighters who responded to nursing home face longer quarantine as bottlenecks delay testing: https://t.co/tmgYJ3ijbv?amp=1

https://twitter.com/jaketapper/status/1237489777118674944
Jake Tapper
@jaketapper
CNN's @OmarJimenez reports that a spokesman for Life Care Center in Kirkland WA says the nursing facility has finally begun testing employees after what many considered a long delay. Test results are not yet available for 30 employees who were tested off site.

1/

https://twitter.com/NitzaSoledad/status/1237502741968191490
Nitza Soledad Perez
@NitzaSoledad
While Germany has drive-in testing facilities, ppl in the US struggle to get screened for coronavirus. Health and Human Services ☐
@SecAzar
☐ just said to the public that there is a surplus of tests. The misinformation from the White House continues. #COVID19 #coronavirus

https://twitter.com/markknoller/status/1237502685839945728
Mark Knoller
@markknoller
Though millions of Coronavirus tests are being produced, @SecAzar says persons who want to be tested need to go through their doctor or hospital and cannot just demand a test. Stresses persons should call their doctor and ask to be considered for a Coronavirus test.

https://twitter.com/chrislhayes/status/1237502187762257931
Chris Hayes

@chrislhayes
Hey doctors: as @SecAzar says there's actually a "surplus" of tests available, I'm curious if this your experience at point of care as of today, March 10th.

https://twitter.com/laallergydoc/status/1237503671534927872
Marc Meth, MD
@chrislhayes The answer is no. I've tried to get swabs to actually perform the testing if needed to give to Quest or Labcorp and there are NONE available.

https://twitter.com/rcbutter1/status/1237502598791512065
RB
@rcbutter1
No! I cant keep hearing these answers. I'm a primary care doctor in Albany, NY. There are no tests unless a patient meets strict criteria which DO NOT include travel to Seattle, Westchester or California!

https://twitter.com/MORDE110/status/1237503914703904768
MORDE1
@MORDE110
Untrue.
Sick patients must meet a critical 3+ level to be tested in California.

https://twitter.com/MollyJongFast/status/1237502769495506946
Molly Jong-Fast
@MollyJongFast
“there are millions of tests out there now,” say @SecAzar but this doesn’t sound right

Michael J. Pratt
Director, Strategic Communications & Campaigns
Office of the Assistant Secretary for Public Affairs
U.S. Department of Health and Human Services
michael.pratt@hhs.gov
202.690.7471 **(b)(6)** (m)

From: Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]
Sent: 3/11/2020 10:58:40 AM
To: Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; McWilliams, Carly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: RE: TPs for Commissioner
Attachments: Diagnostics Timeline and TPs.docx

Hi Stacy –
Agree that would be helpful for me too
Here is one set of testing TP that I was cc'd on…
Anand

PRE-DECISIONAL, CONFIDENTIAL

From: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Sent: Wednesday, March 11, 2020 10:56 AM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: TPs for Commissioner

I am not getting all the TPs and data that Centers are sending the Commissioner. Who can help make sure I am seeing that stuff too and getting copies forwarded? I am getting pinged all day and night by the WH and Dept on many of the same issues and want to be on the same message/have the same info so we don't look incompetent.

On that note – can I please have whatever are the most recent info or TPs on the tests?

Thank you for any help!

****
Stacy Cline Amin
Chief Counsel
Food and Drug Administration
Deputy General Counsel
Department of Health and Human Services

From: Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]
Sent: 3/11/2020 11:02:00 AM
To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
Subject: Fwd: Social monitoring - testing

Sent from my iPhone

Begin forwarded message:

From: "Pratt, Michael (OS/ASPA)" <Michael.Pratt@hhs.gov>
Date: March 11, 2020 at 10:52:44 AM EDT
To: "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>, "Stecker, Judy (OS)" <Judy.Stecker@hhs.gov>
Cc: "Bonds, Michelle E (CDC)" <meb0@cdc.gov>, ASPA-Deputies <ASPA-Deputies@hhs.gov>, "Giroir, Brett (OS)" <Brett.Giroir@hhs.gov>, "Caliguiri, Laura" <Laura.Caliguiri@fda.hhs.gov>
Subject: RE: Social monitoring - testing

https://twitter.com/MikeDelMoro/status/1237723105251991552
Michael Del Moro @MikeDelMoro
Illinois Gov. Pritzker says on @Morning_Joe that his state still does not have enough tests for the coronavirus, says it's "extraordinarily frustrating."
"The truth is this has been slow in coming, too slow... we need more testing capability."

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, March 11, 2020 10:32 AM
To: Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov>
Cc: Pratt, Michael (OS/ASPA) <Michael.Pratt@hhs.gov>; Bonds, Michelle E. (CDC/OD/OADC) <meb0@cdc.gov>; ASPA-Deputies <ASPA-Deputies@hhs.gov>; Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Caliguiri, Laura (FDA/OC) <Laura.Caliguiri@fda.hhs.gov>
Subject: Re: Social monitoring - testing

On it.

Sent from my iPhone

On Mar 11, 2020, at 10:01 AM, Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov> wrote:

(b)(5)

Sent from my iPhone

On Mar 11, 2020, at 9:56 AM, Pratt, Michael (OS/ASPA) <Michael.Pratt@hhs.gov> wrote:

As part of what was discussed this morning, (b)(5)

(b)(5)

https://twitter.com/JonVigliotti/status/1237736498390130688
Jonathan Vigliotti @JonVigliotti
@secazar is delivering an alternate reality. Consider this: The US and South Korea discovered their first cases around the same time. SK has capacity to test 10,000 a day. US has administered 8,500 since February.

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Sent: Tuesday, March 10, 2020 10:36 PM
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Cc: Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; ASPA-Deputies <ASPA-Deputies@hhs.gov>; Bonds, Michelle E. (CDC/OD/OADC) <meb0@cdc.gov>
Subject: Re: Social monitoring - testing

More:

https://twitter.com/ncdhhs/status/1237408712559669250?s=21

https://twitter.com/billkristol/status/1237566901603065858?s=21

https://twitter.com/jsodonoghue/status/1237562508258340869?s=21

Sent from my iPhone

On Mar 10, 2020, at 8:28 PM, Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov> wrote:

AGREE:

(b)(5)

https://www.cdc.gov/coronavirus/2019-ncov/lab/index.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fguidance-laboratories.html
I just talked to the Commissioner – awesome – and I may want to have a quick talk with Keagan. Call me?

Ryan: If you need to chat, call me.

Brett P. Giroir, MD
ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW

Washington, DC 20201
Office Phone: 202-690-7694

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Sent: Tuesday, March 10, 2020 8:24 PM
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Cc: Pratt, Michael (OS/ASPA) <Michael.Pratt@hhs.gov>; ASPA-Deputies <ASPA-Deputies@hhs.gov>; Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Bonds, Michelle E. (CDC/OD/OADC) <meb0@cdc.gov>
Subject: Re: Social monitoring - testing

Who should get the test is CDC guidance I believe. I think it is online, but yield to them. How to make a test or the guidance or how to interact with the FDA around tests in posted online.

Sent from my iPhone

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Isn't the testing guidance online?

On Mar 10, 2020, at 6:34 PM, Pratt, Michael (OS/ASPA) <Michael.Pratt@hhs.gov> wrote:

https://twitter.com/jaketapper/status/1237500452222222336
Jake Tapper
@jaketapper Washington firefighters who responded to nursing home face longer quarantine as bottlenecks delay testing: https://t.co/tmgYJ3ijbv?amp=1

https://twitter.com/jaketapper/status/1237489777118674944
Jake Tapper
@jaketapper
CNN's @OmarJimenez reports that a spokesman for Life Care Center in Kirkland WA says the nursing facility has finally begun testing employees after what many considered a long delay. Test results are not yet available for 30 employees who were tested off site.

1/

https://twitter.com/NitzaSoledad/status/1237502741968191490
Nitza Soledad Perez
@NitzaSoledad
While Germany has drive-in testing facilities, ppl in the US struggle to get screened for coronavirus. Health and Human Services ☐
@SecAzar

☐ just said to the public that there is a surplus of tests. The misinformation from the White House continues. #COVID19 #coronavirus

https://twitter.com/markknoller/status/1237502685839945728
Mark Knoller
@markknoller
Though millions of Coronavirus tests are being produced, @SecAzar says persons who want to be tested need to go through their doctor or hospital and cannot just demand a test. Stresses persons should call their doctor and ask to be considered for a Coronavirus test.

https://twitter.com/chrislhayes/status/1237502187762257931
Chris Hayes
@chrislhayes
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Director, Strategic Communications & Campaigns
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U.S. Department of Health and Human Services
michael.pratt@hhs.gov
202.690.7471 | **(b)(5)** m)

From: Pratt, Michael (OS/ASPA) [Michael.Pratt@hhs.gov]
Sent: 3/11/2020 11:04:17 AM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
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Subject: RE: Social monitoring - testing

Happy to.

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Sent: Wednesday, March 11, 2020 11:03 AM
To: Pratt, Michael (OS/ASPA) <Michael.Pratt@hhs.gov>; Caccomo, Stephanie (FDA/OC) <Stephanie.Caccomo@fda.hhs.gov>
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1/

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Michelle – anyone else from CDC I should add?
Andy Slavitt: https://twitter.com/aslavitt/status/1237727569342054407?s=21

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From: McWilliams, Carly [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B68C7458214244D08424FD441FEA4FDA-CARLYLE.MCW]
Sent: 3/11/2020 3:01:56 PM
To: Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; Copeland, Jakea [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7fe05ed233c42b68be990b12ae2c8c8-Jakea.Copel]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
Subject: WHTF Briefing 03.11.2020.docx
Attachments: WHTF Briefing 03.11.2020.docx

All in this document

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 3/11/2020 3:12:31 PM
To: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: FW: TALKING POINTS AND BACKGROUND 3.11.20
Attachments: WHTF Briefing 03.11.2020.docx

He doesn't have these? Can someone print for him? Just the new ones he needs?

From: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Sent: Wednesday, March 11, 2020 3:10 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Cc: Beshara, Nicholas <Nicholas.Beshara@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Subject: TALKING POINTS AND BACKGROUND 3.11.20

Hello all, attached are talking points and updates for the commissioner. This was a down to the second process.

While the document seems long, I put the most pressing issues on top and then put in pertinent updates from the sit rep below. For ease of printing these are the same document. (and who doesn't love one less attachment?)

Maren, there is information from CDER regarding hand sanitizer, reporting and how we are handling if you want to follow up from this morning.

Andy and Karas: these talking points are going to be used for tomorrow's house side briefing with Commissioner Hahn. I think you could re-arrange to address what you are getting most pressed on.

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Subject: RE: Social monitoring - testing

NPR: No guarantee you'll get a test even if your doctor requires:
https://www.npr.org/sections/health-shots/2020/03/11/814189027/no-guarantee-youll-get-tested-for-covid-19-even-if-your-doctor-requests-it

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Sent: Wednesday, March 11, 2020 11:03 AM
To: Pratt, Michael (OS/ASPA) <Michael.Pratt@hhs.gov>; Caccomo, Stephanie (FDA/OC) <Stephanie.Caccomo@fda.hhs.gov>
Cc: Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov>; Bonds, Michelle E. (CDC/OD/OADC) <meb0@cdc.gov>; ASPA-Deputies <ASPA-Deputies@hhs.gov>; Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Caliguiri, Laura (FDA/OC) <Laura.Caliguiri@fda.hhs.gov>
Subject: Re: Social monitoring - testing

Can you pls include Stephanie on these?

Sent from my iPhone

On Mar 11, 2020, at 10:52 AM, Pratt, Michael (OS/ASPA) <Michael.Pratt@hhs.gov> wrote:

https://twitter.com/MikeDelMoro/status/1237723105251991552
Michael Del Moro @MikeDelMoro
Illinois Gov. Pritzker says on @Morning_Joe that his state still does not have enough tests for the coronavirus, says it's "extraordinarily frustrating."
"The truth is this has been slow in coming, too slow... we need more testing capability."

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, March 11, 2020 10:32 AM
To: Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov>
Cc: Pratt, Michael (OS/ASPA) <Michael.Pratt@hhs.gov>; Bonds, Michelle E. (CDC/OD/OADC) <meb0@cdc.gov>; ASPA-Deputies <ASPA-Deputies@hhs.gov>; Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Caliguiri, Laura (FDA/OC)

<Laura.Caliguiri@fda.hhs.gov>
Subject: Re: Social monitoring - testing

On it.

Sent from my iPhone

On Mar 11, 2020, at 10:01 AM, Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov> wrote:

(b)(5)

Sent from my iPhone

On Mar 11, 2020, at 9:56 AM, Pratt, Michael (OS/ASPA) <Michael.Pratt@hhs.gov> wrote:

As part of what was discussed this morning **(b)(5)**

(b)(5)

https://twitter.com/JonVigliotti/status/1237736498390130688
Jonathan Vigliotti @JonVigliotti
@secazar is delivering an alternate reality. Consider this: The US and South Korea discovered their first cases around the same time. SK has capacity to test 10,000 a day. US has administered 8,500 since February.

From: Pratt, Michael (OS/ASPA) <Michael.Pratt@hhs.gov>
Sent: Tuesday, March 10, 2020 10:36 PM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Cc: Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; ASPA-Deputies <ASPA-Deputies@hhs.gov>; Bonds, Michelle E. (CDC/OD/OADC) <meb0@cdc.gov>
Subject: Re: Social monitoring - testing

More:

https://twitter.com/ncdhhs/status/1237408712559669250?s=21

https://twitter.com/billkristol/status/1237566901603065858?s=21

https://twitter.com/jsodonoghue/status/1237562508258340869?s=21

Sent from my iPhone

On Mar 10, 2020, at 8:28 PM, Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov> wrote:

AGREE:

(b)(5)

https://www.cdc.gov/coronavirus/2019-ncov/lab/index.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fguidance-laboratories.html
I just talked to the Commissioner – awesome – and I may want to have a quick talk with Keagan. Call me?

Ryan: If you need to chat, call me.

Brett P. Giroir, MD
ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Tuesday, March 10, 2020 8:24 PM
To: Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>
Cc: Pratt, Michael (OS/ASPA) <Michael.Pratt@hhs.gov>; ASPA-Deputies <ASPA-Deputies@hhs.gov>; Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Bonds, Michelle E. (CDC/OD/OADC) <meb0@cdc.gov>
Subject: Re: Social monitoring - testing

Who should get the test is CDC guidance I believe. I think it is online, but yield to them. How to make a test or the guidance or how to interact with the FDA around tests in posted online.

Sent from my iPhone

On Mar 10, 2020, at 7:37 PM, Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov> wrote:

Isn't the testing guidance online?

On Mar 10, 2020, at 6:34 PM, Pratt, Michael (OS/ASPA) <Michael.Pratt@hhs.gov> wrote:

https://twitter.com/jaketapper/status/1237500452222222336
Jake Tapper
@jaketapper Washington firefighters who responded to nursing home face longer quarantine as bottlenecks delay testing: https://t.co/tmgYJ3ijbv?amp=1

https://twitter.com/jaketapper/status/1237489777118674944

Jake Tapper
@jaketapper
CNN's @OmarJimenez reports that a spokesman for Life Care Center in Kirkland WA says the nursing facility has finally begun testing employees after what many considered a long delay. Test results are not yet available for 30 employees who were tested off site.

1/

https://twitter.com/NitzaSoledad/status/1237502741968191490
Nitza Soledad Perez
@NitzaSoledad
While Germany has drive-in testing facilities, ppl in the US struggle to get screened for coronavirus. Health and Human Services ☐
@SecAzar
☐ just said to the public that there is a surplus of tests. The misinformation from the White House continues. #COVID19 #coronavirus

https://twitter.com/markknoller/status/1237502685839945728
Mark Knoller
@markknoller
Though millions of Coronavirus tests are being produced, @SecAzar says persons who want to be tested need to go through their doctor or hospital and cannot just demand a test. Stresses persons should call their doctor and ask to be considered for a Coronavirus test.

https://twitter.com/chrislhayes/status/1237502187762257931
Chris Hayes
@chrislhayes
Hey doctors: as @SecAzar says there's actually a "surplus" of tests available, I'm curious if this your experience at point of care as of today, March 10th.

https://twitter.com/laallergydoc/status/1237503671534927872
Marc Meth, MD
@chrislhayes The answer is no. I've tried to get swabs to actually perform the testing if needed to give to Quest or Labcorp and there are NONE available.

https://twitter.com/rcbutter1/status/1237502598791512065
RB
@rcbutter1
No! I cant keep hearing these answers. I'm a primary care doctor in Albany, NY. There are no tests unless a patient meets strict criteria which DO NOT include travel to Seattle, Westchester or California!

https://twitter.com/MORDE110/status/1237503914703904768
MORDE1
@MORDE110
Untrue.
Sick patients must meet a critical 3+ level to be tested in California.

https://twitter.com/MollyJongFast/status/1237502769495506946
Molly Jong-Fast
@MollyJongFast
"there are millions of tests out there now," say @SecAzar but this doesn't sound right

Michael J. Pratt

Director, Strategic Communications & Campaigns
Office of the Assistant Secretary for Public Affairs
U.S. Department of Health and Human Services
michael.pratt@hhs.gov
202.690.7471 | (b)(6) (m)

From: OS Secretarys Operations Center [hhs.soc@hhs.gov]
Sent: 3/11/2020 6:30:12 PM
To: OS Secretarys Operations Center [hhs.soc@hhs.gov]
Subject: HHS International SPOTREP: COVID-19 (Update #149)
Attachments: COVID-19 SLB 11Mar20 Final.pdf

UNCLASSIFIED // FOR OFFICIAL USE ONL

HHS International SPOTREP: COVID-19 (Update #149)

Source: Interagency

What: Please see the attached COVID-19 Senior Leader Brief for **11Mar20** for more information.

When: 11Mar20 **1830ET**

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.*

Prepared by: Brian Pittman, Watch Officer
Approved by: Brandon W. Britton, Senior Watch Officer

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

From: McWilliams, Carly [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B68C7458214244D08424FD441FEA4FDA-CARLYLE.MCW]
Sent: 3/12/2020 2:11:41 PM
To: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; Copeland, Jakea [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7fe05ed233c42b68be990b12ae2c8c8-Jakea.Copel]; Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]
CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]
Subject: DRAFT WHTF Briefing 03.12.2020.docx
Attachments: DRAFT WHTF Briefing 03.12.2020.docx

ATTACHED!

From: Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]
Sent: 3/12/2020 3:35:56 PM
To: Courtney, Brooke [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=261a2a3791e24e19b095ac0172485ebd-Brooke.Cour]
CC: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
Subject: Re: COV-Supply Chain Coordination Working Group

Thanks.

Sent from my iPhone

On Mar 12, 2020, at 3:32 PM, Courtney, Brooke <Brooke.Courtney@fda.hhs.gov> wrote:

I don't have additional details, but let me see if I can get in touch with Seth now to find out more.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Thursday, March 12, 2020 3:31 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: Re: COV-Supply Chain Coordination Working Group

Is this a daily in person meeting? Brooke is the one that understands this and is a part of it. A/S level is stretched thin. Would like to understand why they are elevating.

Sent from my iPhone

On Mar 12, 2020, at 3:24 PM, Hinton, Denise <Denise.Hinton@fda.hhs.gov> wrote:

Thanks Brooke. Keagan, Anand and I will touch base today and provide a response to you and Seth. Any updates from today?

From: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Sent: Thursday, March 12, 2020 3:18 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: FW: COV-Supply Chain Coordination Working Group

Hi Keagan and Denise,

As described below, the NSC Supply Chain Coordination WG is transitioning to become a PCC. By tomorrow (Friday, 03/13/2020) COB, we need to reconfirm who the principal member will be for FDA. Generally, PCCs should be attended

at the Assistant Secretary level, so it seems to make sense for one of you to be the new principal. However, I'm happy to help support your efforts on this moving forward and have TS clearance if you were to ever need extra coverage.

Thanks,
Brooke

From: Jonas, Seth H. EOP/NSC (b)(6)
Sent: Thursday, March 12, 2020 3:04 PM
To: (b)(6) Glenn, Robert <robert.glenn@fema.dhs.gov>; (b)(6); (b)(6) Polowczyk, John P RADM USN JS J4 (USA (b)(6); OBRIEN, Kristina M SES JS J4 (USA <(b)(6) Kless, David Ronald SES DLA LOGISTICS OPERATIONS (USA (b)(6) LaBrecque, Michael F (Mike) COL USARMY DLA LOGISTICS OPERATIONS (USA (b)(6); Peck, Travis G MAJ USARMY DLA LOGISTICS OPERATIONS (USA (b)(6) Brown, Christopher K. - OSHA <Brown.Christopher.K@dol.gov>; (b)(6) donna.o'berry@dot.gov; S60.Policy@dot.gov; Smith, Matthew (OS) <Matthew.Smith@hhs.gov>; Falcon, Jessica (OS) <Jessica.Falcon@hhs.gov>; Cooper, Kevin (OS) <Kevin.Cooper@hhs.gov>; Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>; DeBord, Kristin (OS) <Kristin.DeBord@hhs.gov>; Zebley, Kyle (OS) <Kyle.Zebley@hhs.gov>; Marston, Hilary D (NIH) <hilary.marston@nih.gov>; Heather.Trew@treasury.gov; Paul.Ahern@treasury.gov; Wolf, Laura K (OS) <Laura.Wolf@hhs.gov>; Adams, Steven A (CDC) <saa1@cdc.gov>; alexis.haakensen@trade.gov; Bartosh, Ernest (Federal <EBartosh@doc.gov>; Edens, Mandy - OSHA <Edens.Mandy@dol.gov>; Nazak.Nikakhtar@trade.gov; Patel, Anita (CDC) <bop1@cdc.gov>; Hanson, Elizabeth A Col USAF JS J4 (USA (b)(6) Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Cc: Davis, May M. EOP/WHO <May.Davis@who.eop.gov>; Honeycutt, Maria G. EOP/OSTP (b)(6); Sinclair, Michael R. EOP/NSC (b)(6); Hoelscher, Douglas L. EOP/WHO (b)(6); Goel, Andrea L. EOP/OMB (b)(6); Chafin, Kelly B. EOP/NSC (b)(6); Ferro, Phil J. EOP/NSC (b)(6); Fabina, Lauren C. EOP/NSC (b)(6); Butterfield, Nicholas W. EOP/WHO (b)(6) Abbott, Christopher J. EOP/WHO (b)(6) Farquharson, Christine E. EOP/OMB (b)(6) Carter, Hillary H. EOP/NSC (b)(6); Crozer, William F. EOP/WHO <(b)(6); Garufi, Marc A. EOP/OMB (b)(6); Baehr, James S. EOP/WHO (b)(6) Merkel, Theo W. EOP/WHO (b)(6); Blum, Mathew C. EOP/OMB (b)(6) jon.krohmer@dot.gov; Olszowka, Adam R (Beijing) (b)(6); david.short@dot.gov; Dubray, Michael R (Wuhan) <DubrayMR@state.gov>; Nicole.Bambas@dot.gov; amie.kalsbeek@dot.gov; Benjamin Carlson <Benjamin.Carlson@trade.gov>; Bedan, Morgan E. EOP/WHO (b)(6) LaBrecque, Michael F (Mike) COL USARMY DLA LOGISTICS OPERATIONS (USA) (b)(6); Dragseth, John (b)(6) Lerner, Andrea M (NIH) <andrea.lerner@nih.gov>; KEENE, CHRISTOPHER (b)(6); Scott, Heather (b)(6); Zapata, Carmen (b)(6) Kroese, Daniel <(b)(6); Diana, Kevin (b)(6) Ahr, Danie (b)(6) Phillips, Sally (OS) <Sally.Phillips@hhs.gov>; Rausch, John T CIV OSD OUSD A-S (USA <(b)(6); Wurst, Nathan J CTR OSD OUSD A-S (USA (b)(6); Copes, Robert B (Brian) Col USAF OSD OUSD A-S (USA (b)(6) Wilkinson, David <(b)(6); Armstrong, Sue E <(b)(6) (b)(6) Walrod, Margaret H (Beijing) (b)(6); PRUE, ANGELA (CTR) (b)(6) Pillai, Satish K (CDC) <vig8@cdc.gov>; Stevens, Kathleen E (b)(6); Dole, Mark J COL USARMY OSD HA (USA (b)(6) Jesse.Baker@treasury.gov; Ashok.Pinto@treasury.gov; Anderson, Jacob (b)(6) Alexander, Christopher <(b)(6); Brown, Gregory (OST) <Gregory.Brown@dot.gov>; Abigail.Demopulos@treasury.gov; Sappenfield, Christine A (b)(6); Powers, Billy (b)(6); Joseph.Clark2@treasury.gov; DL NSC Supply Chain <(b)(6)
Subject: RE: COV-Supply Chain Coordination Working Group

Dear All,

The Supply Chain Coordination Working Group (SCCWG) is going through some administrative changes. Tomorrow's meeting of the SCCWG will be cancelled in favor of a restricted working group to discuss a specific issue.

Path forward for the SCCWG

The SCCWG has been chartered as a Policy Coordination Committee (PCC) and will transition accordingly. We plan to kick off the PCC next week with an in-person meeting for principal members of the PCC. The first PCC will cover, among other things, the structure and path forward, ensuring we have appropriate coverage across all lines of effort. **By tomorrow (Friday, 03/13/2020) COB**, could you please reconfirm who the principal member is for your agency. Generally, PCC should be attended at the Assistant Secretary level.

Thanks,
Seth.

-----Original Appointment-----
From: Jonas, Seth H. EOP/NSC
Sent: Wednesday, February 26, 2020 3:15 PM
To: Jonas, Seth H. EOP/NSC; (b)(6) Glenn, Robert (b)(6) (b)(6) Polowczyk, John P RADM USN JS J4 (USA; OBRIEN, Kristina M SES JS J4 (USA; Kless, David Ronald SES DLA LOGISTICS OPERATIONS (USA; LaBrecque, Michael F (Mike) COL USARMY DLA LOGISTICS OPERATIONS (USA; Peck, Travis G MAJ USARMY DLA LOGISTICS OPERATIONS (USA (b)(6) (b)(6) Brown, Christopher K. - OSHA; GlasserJL@state.gov; donna.o'berry@dot.gov; S60.Policy@dot.gov; matthew.smith@hhs.gov; Jessica.falcon@hhs.gov; kevin.cooper@hhs.gov; Bryan.Shuy@hhs.gov; Kristin.DeBord@hhs.gov; Zebley, Kyle (HHS/OS/OGA; Marston, Hilary (NIH/NIAID) [E; Heather.Trew@treasury.gov; Paul.Ahern@treasury.gov; laura.wolf@hhs.gov; saa1@cdc.gov; alexis.haakensen@trade.gov; Bartosh, Ernest (Federal; Edens, Mandy - OSHA; Nazak.Nikakhtar@trade.gov; bop1@cdc.gov; Hanson, Elizabeth A Col USAF JS J4 (USA; Brooke.Courtney@fda.hhs.gov
Cc: Waterman, Paige E. EOP/OSTP; Lin, Merry S. EOP/WHO; Watson, Ian D. EOP/OSTP; Davis, May M. EOP/WHO; Honeycutt, Maria G. EOP/OSTP; Sinclair, Michael R. EOP/NSC; Hoelscher, Douglas L. EOP/WHO; Goel, Andrea L. EOP/OMB; Chafin, Kelly B. EOP/NSC; Ferro, Phil J. EOP/NSC; Fabina, Lauren C. EOP/NSC; Rubini, Jeffrey H. EOP/NSC; Butterfield, Nicholas W. EOP/WHO; Abbott, Christopher J. EOP/WHO; Farquharson, Christine E. EOP/OMB; Carter, Hillary H. EOP/NSC; DL NSC Resilience; Crozer, William F. EOP/WHO; Garufi, Marc A. EOP/OMB; Baehr, James S. EOP/WHO; Williams, James H. EOP/WHO; Merkel, Theo W. EOP/WHO; Blum, Mathew C. EOP/OMB; jon.krohmer@dot.gov; Olszowka, Adam R (Beijing); david.short@dot.gov; Dubray, Michael R (Wuhan); Nicole.Bambas@dot.gov; amie.kalsbeek@dot.gov; Cavanaugh, Brian J. EOP/NSC; Troye, Olivia EOP/NSC; Benjamin Carlson; Mroz, Sara K. EOP/NSC; Bedan, Morgan E. EOP/WHO; LaBrecque, Michael F (Mike) COL USARMY DLA LOGISTICS OPERATIONS (USA); Dragseth, John; Lerner, Andrea (NIH/NIAID) [E]; KEENE, CHRISTOPHER; Scott, Heather; Zapata, Carmen; Kroese, Daniel; Diana, Kevin; Ahr, Daniel; Sally.phillips@hhs.gov; Rausch, John T CIV OSD OUSD A-S (USA; Wurst, Nathan J CTR OSD OUSD A-S (USA; Copes, Robert B (Brian) Col USAF OSD OUSD A-S (USA; Wilkinson, David; Armstrong, Sue E; S CGRCU@groups.state.gov; Walrod, Margaret H (Beijing); PRUE, ANGELA (CTR); vig8@cdc.gov; Stevens, Kathleen E; Dole, Mark J COL USARMY OSD HA (USA); Jesse.Baker@treasury.gov; Jennison, Peter J. EOP/NSC; Ashok.Pinto@treasury.gov; Anderson, Jacob; Alexander, Christopher; Brown, Gregory (OST); Abigail.Demopulos@treasury.gov; Sappenfield, Christine A; Powers, Billy; Joseph.Clark2@treasury.gov
Subject: COV-Supply Chain Coordination Working Group
When: Friday, March 13, 2020 10:30 AM-11:30 AM (UTC-05:00) Eastern Time (US & Canada).
Where: EEOB Rm 428 or Teleco (b)(6)

COV-Supply Chain Coordination Working Group.

Will update and agenda and read aheads become available

From: Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]
Sent: 3/13/2020 7:56:33 AM
To: Courtney, Brooke [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=261a2a3791e24e19b095ac0172485ebd-Brooke.Cour]
CC: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
Subject: Re: Response requested

I think you can still manage, but if they really need higher level let me know and we can find someone.

Sent from my iPhone

On Mar 12, 2020, at 11:04 PM, Courtney, Brooke <Brooke.Courtney@fda.hhs.gov> wrote:

Hi Keagan and Denise,

I just spoke with Seth Jonas from the SCCWG. The NSC is still working to finalize the administrative aspects, but here's what they have so far:

(b)(5)

Thanks,
Brooke

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Thursday, March 12, 2020 3:31 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: Re: COV-Supply Chain Coordination Working Group

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To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: FW: COV-Supply Chain Coordination Working Group

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From: Jonas, Seth H. EOP/NSC (b)(6)
Sent: Thursday, March 12, 2020 3:04 PM
To (b)(6) Glenn, Robert <robert.glenn@fema.dhs.gov>; (b)(6) (b)(6) Polowczyk, John P RADM USN JS J4 (USA (b)(6) ; OBRIEN, Kristina M SES JS J4 (USA (b)(6) ; Kless, David Ronald SES DLA LOGISTICS OPERATIONS (USA (b)(6) ; LaBrecque, Michael F (Mike) COL USARMY DLA LOGISTICS OPERATIONS (USA (b)(6) ; Peck, Travis G MAJ USARMY DLA LOGISTICS OPERATIONS (USA (b)(6) Brown, Christopher K. - OSHA <Brown.Christopher.K@dol.gov>; GlasserJL@state.gov; donna.o'berry@dot.gov; S60.Policy@dot.gov; Smith, Matthew (OS) <Matthew.Smith@hhs.gov>; Falcon, Jessica (OS) <Jessica.Falcon@hhs.gov>; Cooper, Kevin (OS) <Kevin.Cooper@hhs.gov>; Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>; DeBord, Kristin (OS) <Kristin.DeBord@hhs.gov>; Zebley, Kyle (OS) <Kyle.Zebley@hhs.gov>; Marston, Hilary D (NIH) <hilary.marston@nih.gov>; Heather.Trew@treasury.gov; Paul.Ahern@treasury.gov; Wolf, Laura K (OS) <Laura.Wolf@hhs.gov>; Adams, Steven A (CDC) <saa1@cdc.gov>; alexis.haakensen@trade.gov; Bartosh, Ernest (Federal <EBartosh@doc.gov>; Edens, Mandy - OSHA <Edens.Mandy@dol.gov>; Nazak.Nikakhtar@trade.gov; Patel, Anita (CDC) <bop1@cdc.gov>; Hanson, Elizabeth A Col USAF JS J4 (USA (b)(6) Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Cc: Davis, May M. EOP/WHO (b)(6) ; Honeycutt, Maria G. EOP/OSTP (b)(6) Sinclair, Michael R. EOP/NSC < (b)(6) Hoelscher, Douglas L. EOP/WHO (b)(6) ; Goel, Andrea L. EOP/OMB < (b)(6) Chafin, Kelly B. EOP/NSC (b)(6) Ferro, Phil J. EOP/NSC (b)(6) Fabina, Lauren C. EOP/NSC < (b)(6) Butterfield, Nicholas W. EOP/WHO (b)(6) Abbott, Christopher J. EOP/WHO < (b)(6) Farquharson, Christine E. EOP/OMB < (b)(6) ; Carter, Hillary H. EOP/NSC (b)(6) ; Crozer, William F. EOP/WHO (b)(6) ; Garufi, Marc A. EOP/OMB (b)(6) Baehr, James S. EOP/WHO < (b)(6) ; Merkel, Theo W. EOP/WHO (b)(6) Blum, Mathew C. EOP/OMB (b)(6) ; jon.krohmer@dot.gov; Olszowka, Adam R (Beijing) < (b)(6) ; david.short@dot.gov; Dubray, Michael R (Wuhan (b)(6) Nicole.Bambas@dot.gov; amie.kalsbeek@dot.gov; Benjamin Carlson <Benjamin.Carlson@trade.gov>; Bedan, Morgan E. EOP/WH (b)(6) LaBrecque, Michael F (Mike) COL USARMY DLA LOGISTICS OPERATIONS (USA) <Michael.Labrecque@dla.mil>; Dragseth, John (b)(6) ; Lerner, Andrea M (NIH) <andrea.lerner@nih.gov>; KEENE, CHRISTOPHER (b)(6) Scott, Heathe (b)(6) Zapata, Carmen (b)(6) Kroese, Daniel (b)(6) Diana, Kevin (b)(6) Ahr, Daniel <daniel.ahr@cisa.dhs.gov>; Phillips, Sally (OS) <Sally.Phillips@hhs.gov>;

Rausch, John T CIV OSD OUSD A-S (USA (b)(6); Wurst, Nathan J CTR OSD OUSD A-S (USA (b)(6); Copes, Robert B (Brian) Col USAF OSD OUSD A-S (USA < (b)(6) Wilkinson, David (b)(6); Armstrong, Sue E (b)(6); (b)(6) Walrod, Margaret H (Beijing (b)(6); PRUE, ANGELA (CTR) (b)(6); Pillai, Satish K (CDC) <vig8@cdc.gov>; Stevens, Kathleen E (b)(6) Dole, Mark J COL USARMY OSD HA (USA) (b)(6) Jesse.Baker@treasury.gov; Ashok.Pinto@treasury.gov; Anderson, Jacob (b)(6); Alexander, Christopher (b)(6); Brown, Gregory (OST) <Gregory.Brown@dot.gov>; Abigail.Demopulos@treasury.gov; Sappenfield, Christine A (b)(6); Powers, Billy (b)(6) Joseph.Clark2@treasury.gov; DL NSC Supply Chain (b)(6)

Subject: RE: COV-Supply Chain Coordination Working Group

Dear All,

The Supply Chain Coordination Working Group (SCCWG) is going through some administrative changes. Tomorrow's meeting of the SCCWG will be cancelled in favor of a restricted working group to discuss a specific issue.

Path forward for the SCCWG

The SCCWG has been chartered as a Policy Coordination Committee (PCC) and will transition accordingly. We plan to kick off the PCC next week with an in-person meeting for principal members of the PCC. The first PCC will cover, among other things, the structure and path forward, ensuring we have appropriate coverage across all lines of effort. **By tomorrow (Friday, 03/13/2020) COB**, could you please reconfirm who the principal member is for your agency. Generally, PCC should be attended at the Assistant Secretary level.

Thanks,
Seth.

-----Original Appointment-----
From: Jonas, Seth H. EOP/NSC
Sent: Wednesday, February 26, 2020 3:15 PM
To: Jonas, Seth H. EOP/NSC; (b)(6) Glenn, Robert (b)(6); (b)(6); Polowczyk, John P RADM USN JS J4 (USA; OBRIEN, Kristina M SES JS J4 (USA; Kless, David Ronald SES DLA LOGISTICS OPERATIONS (USA; LaBrecque, Michael F (Mike) COL USARMY DLA LOGISTICS OPERATIONS (USA; Peck, Travis G MAJ USARMY DLA LOGISTICS OPERATIONS (USA (b)(6); (b)(6) Brown, Christopher K. - OSHA (b)(6); donna.o'berry@dot.gov; S60.Policy@dot.gov; matthew.smith@hhs.gov; Jessica.falcon@hhs.gov; kevin.cooper@hhs.gov; Bryan.Shuy@hhs.gov; Kristin.DeBord@hhs.gov; Zebley, Kyle (HHS/OS/OGA; Marston, Hilary (NIH/NIAID) [E; Heather.Trew@treasury.gov; Paul.Ahern@treasury.gov; laura.wolf@hhs.gov; saa1@cdc.gov; alexis.haakensen@trade.gov; Bartosh, Ernest (Federal; Edens, Mandy - OSHA; Nazak.Nikakhtar@trade.gov; bop1@cdc.gov; Hanson, Elizabeth A Col USAF JS J4 (USA; Brooke.Courtney@fda.hhs.gov
Cc: Waterman, Paige E. EOP/OSTP; Lin, Merry S. EOP/WHO; Watson, Ian D. EOP/OSTP; Davis, May M. EOP/WHO; Honeycutt, Maria G. EOP/OSTP; Sinclair, Michael R. EOP/NSC; Hoelscher, Douglas L. EOP/WHO; Goel, Andrea L. EOP/OMB; Chafin, Kelly B. EOP/NSC; Ferro, Phil J. EOP/NSC; Fabina, Lauren C. EOP/NSC; Rubini, Jeffrey H. EOP/NSC; Butterfield, Nicholas W. EOP/WHO; Abbott, Christopher J. EOP/WHO; Farquharson, Christine E. EOP/OMB; Carter, Hillary H. EOP/NSC; DL NSC Resilience; Crozer, William F. EOP/WHO; Garufi, Marc A. EOP/OMB; Baehr, James S. EOP/WHO; Williams, James H. EOP/WHO; Merkel, Theo W. EOP/WHO; Blum, Mathew C. EOP/OMB; jon.krohmer@dot.gov; Olszowka, Adam R (Beijing); david.short@dot.gov; Dubray, Michael R (Wuhan); Nicole.Bambas@dot.gov; amie.kalsbeek@dot.gov; Cavanaugh, Brian J. EOP/NSC; Troye, Olivia EOP/NSC; Benjamin Carlson; Mroz, Sara K. EOP/NSC; Bedan, Morgan E. EOP/WHO; LaBrecque, Michael F (Mike) COL USARMY DLA LOGISTICS OPERATIONS (USA); Dragseth, John; Lerner, Andrea (NIH/NIAID) [E]; KEENE, CHRISTOPHER; Scott, Heather; Zapata, Carmen; Kroese, Daniel; Diana, Kevin; Ahr, Daniel; Sally.phillips@hhs.gov; Rausch, John T CIV OSD OUSD A-S (USA; Wurst, Nathan J CTR OSD OUSD A-S (USA; Copes, Robert B (Brian) Col USAF OSD OUSD A-S (USA; Wilkinson, David; Armstrong, Sue E;

(b)(6) Valrod, Margaret H (Beijing); PRUE, ANGELA (CTR); vig8@cdc.gov; Stevens, Kathleen E; Dole, Mark J COL USARMY OSD HA (USA); Jesse.Baker@treasury.gov; Jennison, Peter J. EOP/NSC; Ashok.Pinto@treasury.gov; Anderson, Jacob; Alexander, Christopher; Brown, Gregory (OST); Abigail.Demopulos@treasury.gov; Sappenfield, Christine A; Powers, Billy; Joseph.Clark2@treasury.gov
Subject: COV-Supply Chain Coordination Working Group
When: Friday, March 13, 2020 10:30 AM-11:30 AM (UTC-05:00) Eastern Time (US & Canada).
Where: EEOB Rm 428 or Telecon **(b)(6)**

COV-Supply Chain Coordination Working Group.

Will update and agenda and read aheads become available

From: HHS Office of Public Affairs [hhsopa@hhs.gov]
Sent: 3/13/2020 8:00:31 AM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: HHS funds development of COVID-19 diagnostic tests

News Release

U.S. Department of Health and Human Services

202-205-8117
asprmedia@hhs.gov
www.hhs.gov/news
Twitter @SpoxHHS

FOR IMMEDIATE RELEASE
Friday, March 13, 2020

HHS funds development of COVID-19 diagnostic tests

Two diagnostic tests that may detect severe acute respiratory syndrome-related coronavirus 2 (SARS-CoV-2) in approximately one hour will receive advanced development support from the U.S. Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response (ASPR).

The Biomedical Advanced Research and Development Authority (BARDA) within ASPR will provide approximately $679,000 to DiaSorin Molecular, LLC of Cypress, California, to rapidly develop the Simplexa COVID-19 Direct Assay, and approximately $598,000 to QIAGEN LLC of Germantown, Maryland, to accelerate development of the QIAstat-Dx RPS2 test for COVID-19. The companies will provide the remaining funds for developing their respective diagnostic tests.

"Americans need access to rapid diagnostic testing. The sooner clinicians, patients, and public health officials know whether someone is infected with the novel coronavirus, the sooner they can take action to mitigate the spread of COVID-19," said BARDA Director, Rick A. Bright, PhD. "Rapid diagnostic tests are critical in this public health response. We are working with the private sector at an urgent pace to make these tests available on as many diagnostic platforms as we can in the coming weeks."

DiaSorin Molecular's test will use a nasopharyngeal (back of the nose and throat) swab from patients and is being designed for use with the company's Simplexa Direct technology, an FDA-cleared platform currently used for their influenza and Respiratory Syncytial Virus (RSV) tests.

The COVID-19 test would run on DiaSorin's LIAISON MDX instrument, which works in conjunction with LIAISON MDX Studio software. This technology uses a sample-to-answer approach with minimal operator input; hundreds of the company's diagnostic devices are in use in large commercial and hospital laboratories around the country. The COVID-19 test could potentially be ready within six weeks for Emergency Use Authorization (EUA) consideration by the U.S. Food and Drug Administration (FDA).

QIAGEN will develop a COVID-19 test, QIAstat-Dx RPS2, to be added to the QIAstat-Dx Respiratory Panel. The device is used to run FDA-cleared tests for 21 respiratory pathogens. The device features easy-to-use molecular testing with novel workflows. The COVID-19 test could be ready within 12 weeks for EUA consideration by the FDA.

Both development projects were selected through a business-friendly EZ-BAA application process that streamlines the way BARDA collaborates with industry and entrepreneurs. BARDA recently opened the EZ-BAA for diagnostics that utilize platforms already cleared by the FDA, with a viable plan to meet requirements for the FDA to consider emergency use authorization.

In addition to the EZ-BAA, BARDA expanded its standard broad agency announcement to accept proposals for advanced development of diagnostics, vaccines, therapeutics and other medical products for use in the current COVID-19 emergency response and future coronavirus outbreaks.

There are currently no approved diagnostics, vaccines or treatments for COVID-19. However, the FDA issued emergency use authorization for diagnostic tests from the Centers for Disease Control and Prevention (CDC) and other authorized public health laboratories, and for use of New York State's Wadsworth diagnostics test. In addition, FDA also issued a new policy Feb. 29 to help expedite the availability of diagnostics.

HHS continues to work across the U.S. government, including with the Department of Defense, to review potential products from public and private sectors to identify promising candidates that could detect, protect against or treat COVID-19 for development and licensure. HHS divisions, including the National Institutes of Health (NIH) and ASPR, have begun supporting development of multiple vaccines and potential therapeutic treatments for COVID-19.

To obtain information about any potential products in development in the private sector that could be used in responding to the novel coronavirus outbreak, the U.S. government launched a single point-of-entry website for innovators and product developers to submit brief descriptions of their diagnostics, therapeutics, vaccines, and other products or technologies being developed for COVID-19.

To shorten the time to apply for product licensure and to reduce the spread of COVID-19, federal agencies are particularly interested in identifying products and technologies that have progressed beyond non-clinical studies, have established domestic large-scale manufacturing capability with commercial Good Manufacturing Practices (cGMP), and have utilized a platform used to manufacture a product already approved by the FDA.

About HHS, ASPR, and BARDA

HHS works to enhance and protect the health and well-being of all Americans, providing for effective health and human services and fostering advances in medicine, public health, and social services. The mission of ASPR is to save lives and protect Americans from 21st century health security threats. Within ASPR, BARDA invests in the innovation, advanced research and development, acquisition, and manufacturing of medical countermeasures – vaccines, drugs, therapeutics, diagnostic tools, and non-pharmaceutical products needed to combat health security threats. To date, 54 BARDA-supported products have achieved regulatory approval, licensure or clearance.

###

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From: Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]
Sent: 3/13/2020 8:10:07 AM
To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
Subject: Fwd: HHS. Sec Azar Designates ADM Giroir to Coordinate COVID-19 Diagnostic Testing Efforts

Sent from my iPhone

Begin forwarded message:

From: "Oakley, Caitlin B. (OS/ASPA)" <Caitlin.Oakley@HHS.GOV>
Date: March 13, 2020 at 7:00:29 AM EDT
To: "Oakley, Caitlin B (OS)" <Caitlin.Oakley@HHS.GOV>
Cc: "McKeogh, Katherine (OS)" <Katherine.McKeogh@hhs.gov>
Subject: HHS. Sec Azar Designates ADM Giroir to Coordinate COVID-19 Diagnostic Testing Efforts

Good morning,

On background: On Thursday, HHS Secretary Alex Azar designated Admiral Brett Giroir, M.D., Assistant Secretary for Health and head of the Public Health Service, to coordinate COVID-19 diagnostic testing efforts among Public Health Service agencies, including the Centers for Disease Control and Prevention and the Food and Drug Administration, as well as state and local public health authorities and private or public clinical laboratories.

Dr. Giroir's area of responsibility encompasses the complete, end-to-end set of diagnostic testing activities, including the customer and patient experience, specimen collection, logistics, testing, result return, and supply chain. To facilitate this coordination, CDC Director Robert Redfield and Commissioner of Food and Drugs Stephen Hahn will report to the Secretary through Dr. Giroir for all issues and activities associated with COVID-19 diagnostic testing.

Dr. Giroir has previously served as Acting Commissioner of Food and Drugs and as Senior Advisor to the Secretary on matters involving CDC. Following is a statement from Secretary Azar regarding the appointment:

"Like all of our public health leaders at HHS, Dr. Giroir has been helping with our response to COVID-19 from the start. Dr. Giroir has worked closely with CDC and FDA to coordinate numerous complex public health efforts in his time at HHS. As the outbreak evolves, he is ideally situated to help ensure that any American who needs a test for COVID-19 can receive it. A key priority is to ensure that patients, doctors, and hospitals can access tests seamlessly and with maximum ease, and Dr. Giroir will lead efforts to execute on that goal."

All the best,

Caitlin B. Oakley
Deputy Assistant Secretary, National Spokesperson
Office of the Assistant Secretary for Public Affairs
U.S. Department of Health and Human Services
caitlin.oakley@hhs.gov

From: Shannon Curtis [Shannon.Curtis@ama-assn.org]
Sent: 3/13/2020 2:21:46 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; McWilliams, Carly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]
CC: Margaret Garikes [Margaret.Garikes@ama-assn.org]
Subject: AMA Letter to Sec Azar on COVID-19
Attachments: 2020-3-13 Letter to Azar re COVID 19.pdf

Hi Keagan and Carly-

Margaret asked that I share with you the attached letter the AMA sent to Secretary Azar this afternoon. The letter included some recommendations regarding the FDA around exercising maximum flexibilities, however, we know the agency is doing tremendous work in this space. Thank you all for your work, and please let me know if you have questions or if there is anything the AMA can do to be helpful.

Shannon

Shannon Curtis, J.D.
Assistant Director, Federal Affairs
25 Massachusetts Avenue, NW
Suite 600
Washington, DC 20001-7400

P: (202) 789-8510
(b)(6)
F: (202) 789-4581
Shannon.Curtis@ama-assn.org

From: Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]
Sent: 3/13/2020 2:24:39 PM
To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
Subject: Fwd: AMA Letter to Sec Azar on COVID-19
Attachments: image002.png; ATT00001.htm; 2020-3-13 Letter to Azar re COVID 19.pdf; ATT00002.htm

Annoying they are asking for something they admit we are already doing.

Sent from my iPhone

Begin forwarded message:

From: Shannon Curtis <Shannon.Curtis@ama-assn.org>
Date: March 13, 2020 at 2:22:44 PM EDT
To: "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>, "McWilliams, Carly" <Carly.McWilliams@fda.hhs.gov>
Cc: Margaret Garikes <Margaret.Garikes@ama-assn.org>
Subject: AMA Letter to Sec Azar on COVID-19

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From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 3/13/2020 2:25:01 PM
To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
Subject: Fwd: AMA Letter to Sec Azar on COVID-19
Attachments: image002.png; ATT00001.htm; 2020-3-13 Letter to Azar re COVID 19.pdf; ATT00002.htm

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Sent from my iPhone

Begin forwarded message:

From: Shannon Curtis <Shannon.Curtis@ama-assn.org>
Date: March 13, 2020 at 2:22:44 PM EDT
To: "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>, "McWilliams, Carly" <Carly.McWilliams@fda.hhs.gov>
Cc: Margaret Garikes <Margaret.Garikes@ama-assn.org>
Subject: AMA Letter to Sec Azar on COVID-19

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Shannon

From: Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]
Sent: 3/13/2020 2:36:10 PM
To: McWilliams, Carly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]
CC: Shannon Curtis [Shannon.Curtis@ama-assn.org]; Margaret Garikes [Margaret.Garikes@ama-assn.org]
Subject: Re: AMA Letter to Sec Azar on COVID-19

Thanks. We would appreciate AMAs recognition of the work and flexibility we have and continue to show, if possible.

Sent from my iPhone

On Mar 13, 2020, at 2:25 PM, McWilliams, Carly <Carly.McWilliams@fda.hhs.gov> wrote:

Thank you for sending. I am pasting our latest news we issued this morning about diagnostics:

1. <!--[if !supportLists]--><!--[endif]-->Press Announcements

FDA NEWS RELEASE

Coronavirus (COVID-19) Update: FDA gives flexibility to New York State Department of Health, FDA issues Emergency Use Authorization diagnostic

For Immediate Release:

March 13, 2020

Yesterday, the U.S. Food and Drug Administration took two significant actions in the agency's ongoing and aggressive commitment to address the coronavirus outbreak (C●VID19).

First, the agency issued enforcement discretion and is not objecting to the New York State Department of Health (NYSD●H) authorizing certain laboratories in New York to begin patient testing after validating their tests and notifying the NYSD●H. Under NYSD●H's approach, laboratories will provide validation data to NYSD●H within 15 days in lieu of pursuing an Emergency Use Authorization (EUA) with FDA.

Second, the FDA authorized the Roche cobas SARS-CoV-2 Test, the third Emergency Use Authorization (EUA) granted for a diagnostic test during the C●VID-19 outbreak.

"These actions today show our commitment to working around the clock to help expedite the availability of tests. This NYSD●H action shows the FDA's extreme flexibility and adaptability during times of public health emergencies," said FDA Commissioner Stephen M. Hahn, M.D. "As a practical matter, what this action means is that labs, authorized by NYSD●H, will not engage with FDA to begin patient testing. Nor will they get an Emergency Use Authorization from the FDA. These labs will interact solely with NYSD●H, which should expedite the availability of patient testing in New York State. This action demonstrates FDA's responsiveness to the needs of our country during this time."

The FDA is granting this flexibility to NYSD●H based on the urgent public health need for additional testing capacity. The FDA weighed several factors in this decision, including that the NYSD●H has a long-established framework in place for oversight of laboratory developed tests in New York State. The FDA had also previously accredited Wadsworth be a third-party reviewer for certain molecular tests.

Additionally, the FDA issued an EUA to Roche Molecular Systems for its cobas SARS-CoV-2 test within 24 hours of receiving the application. This is the first commercially distributed diagnostic test to receive an EUA during the COVID-19 outbreak. To expedite access to this test, FDA did not object to Roche pre-positioning its test so that labs could be ready to initiate testing immediately upon authorization of the EUA. Because of that pre-positioning, laboratories can immediately run tests on Roche's high-volume platform, which will greatly increase national testing capacity.

"We have been encouraging test developers to come to the FDA and work with us," said Jeff Shuren, M.D., J.D., director of the FDA's Center for Devices and Radiological Health. "Since the beginning of this outbreak, more than 60 developers have sought our assistance with development and validation of tests they plan to bring through the Emergency Use Authorization process. Additionally, more than 30 laboratories have notified us they are testing or intend to begin testing soon under our new policy for laboratory developed tests for this emergency."

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

From: Shannon Curtis <Shannon.Curtis@ama-assn.org>
Sent: Friday, March 13, 2020 2:22 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Cc: Margaret Garikes <Margaret.Garikes@ama-assn.org>
Subject: AMA Letter to Sec Azar on COVID-19

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Shannon

<image001.png>

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P: (202) 789-8510
(b)(6)
F: (202) 789-4581
Shannon.Curtis@ama-assn.org

From: Heck, Mia (HHS/OASH) [Mia.Heck@hhs.gov]
Sent: 3/13/2020 3:56:49 PM
To: Oakley, Caitlin B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8feed045e954557aa1e0052f925865f-HHS-Caitlin]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; McGowan, Robert K (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e6175b088b1d49a4bfa2de3862800d4a-HHS-omc2-cd]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Valentine, Steven (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=80fb5b9a36fc48438ba1af4a17b63af4-HHS-Steven.]; Bonds, Michelle E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=55bb1c6e16fc49c6840de58f10bce69f-HHS-meb0-cd]; Galatas, Kate (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0a0623b3cb34f86a2f6f9d14afe115e-HHS-kkg2-cd]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
CC: Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Hall, Bill (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e56218361cd4ffbacdd06ac2d7b809d-HHS-bill.ha]; McKeogh, Katherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3facab3fd03480f8553892121fd2009-HHS-Katheri]; Pratt, Michael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=facc5c0e27c74fd4964699547a71849d-HHS-Michael]; Brennan, Patrick (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e87181146141b1ba0978553d9ff156-HHS-Patrick]
Subject: RE: HHS. Sec Azar Designates ADM Giroir to Coordinate COVID-19 Diagnostic Testing Efforts

If you haven't yet we'd love it if you could RT!

ADM Brett P. Giroir (@HHS_ASH)

3/13/20, 9:20 AM
We are working to ensure that every American who needs a test for #COVID19 will receive it. Honored to lead the coordination of COVID-19 diagnostic testing efforts among #PublicHealth service agencies, including .@CDCgov. and .@US_FDA.

From: Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>
Sent: Friday, March 13, 2020 3:54 PM
To: Caliguiri, Laura (FDA/OC) <Laura.Caliguiri@fda.hhs.gov>; McGowan, Robert (Kyle) (CDC/OD/OCS) <omc2@cdc.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Valentine, Steven (HHS/OASH) <Steven.Valentine@hhs.gov>; Bonds, Michelle E. (CDC/OD/OADC) <meb0@cdc.gov>; Galatas, Kate (CDC/OD/OADC) <kkg2@cdc.gov>; Caccomo, Stephanie (FDA/OC) <Stephanie.Caccomo@fda.hhs.gov>; Heck, Mia (HHS/OASH) <Mia.Heck@hhs.gov>
Cc: Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>; McKeogh, Katherine (OS/ASPA) <Katherine.McKeogh@hhs.gov>; Pratt, Michael (OS/ASPA) <Michael.Pratt@hhs.gov>; Brennan, Patrick (OS/ASPA) <Patrick.Brennan@hhs.gov>
Subject: RE: HHS. Sec Azar Designates ADM Giroir to Coordinate COVID-19 Diagnostic Testing Efforts

Thanks all. Were y'all able to tweet?

Caitlin B. Oakley
Deputy Assistant Secretary, National Spokesperson
Office of the Assistant Secretary for Public Affairs
U.S. Department of Health and Human Services
caitlin.oakley@hhs.gov

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Sent: Friday, March 13, 2020 7:06 AM
To: Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>; McGowan, Robert (Kyle) (CDC/OD/OCS) <omc2@cdc.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Valentine, Steven (HHS/OASH) <Steven.Valentine@hhs.gov>; Bonds, Michelle E. (CDC/OD/OADC) <meb0@cdc.gov>; Galatas, Kate (CDC/OD/OADC) <kkg2@cdc.gov>; Caccomo, Stephanie (FDA/OC) <Stephanie.Caccomo@fda.hhs.gov>; Heck, Mia (HHS/OASH) <Mia.Heck@hhs.gov>
Cc: Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>; McKeogh, Katherine (OS/ASPA) <Katherine.McKeogh@hhs.gov>; Pratt, Michael (OS/ASPA) <Michael.Pratt@hhs.gov>; Brennan, Patrick (OS/ASPA) <Patrick.Brennan@hhs.gov>
Subject: RE: HHS. Sec Azar Designates ADM Giroir to Coordinate COVID-19 Diagnostic Testing Efforts

Will do

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Sent: Friday, March 13, 2020 7:04 AM
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Sent: Friday, March 13, 2020 7:00 AM
To: Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>
Cc: McKeogh, Katherine (OS/ASPA) <Katherine.McKeogh@hhs.gov>
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All the best,

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caitlin.oakley@hhs.gov

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Sent: 3/13/2020 3:57:09 PM
To: Oakley, Caitlin B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8feed045e954557aa1e0052f925865f-HHS-Caitlin]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; McGowan, Robert K (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e6175b088b1d49a4bfa2de3862800d4a-HHS-omc2-cd]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Valentine, Steven (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=80fb5b9a36fc48438ba1af4a17b63af4-HHS-Steven.]; Bonds, Michelle E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=55bb1c6e16fc49c6840de58f10bce69f-HHS-meb0-cd]; Galatas, Kate (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0a0623b3cb34f86a2f6f9d14afe115e-HHS-kkg2-cd]; Heck, Mia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=656b2fa5aca84a18851397d417a16672-HHS-Mia.Hec]
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Subject: RE: HHS. Sec Azar Designates ADM Giroir to Coordinate COVID-19 Diagnostic Testing Efforts

Yup! FDA posted earlier today: https://twitter.com/SteveFDA/status/1238450460459241473

Stephanie Caccomo
Press Officer

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

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

From: Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]
Sent: 3/13/2020 5:26:46 PM
To: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
Subject: Fwd: lab testing for Covid 19

Do you want Hahn to call him?

Sent from my iPhone

Begin forwarded message:

From: "Goldie, Christina" <Christina.Goldie@fda.hhs.gov>
Date: March 13, 2020 at 4:47:46 PM EDT
To: "Shuren, Jeff" <Jeff.Shuren@fda.hhs.gov>
Cc: "Goldie, Christina" <Christina.Goldie@fda.hhs.gov>, "Rom, Colin" <Colin.Rom@fda.hhs.gov>, "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>, "Lloyd, Lindsay" <Lindsay.Lloyd@fda.hhs.gov>
Subject: FW: lab testing for Covid 19

Hi Lindsay,
Just checking to see if you need me to do anything to assist. Let me know. Thanks.

Best regards,

Christina M. Goldie (Chrisy)
Lead Management Analyst / Notary

Tel: 301-796-6833 / Main office 301-796-5[redacted]
christina.goldie@fda.hhs.gov

From: Robert Califf <robertcaliff@verily.com>
Sent: Friday, March 13, 2020 4:31 PM
To: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Goldie, Christina <Christina.Goldie@fda.hhs.gov>
Subject: lab testing for Covid 19

Jeff and Chrisy,

You may have just seen that the Pres went a little overboard on Google's role in directing people to lab testing. We do need to be in contact with whomever is keeping track of which facilities are testing so we can link people up.

rmc

From: McWilliams, Carly [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B68C7458214244D08424FD441FEA4FDA-CARLYLE.MCW]
Sent: 3/15/2020 2:47:18 PM
To: Shannon Curtis [Shannon.Curtis@ama-assn.org]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Margaret Garikes [Margaret.Garikes@ama-assn.org]
Subject: RE: AMA Letter to Sec Azar on COVID-19

Hi Shannon, I wanted to make sure you saw the latest steps we have taken for diagnostic tests and a letter we send to providers re: PPE. You may have already seen but there are a lot of things coming out from us so I wanted to make sure you were aware.

Thank you.

Carly

FDA NEWS RELEASE

Coronavirus (COVID-19) Update: FDA gives flexibility to New York State Department of Health, FDA issues Emergency Use Authorization diagnostic

For Immediate Release:

March 13, 2020

Yesterday, the U.S. Food and Drug Administration took two significant actions in the agency's ongoing and aggressive commitment to address the coronavirus outbreak (COVID19).

First, the agency issued enforcement discretion and is not objecting to the New York State Department of Health (NYSDOH) authorizing certain laboratories in New York to begin patient testing after validating their tests and notifying the NYSDOH. Under NYSDOH's approach, laboratories will provide validation data to NYSDOH within 15 days in lieu of pursuing an Emergency Use Authorization (EUA) with FDA.

Second, the FDA authorized the Roche cobas SARS-CoV-2 Test, the third Emergency Use Authorization (EUA) granted for a diagnostic test during the COVID-19 outbreak.

"These actions today show our commitment to working around the clock to help expedite the availability of tests. This NYSDOH action shows the FDA's extreme flexibility and adaptability during times of public health emergencies," said FDA Commissioner Stephen M. Hahn, M.D. "As a practical matter, what this action means is that labs, authorized by NYSDOH, will not engage with FDA to begin patient testing. Nor will they get an Emergency Use Authorization from the FDA. These labs will interact solely with NYSDOH, which should expedite the availability of patient testing in New York State. This action demonstrates FDA's responsiveness to the needs of our country during this time."

The FDA is granting this flexibility to NYSDOH based on the urgent public health need for additional testing capacity. The FDA weighed several factors in this decision, including that the NYSDOH has a long-established framework in place for oversight of laboratory developed tests in New York State. The FDA had also previously accredited Wadsworth be a third-party reviewer for certain molecular tests.

Additionally, the FDA issued an EUA to Roche Molecular Systems for its cobas SARS-CoV-2 test within 24 hours of receiving the application. This is the first commercially distributed diagnostic test to receive an EUA during the COVID-19 outbreak. To expedite access to this test, FDA did not object to Roche pre-positioning its test so that labs could be ready to initiate testing immediately upon authorization of the EUA. Because of that pre-

positioning, laboratories can immediately run tests on Roche's high-volume platform, which will greatly increase national testing capacity.

"We have been encouraging test developers to come to the FDA and work with us," said Jeff Shuren, M.D., J.D., director of the FDA's Center for Devices and Radiological Health. "Since the beginning of this outbreak, more than 60 developers have sought our assistance with development and validation of tests they plan to bring through the Emergency Use Authorization process. Additionally, more than 30 laboratories have notified us they are testing or intend to begin testing soon under our new policy for laboratory developed tests for this emergency."

https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-gives-flexibility-new-york-state-department-health-fda-issues

Coronavirus (COVID-19) Update: FDA Issues Emergency Use Authorization to Thermo Fisher

For Immediate Release:

March 13, 2020

Today, the U.S. Food and Drug Administration took another significant diagnostic action during the coronavirus outbreak (COVID-19). The FDA issued the fourth COVID-19 diagnostic Emergency Use Authorization (EUA) to Thermo Fisher for its TaqPath COVID-19 Combo Kit.

"This action today shows our agency's dedication to working around the clock to review and authorize diagnostics during this public health emergency," said FDA Commissioner Stephen M. Hahn, M.D. "We have been engaging with test developers and encouraging them to come to the FDA and work with us. Since the beginning of this outbreak, more than 80 test developers have sought our assistance with development and validation of tests they plan to bring through the Emergency Use Authorization process. Additionally, more than 30 laboratories have notified us they are testing or intend to begin testing soon under our new policy for laboratory-developed tests for this emergency. The number of products in the pipeline reflects the significant role diagnostics play in this outbreak and the large number of organizations we are working with to bring tests to market."

The FDA issued an EUA to Thermo Fisher for its diagnostic test within 24 hours of receiving the request. This is the second commercially distributed test to receive an EUA during the COVID-19 outbreak.

https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-emergency-use-authorization-thermo-fisher

Of interest to you is the PPE letter we sent to healthcare providers:

On March 11, 2020, the FDA issued Surgical Mask and Gown Conservation Strategies - Letter to Healthcare Providers - The conservation strategies are intended to assist healthcare organizations as they determine operating procedures during the COVID-19 outbreak. The FDA is also collaborating with manufacturers of personal protective equipment (PPE) to help facilitate mitigation strategies related to the COVID-19 outbreak. Also see: FAQs on Shortages of Surgical Masks and Gowns.

We also have Emergency Use Authorization page that is updated with information:

- Coronavirus Disease 2019 (COVID-19) Emergency Use Authorizations
  - Personal Protective Equipment EUA
  - In Vitro Diagnostic EUAs

From: McWilliams, Carly
Sent: Friday, March 13, 2020 2:25 PM
To: Shannon Curtis <Shannon.Curtis@ama-assn.org>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Margaret Garikes <Margaret.Garikes@ama-assn.org>
Subject: RE: AMA Letter to Sec Azar on COVID-19

Thank you for sending. I am pasting our latest news we issued this morning about diagnostics:

1. Press Announcements

FDA NEWS RELEASE

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Additionally, the FDA issued an EUA to Roche Molecular Systems for its cobas SARS-CoV-2 test within 24 hours of receiving the application. This is the first commercially distributed diagnostic test to receive an EUA during the COVID-19 outbreak. To expedite access to this test, FDA did not object to Roche pre-positioning its test so that labs could be ready to initiate testing immediately upon authorization of the EUA. Because of that pre-positioning, laboratories can immediately run tests on Roche's high-volume platform, which will greatly increase national testing capacity.

"We have been encouraging test developers to come to the FDA and work with us," said Jeff Shuren, M.D., J.D., director of the FDA's Center for Devices and Radiological Health. "Since the beginning of this outbreak, more than 60 developers have sought our assistance with development and validation of tests they plan to bring through the Emergency Use Authorization process. Additionally, more than 30 laboratories have notified us they are testing or intend to begin testing soon under our new policy for laboratory developed tests for this emergency."

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

From: Shannon Curtis <Shannon.Curtis@ama-assn.org>
Sent: Friday, March 13, 2020 2:22 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Cc: Margaret Garikes <Margaret.Garikes@ama-assn.org>
Subject: AMA Letter to Sec Azar on COVID-19

Hi Keagan and Carly-

Margaret asked that I share with you the attached letter the AMA sent to Secretary Azar this afternoon. The letter included some (b)(5) (b)(5) Thank you all for your work, and please let me know if you have questions or if there is anything the AMA can do to be helpful.

Shannon

Shannon Curtis, J.D.
Assistant Director, Federal Affairs
25 Massachusetts Avenue, NW
Suite 600
Washington, DC 20001-7400

P: (202) 789-8510
(b)(6)
F: (202) 789-4581
Shannon.Curtis@ama-assn.org

From: Felberbaum, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4819A643CA2945CDB1A2631B83E69673-MICHAEL.FEL]
Sent: 3/15/2020 3:38:23 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
Subject: RE: FOR URGENT REVIEW BY 4:30 PM: Remarks for HHS Briefing on COVID Testing

Thanks!

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Sunday, March 15, 2020 3:38 PM
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: Re: FOR URGENT REVIEW BY 4:30 PM: Remarks for HHS Briefing on COVID Testing

I am good.

Sent from my iPhone

On Mar 15, 2020, at 3:31 PM, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov> wrote:

Hello all,

Sharing, on Stephanie's behalf, Dr. Hahn's remarks for the HHS briefing this evening on COVID testing for urgent review by 4:30 p.m. OMA tried to use as much previously cleared content as possible.

The document for concurrent review is available in SharePoint: http://sharepoint.fda.gov/orgs/OC-OEA/OMA/Comms%20for%20Editing/opening%20remarks%20drive%20by%20testing.docx

Thank you,

Michael

Michael Felberbaum
Senior Adviser

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

<image013.png>

<image014.jpg>

<image015.jpg>

<image016.jpg>

<image017.jpg>

<image018.jpg>

From: Margaret Garikes [Margaret.Garikes@ama-assn.org]
Sent: 3/15/2020 5:07:51 PM
To: McWilliams, Carly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]; Shannon Curtis [Shannon.Curtis@ama-assn.org]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: RE: AMA Letter to Sec Azar on COVID-19

Carly,
Thanks for the heads up. Sorry I was off line for a little bit. Thanks again. Margaret

---

From: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Sent: Sunday, March 15, 2020 2:47 PM
To: Shannon Curtis <Shannon.Curtis@ama-assn.org>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Margaret Garikes <Margaret.Garikes@ama-assn.org>
Subject: RE: AMA Letter to Sec Azar on COVID-19

[Warning External Email]
Hi Shannon, I wanted to make sure you saw the latest steps we have taken for diagnostic tests and a letter we send to providers re: PPE. You may have already seen but there are a lot of things coming out from us so I wanted to make sure you were aware.

Thank you.

Carly

FDA NEWS RELEASE

Coronavirus (COVID-19) Update: FDA gives flexibility to New York State Department of Health, FDA issues Emergency Use Authorization diagnostic

For Immediate Release:

March 13, 2020

Yesterday, the U.S. Food and Drug Administration took two significant actions in the agency's ongoing and aggressive commitment to address the coronavirus outbreak (COVID19).

First, the agency issued enforcement discretion and is not objecting to the New York State Department of Health (NYSDOH) authorizing certain laboratories in New York to begin patient testing after validating their tests and notifying the NYSDOH. Under NYSDOH's approach, laboratories will provide validation data to NYSDOH within 15 days in lieu of pursuing an Emergency Use Authorization (EUA) with FDA.

Second, the FDA authorized the Roche cobas SARS-CoV-2 Test, the third Emergency Use Authorization (EUA) granted for a diagnostic test during the COVID-19 outbreak.

"These actions today show our commitment to working around the clock to help expedite the availability of tests. This NYSDOH action shows the FDA's extreme flexibility and adaptability during times of public health emergencies," said FDA Commissioner Stephen M. Hahn, M.D. "As a practical matter, what this action means is that labs, authorized by NYSDOH, will not engage with FDA to begin patient testing. Nor will they get an Emergency Use Authorization from the FDA. These labs will interact solely with NYSDOH, which should expedite

the availability of patient testing in New York State. This action demonstrates FDA's responsiveness to the needs of our country during this time."

The FDA is granting this flexibility to NYSDOH based on the urgent public health need for additional testing capacity. The FDA weighed several factors in this decision, including that the NYSDOH has a long-established framework in place for oversight of laboratory developed tests in New York State. The FDA had also previously accredited Wadsworth be a third-party reviewer for certain molecular tests.

Additionally, the FDA issued an EUA to Roche Molecular Systems for its cobas SARS-CoV-2 test within 24 hours of receiving the application. This is the first commercially distributed diagnostic test to receive an EUA during the COVID-19 outbreak. To expedite access to this test, FDA did not object to Roche pre-positioning its test so that labs could be ready to initiate testing immediately upon authorization of the EUA. Because of that pre-positioning, laboratories can immediately run tests on Roche's high-volume platform, which will greatly increase national testing capacity.

"We have been encouraging test developers to come to the FDA and work with us," said Jeff Shuren, M.D., J.D., director of the FDA's Center for Devices and Radiological Health. "Since the beginning of this outbreak, more than 60 developers have sought our assistance with development and validation of tests they plan to bring through the Emergency Use Authorization process. Additionally, more than 30 laboratories have notified us they are testing or intend to begin testing soon under our new policy for laboratory developed tests for this emergency."

https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-gives-flexibility-new-york-state-department-health-fda-issues

Coronavirus (COVID-19) Update: FDA Issues Emergency Use Authorization to Thermo Fisher

For Immediate Release:

March 13, 2020

Today, the U.S. Food and Drug Administration took another significant diagnostic action during the coronavirus outbreak (COVID-19). The FDA issued the fourth COVID-19 diagnostic Emergency Use Authorization (EUA) to Thermo Fisher for its TaqPath COVID-19 Combo Kit.

"This action today shows our agency's dedication to working around the clock to review and authorize diagnostics during this public health emergency," said FDA Commissioner Stephen M. Hahn, M.D. "We have been engaging with test developers and encouraging them to come to the FDA and work with us. Since the beginning of this outbreak, more than 80 test developers have sought our assistance with development and validation of tests they plan to bring through the Emergency Use Authorization process. Additionally, more than 30 laboratories have notified us they are testing or intend to begin testing soon under our new policy for laboratory-developed tests for this emergency. The number of products in the pipeline reflects the significant role diagnostics play in this outbreak and the large number of organizations we are working with to bring tests to market."

The FDA issued an EUA to Thermo Fisher for its diagnostic test within 24 hours of receiving the request. This is the second commercially distributed test to receive an EUA during the COVID-19 outbreak.

https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-emergency-use-authorization-thermo-fisher

Of interest to you is the PPE letter we sent to healthcare providers:

On March 11, 2020, the FDA issued Surgical Mask and Gown Conservation Strategies - Letter to Healthcare Providers - The conservation strategies are intended to assist healthcare organizations as they determine operating procedures during the COVID-19 outbreak. The FDA is also collaborating with manufacturers of

personal protective equipment (PPE) to help facilitate mitigation strategies related to the COVID-19 outbreak. Also see: FAQs on Shortages of Surgical Masks and Gowns.

We also have Emergency Use Authorization page that is updated with information:

- Coronavirus Disease 2019 (COVID-19) Emergency Use Authorizations
  - Personal Protective Equipment EUA
  - In Vitro Diagnostic EUAs

From: McWilliams, Carly
Sent: Friday, March 13, 2020 2:25 PM
To: Shannon Curtis <Shannon.Curtis@ama-assn.org>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Margaret Garikes <Margaret.Garikes@ama-assn.org>
Subject: RE: AMA Letter to Sec Azar on COVID-19

Thank you for sending. I am pasting our latest news we issued this morning about diagnostics:

1. Press Announcements

FDA NEWS RELEASE

Coronavirus (COVID-19) Update: FDA gives flexibility to New York State Department of Health, FDA issues Emergency Use Authorization diagnostic

For Immediate Release:

March 13, 2020

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The FDA is granting this flexibility to NYSD●H based on the urgent public health need for additional testing capacity. The FDA weighed several factors in this decision, including that the NYSD●H has a long-established framework in place for oversight of laboratory developed tests in New York State. The FDA had also previously accredited Wadsworth be a third-party reviewer for certain molecular tests.

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expedite access to this test, FDA did not object to Roche pre-positioning its test so that labs could be ready to initiate testing immediately upon authorization of the EUA. Because of that pre-positioning, laboratories can immediately run tests on Roche's high-volume platform, which will greatly increase national testing capacity.

"We have been encouraging test developers to come to the FDA and work with us," said Jeff Shuren, M.D., J.D., director of the FDA's Center for Devices and Radiological Health. "Since the beginning of this outbreak, more than 60 developers have sought our assistance with development and validation of tests they plan to bring through the Emergency Use Authorization process. Additionally, more than 30 laboratories have notified us they are testing or intend to begin testing soon under our new policy for laboratory developed tests for this emergency."

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

From: Shannon Curtis <Shannon.Curtis@ama-assn.org>
Sent: Friday, March 13, 2020 2:22 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Cc: Margaret Garikes <Margaret.Garikes@ama-assn.org>
Subject: AMA Letter to Sec Azar on COVID-19

Hi Keagan and Carly-

Margaret asked that I share with you the attached letter the AMA sent to Secretary Azar this afternoon. The letter included some **(b)(5)** **(b)(5)** Thank you all for your work and please let me know if you have questions or if there is anything the AMA can do to be helpful.

Shannon

Shannon Curtis, J.D.
Assistant Director, Federal Affairs
25 Massachusetts Avenue, NW
Suite 600
Washington, DC 20001-7400

P: (202) 789-8510
(b)(6)
F: (202) 789-4581
Shannon.Curtis@ama-assn.org

From: Trueman, Laura (HHS/IEA) [Laura.Trueman@hhs.gov]
Sent: 3/15/2020 5:36:57 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: RE: 7pm logistics
Attachments: Information for Stakeholder Call on Testing.docx

-----Original Message-----
From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Sunday, March 15, 2020 4:58 PM
To: Trueman, Laura (HHS/IEA) <Laura.Trueman@hhs.gov>
Subject: 7pm logistics

Can you send to me pls!! Boss needs them.

Sent from my iPhone

From: Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]
Sent: 3/15/2020 9:47:40 PM
To: Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]
Subject: Re: AMA prep for COVID 19 Testing call

Sorry. We we knew about it. It's been an insane day!!

Sent from my iPhone

On Mar 15, 2020, at 6:32 PM, Sheehy, Janice <Janice.Sheehy@fda.hhs.gov> wrote:

This just came in for 6:45 this evening

-----Original Appointment-----
From: Secretary Scheduler (OS/IOS) <Secretary.Scheduler@hhs.gov>
Sent: Sunday, March 15, 2020 6:28 PM
To: Secretary Scheduler (OS/IOS); AMA2 (OS/IOS); Apple, Matthew (OS); Harrison, Brian (OS); Mango, Paul (OS); Puesan, Cesar (OS); Stecker, Judy (OS); Tignor, Beth (OS); Trueman, Laura (OS); Beck, Gary (OS); Brennan, Patrick (OS); Giroir, Brett (OS); Bante, Katie (OS); Redfield, Robert R (CDC); Williams, Teresa (CDC); Gershman, Lynn E (CDC); Hahn, Stephen; Sheehy, Janice; Kadlec, Robert P (OS); Ford-Barnes, Arwenthia (OS); Fauci, Anthony S (NIH); Conrad, Patricia L (NIH); Smith, Brad (CMS)
Subject: AMA prep for COVID 19 Testing call
When: Sunday, March 15, 2020 6:45 PM-7:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: Roosvelet Room

Hi All

Thank you for participating in tonight's call on COVID-19 testing.

Here is what you need to know:

Location: White House, Roosevelt Room

Time: Pre-Gathering: 6:45 PM
Call: 7:00 PM – 8:00 PM

Audience:
Private: Major Health Systems, FAH, AHA, America's Essential Hospitals Association, Physician Hospitals of America, Catholic Health Association, Public and Private Lab Associations (ACLA and APHL), National Rural Health Association, College of American Pathologists, Range of individual hospitals

Public: Governors (COS, Policy Director, State Federal Affairs Reps); State Health Officers, County Health Officers

Format:
We are going to use a interactive format. After openers from Birx and Azar, Azar will act as a moderator of sorts, asking questions to the key participants. These questions represent the queries that IEA and others are receiving the most often.

If you feel that we have crafted the wrong question for you, please send back a note and we will revise.

Run of Show
Ambassador Birx – Opening Remarks, 1-2 minutes, pitches it to Secretary Azar
Secretary Azar – Opening Remarks, introduces Admiral Giroir, and asks him:

(b)(5)

(b)(5)

From: McWilliams, Carly [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B68C7458214244D08424FD441FEA4FDA-CARLYLE.MCW]
Sent: 3/16/2020 7:55:45 AM
To: Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: Re: URGENT: UCSF Critical Reagent Shortage

Yes-drafting Email now.

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Date: March 16, 2020 at 7:55:01 AM EDT
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Subject: Re: URGENT: UCSF Critical Reagent Shortage

Thank you.

Carly, **(b)(5)** Pls lmk. Thanks.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Date: March 16, 2020 at 7:48:30 AM EDT
To: Shah, Anand <Anand.Shah@fda.hhs.gov>, McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Subject: Fwd: URGENT: UCSF Critical Reagent Shortage

Anand- another one for you **(b)(5)**

Sent from my iPhone

Begin forwarded message:

From: Margaret Garikes <Margaret.Garikes@ama-assn.org>
Date: March 16, 2020 at 7:46:59 AM EDT
To: "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>, "McWilliams, Carly" <Carly.McWilliams@fda.hhs.gov>
Cc: Shannon Curtis <Shannon.Curtis@ama-assn.org>
Subject: FW: URGENT: UCSF Critical Reagent Shortage

Carly and Keagan-
Sorry to bother you. Below is an email from a former chairman of the AMA's Board of Trustees. Jack is a very measured guy. He is also very senior at UCSF which has been on the front lines of this COVID issue for several weeks. See the situation below with reagents. When I spoke to Jack on the phone last night he told me they had about 5 days left in the supply. Can you all assist or point me in the direction of someone who can? Or provide me with the name of a senior person at Roche? Thanks so much. Margaret

---

From: Resneck Jr, Jack <Jack.Resneck@ucsf.edu>
Sent: Sunday, March 15, 2020 9:46 PM

To: Margaret Garikes <Margaret.Garikes@ama-assn.org>
Subject: URGENT: UCSF Critical Reagent Shortage

[Warning External Email]

Margaret,

Thank you for passing our UCSF concerns on to FDA leadership to see if we can get assistance.

We have been caring for several COVID-infected patients in our hospital.
Thanks to FDA approval and removal of regulatory challenges, we have been running our own tests on symptomatic patients at UCSF since last Tuesday, though our testing capacity has remained severely limited.

However, our current threat is a **severe shortage of reagents** for RNA extraction. We have run out of the reagent for the more rapid platform, and only have a few days supply of reagents for our slower platform, which has further limited our testing capacity as we conserve. A partner hospital who takes some of our overflow tests faces similar reagent shortages. And the tests at commercial labs are taking 4-5 days (as opposed to our <24 hour turnaround) -- we can't wait that long for results on inpatients.

The items we desperately need are reagent kits for Roche MagNA Pure 24 and Qiagen EZ1 RNA extractors. We have been trying to communicate with Roche about the supply chain limitations.

We need federal help either in securing additional reagents or intervention in the supply chain to redistribute reagents from research labs or other geographies where they are not currently critically needed.

Thanks for seeing if FDA can be of assistance.

Best,
Jack

Jack Resneck, Jr, MD
Board of Trustees, American Medical Association (Immediate Past Chair)
Professor and Vice-Chair of Dermatology, UCSF School of Medicine

From: Margaret Garikes [Margaret.Garikes@ama-assn.org]
Sent: 3/16/2020 8:14:28 AM
To: McWilliams, Carly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Shannon Curtis [Shannon.Curtis@ama-assn.org]
Subject: RE: URGENT: UCSF Critical Reagent Shortage

Carly --Thanks for the response. Margaret

From: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Sent: Monday, March 16, 2020 8:10 AM
To: Margaret Garikes <Margaret.Garikes@ama-assn.org>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Shannon Curtis <Shannon.Curtis@ama-assn.org>
Subject: Re: URGENT: UCSF Critical Reagent Shortage

[Warning External Email]

Margaret, thanks for reaching out. We have a 24/7 toll-free line, 1-888-INFO-FDA, to help labs with supply issues. We also have a faq website that answers questions about supply issues. I pasted information about Roche tests below and link to faq is below.

Q: What happens if I do not have the extraction platform referenced in the authorization of CDC's EUA-authorized test?

A: FDA believes that the CDC's EUA-authorized test could be used with the following extraction platforms:

- **Roche MagNA Pure LC**

Kit: Roche MagNA Pure Total Nucleic Acid Kit
Protocol: Total NA External_lysis
Recommendation(s): Add 100 µL of sample to 300 µL of pre-aliquoted TNA isolation kit lysis buffer (total input sample volume is 400 µL). Elution volume is 100 µL.

- **Roche MagNA Pure Compact**

Kit: Roche MagNA Pure Nucleic Acid Isolation Kit I
Protocol: Total_NA_Plasma100_400
Recommendation(s): Add 100 µL of sample to 300 µL of pre-aliquoted TNA isolation kit lysis buffer (total input sample volume is 400 µL). Elution volume is 100 µL.

- **Roche MagNA Pure 96**

Kit: Roche MagNA Pure 96 DNA and Viral NA Small Volume Kit
Protocol: Viral NA Plasma Ext Lys SV Protocol
Recommendation(s): Add 100 µL of sample to 350 µL of pre-aliquoted External Lysis Buffer (supplied separately) (total input sample volume is 450 µL). Proceed with the extraction on the MagNA Pure 96. (Note: Internal Control = None). Elution volume is 100 µL.

https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2#donothaveextractionplatform

---

From: Margaret Garikes <Margaret.Garikes@ama-assn.org>
Date: March 16, 2020 at 7:46:59 AM EDT
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Cc: Shannon Curtis <Shannon.Curtis@ama-assn.org>
Subject: FW: URGENT: UCSF Critical Reagent Shortage
Importance: High

Carly and Keagan-

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---

From: Resneck Jr, Jack <Jack.Resneck@ucsf.edu>
Sent: Sunday, March 15, 2020 9:46 PM
To: Margaret Garikes <Margaret.Garikes@ama-assn.org>
Subject: URGENT: UCSF Critical Reagent Shortage

[Warning External Email]

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Jack Resneck, Jr, MD

Board of Trustees, American Medical Association (Immediate Past Chair)

Professor and Vice-Chair of Dermatology, UCSF School of Medicine

From: Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]
Sent: 3/16/2020 8:18:45 AM
To: McWilliams, Carly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: Re: URGENT: UCSF Critical Reagent Shortage

Thank you !

From: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Date: March 16, 2020 at 8:18:03 AM EDT
To: Shah, Anand <Anand.Shah@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: Re: URGENT: UCSF Critical Reagent Shortage

Email I sent them for reference

[Warning External Email]

Margaret, thanks for reaching out. We have a 24/7 toll-free line, 1-888-INFO-FDA, to help labs with supply issues. We also have a faq website that answers questions about supply issues. I pasted information about Roche tests below and link to faq is below.

Q: What happens if I do not have the extraction platform referenced in the authorization of CDC's EUA-authorized test?

A: FDA believes that the CDC's EUA-authorized test could be used with the following extraction platforms:

- **Roche MagNA Pure LC**

Kit: Roche MagNA Pure Total Nucleic Acid Kit
Protocol: Total NA External_lysis
Recommendation(s): Add 100 µL of sample to 300 µL of pre-aliquoted TNA isolation kit lysis buffer (total input sample volume is 400 µL). Elution volume is 100 µL.

- **Roche MagNA Pure Compact**

Kit: Roche MagNA Pure Nucleic Acid Isolation Kit I
Protocol: Total_NA_Plasma100_400
Recommendation(s): Add 100 µL of sample to 300 µL of pre-aliquoted TNA isolation kit lysis buffer (total input sample volume is 400 µL). Elution volume is 100 µL.

- **Roche MagNA Pure 96**

Kit: Roche MagNA Pure 96 DNA and Viral NA Small Volume Kit
Protocol: Viral NA Plasma Ext Lys SV Protocol
Recommendation(s): Add 100 µL of sample to 350 µL of pre-aliquoted External Lysis Buffer (supplied separately) (total input sample volume is 450 µL). Proceed with the extraction on the MagNA Pure 96. (Note: Internal Control = None). Elution volume is 100 µL.

https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2#donothaveextractionplatform

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From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Date: March 16, 2020 at 7:55:01 AM EDT
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Subject: Re: URGENT: UCSF Critical Reagent Shortage

Thank you.

Carly, **(b)(5)** Pls lmk. Thanks.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Date: March 16, 2020 at 7:48:30 AM EDT
To: Shah, Anand <Anand.Shah@fda.hhs.gov>, McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Subject: Fwd: URGENT: UCSF Critical Reagent Shortage

Anand- another one for you. **(b)(5)**

Sent from my iPhone

Begin forwarded message:

From: Margaret Garikes <Margaret.Garikes@ama-assn.org>
Date: March 16, 2020 at 7:46:59 AM EDT
To: "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>, "McWilliams, Carly" <Carly.McWilliams@fda.hhs.gov>
Cc: Shannon Curtis <Shannon.Curtis@ama-assn.org>
Subject: FW: URGENT: UCSF Critical Reagent Shortage

Carly and Keagan-
Sorry to bother you. Below is an email from a former chairman of the AMA's Board of Trustees. Jack is a very measured guy. He is also very senior at UCSF which has been on the front lines of this COVID issue for several weeks. See the situation below with reagents. When I spoke to Jack on the phone last night he told me they had about 5 days left in the supply. Can you all assist or point me in the direction of someone who can? Or provide me with the name of a senior person at Roche? Thanks so much. Margaret

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From: Resneck Jr, Jack <Jack.Resneck@ucsf.edu>
Sent: Sunday, March 15, 2020 9:46 PM
To: Margaret Garikes <Margaret.Garikes@ama-assn.org>
Subject: URGENT: UCSF Critical Reagent Shortage

[Warning External Email]

Margaret,

Thank you for passing our UCSF concerns on to FDA leadership to see if we can get assistance.

We have been caring for several COVID-infected patients in our hospital.
Thanks to FDA approval and removal of regulatory challenges, we have been running our own tests on symptomatic patients at UCSF since last Tuesday, though our testing capacity has remained severely limited.

However, our current threat is a **severe shortage of reagents** for RNA extraction. We have run out of the reagent for the more rapid platform, and only have a few days supply of reagents for our slower platform, which has further limited our testing capacity as we conserve. A partner hospital who takes some of our overflow tests faces similar reagent shortages. And the tests at commercial labs are taking 4-5 days (as opposed to our <24 hour turnaround) -- we can't wait that long for results on inpatients.

The items we desperately need are reagent kits for Roche MagNA Pure 24 and Qiagen EZ1 RNA extractors. We have been trying to communicate with Roche about the supply chain limitations.

We need federal help either in securing additional reagents or intervention in the supply chain to redistribute reagents from research labs or other geographies where they are not currently critically needed.

Thanks for seeing if FDA can be of assistance.

Best,
Jack

Jack Resneck, Jr, MD
Board of Trustees, American Medical Association (Immediate Past Chair)
Professor and Vice-Chair of Dermatology, UCSF School of Medicine

From: Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]
Sent: 3/16/2020 8:34:47 AM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
Subject: Fwd: Head up: Updated COVID diagnostic testing guidance coming for clearance

Hopefully we can get up by 5pm.

Sent from my iPhone

Begin forwarded message:

From: "Roth, Lauren" <Lauren.Roth@fda.hhs.gov>
Date: March 16, 2020 at 8:28:46 AM EDT
To: "Steele, Danielle (OS)" <Danielle.Steele@hhs.gov>, "Giroir, Brett (OS)" <Brett.Giroir@hhs.gov>, "Mango, Paul (OS)" <Paul.Mango@hhs.gov>, "Hawkins, Jamar (OS)" <jamar.hawkins@hhs.gov>, "Robinson, Wilma (OS)" <Wilma.Robinson@hhs.gov>
Cc: "Schiller, Lowell" <Lowell.Schiller@fda.hhs.gov>, "Malliou, Ekaterini (OS)" <Ekaterini.Malliou@hhs.gov>, "Lomax, Tinisha (OS)" <Tinisha.Lomax@hhs.gov>, "Shipley, Samuel (OS)" <Samuel.Shipley@HHS.GOV>, "Horska, Katerina (OS)" <Katerina.Horska@hhs.gov>, "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>, "Amin, Stacy" <Stacy.Amin@fda.hhs.gov>
Subject: Head up: Updated COVID diagnostic testing guidance coming for clearance

HHS team,

Yesterday, FDA drafted updates to the COVID19 diagnostic testing policy guidance (issued on February 29th). We will be sending the revised draft to you this morning with a goal of HHS and OIRA clearances as soon as possible today.

I'm including Admiral Giroir, Paul, and Danielle as a heads up on this email, but will take them off the chain to spare their inboxes as we get into the clearance process itself.

By way of background, the guidance now includes four policies:

(b)(5)

If possible, we respectfully request a 2-hour clearance by HHS, and a 2-hour clearance by OIRA, given the importance of issuing this information today and that this has been the approximate times for clearance of the other urgent FDA guidances. In addition, can HHS please let OIRA know that this is coming?

Please let me know if you have any questions.

Many thanks,
Lauren

Lauren K. Roth, JD
Associate Commissioner for Policy

Office of Policy
U.S. Food and Drug Administration

(240) 402-1671
lauren.roth@fda.hhs.gov

From: Torres, Alfonso (HHS/ASL) [Alfonso.Torres@hhs.gov]
Sent: 3/16/2020 9:05:29 AM
To: OS - ASL [ASL2@hhs.gov]; Torres, Alfonso (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=289d0f241273408898284b056ea0e05c-HHS-Alfonso]; Pollard, Ashton (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0eba064633c94d69ac56385c0972e3da-HHS-Ashton.]; Barbara_A_Menard@omb.eop.gov; Hayley_W_Myers@omb.eop.gov; Brooks, John (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d8d251ad1ebd447f8378d71031e0dabf-HHS-John.Br]; Johnson-Weider, Michelle (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fe2b379846da4fff88e653b5838225ef-HHS-Michell]; Bush, Laina (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7596731c21444c8b89b13d454b403efd-HHS-Laina.B]; Jackson, Chazeman S (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7502e7b60d604f9f92be6247500ed35c-HHS-Chazema]; Delew, Nancy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6b9150131daa49fbbf486e3c4affcfc9-HHS-Nancy.D]; Cash, Lester (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=367e72e3a24b42e686a0ad88ededaca5-HHS-Lester.]; Cochran, Norris (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=996319874d544434b96eef30e8232610-HHS-norris.]; Griswold, Nancy J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8299c0880da64303b4ea8788eb1bb6c9-HHS-Nancy.G]; Fischbach, Aaron (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8ea33b46039b40e28161700df7dcfd45-HHS-Aaron.F]; Hirshorn, Rebecca (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5fe9d768c04d43e5974c4b87c2cd6ae6-HHS-Rebecca]; Hawkins, Jamar (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bd7c1a4031647ce89237aef4deb5d89-HHS-jamar.h]; Grove, Matthew R (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=74ee04cf984940678e277d7b3390efbc-HHS-Matthew]; Shipley, Samuel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a640bbaa8f2c4a4086e6375495796325-HHS-Samuel.]; Weber, Mark (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a80e62b41b2d4981af48d6cabbd923e9-HHS-Mark.We]; Daniels, Carla L (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec0430c977294a79b2b2d8f42f75992d-HHS-Carla.D]; Robinson, Michael J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4118fde5239947c6bccbdbd4cb7488fa-HHS-michael]; Myrie, Simone (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0ae0858be3ac46f8a346c6e6316fe36d-HHS-Simone.]; Formoso, Paula (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ef23a919842c4da7a77b27d1c9cd739a-HHS-Paula.F]; Hall, Bill (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e56218361cd4ffbacdd06ac2d7b809d-HHS-bill.ha]; Oakley, Caitlin B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8feed045e954557aa1e0052f925865f-HHS-Caitlin]; Stecker, Judy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e205440400ab4f629be1faccfe0846fc-HHS-Judy.St]; Boyse, Natalie R (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=650286c0f0f540108f008d554367493b-HHS-Natalie]; OS GCL, EMAIL (HHS/OGC) [EMAIL.GCL@HHS.GOV]; Friedman, Richard (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd0f78628e644da19ba0beb949181a89-HHS-Richard]; Hertzog, Christian P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52352e0f056a4835be7630c5742f336d-HHS-Christi]; Blackwell, Edith (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2addd26dc8bd43a1a5b8b0656c43850d-HHS-Edith.B]; Nelson, Thayer (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=15cc5e0955e148bc83993d1f37c96d80-HHS-Thayer.]; Schavio, Brad (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5488b685b4694e0f8ad31ca72f56b564-HHS-Brad.Sc]; Fan, Jennifer (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d31c25a3461d46fe84cad19c6438bc01-HHS-Jennife]; Slothouber, Doug (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ef0bed17d6ba457887fa76d160a86bb5-HHS-Doug.Sl]; Duffy, Ashley (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f024806e85e947df979ccc5aacf00f1b-HHS-Ashley.]; Musante, Sarah (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f923014ad00d490883d1357a48036d9d-HHS-Sarah.M]; Hayman, Lori (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6be37a3d8eaa4e1b882cb691cb133942-HHS-Lori.Ha]; Atkinson, Leslie (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3e069df597d64b8ab2cf1cfcf568cca9-HHS-LAtkins]; Cristinzio, Dayle [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b5a8dc4e587946fa938714a962df4246-Dayle.Crist]; OC OL Staff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1a35f07a0600471ba92352df4d23029f-OC OL Staff]; Emmitt, Keenan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e073d2ec469649779449891cb37d4aac-Keenan.Emmi]; Menon, Ramesh [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=42b14aeaac6a4c368f081f80f66beb0d-Ramesh.Meno]; Nguyen, Michael A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bd81ee5310745588f739376431ea14b-Michael.Ngu]; Emmitt, Keenan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e073d2ec469649779449891cb37d4aac-Keenan.Emmi]; Hattis, Daniel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eea12bdaa04f42f0afb9dd6abf39793a-Daniel.Hatt]; Emmitt, Keenan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e073d2ec469649779449891cb37d4aac-Keenan.Emmi]; Roberts, Michelle [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e1c09da5d79049fb902729d7e8328a34-Michelle.Ro]; Logan, Scott (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8db8b538e63e4139aae759dcd223f7ec-HHS-scott.l]; Klocinski, Jennifer (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9ecb7ac09fc44f0c8b5d60daf4046c10-HHS-Jennife]; Osborne, Jonathan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4f4dd36bcc9462e9c4582553cee9263-HHS-Jonatha]; Mitchell, Michelle D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1a0158f5a17145f2b96fdbff4c4345bd-HHS-michell]; Usher, Adrienne H (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05dcba635daa4cb09ad8bdea916ac43b-HHS-adrienn]; Vo, Thuy N (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f9e1524b18d34e04bc57751f99c5f652-HHS-vot-mai]; LaMontagne, Karen A (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=556f3d319c9c4a3e8c0cb28ba4529cb0-HHS-karen.l]; Crews, Donna P (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f8780841f2e462aa59609bc5f708b29-HHS-donna.c]; Everett, Chris L (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=db581543f757416f89d80b3141d4b8b7-HHS-chris.e]; Higgins, Lauren G (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b1f46ebca35e4fbea2bb2de2d8eb4ddc-HHS-Higgins]; Berkson, Laura D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a50c756368ad4cb98b0c74515668c3b5-HHS-laura.b]; Hansberger, Patti B (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9fcb9c5bab1c40f0bdb8659a17f96ceb-HHS-BrandtP]; Mullman, Lauren E (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=5d92f61d374c49f2b55c03d478c6d775-HHS-lauren.]; Motley, Essence R (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e60990f192c34ec5ad4f45e446c5cce5-HHS-essence]; Culhane, Ned C (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9af4c3305d5a406cb42920e2be577287-HHS-culhane]; Brand, Anstice M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4769e64323944161a994c2086b645f4c-HHS-atb6-cd]; Bigham, Jane E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58d05801bf1d46d883ff225114683c3a-HHS-vsy0-cd]; Burns, Annina (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=868b392bc113454f897f4753c2427291-HHS-vjg7-cd]; Greaser, Jennifer L (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6007c3bba4a1420bb704298c5e49f29b-HHS-cbx5-cd]; Workman, Sara R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b6832bc2f329499fbac97ce409378b07-HHS-hvh0-cd]; Katsoyannis, Miranda G (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=65fc60cdb01341a2ab99774bbc0f9e06-HHS-mtk7-cd]; Klingbeil, Martin (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c5fdab2392bc4a04a49de76f6ed42616-HHS-ypf2-cd]; Rogers, Barbara A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dbacc2dd32d542198f76450b6754cb57-HHS-bkr6-cd]; Schwarcz, Cristi L (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eccc9ac26e3544a9aec40dc54a73f0ef-HHS-zcj1-cd]; Serna, Christina (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4da9a12770147b1a2967a9a9e7884f3-HHS-yyh9-cd]; THOMAS, MARISSA (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98ed8c014efd496b8817fed1e6cce027-HHS-kzu2-cd]; Tourk, Nancy R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdb086e24ad14975bcc32097b68271fb-HHS-wxk8-cd]; Wolfe, Mitchell (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6a21848015074b41965a8925c65edf21-HHS-msw6-cd]; Rose-Wood, Alyson (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d7d68cd184940b5849eb04f2b86147c-HHS-ifd6-cd]; Wortman, Eric J (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12160139c2b943ec91e7a73d76194848-HHS-ltr3-cd]; Rice, Peggie L (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0fc04b7a68c45749e42bbe7a273b15b-HHS-ksp4-cd]; Ginieczki, Boyce (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eb98c380572f4f5ea9d3b2293c0b8e56-HHS-Boyce.G]; Boulanger, Jennifer L (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e8614e05d954061a2c6987949abb723-HHS-Jennife]; Stahlman, Mary Ellen (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dea17995d03a4110a9b124d2e84144e2-HHS-MaryEll]; Dawson, Andrew (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1046e569129949bd880c6dbea0b5fe6b-HHS-Andrew.]; Ferraina, Steven (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=028a6559c9114b8ba75ebaf5f575e407-HHS-Steven.]; Martino, Maria (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6618e23281ba4279931e9c2f680d6b9f-HHS-Maria.M]; Newlin, Manda (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8ba660bbea89488abf3e058923536932-HHS-Manda.N]; Harris, William (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=49b6fc800e154277951ef1aa6c4bd503-HHS-William]; Druckman, Jennifer (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77f7417315524715908814945f9a4fa5-HHS-Jennife]; Brady, Kevin (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6c751ec54b640d98921b4b516bd4754-HHS-Kevin.B]; Wilson, Lisa J (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group

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(FYDIBOHF23SPDLT)/cn=Recipients/cn=be9bafe245ae491baa1c01e7e03ad9e4-HHS-Brady.B]; Stirrup, Heidi (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f466d5c45cfd47d88cd4c10282849ce1-HHS-Heidi.S]; Meszaros, Marie (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=25e864d1351b40c0960f03015e15609d-HHS-marie.m]; Pilato, Anna (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=303af811a1a64ea79cb494a7208dc71e-HHS-Anna.Pi]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Parker, Jim (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0601902140f426e9c5a139f7134a3c5-HHS-Jim.Par]; Morse, Sara N (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4080ee237c084683ae674366e5cde21d-HHS-Sara.Mo]; Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Armstrong, Rebekah W (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ced6b9e2a4ba45bb9843f31a5daae598-HHS-Rebekah]; Vitek, Traci (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=97f8080425b44edfb0e2d60cc77a7ffe-HHS-Traci.V]; Agnew, Ann (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=daa06163025f427aa913c47cafaf6589-HHS-Ann.Agn]; Wagner, Steven (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7064f721cdcb47ca8539583635c064bc-HHS-Steven.]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Royce, Shannon (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3f3d87b609bb462e90777e39aef3d4bf-HHS-Shannon]; Wagner, Steven (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7064f721cdcb47ca8539583635c064bc-HHS-Steven.]; Carter, Clarence H (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edb075ac5a3847bcbad1c966fbaefba0-HHS-Clarenc]; Christian, Shannon (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=10c6064519f247d7b1d5aa166e9f74ce-HHS-Shannon]; Moreno, Pedro C (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d1c3d742526542889fe4b9b9df3cf11d-HHS-Pedro.M]; Lazare, Mary (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f67265c7ea6b401baa938ac1f5ce7c55-HHS-Mary.La]; Brandt, Kimberly (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c27a38a5cf444a9eb4db07014d44f848-HHS-Kimberl]; Kleinschmidt, Arthur G (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95d7eee7609d432892f5b349c39d22bd-HHS-Arthur.]; Robertson, Lance (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e5ca0f7ed65142be8a4afc3665439486-HHS-Lance.R]; Huber, Valerie (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a20d65a6a2e74936bb2a9ba190d633b5-HHS-Valerie]; Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Hayes, Jonathan H (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc52bfdbbde141b2b21aadd78165f502-HHS-Jonatha]; Anger, Amanda (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=037a7c529eca45ff932b179fc1b60e32-HHS-Amanda.]; Pence, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3f21407a02d44cd4901bcce26f9b3074-HHS-Laura.P]

Subject: ASL Daily Memo 16 March 2020

Department of Health and Human Services
Office of the Assistant Secretary for Legislation

ASL Daily Memo for March 16, 2020
(* denotes new or updated item)

The Senate convenes at 3pm and resumes consideration of the motion to proceed to H.R.6172, the USA FREEDOM Reauthorization Act of 2020.

The House reconvenes at 11am.

SENATE

COMMITTEE: Senate Committee on Health, Education, Labor, and Pensions
SUBJECT: An Emerging Disease Threat: How the US is responding to COVID-19, the Novel Coronavirus, Part 2
DATE/TIME: Wednesday, March 18, 2020 at 10:00am; 216 Hart Senate Office Building
WITNESSES:
- Dr. Anne Schuchat, Principal Deputy Director, CDC
- Dr. Anthony Fauci, Director, National Institute of Allergy and Infectious Diseases, NIH
- Dr. Robert Kadlec, Asst Secretary for Preparedness and Response, HHS
- Dr. Stephen Hahn, Commissioner, FDA

HOUSE

None

Thanks,

ALFONSO TORRES
Policy Advisor
Department of Health and Human Services
Office of the Assistant Secretary for Legislation
(202) 730-8713

From: Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]
Sent: 3/16/2020 3:04:36 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: RE: TWEETS for REVIEW: COVID - Testing Availability

Yes doing now

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Monday, March 16, 2020 2:55 PM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: Fwd: TWEETS for REVIEW: COVID - Testing Availability

Can you pls review?

Sent from my iPhone

Begin forwarded message:

From: "Kimberly, Brad" <Brad.Kimberly@fda.hhs.gov>
Date: March 16, 2020 at 2:18:41 PM EDT
To: "Hahn, Stephen" <SH1@fda.hhs.gov>
Cc: "Caliguiri, Laura" <Laura.Caliguiri@fda.hhs.gov>, "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>, "Lynch, Sarah" <Sarah.Lynch@fda.hhs.gov>, "Rebello, Heidi" <Heidi.Rebello@fda.hhs.gov>, "Rom, Colin" <Colin.Rom@fda.hhs.gov>, "Shah, Anand" <Anand.Shah@fda.hhs.gov>, "Thorpe, Valarie" <Valarie.Thorpe@fda.hhs.gov>
Subject: RE: TWEETS for REVIEW: COVID - Testing Availability

Good afternoon… floating this to the top of your inbox.

Brad Kimberly
Director, Social Media

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel 240-402-1002 | Cell (b)(6)
brad.kimberly@fda.hhs.gov

From: Kimberly, Brad
Sent: Monday, March 16, 2020 10:40 AM
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Thorpe, Valarie <Valarie.Thorpe@fda.hhs.gov>
Subject: TWEETS for REVIEW: COVID - Testing Availability

Good morning… some tweets for your review. Our intent is to get these out by noon. Thanks! --Brad

===

Testing Availability
Thread

1. FDA's Center for Devices & Radiological Health is working around the clock to increase testing availability across the country. We are working closely with @CDCgov, commercial test distributors, labs & others to facilitate the distribution of tests across the country.
2. The policy we issued two weeks ago to achieve more rapid testing in the U.S. provides regulatory relief & clarity to encourage the development of new #coronavirus diagnostic tests for Americans.
3. Under this policy, we have heard from more than 40 labs, many of which have already begun patient testing.

(b)(5)

https://twitter.com/WhiteHouse/status/1239330551762432005/video/1

5. We will continue to update the American people on the availability of #COVID19 tests & their components. We are focused on making sure tests are distributed & and that test developers & labs have the materials they need to run their tests.

CDRH FAQ Individual Tweets

@SteveFDA Account

1. FDA is open 24/7 & we are here to help labs & test developers get tests into the field & the materials they need to develop the tests. Our #FAQs for labs are always updated, providing info on alternative sources of reagents, extraction kits, swabs & more. https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2

(b)(5)

Brad Kimberly
Director, Social Media

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-1002 | Ce **(b)(6)**
brad.kimberly@fda.hhs.gov

From: Caliguiri, Laura [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AA086F2D6C0346C49E996932D86AC62E-LAURA.CALIG]
Sent: 3/16/2020 3:48:20 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Hebert, Angelique A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aa08f3428a045f88eb3bd92c68a27cf-Angelique.H]
CC: Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Kimberly, Brad [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08bc909ed76d49868a5ff92c3c70fb72-Bradley.Kim]; Lynch, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d24ee4a4fc6241f48110d6b35e6704ed-Sarah.Lynch]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
Subject: The President's Coronavirus Guidelines for America - 15 Days to Slow the Spread

THE WHITE HOUSE

Today, the White House released: **The President's Coronavirus Guidelines for America - 15 Days to Slow the Spread**. Guidelines can be found below.

The President's Coronavirus Guidelines for America - 15 Days to Slow the Spread

(graphic below)

1. Listen to and follow the directions of your state and local authorities.

2. If you feel sick, stay home. Do not go to work. Contact your medical provider.

3. If your children are sick, keep them at home. Do not send them to school. Contact your medical provider.

4. If someone in your household has tested positive for the coronavirus, keep the entire household at home. Do not go to work. Do not go to school. Contact your medical provider.

5. If you are an older person, stay home and away from other people.

6. If you are a person with a serious underlying health condition that can put you at increased risk (for example, a condition that impairs your lung or heart function or weakens your immune system), stay home and away from other people.

7. Even if you are young, or otherwise healthy, you are at risk and your activities can increase the risk for others. It is critical that you do your part to stop the spread of the coronavirus:

➢ Work or engage in schooling from home whenever possible.

➢ If you work in a critical infrastructure industry, as defined by the Department of Homeland Security, such as healthcare services and pharmaceutical and food supply, you have a special responsibility to maintain your normal work schedule. You and your employers should follow CDC guidance to protect your health at work.

➢ Avoid social gatherings in groups of more than 10 people.

➢ Avoid eating or drinking in bars, restaurants, and food courts – use drive-thru, pickup, or delivery options.

➢ Avoid discretionary travel, shopping trips, and social visits.

➢ Do not visit nursing homes or retirement or long-term care facilities unless to provide critical assistance.

➢ Practice good hygiene:
- Wash your hands, especially after touching any frequently used item or surface.
- Avoid touching your face.
- Sneeze or cough into a tissue, or the inside of your elbow.
- Disinfect frequently used items and surfaces as much as possible.

* School operations can accelerate the spread of the coronavirus. Governors of states with evidence of community transmission should close schools in affected and surrounding areas. Governors should close schools in communities that are near areas of community transmission, even if those areas are in neighboring states. In addition, state and local officials should close schools where coronavirus has been identified in the population associated with the school. States and localities that close schools need to address childcare needs of critical responders, as well as the nutritional needs of children.

** Older people are particularly at risk from the coronavirus. All states should follow Federal guidance and halt social visits to nursing homes and retirement and long-term care facilities.

*** In states with evidence of community transmission, bars, restaurants, food courts, gyms, and other indoor and outdoor venues where groups of people congregate should be closed.

THE PRESIDENT'S **CORONAVIRUS GUIDELINES** FOR AMERICA

15 DAYS TO SLOW THE SPREAD

Listen to and follow the directions of your **STATE AND LOCAL AUTHORITIES.**

IF YOU FEEL SICK, stay home. Do not go to work. Contact your medical provider.

IF YOUR CHILDREN ARE SICK, keep them at home. Do not send them to school. Contact your medical provider.

IF SOMEONE IN YOUR HOUSEHOLD HAS TESTED POSITIVE for the coronavirus, keep the entire household at home. Do not go to work. Do not go to school. Contact your medical provider.

IF YOU ARE AN OLDER PERSON, stay home and away from other people.

IF YOU ARE A PERSON WITH A SERIOUS UNDERLYING HEALTH CONDITION that can put you at increased risk (for example, a condition that impairs your lung or heart function or weakens your immune system), stay home and away from other people.

CDC

For more information, please visit
CORONAVIRUS.GOV

THE PRESIDENT'S **CORONAVIRUS GUIDELINES** FOR AMERICA

DO YOUR PART TO SLOW THE SPREAD OF THE CORONAVIRUS

Even if you are young, or otherwise healthy, you are at risk and your activities can increase the risk for others. It is critical that you do your part to slow the spread of the coronavirus.

Work or engage in schooling **FROM HOME** whenever possible.

IF YOU WORK IN A CRITICAL INFRASTRUCTURE INDUSTRY, as defined by the Department of Homeland Security, such as healthcare services and pharmaceutical and food supply, you have a special responsibility to maintain your normal work schedule. You and your employers should follow CDC guidance to protect your health at work.

AVOID SOCIAL GATHERINGS in groups of more than 10 people.

Avoid eating or drinking at bars, restaurants, and food courts — **USE DRIVE-THRU, PICKUP, OR DELIVERY OPTIONS.**

AVOID DISCRETIONARY TRAVEL, shopping trips, and social visits.

DO NOT VISIT nursing homes or retirement or long-term care facilities unless to provide critical assistance.

PRACTICE GOOD HYGIENE:

- *Wash your hands, especially after touching any frequently used item or surface.*
- *Avoid touching your face.*
- *Sneeze or cough into a tissue, or the inside of your elbow.*
- *Disinfect frequently used items and surfaces as much as possible.*

CORONAVIRUS.GOV

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From: McWilliams, Carly [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B68C7458214244D08424FD441FEA4FDA-CARLYLE.MCW]
Sent: 3/16/2020 7:54:32 PM
To: Margaret Garikes [Margaret.Garikes@ama-assn.org]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Shannon Curtis [Shannon.Curtis@ama-assn.org]
Subject: RE: URGENT: UCSF Critical Reagent Shortage

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https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2#donothaveextractionplatform

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From: Margaret Garikes <Margaret.Garikes@ama-assn.org>
Date: March 16, 2020 at 7:46:59 AM EDT
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Cc: Shannon Curtis <Shannon.Curtis@ama-assn.org>
Subject: FW: URGENT: UCSF Critical Reagent Shortage
Importance: High

Carly and Keagan-

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Sent: Sunday, March 15, 2020 9:46 PM

To: Margaret Garikes <Margaret.Garikes@ama-assn.org>
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Jack Resneck, Jr, MD

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Professor and Vice-Chair of Dermatology, UCSF School of Medicine

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https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-provides-more-regulatory-relief-during-outbreak-continues-help?utm_campaign=031620_Statement_FDA%20Provides%20More%20Regulatory%20Relief%20During%20Outbreak&utm_medium=email&utm_source=Elogua

Have a good evening!
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Sent: Monday, March 16, 2020 7:58 PM
To: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
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Date: March 16, 2020 at 7:46:59 AM EDT
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
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To: Margaret Garikes <Margaret.Garikes@ama-assn.org>
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Sent: 3/17/2020 4:39:52 PM
To: Margaret Garikes [Margaret.Garikes@ama-assn.org]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Shannon Curtis [Shannon.Curtis@ama-assn.org]
Subject: RE: URGENT: UCSF Critical Reagent Shortage

Hi Margaret, another updated to FAQ went live:

If your email program has trouble displaying this email, view it as a web page.

Mar 17 Update: New Information on Diagnostic Testing for SARS-CoV-2

Thank you for your interest in development of diagnostics for SARS-CoV-2. The FDA has updated the frequently asked questions on diagnostic testing for SARS-CoV-2 following yesterday's update to the *Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency: Immediately in Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff*.

- What laboratories are offering testing under the Policy for Diagnostic Tests for Coronavirus Disease-2019?
- I am developing a COVID-19 assay that is a modification of a previously EUA authorized COVID-19 assay. Do I need to start from scratch with my validation or can I validate my test with a bridging study?
- I am developing a SARS-CoV-2 test kit for distribution to clinical laboratories. Can I follow the policy outlined in the Policy for Diagnostic Tests for Coronavirus Disease-2019?

See Updates to FAQs

From: Margaret Garikes <Margaret.Garikes@ama-assn.org>
Sent: Monday, March 16, 2020 9:56 PM
To: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Shannon Curtis <Shannon.Curtis@ama-assn.org>
Subject: Re: URGENT: UCSF Critical Reagent Shortage

Carly,
This is great. We will push out. Thanks again. Margaret

Get Outlook for iOS

From: Margaret Garikes <Margaret.Garikes@ama-assn.org>
Sent: Monday, March 16, 2020 8:33:07 PM
To: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Shannon Curtis <Shannon.Curtis@ama-assn.org>
Subject: Re: URGENT: UCSF Critical Reagent Shortage

Thank you so much really appreciate it.

Get Outlook for iOS

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From: HHS Office of Public Affairs [hhsopa@hhs.gov]
Sent: 3/18/2020 10:29:52 AM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: HHS supports Mesa Biotech to develop a rapid diagnostic to detect novel coronavirus infections

News Release

U.S. Department of Health and Human Services

202-205-8117
asprmedia@hhs.gov
www.hhs.gov/news
Twitter @SpoxHHS

FOR IMMEDIATE RELEASE
Wednesday, March 18, 2020

HHS supports Mesa Biotech to develop a rapid diagnostic to detect novel coronavirus infections

In response to the now global pandemic, the Biomedical Advanced Research and Development Authority (BARDA), part of the HHS Office of the Assistant Secretary for Preparedness and Response (ASPR), continues to work with its public-private partners to find solutions to mitigate the public health impact of the coronavirus disease 2019 (COVID-19). Part of this landscape is the immediate need for diagnostics tests that can quickly and accurately diagnose COVID-19 infections in order to identify the virus and mitigate the spread of the disease.

BARDA will provide Mesa Biotech, Inc. of San Diego, California, with technical expertise and $561,330 in immediate funding to pursue eventual Food and Drug Administration (FDA) approval or clearance of its diagnostic test. With BARDA's support, the company can complete the development work necessary to request Emergency Use Authorization (EUA) from the FDA for the Accula COVID-19 point-of-care test within two months of the award. The Accula COVID-19 diagnostic test requires minimal sample handling, and a 30-minute sample-to-result time.

"Diagnostics are a critical need in the overall strategy to fight this newest global public health threat. We need increased testing capacity in the U.S to rapidly identify, isolate, and treat those infected with COVID-19 in order to limit transmission of the virus, and we need those tests as close to the patients as possible," said BARDA Director Rick A. Bright, Ph.D. "This partnership is the latest example of our strong commitment to make diagnostic tests available as quickly and broadly as possible for Americans. We are working tirelessly to advance multiple diagnostics to EUA status so healthcare providers can rapidly diagnose and treat patients with COVID-19."

The Accula COVID-19 test will leverage Mesa Biotech's Accula Dock instrument that is used with several 510(k)-cleared tests; FDA has categorized the Accula Dock influenza point-of-care test as Clinical Laboratory Improvement Amendments (CLIA) waived. Utilizing the Accula Dock, the new test will provide molecular results indicating the presence of the virus based on nasopharyngeal (back of the nose and throat) swab samples. The diagnostic test is intended for use in clinical and hospital laboratories.

Mesa Biotech's test is the fourth COVID-19 molecular diagnostic to receive development funding from BARDA. The project was selected through a business-friendly EZ-BAA application process that streamlines the way BARDA collaborates with industry and entrepreneurs. BARDA's EZ-BAA is open for molecular diagnostic tests that utilize platforms already cleared by the FDA, point-of-care tests to detect severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes COVID-19, and tests that detect COVID-19 disease; all submissions require a viable plan to meet the FDA's EUA requirements.

In addition to the EZ-BAA, BARDA expanded its standard broad agency announcement to accept proposals for advanced development of diagnostics, vaccines, therapeutics and other medical products for use in the current COVID-19 public health emergency response and future coronavirus outbreaks.

There are currently no FDA approved or cleared diagnostics, vaccines, or treatments for COVID-19. However, the FDA authorized emergency use of a several diagnostic tests under its EUA authority. HHS continues to work across the U.S. government to review potential products from public and private sectors to identify promising candidates that could detect, protect against or treat COVID-19 for development and FDA approval/clearance. HHS divisions, including the National Institutes of Health (NIH) and ASPR, are also supporting the development of multiple vaccines and therapeutic treatments for COVID-19.

To obtain information about products in development in the private sector that could be used in responding to COVID-19, the U.S. government launched a single point-of-entry website for innovators and product developers to submit brief descriptions of their diagnostics, therapeutics, vaccines, and other products or technologies being developed for COVID-19.

To shorten the time to apply for product licensure and to reduce the spread of COVID-19, federal agencies are particularly interested in identifying products and technologies that have progressed beyond non-clinical studies, have established domestic large-scale manufacturing capability with commercial Good Manufacturing Practices (cGMP), and have utilized a platform used to manufacture a product already cleared by the FDA.

About HHS, ASPR, and BARDA

HHS works to enhance and protect the health and well-being of all Americans, providing for effective health and human services and fostering advances in medicine, public health, and social services. The mission of ASPR is to save lives and protect Americans from 21st century health security threats. Within ASPR, BARDA invests in the innovation, advanced research and development, acquisition, and manufacturing of medical countermeasures – vaccines, drugs, therapeutics, diagnostic tools, and non-pharmaceutical products needed to combat health security threats. To date, 54 BARDA-supported products have achieved regulatory approval, licensure or clearance.

###

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From: Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]
Sent: 3/18/2020 10:37:52 AM
To: Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Bright, Rick (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1-HHS-Rick.Br]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]; Guram, Jeet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ef73bea97e2b477b847ea302c4730ccf-Gurjeet.Gur]; Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]; Roberts, Rosemary [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b7838eab964e4ca1a7d703876d08411b-ROBERTSR]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Davis, May M. EOP/WHO [May.Davis@who.eop.gov]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Edmonds, Amanda [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=232186a24a53474298d2760c060a4cc7-Amanda.Edmo]; Beers, Donald [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d079bf15a01744bd94687d6718ca4c42-Donald.Beer]; Zembower, Jenna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83f9eb4b88564c3797b4238da3842ef8-Jenna.Zembo]; Uyeki, Timothy M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f106bd981def4bfeb945e86b266662b2-HHS-tmu0-cd]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Wolinetz, Carrie D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4c547ca11976474a8fdcfcc02744b3a6-HHS-carrie.]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Disbrow, Gary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0265d217b2344c6bbbaad0cbb2f0c6a-HHS-Gary.Di]; Auchincloss, Hugh (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab02b9d7c8514b538a08bab4a6659fba-HHS-auchinc]

Subject: Int Call - FDA / BARDA / NIH / CDC (chloroquine / COVID-19)
Location: 877-465-7975; 906 184 528#

Start: 3/18/2020 12:00:00 PM
End: 3/18/2020 12:45:00 PM
Show Time As: Busy

Required Attendees: Bright, Rick (OS); Fauci, Anthony S (NIH); Woodcock, Janet; Cavazzoni, Patrizia; Guram, Jeet; Farley, John; Roberts, Rosemary; Amin, Stacy; Davis, May M. EOP/WHO; Raza, Mark; Edmonds, Amanda; Beers, Donald; Zembower, Jenna; Uyeki, Timothy M (CDC); Lenihan, Keagan; Wolinetz, Carrie D (NIH); Shuy, Bryan (OS); Disbrow, Gary (OS); Auchincloss, Hugh (NIH)

Bayer has been in touch with FDA on the offer to donate Resochin (branded chloroquine phosphate).

Would you both, or a designee, be available for a call at 12:00pm today (Wednesday, March 18th) to discuss this offer and the potential to establish an academic consortium for a clinical trial of this drug for COVID-19? An invitation will be forthcoming, please let me know if you have any questions.

Thank you

Best,
Anand

-- Do not delete or change any of the following text. --

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+1-877-465-7975 US Toll Free
Global call-in numbers | Toll-free calling restrictions

If you are a host, go here to view host information.

Need help? Go to http://help.webex.com

Sent: 3/18/2020 10:42:04 AM
To: Guram, Jeet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ef73bea97e2b477b847ea302c4730ccf-Gurjeet.Gur]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]
CC: Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]; Roberts, Rosemary [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b7838eab964e4ca1a7d703876d08411b-ROBERTSR]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Beers, Donald [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d079bf15a01744bd94687d6718ca4c42-Donald.Beer]; Zembower, Jenna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83f9eb4b88564c3797b4238da3842ef8-Jenna.Zembo]
Subject: RE: Draft email to David Boulware (UMN) and BARDA

Did you all speak with Gary and Hugh so they know what this call is about?

From: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Sent: Wednesday, March 18, 2020 10:37 AM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Cc: Farley, John <John.Farley@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Zembower, Jenna <Jenna.Zembower@fda.hhs.gov>
Subject: RE: Draft email to David Boulware (UMN) and BARDA

I just spoke with Anand – Jenna, can you please forward the invite for the internal call at noon today to Rick Bright and Tony Fauci's deputies, who are listed below?

Disbrow, Gary (OS/BARDA) <Gary.Disbrow@hhs.gov>
Auchincloss, Hugh (NIH) **(b)(6)**

--
Jeet Guram, M.D.
Senior Advisor, Office of the Commissioner
Food and Drug Administration
+1 (202) 230-0451 | jeet.guram@fda.hhs.gov

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Wednesday, March 18, 2020 10:09 AM
To: Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>

Cc: Farley, John <John.Farley@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: Draft email to David Boulware (UMN) and BARDA

Jenna will send an invite momentarily. Pls forward as needed. I have kept the call internal to .gov for now

---

From: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Sent: Wednesday, March 18, 2020 10:03 AM
To: Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Farley, John <John.Farley@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: Draft email to David Boulware (UMN) and BARDA

Keagan is contacting NIH COS to find a good contact. Looping her here. Who is your POC at BARDA?

From: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Sent: Wednesday, March 18, 2020 10:00 AM
To: Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Farley, John <John.Farley@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>
Subject: RE: Draft email to David Boulware (UMN) and BARDA

Sounds good – (b)(5) Revised email below.

--

(b)(5)

--
Jeet Guram, M.D.
Senior Advisor, Office of the Commissioner
Food and Drug Administration
+1 (202) 230-0451 | jeet.guram@fda.hhs.gov

U.S. FOOD & DRUG ADMINISTRATION

From: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Sent: Wednesday, March 18, 2020 9:56 AM
To: Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Farley, John <John.Farley@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>
Subject: RE: Draft email to David Boulware (UMN) and BARDA

(b)(5)

From: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Sent: Wednesday, March 18, 2020 9:53 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Farley, John <John.Farley@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>
Subject: Draft email to David Boulware (UMN) and BARDA

To be sent from **(b)(5), (b)(6)**
(b)(5) If folks have edits please share with this chain:

(b)(5)

--
Jeet Guram, M.D.
Senior Advisor, Office of the Commissioner
Food and Drug Administration
+1 (202) 230-0451 | jeet.guram@fda.hhs.gov

U.S. FOOD & DRUG ADMINISTRATION

From: Ford-Barnes, Arwenthia (OS/ASPR/IO) [Arwenthia.FordBarnes@hhs.gov]
on behalf of Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]
Sent: 3/18/2020 10:52:44 AM
To: Lewis, Brian [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7350948ce7c544d493dae5a34b86c21f-BEL]; Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: RE: Question

Thank you Sir received

Arwenthia Ford-Barnes
Executive Assistant to the ASPR | *Dr. Robert Kadlec*
Office: (202) 205-8905 Mobile: (b)(6)
Email: Arwenthia.FordBarnes@hhs.gov

(Please make sure your telephone is at the bottom of your salutation)

ASPR
ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE

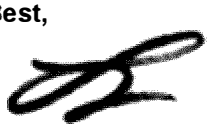
While others rest…we 'ASPR' are fighting the mission…

From: Lewis, Brian <Brian.Lewis@fda.hhs.gov>
Sent: Wednesday, March 18, 2020 9:27 AM
To: Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: Question

Dr. Kadlec,

I visited not long ago to connect in person. CAPT Denis and I have worked together for many years. Please depend on me for support.

Best,



CAPT Brian Lewis, MD
US Public Health Service – In the Service of Health *"In Officio Salutis"*
Physician Chief Professional Officer, USPHS, Office of the Surgeon General

Senior Medical Review Officer, Implantable Electrophysiology Devices Team, USFDA CDRH
Office Phone: 301-796-6361
Mobile/Text (b)(6)
brian.lewis@fda.hhs.gov

From: Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
Sent: Wednesday, March 18, 2020 9:20 AM
To: Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Lewis, Brian <Brian.Lewis@fda.hhs.gov>
Subject: RE: Question

Sir,
By way of this email, I am connecting you with CAPT Brian Lewis, one of our CDRH PHS Officers on duty for COVID-19 here at CDRH, (who also serves in the role of Physician Chief Professional Officer for PHS) to be your POC for FDA-cleared surgical masks.

I am available as backup as well.

Suzanne

Suzanne B. Schwartz, MD, MBA
Deputy Director (& Acting Office Director) Office of Strategic Partnerships & Technology Innovation
Center for Devices and Radiological Health (CDRH)
Office of Strategic Partnerships and Technology Innovation (OST)
U.S. Food and Drug Administration
WO66, Room 5410
Tel: 301-796-6937
Cell (b)(6)
Suzanne.Schwartz@fda.hhs.gov

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

From: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>
Sent: Tuesday, March 17, 2020 4:10 PM
To: Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: Question

Thank you Suzanne Yes please nothing truly urgent Best Bob

From: Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
Sent: Tuesday, March 17, 2020 4:08 PM

To: Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>
Subject: RE: Question

Dr. Kadlec,
I will get you the POC. It will be someone in my shop anyway so if there is anything I can immediately help you with, please reach out to me.
suzanne

Suzanne B. Schwartz, MD, MBA
Deputy Director (& Acting Office Director) Office of Strategic Partnerships & Technology Innovation
Center for Devices and Radiological Health (CDRH)
Office of Strategic Partnerships and Technology Innovation (OST)
U.S. Food and Drug Administration
WO66, Room 5410
Tel: 301-796-6937
Cell: (b)(6)
Suzanne.Schwartz@fda.hhs.gov

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Tuesday, March 17, 2020 3:57 PM
To: Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>
Cc: Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
Subject: Re: Question

+ Suzanne

Sent from my iPhone

On Mar 17, 2020, at 3:45 PM, Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov> wrote:

Keagan-is there a POC for FDA approved surgical masks? If you could please put me in touch with him I would appreciate it. Best Bo b

From: Flowers, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9418B62EC07642D7BC53C564E008F5CE-SUSAN.FLOWE]
Sent: 3/18/2020 11:47:24 AM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: Participants on 12:00 Int Call - FDA / ASPR / BARDA / NIH / CDC (chloroquine / COVID-19)

Participants on this call:

FDA

- Anand Shah, Office of the Commissioner, Deputy Commissioner for Medical & Scientific Affairs
- Keagan Lenihan, Office of the Commissioner, Chief of Staff
- Jeet Guram, Office of the Commissioner, Senior Advisor
- Janet Woodcock, CDER, Director
- Patrizia Cavazzoni, CDER, Deputy Director for Operations
- John Farley, CDER Office of Infectious Diseases, Director
- Rosemary Roberts, CDER Counter-Terrorism and Emergency Coordination Staff, Director
- Stacy Amin, Office of the Chief Counsel, Chief Counsel
- Mark Raza, Office of the Chief Counsel, Deputy Chief Counsel
- Amanda Edmonds, Office of the Chief Counsel, Deputy Chief Counsel for Program Review for Biologics and Drugs

ASPR/BARDA

- Rick Bright, Deputy Assistant Secretary for Preparedness and Response (ASPR) & Director of the Biomedical Advances Research and Development Authority (BARDA)
- Brian Shuy, ASPR Deputy Assistant Secretary and Chief of Staff
- Gary Disbrow, Acting Deputy Director of BARDA

NIH

- Anthony Fauci, NIAID, Director
- Hugh Auchincloss, NIAID, Principal Deputy Director
- Carrie Wolinetz, Acting Chief of Staff
- Hilary Marston, Office of the Chief of Staff, Medical Officer/Policy Advisor

CDC

- Timothy Uyeki, National Center for Immunization and Respiratory Diseases

White House

- May Davis, Associate White House Counsel

From: Finnen, April [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=43D74B30BB1D429184B0D9081EFE19BF-APRIL.FINNE]
Sent: 3/18/2020 11:48:46 AM
To: Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; 2019-nCoV FDA IMG JIC [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=289715a1146847558b07a33ccab6bccf-2019-nCoV F]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]
CC: OCCRequests-COVID19 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcb756008a41407282a58324a7b5144a-OCCRequests]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]; Courtney, Brooke [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=261a2a3791e24e19b095ac0172485ebd-Brooke.Cour]
Subject: RE: FOR JIC REVIEW BY 11:30 AM: Statement on Therapeutics and Vaccine Development

If you want to add as a reference link, the What are MCMs web page (+infographic) was updated today (in conjunction w/MCMi report publication, to update infographic #s). OCET has reviewed. Thanks.

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Sent: Wednesday, March 18, 2020 11:41 AM
To: 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Cc: OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>
Subject: RE: FOR JIC REVIEW BY 11:30 AM: Statement on Therapeutics and Vaccine Development

Hi all –

Just re-upping as only one person has provided edits to this statement by the deadline. Can folks please let me know where the reviews are in their respective centers and I am asking for edits/clearance **by 12:15**.

Thanks!

Michael

Michael Felberbaum
Senior Advisor

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

FDA U.S. FOOD & DRUG ADMINISTRATION

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Sent: Wednesday, March 18, 2020 9:55 AM
To: 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Cc: OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>
Subject: FOR JIC REVIEW BY 11:30 AM: Statement on Therapeutics and Vaccine Development
Importance: High

Hi all,

I have drafted a statement on our therapeutics and vaccine work that I am sending for concurrent review for your respective centers and offices as we are hoping to put this out tomorrow AM. This is primarily based on talking points that were cleared by CDER and CBER leadership, as well as OCC, so I'm hoping clearance will be fairly easy. FYI – OCC, this will come your way after the JIC review deadline.

Please input your edits **BY 11:30 AM, WEDNESDAY, MARCH 18**, to this SharePoint link:
http://sharepoint.fda.gov/orgs/OC-OEA/OMA/Comms%20for%20Editing/DRAFT STMT COVID%20Therapuetics%20and%20Vaccines%20Efforts%2003182020.docx

Copying below for awareness only, please make edits in SharePoint:

(b)(5)

(b)(5)

(b)(5)

Additional Resources:

- Coronavirus Disease (COVID-19)

###

Thanks!

Michael

Michael Felberbaum
Senior Advisor

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

From: McWilliams, Carly [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B68C7458214244D08424FD441FEA4FDA-CARLYLE.MCW]
Sent: 3/18/2020 12:48:08 PM
To: Margaret Garikes [Margaret.Garikes@ama-assn.org]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Shannon Curtis [Shannon.Curtis@ama-assn.org]
Subject: RE: URGENT: UCSF Critical Reagent Shortage

Hi Margaret, not sure if you are hearing about any clinical trials being impacted but we issued a guidance and press release on this today.

Be well,

Carly

FDA NEWS RELEASE

Coronavirus (COVID-19) Update: FDA Issues Guidance for Conducting Clinical Trials

For Immediate Release:
March 18, 2020

The U.S. Food and Drug Administration today issued a guidance for industry, investigators and institutional review boards conducting clinical trials during the coronavirus (COVID-19) pandemic.

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The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

From: Margaret Garikes <Margaret.Garikes@ama-assn.org>
Sent: Tuesday, March 17, 2020 4:45 PM
To: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Shannon Curtis <Shannon.Curtis@ama-assn.org>
Subject: RE: URGENT: UCSF Critical Reagent Shortage

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- What laboratories are offering testing under the Policy for Diagnostic Tests for Coronavirus Disease-2019?
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See Updates to FAQs

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Subject: Re: URGENT: UCSF Critical Reagent Shortage

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Get Outlook for iOS

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[Warning External Email]
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https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-provides-more-regulatory-relief-during-outbreak-continues-help?utm_campaign=031620_Statement_FDA%20Provides%20More%20Regulatory%20Relief%20During%20Outbreak&utm_medium=email&utm_source=Eloqua

Have a good evening!
Carly

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Sent: Monday, March 16, 2020 7:58 PM
To: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Shannon Curtis <Shannon.Curtis@ama-assn.org>
Subject: RE: URGENT: UCSF Critical Reagent Shortage

Carly- Appreciate the information. Take care. Margaret

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- Fact Sheet for Healthcare Providers
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- Manufacturer Instructions/Package

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- Letter of Authorization
- Fact Sheet for Healthcare Providers
- Fact Sheet for Patients
- EUA Summary

From: McWilliams, Carly
Sent: Monday, March 16, 2020 8:10 AM
To: Margaret Garikes <Margaret.Garikes@ama-assn.org>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Shannon Curtis <Shannon.Curtis@ama-assn.org>
Subject: Re: URGENT: UCSF Critical Reagent Shortage

Margaret, thanks for reaching out. We have a 24/7 toll-free line, 1-888-INFO-FDA, to help labs with supply issues. We also have a faq website that answers questions about supply issues. I pasted information about Roche tests below and link to faq is below.

Q: What happens if I do not have the extraction platform referenced in the authorization of CDC's EUA-authorized test?

A: FDA believes that the CDC's EUA-authorized test could be used with the following extraction platforms:

- **Roche MagNA Pure LC**

Kit: Roche MagNA Pure Total Nucleic Acid Kit
Protocol: Total NA External_lysis
Recommendation(s): Add 100 µL of sample to 300 µL of pre-aliquoted TNA isolation kit lysis buffer (total input sample volume is 400 µL). Elution volume is 100 µL.

- **Roche MagNA Pure Compact**

Kit: Roche MagNA Pure Nucleic Acid Isolation Kit I
Protocol: Total_NA_Plasma100_400

Recommendation(s): Add 100 µL of sample to 300 µL of pre-aliquoted TNA isolation kit lysis buffer (total input sample volume is 400 µL). Elution volume is 100 µL.

- **Roche MagNA Pure 96**

Kit: Roche MagNA Pure 96 DNA and Viral NA Small Volume Kit
Protocol: Viral NA Plasma Ext Lys SV Protocol
Recommendation(s): Add 100 µL of sample to 350 µL of pre-aliquoted External Lysis Buffer (supplied separately) (total input sample volume is 450 µL). Proceed with the extraction on the MagNA Pure 96. (Note: Internal Control = None). Elution volume is 100 µL.

https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2#donothaveextractionplatform

---

From: Margaret Garikes <Margaret.Garikes@ama-assn.org>
Date: March 16, 2020 at 7:46:59 AM EDT
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Cc: Shannon Curtis <Shannon.Curtis@ama-assn.org>
Subject: FW: URGENT: UCSF Critical Reagent Shortage
Importance: High

Carly and Keagan-
Sorry to bother you. Below is an email from a former chairman of the AMA's Board of Trustees. Jack is a very measured guy. He is also very senior at UCSF which has been on the front lines of this COVID issue for several weeks. See the situation below with reagents. When I spoke to Jack on the phone last night he told me they had about 5 days left in the supply. Can you all assist or point me in the direction of someone who can? Or provide me with the name of a senior person at Roche? Thanks so much. Margaret

---

From: Resneck Jr, Jack <Jack.Resneck@ucsf.edu>
Sent: Sunday, March 15, 2020 9:46 PM
To: Margaret Garikes <Margaret.Garikes@ama-assn.org>
Subject: URGENT: UCSF Critical Reagent Shortage

[Warning External Email]

Margaret,

Thank you for passing our UCSF concerns on to FDA leadership to see if we can get assistance.

We have been caring for several COVID-infected patients in our hospital.
Thanks to FDA approval and removal of regulatory challenges, we have been running our own tests on symptomatic patients at UCSF since last Tuesday, though our testing capacity has remained severely limited.

However, our current threat is a **severe shortage of reagents** for RNA extraction. We have run out of the reagent for the more rapid platform, and only have a few days supply of reagents for our slower platform, which has further limited our testing capacity as we conserve. A partner hospital who takes some of our overflow tests faces similar reagent shortages. And the tests at commercial labs are taking 4-5 days (as opposed to our <24 hour turnaround) -- we can't wait that long for results on inpatients.

The items we desperately need are reagent kits for Roche MagNA Pure 24 and Qiagen EZ1 RNA extractors. We have been trying to communicate with Roche about the supply chain limitations.

We need federal help either in securing additional reagents or intervention in the supply chain to redistribute reagents from research labs or other geographies where they are not currently critically needed.

Thanks for seeing if FDA can be of assistance.

Best,
Jack

Jack Resneck, Jr, MD
Board of Trustees, American Medical Association (Immediate Past Chair)
Professor and Vice-Chair of Dermatology, UCSF School of Medicine

From: McWilliams, Carly [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B68C7458214244D08424FD441FEA4FDA-CARLYLE.MCW]
Sent: 3/18/2020 12:56:34 PM
To: Margaret Garikes [Margaret.Garikes@ama-assn.org]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Shannon Curtis [Shannon.Curtis@ama-assn.org]
Subject: RE: URGENT: UCSF Critical Reagent Shortage

Appreciate your help getting these resources out.

From: Margaret Garikes <Margaret.Garikes@ama-assn.org>
Sent: Wednesday, March 18, 2020 12:55 PM
To: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Shannon Curtis <Shannon.Curtis@ama-assn.org>
Subject: RE: URGENT: UCSF Critical Reagent Shortage

Thank you for flagging. Our social media team highlighted FDA's work on LDT's. Shannon, can you please make sure they see it. Thanks.

From: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Sent: Wednesday, March 18, 2020 12:48 PM
To: Margaret Garikes <Margaret.Garikes@ama-assn.org>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
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Cc: Shannon Curtis <Shannon.Curtis@ama-assn.org>
Subject: Re: URGENT: UCSF Critical Reagent Shortage

Margaret, thanks for reaching out. We have a 24/7 toll-free line, 1-888-INFO-FDA, to help labs with supply issues. We also have a faq website that answers questions about supply issues. I pasted information about Roche tests below and link to faq is below.

Q: What happens if I do not have the extraction platform referenced in the authorization of CDC's EUA-authorized test?

A: FDA believes that the CDC's EUA-authorized test could be used with the following extraction platforms:

- **Roche MagNA Pure LC**

Kit: Roche MagNA Pure Total Nucleic Acid Kit
Protocol: Total NA External_lysis
Recommendation(s): Add 100 µL of sample to 300 µL of pre-aliquoted TNA isolation kit lysis buffer (total input sample volume is 400 µL). Elution volume is 100 µL.

- **Roche MagNA Pure Compact**

Kit: Roche MagNA Pure Nucleic Acid Isolation Kit I
Protocol: Total_NA_Plasma100_400
Recommendation(s): Add 100 µL of sample to 300 µL of pre-aliquoted TNA isolation kit lysis buffer (total input sample volume is 400 µL). Elution volume is 100 µL.

- **Roche MagNA Pure 96**

Kit: Roche MagNA Pure 96 DNA and Viral NA Small Volume Kit
Protocol: Viral NA Plasma Ext Lys SV Protocol
Recommendation(s): Add 100 µL of sample to 350 µL of pre-aliquoted External Lysis Buffer (supplied separately) (total input sample volume is 450 µL). Proceed with the extraction on the MagNA Pure 96. (Note: Internal Control = None). Elution volume is 100 µL.

https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2#donothaveextractionplatform

---

From: Margaret Garikes <Margaret.Garikes@ama-assn.org>
Date: March 16, 2020 at 7:46:59 AM EDT
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Cc: Shannon Curtis <Shannon.Curtis@ama-assn.org>
Subject: FW: URGENT: UCSF Critical Reagent Shortage
Importance: High

Carly and Keagan-
Sorry to bother you. Below is an email from a former chairman of the AMA's Board of Trustees. Jack is a very measured guy. He is also very senior at UCSF which has been on the front lines of this COVID issue for several weeks. See the situation below with reagents. When I spoke to Jack on the phone last night he told me they had about 5 days left in the supply. Can you all assist or point me in the direction of someone who can? Or provide me with the name of a senior person at Roche? Thanks so much. Margaret

From: Resneck Jr, Jack <Jack.Resneck@ucsf.edu>
Sent: Sunday, March 15, 2020 9:46 PM
To: Margaret Garikes <Margaret.Garikes@ama-assn.org>
Subject: URGENT: UCSF Critical Reagent Shortage

[Warning External Email]

Margaret,

Thank you for passing our UCSF concerns on to FDA leadership to see if we can get assistance.

We have been caring for several COVID-infected patients in our hospital.
Thanks to FDA approval and removal of regulatory challenges, we have been running our own tests on symptomatic patients at UCSF since last Tuesday, though our testing capacity has remained severely limited.

However, our current threat is a **severe shortage of reagents** for RNA extraction. We have run out of the reagent for the more rapid platform, and only have a few days supply of reagents for our slower platform, which has further limited our testing capacity as we conserve. A partner hospital who takes some of our overflow tests faces similar reagent shortages. And the tests at commercial labs are taking 4-5 days (as opposed to our <24 hour turnaround) -- we can't wait that long for results on inpatients.

The items we desperately need are reagent kits for Roche MagNA Pure 24 and Qiagen EZ1 RNA extractors. We have been trying to communicate with Roche about the supply chain limitations.

We need federal help either in securing additional reagents or intervention in the supply chain to redistribute reagents from research labs or other geographies where they are not currently critically needed.

Thanks for seeing if FDA can be of assistance.

Best,
Jack

Jack Resneck, Jr, MD
Board of Trustees, American Medical Association (Immediate Past Chair)
Professor and Vice-Chair of Dermatology, UCSF School of Medicine

From: Felberbaum, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4819A643CA2945CDB1A2631B83E69673-MICHAEL.FEL]
Sent: 3/18/2020 1:14:30 PM
To: Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
Subject: RE: FOR JIC REVIEW BY 11:30 AM: Statement on Therapeutics and Vaccine Development

OK – Stephanie and I are going to call you shortly.

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Wednesday, March 18, 2020 1:12 PM
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: RE: FOR JIC REVIEW BY 11:30 AM: Statement on Therapeutics and Vaccine Development

I don't think we are quite ready on comms related to chloroquine. Michael, happy to work with you and Stephanie in tandem with Patrizia as that discussion moves forward

---

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Sent: Wednesday, March 18, 2020 11:54 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: RE: FOR JIC REVIEW BY 11:30 AM: Statement on Therapeutics and Vaccine Development

OK, thanks. We'll standby for that info.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, March 18, 2020 11:53 AM
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: RE: FOR JIC REVIEW BY 11:30 AM: Statement on Therapeutics and Vaccine Development

There are a lot of moving pieces around this right now. **(b)(5)** **(b)(5)** Anand is having an interagency call in 10 mins and can get back to you.

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Sent: Wednesday, March 18, 2020 11:41 AM
To: 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Cc: OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>
Subject: RE: FOR JIC REVIEW BY 11:30 AM: Statement on Therapeutics and Vaccine Development

Hi all –

Just re-upping as only one person has provided edits to this statement by the deadline. Can folks please let me know where the reviews are in their respective centers and I am asking for edits/clearance **by 12:15**.

Thanks!

Michael

Michael Felberbaum
Senior Advisor

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

U.S. FOOD & DRUG ADMINISTRATION

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Sent: Wednesday, March 18, 2020 9:55 AM
To: 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Cc: OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>
Subject: FOR JIC REVIEW BY 11:30 AM: Statement on Therapeutics and Vaccine Development
Importance: High

Hi all,

I have drafted a statement on our therapeutics and vaccine work that I am sending for concurrent review for your respective centers and offices as we are hoping to put this out tomorrow AM. This is primarily based on talking points that were cleared by CDER and CBER leadership, as well as OCC, so I'm hoping clearance will be fairly easy. FYI – OCC, this will come your way after the JIC review deadline.

Please input your edits **BY 11:30 AM, WEDNESDAY, MARCH 18**, to this SharePoint link:
http://sharepoint.fda.gov/orgs/OC-OEA/OMA/Comms%20for%20Editing/DRAFT STMT COVID%20Therapuetics%20and%20Vaccines%20Efforts%2003182020.docx

Copying below for awareness only, please make edits in SharePoint:

(b)(5)

(b)(5)

(b)(5)

Additional Resources:

- Coronavirus Disease (COVID-19)

###

Thanks!

Michael

Michael Felberbaum
Senior Advisor

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

From: Rawlings, Kimberly [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AE46D13993DC46E190AE70B61E1D4871-KRAWLING]
Sent: 3/18/2020 1:26:04 PM
To: Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; 2019-nCoV FDA IMG JIC [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=289715a1146847558b07a33ccab6bccf-2019-nCoV F]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]
CC: OCCRequests-COVID19 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcb756008a41407282a58324a7b5144a-OCCRequests]; Kohler, Charles [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52cff2cb93364d77af22b1cb6d0a5abc-Charles.Koh]; Baumgartner, Kristofer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8f49b4b6cfcf4d249f8b1802a2c7dc40-BAUMGARTNER]
Subject: RE: FOR JIC REVIEW BY 11:30 AM: Statement on Therapeutics and Vaccine Development

Got it. Please keep us posted.
Thanks

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Sent: Wednesday, March 18, 2020 1:22 PM
To: Rawlings, Kimberly <Kimberly.Rawlings@fda.hhs.gov>; 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Cc: OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>
Subject: RE: FOR JIC REVIEW BY 11:30 AM: Statement on Therapeutics and Vaccine Development

TBD – we are working things out and needing to revise so we are not 100% sure.

From: Rawlings, Kimberly <Kimberly.Rawlings@fda.hhs.gov>
Sent: Wednesday, March 18, 2020 1:20 PM
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Cc: OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>
Subject: RE: FOR JIC REVIEW BY 11:30 AM: Statement on Therapeutics and Vaccine Development

Hi Michael,

What is the timing for the release?

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Sent: Wednesday, March 18, 2020 1:12 PM
To: 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Cc: OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>
Subject: RE: FOR JIC REVIEW BY 11:30 AM: Statement on Therapeutics and Vaccine Development

We are moving this to OCC now. Please note, **(b)(5)**

(b)(5)

From: Felberbaum, Michael
Sent: Wednesday, March 18, 2020 11:41 AM
To: 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Cc: OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>
Subject: RE: FOR JIC REVIEW BY 11:30 AM: Statement on Therapeutics and Vaccine Development

Hi all –

Just re-upping as only one person has provided edits to this statement by the deadline. Can folks please let me know where the reviews are in their respective centers and I am asking for edits/clearance **by 12:15**.

Thanks!

Michael

Michael Felberbaum
Senior Advisor

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

FDA U.S. FOOD & DRUG ADMINISTRATION

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Sent: Wednesday, March 18, 2020 9:55 AM
To: 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Cc: OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>
Subject: FOR JIC REVIEW BY 11:30 AM: Statement on Therapeutics and Vaccine Development
Importance: High

Hi all,

I have drafted a statement on our therapeutics and vaccine work that I am sending for concurrent review for your respective centers and offices as we are hoping to put this out tomorrow AM. This is primarily based on talking points that were cleared by CDER and CBER leadership, as well as OCC, so I'm hoping clearance will be fairly easy. FYI – OCC, this will come your way after the JIC review deadline.

Please input your edits **BY 11:30 AM, WEDNESDAY, MARCH 18**, to this SharePoint link:
http://sharepoint.fda.gov/orgs/OC-OEA/OMA/Comms%20for%20Editing/DRAFT STMT COVID%20Therapuetics%20and%20Vaccines%20Efforts%2003182020.docx

Copying below for awareness only, please make edits in SharePoint:

(b)(5)

The following is attributed to FDA Commissioner Stephen M. Hahn, M.D.

(b)(5)

(b)(5)

Additional Resources:

- Coronavirus Disease (COVID-19)

###

Thanks!

Michael

Michael Felberbaum
Senior Advisor

Office of Media Affairs
Office of External Affairs

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

From: Guram, Jeet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EF73BEA97E2B477B847EA302C4730CCF-GURJEET.GUR]
Sent: 3/18/2020 4:27:16 PM
To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]
Subject: RE: Materials For Drug Rollout
Attachments: v4 2020.03.17 Draft Therapeutics Talking Points with Chloroquine.docx

I know the **(b)(5)** if it's helpful to use those as the starting point.

--
Jeet Guram, M.D.
Senior Advisor, Office of the Commissioner
Food and Drug Administration
+1 (202) 230-0451 | jeet.guram@fda.hhs.gov

FDA U.S. FOOD & DRUG ADMINISTRATION

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Wednesday, March 18, 2020 4:25 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Subject: RE: Materials For Drug Rollout

Ok, you would like MF and I pull together? Just want to be clear bc **(b)(5)** We'll pull TPs from statement. Bigger picture though.

Stephanie Caccomo
Press Officer

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

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, March 18, 2020 4:23 PM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: FW: Materials For Drug Rollout

Can we get them something POTUS can use?

From: Lyons, Derek S. EOP/WHO **(b)(6)**
Sent: Wednesday, March 18, 2020 4:21 PM
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: Materials For Drug Rollout

Dr. Hahn,

I know there's a lot to do to get the h (b)(5) That said, we could really use (b)(5) and other rollout materials. When do you think there will be some paperwork ready to work from?

Thanks,
Derek

From: Guram, Jeet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EF73BEA97E2B477B847EA302C4730CCF-GURJEET.GUR]
Sent: 3/18/2020 4:51:13 PM
To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
Subject: RE: potus TPs
Attachments: v4 2020.03.17 Draft Therapeutics Talking Points with Chloroquine.docx

Sounds good to me – just to clarify, are the attached TPs the technical ones you're referring to? I don't have any edits to the TPs below.

--
Jeet Guram, M.D.
Senior Advisor, Office of the Commissioner
Food and Drug Administration
+1 (202) 230-0451 | jeet.guram@fda.hhs.gov

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Wednesday, March 18, 2020 4:47 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Subject: potus TPs

So, I propose we send over the more technical TPs that Jeet/Anand put together, plus these intro remarks. What do you think? If you concur, let me know. I'll send to OCC. And let me know any edits asap!

Briefing on Therapeutics

- I'd like to thank FDA Commissioner Steven Hahn and all the staff at FDA for their tremendous work during this coronavirus outbreak.
- FDA staff, along with people across the government, have been working around the clock.
- I know he has the best and the brightest working at FDA. Literally thousands of doctors and scientists.

- And I've seen them working around the clock. They are doing diagnostic approvals at all hours of the night. Thank you for that work.
- Today, Dr. Hahn will be talking to us about some exciting things that FDA is doing around therapeutics to treat this outbreak.
- A major part of us tackling this coronavirus is not just diagnosing it correctly, but also treating it quickly and with the best treatments for patients.
- The best treatments are going to come from private and public sector working together. We are all in this together.
- I've directed Dr. Hahn and FDA to reduce the regulatory burdens so that treatments can get to patients quickly.
- Innovation during this outbreak is critical. From speaking with Dr. Hahn, I know the FDA is very supportive of doing everything they can. They are being flexible and adaptable so that we can aggressively mitigate this outbreak.
- They've already shown with tests that they'll move quickly to remove regulatory burdens on companies and labs.
- Dr. Hahn has promised his staff will continue this very flexible approach to therapeutics.
- We have great news to share about a donation from Bayer of a product that we will look at thoroughly to see if it holds promise in treating patients.
- We are also looking at other products that could be used, plus very important vaccine trials to combat this disease.
- Dr. Hahn is going to talk to you now about all of these exciting updates.

Stephanie Caccomo
Press Officer

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

From: Schiller, Lowell [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=77949B06919E4F91AA788E9A616C50C7-LOWELL.SCHI]
Sent: 3/18/2020 5:46:49 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]
CC: Roth, Lauren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52bfd08572694f269a20c508f3c04a03-Lauren.Roth]
Subject: RE: HHS Takes New Action to Cut Red Tape to Support COVID-19 Response

(b)(5)

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, March 18, 2020 5:44 PM
To: Schiller, Lowell <Lowell.Schiller@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Cc: Roth, Lauren <Lauren.Roth@fda.hhs.gov>
Subject: RE: HHS Takes New Action to Cut Red Tape to Support COVID-19 Response

(b)(5)

From: Schiller, Lowell <Lowell.Schiller@fda.hhs.gov>
Sent: Wednesday, March 18, 2020 5:42 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Cc: Roth, Lauren <Lauren.Roth@fda.hhs.gov>
Subject: FW: HHS Takes New Action to Cut Red Tape to Support COVID-19 Response

(b)(5)

From: HHS Office of Public Affairs <hhsopa@hhs.gov>
Sent: Wednesday, March 18, 2020 2:51 PM
To: Schiller, Lowell <Lowell.Schiller@fda.hhs.gov>
Subject: HHS Takes New Action to Cut Red Tape to Support COVID-19 Response

News Release

U.S. Department of Health and Human Services

202-690-6343
media@hhs.gov
www.hhs.gov/news
Twitter @SpoxHHS

FOR IMMEDIATE RELEASE
March 18, 2020

HHS Takes New Action to Cut Red Tape to Support COVID-19 Response

On Wednesday, the Health Resources and Services Administration (HRSA) launched an information collection effort to support the Trump Administration's response to the COVID-19 pandemic, surveying HRSA-funded health centers on their involvement in the COVID-19 response, including whether they are offering diagnostic tests. This effort was made possible by a Paperwork Reduction Act waiver issued pursuant to statutory authorities that became available as a result of the public health emergency declared by HHS Secretary Alex Azar in late January.

Secretary Azar issued the following statement:

"Our health centers can provide us with an on-the-ground-perspective on the response to the COVID-19 pandemic and what stresses our healthcare system is experiencing as a result. Health centers are on the frontlines of providing accessible, affordable care in many of our communities, and play a vital role in our response efforts. This action under the emergency authorities given to the Secretary of HHS is just the latest example of the Trump Administration cutting red tape to accelerate our whole-of-government response to the COVID-19 pandemic."

HRSA Administrator Tom Engels issued the following statement:

"HRSA-funded health centers provide high-quality primary care services to 28 million people in the United States. That is 1 in 12 people nationwide. Approximately 1,400 grantees operate 13,000 service delivery sites that are essential to the communities they serve. These health centers are overseen by the people of those communities who play a key role in directing the types of services that are provided. Today's announcement is a strong step to making sure we know what they are going through so HRSA can do all we can to support health centers as they take on the task of responding to COVID-19."

The waiver to the Paperwork Reduction Act granted to HRSA follows other HHS actions to reduce regulatory burdens to support the COVID-19 response: Among other actions, the Food and Drug Administration updated its emergency use authorization policy for COVID-19 diagnostic tests to provide further guidance and more flexibility for the development of diagnostics. On Tuesday, the Centers for Medicare & Medicaid Services, the HHS Office for Civil Rights, and the HHS Office of Inspector General took comprehensive steps to offer Americans unprecedented access to telehealth options during the crisis.

###

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From: Felberbaum, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4819A643CA2945CDB1A2631B83E69673-MICHAEL.FEL]
Sent: 3/18/2020 7:49:40 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
CC: Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
Subject: FW: FOR SH REVIEW: WH Remarks
Attachments: WH Presser Remarks 03182020_SC mf.docx

Can you share with the folks that SH is asking have the remarks?

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Wednesday, March 18, 2020 7:25 PM
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: Re: FOR SH REVIEW: WH Remarks

Beautifully done. Approved. Can we also make sure this goes to Dr. Fauci, Dr. Redfield, and also Joe Grogan/Maria Bonner?
Thanks
STeve

Sent from my iPad

On Mar 18, 2020, at 7:21 PM, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov> wrote:

Hi Dr. Hahn,

Attached and pasted below are your draft remarks for the WH presser tomorrow. This is based on the OCC-cleared larger statement, but we would like your input on tone and content before we run back by them. If you're good with this we'll get reviewed and get you reactive talkers as well.

- Thank you, Mr. President.

(b)(5)

(b)(5)

- Thank you.

Thanks,

Michael

Michael Felberbaum
Senior Adviser

Office of Media Affairs
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Tel: 240-402-9548 / Cel: **(b)(6)**
michael.felberbaum@fda.hhs.gov

<image013.png>

<image014.jpg>

<image015.jpg>

<image016.jpg>

<image017.jpg>

<image018.jpg>

<WH Presser Remarks 03182020_SC mf.docx>

From: Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]
Sent: 3/18/2020 10:03:42 PM
To: Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
CC: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]
Subject: Re: updated PR on chloroquine

Think CDER and OCC needs to review.

Sent from my iPhone

On Mar 18, 2020, at 10:01 PM, Shah, Anand <Anand.Shah@fda.hhs.gov> wrote:

Hi All –
My edits are attached
Let's have CDER (Patrizia) have a quick look at the sentence **(b)(5)**
Thanks,
Anand

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Wednesday, March 18, 2020 9:11 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Subject: updated PR on chloroquine

Copied and attached.

(b)(5)

(b)(5)

(b)(5)

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<as DRAFT_PR_Chloroquine_821pm_3.18.20.docx>

From: Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]
Sent: 3/18/2020 10:05:09 PM
To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]
Subject: RE: updated PR on chloroquine

Yes – let's see what CDER and OCC say

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Wednesday, March 18, 2020 10:04 PM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Subject: RE: updated PR on chloroquine

Could we add this to end of your sentence?

(b)(5)

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From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Wednesday, March 18, 2020 10:02 PM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Subject: RE: updated PR on chloroquine

Hi All –
My edits are attached
Let's have CDER (Patrizia) have a quick look at the sentence **(b)(5)**
Thanks,
Anand

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Wednesday, March 18, 2020 9:11 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Subject: updated PR on chloroquine

Copied and attached.

(b)(5)

(b)(5)

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stephanie.caccomo@fda.hhs.gov

From: Cristinzio, Dayle [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B5A8DC4E587946FA938714A962DF4246-DAYLE.CRIST]
Sent: 3/19/2020 12:18:58 AM
To: Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Lynch, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d24ee4a4fc6241f48110d6b35e6704ed-Sarah.Lynch]; Morin, Steve [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e7ada1e856e450989eca925efcf201a-MORINS]; Fritsch, Beth F. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3625ad3bfbe743b6bf659324fa39dc5a-FRITSCHB]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; McWilliams, Carly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]
Subject: COVID-19 stakeholder outreach feedback
Attachments: Copy of Blank-COVID-19 Stakeholder Tracking List.final.xlsx; Customer Letter SARS-CoV-2 Test Development Update 03172020 (002).pdf

Keagan/Laura -
Wanted to give you a quick update on our progress. I held an initial conference call with Center/Office Stakeholder staff yesterday and asked them to report significant stakeholder engagement to us twice per week. I created a spreadsheet to capture the information (first attachment) and will report up to you and the JIC on Wednesdays and Fridays with updates. In the meantime, our staff continue to call through our top stakeholders and have had many meaningful conversations with them. They are all thankful we are reaching out and eager to help us too. We are regularly feeding this information back to the JIC/Centers as appropriate as well. I know you are inundated with emails/information, so let me know if this cadence and level of detail is what you were hoping for. You should get our first official report Friday morning.

In the meantime, below are significant items from today.

CFSAN Food Program Industry Stakeholder Call - A stakeholder call was held for the food program industry on 3/18/2020 and was attended by 2947 participants. The purpose of the call was to discuss food safety and food supply question related to COVID-19. Frank Yiannas, Deputy Commissioner for Food Policy and Response, Michael Rogers, Assistant Commissioner for Human and Animal Food Operations, Office of Regulatory Affairs, and Susan Mayne, Director, Center for Food Safety and Applied Nutrition provided remarks.

American Hospital Association (AHA) – AHA reached out today concerning a call they received from a health system in New York. Cepheid (device manufacturer who is not covered by 2/29/20 EUA policy) indicated to the New York health system that they are awaiting the FDA's approval of their EUA. The New York health system said that they can perform 800 tests per day once they get the test from Cepheid and the only thing holding that up is the EUA. Is there a way to expedite the EUA for this test so that the health system can move forward with this testing? AHA also indicated that this is a rapid test. (second attachment)

American Lung Association (ALA) – One of ALA's members suggested reaching out to the industrial workforce (mechanics, painters, etc) to find out if they have a supply of N-95 respirators that could be shared with health care workers. ALA wants to be informed about FDA's communications and share them with their members. ALA is hosting webinars to inform members about COVID-19 and is relying on CDC and FDA communications to develop the content.

American College of Emergency Physicians (ACEP) – Drug shortages for many things including Propofol, Kaletra, Ventolin, Parcetamol, Chloroquine and MDI inhalers. **MDI inhalers--** Data suggests that utilizing MDIs is safer than neb

treatments in suspected or confirmed COVID patients. They are already experiencing medication supply issues with MDI inhalers, in particular, albuterol inhalers. Also worried about blood supply shortages.

National Organization for Rare Diseases (NORD) – Worried about shortages and working with insurers to help relax amount filled per month to allow patients to have some supply in reserve. Feels FDA should put out a message specific to shortages on COVID-19 and provide a place to report these issues. Also feels we need to put more information on our website specific to patients – mostly industry specific information is up there now. Also offered to be validator for media inquiries on our regulatory process and success stories for acceleration.

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Director, Stakeholder Engagement
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dayle.cristinzio@fda.hhs.gov

From: Caccomo, Stephanie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=950C32CEBC4B4F80B302C50CF31C8524-STEPHANIE.C]
Sent: 3/19/2020 7:23:46 AM
To: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
CC: Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]
Subject: RE: Reactive talking points for media/pressers
Attachments: topline responsive language_3.18.20.docx

Good to go

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stephanie.caccomo@fda.hhs.gov

From: Rom, Colin <Colin.Rom@fda.hhs.gov>
Sent: Thursday, March 19, 2020 7:19 AM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: RE: Reactive talking points for media/pressers

Any follow up on these?

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Wednesday, March 18, 2020 10:46 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: Reactive talking points for media/pressers

Only a few things we need to clear with OCC. Will send final clean version late tonight or first thing AM.

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Press Officer

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Cell: (b)(6)
stephanie.caccomo@fda.hhs.gov

From: Felberbaum, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4819A643CA2945CDB1A2631B83E69673-MICHAEL.FEL]
Sent: 3/19/2020 8:35:50 AM
To: Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
CC: Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]
Subject: RE: Reactive talking points for media/pressers
Attachments: WH Presser Remarks 03192020 819am.docx; Media Call Remarks 03192020 820am.docx

WH presser and media call remarks attached.

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Sent: Thursday, March 19, 2020 8:22 AM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: RE: Reactive talking points for media/pressers

Placing in mail for reading. Since the other parts are moving, we will hold on bundling his bill of materials for today but will work to do so.

(b)(5)

(b)(5)

(b)(5)

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Thursday, March 19, 2020 7:24 AM
To: Rom, Colin <Colin.Rom@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: RE: Reactive talking points for media/pressers

Good to go

Stephanie Caccomo
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stephanie.caccomo@fda.hhs.gov

From: Rom, Colin <Colin.Rom@fda.hhs.gov>
Sent: Thursday, March 19, 2020 7:19 AM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: RE: Reactive talking points for media/pressers

Any follow up on these?

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
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Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: Reactive talking points for media/pressers

(b)(5)

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stephanie.caccomo@fda.hhs.gov

From: Felberbaum, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4819A643CA2945CDB1A2631B83E69673-MICHAEL.FEL]
Sent: 3/19/2020 9:31:31 AM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
CC: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]
Subject: PLEASE SEE: UPDATED WH REMARKS
Attachments: WH Presser Remarks 03192020 929am.docx

Importance: High

Updated WH presser remarks. Below are what we've revised on the Bayer donation:

(b)(5)

Michael

Michael Felberbaum
Senior Adviser

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From: Caccomo, Stephanie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=950C32CEBC4B4F80B302C50CF31C8524-STEPHANIE.C]
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To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]
Subject: updated PR
Attachments: DRAFT_PR_Chloroquine_3.19.20_FDA + HHS 1020am.docx

Removing (b)(5) reference.

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From: Flowers, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9418B62EC07642D7BC53C564E008F5CE-SUSAN.FLOWE]
Sent: 3/19/2020 10:51:46 AM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: Agenda for Int Call - FDA / ASPR / BARDA / NIH / CDC (chloroquine / COVID-19)

Agenda for Int Call - FDA / ASPR / BARDA / NIH / CDC (chloroquine / COVID-19) -

Agenda

(b)(5)

Participants on this call:

FDA
- Anand Shah, Office of the Commissioner, Deputy Commissioner for Medical & Scientific Affairs
- Keagan Lenihan, Office of the Commissioner, Chief of Staff
- Jeet Guram, Office of the Commissioner, Senior Advisor
- Michael Mair, Acting Assistant Commissioner for Counterterrorism Policy, Office of the Chief Scientist
- Janet Woodcock, CDER, Director
- Patrizia Cavazzoni, CDER, Deputy Director for Operations
- John Farley, CDER Office of Infectious Diseases, Director
- Rosemary Roberts, CDER Counter-Terrorism and Emergency Coordination Staff, Director
- Stacy Amin, Office of the Chief Counsel, Chief Counsel
- Mark Raza, Office of the Chief Counsel, Deputy Chief Counsel
- Amanda Edmonds, Office of the Chief Counsel, Deputy Chief Counsel for Program Review for Biologics and Drugs

ASPR/BARDA
- Rick Bright, Deputy Assistant Secretary for Preparedness and Response (ASPR) & Director of the Biomedical Advances Research and Development Authority (BARDA)
- Brian Shuy, ASPR Deputy Assistant Secretary and Chief of Staff
- Gary Disbrow, Acting Deputy Director of BARDA

NIH
- Anthony Fauci, NIAID, Director
- Hugh Auchincloss, NIAID, Principal Deputy Director
- Carrie Wolinetz, Acting Chief of Staff
- Hilary Marston, Office of the Chief of Staff, Medical Officer/Policy Advisor

CDC
- Timothy Uyeki, National Center for Immunization and Respiratory Diseases

White House
- May Davis, Associate White House Counsel

From: Raza, Mark [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5811A7D72EE34AA78FF3C8CCB59F92EE-MRAZA]
Sent: 3/19/2020 10:55:36 AM
To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]
Subject: RE: latest hahn remarks, pulling out donation

No legal comments. thanks

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Thursday, March 19, 2020 10:47 AM
To: Raza, Mark <Mark.Raza@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: latest hahn remarks, pulling out donation

Ok?

WH Press Briefing Remarks

- Thank you, Mr. President.

(b)(5)

(b)(5)

- Thank you.

Stephanie Caccomo
Press Officer

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

From: Raza, Mark [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5811A7D72EE34AA78FF3C8CCB59F92EE-MRAZA]
Sent: 3/19/2020 11:05:03 AM
To: Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]
Subject: RE: latest hahn remarks, pulling out donation

(b)(5)

From: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Sent: Thursday, March 19, 2020 11:02 AM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: Re: latest hahn remarks, pulling out donation

(b)(5)

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Date: March 19, 2020 at 10:47:29 AM EDT
To: Raza, Mark <Mark.Raza@fda.hhs.gov>, Amin, Stacy <Stacy.Amin@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: latest hahn remarks, pulling out donation

Ok?

WH Press Briefing Remarks

- Thank you, Mr. President.

(b)(5)

(b)(5)

(b)(5)

- Thank you.

Stephanie Caccomo
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: 301.348.1956
Cell: (b)(5)
stephanie.caccomo@fda.hhs.gov

From: Helms Williams, Emily [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=873BE46F1B1A4D2B8DF3FE67137CBDC8-HELMSWILLIA]
Sent: 3/19/2020 12:31:03 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Tobias, Lindsay [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a4766773c717470bbc55d204b5f067b2-Lindsay.Sto]
Subject: FW: COVID-19 Shortage of Personal Protective Equipment
Attachments: Sterigenics Cobb Co ltr Final.pdf

FYI, letter to GA gov has gone out.

From: Meister, Karen G <Karen.Meister@fda.hhs.gov>
Date: March 19, 2020 at 12:25:52 PM EDT
To: Helms Williams, Emily <Emily.HelmsWilliams@fda.hhs.gov>, Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Cc: Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>
Subject: FW: COVID-19 Shortage of Personal Protective Equipment

Just sent letter to governor to his Communications Director with copies to his chief of staff and executive assistant. Now will send to other ccs. (Cobb County and EPA head)

From: Meister, Karen G
Sent: Thursday, March 19, 2020 12:24 PM
To: candice.broce@georgia.gov
Cc: tim.fleming@georgia.gov; skylar.whitaker@georgia.gov
Subject: COVID-19 Shortage of Personal Protective Equipment

Hi Candice-

I am the acting director of FDA's Intergovernmental Affairs Office while Nick Alexander is doing a detail elsewhere in the Agency. Pleased to meet you virtually.

Attached you will find a letter signed by FDA Commissioner Hahn, to Governor Kemp, regarding the shortage of personal protective equipment (PPE) in the context of the COVID-19 outbreak. FDA is asking for Georgia's assistance in helping to increase the supply of PPE to help protect against COVID-19.

We appreciate consideration of this request. If you have any additional questions on this or any other FDA-related issue, please do not hesitate to contact me by email or at any of the contact numbers below or our Intergovernmental Affairs team at IGA@fda.hhs.gov.

Thank you!

Karen

Karen Meister, J.D.
Acting Director, Intergovernmental Affairs
Senior Advisor, Office of Legislation

Office of the Commissioner/OPPLIA
U.S. Food and Drug Administration
(301) 796-8916 office
(b)(6)
(b)(6) *(personal cell- I will call you back on work phone)*

From: Felberbaum, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4819A643CA2945CDB1A2631B83E69673-MICHAEL.FEL]
Sent: 3/19/2020 3:53:22 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
CC: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]
Subject: FYI: Bayer Partners with U.S. Government on Major Product Donation to Fight Coronavirus

FYI …

bayer2019tf.g4web.com

Bayer Partners with U.S. Government on Major Product Donation to Fight Coronavirus

March 19, 2020

WHIPPANY, N.J.--(BUSINESS WIRE)-- Bayer today announced it is joining the U.S. Government's fight against COVID-19 with a donation of 3 million tablets of the drug Resochin (chloroquine phosphate).

Resochin, a product discovered by Bayer in 1934 and indicated for prevention and treatment of malaria, also appears to have broad spectrum antiviral properties and effects on the body's immune response. New data from initial preclinical and evolving clinical research conducted in China, while limited, shows potential for the use of Resochin in treating patients with COVID-19 infection.

Bayer in recent days has been in talks with the White House, HHS, CDC, and the FDA, offering any assistance we can provide with a focus on donating Resochin to help in the government's efforts to combat the virus.

Currently not approved for use in the United States, Bayer is working with appropriate agencies on an Emergency Use Authorization for the drug's use in the U.S.

Bayer thanks the Trump administration for moving quickly to enable this donation and will continue to work closely with the administration to support its efforts in the fight against COVID-19.

Bayer: Science For A Better Life

Bayer is a global enterprise with core competencies in the life science fields of health care and nutrition. Its products and services are designed to benefit people by supporting efforts to overcome the major challenges presented by a growing and aging global population. At the same time, the Group aims to increase its earning power and create value through innovation and growth. Bayer is committed to the principles of sustainable development, and the Bayer brand stands for trust, reliability and quality throughout the world. In fiscal 2019, the Group employed around 104,000 people and had sales of 43.5 billion euros. Capital expenditures amounted to 2.9 billion euros, R&D expenses to 5.3 billion euros. For more information, go to www.bayer.us.

Michael Felberbaum
Senior Advisor

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

Tel: 240-402-9548 / Cell: 202-906-0229
michael.felberbaum@fda.hhs.gov

From: Flowers, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9418B62EC07642D7BC53C564E008F5CE-SUSAN.FLOWE]
Sent: 3/19/2020 4:02:53 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: Meeting Material for AMA Mtg w/ Premier Coalition
Attachments: Premier & Supply Chain Coalition Action plan - 12 page document..docx; Premier & Supply Chain Companies' Coalition Charter 3.19.docx

Meeting material for 4:00 p.m. AMA Mtg w/ Premier Coalition

From: Roth, Lauren [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=52BFD08572694F269A20C508F3C04A03-LAUREN.ROTH]
Sent: 3/19/2020 4:53:07 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: McWilliams, Carly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Schiller, Lowell [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77949b06919e4f91aa788e9a616c50c7-Lowell.Schi]
Subject: RE: Night Note 3/20/20 INTERNAL CONFIDENTIAL DELIBERATIVE

Yes, we will give them a heads up. I checked with the Center; the draft is with them, but should be coming to OP and OCC relatively soon.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Thursday, March 19, 2020 4:09 PM
To: Roth, Lauren <Lauren.Roth@fda.hhs.gov>
Cc: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Schiller, Lowell <Lowell.Schiller@fda.hhs.gov>
Subject: Re: Night Note 3/20/20 INTERNAL CONFIDENTIAL DELIBERATIVE

Can we give HHS/ OMB heads up this is coming? This needs to move.

Sent from my iPhone

On Mar 19, 2020, at 4:07 PM, Roth, Lauren <Lauren.Roth@fda.hhs.gov> wrote:

All,
Just FYI that the timing on this may slip. I haven't seen a draft yet, so it hasn't gone to HHS.

From: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Sent: Thursday, March 19, 2020 3:39 PM
To: Dareshori, Zachary (OS) <Zachary.Dareshori@hhs.gov>; Steele, Danielle (OS) <Danielle.Steele@hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Beshara, Nicholas <Nicholas.Beshara@fda.hhs.gov>; Beardsley, Sara <Sara.Beardsley@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Flahive, James <James.Flahive@fda.hhs.gov>; Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>; Giroir, Brett (OS) <Brett.Giroir@hhs.gov>
Subject: RE: Night Note 3/20/20 INTERNAL CONFIDENTIAL DELIBERATIVE

INTERNAL MANAGEMENT DELIBERATIVE - THIS EMAIL SHOULD NOT BE SHARED WITH HHS OP-DIVS. IT CONTAINS CONFIDENTIAL AND/OR SENSITIVE INFORMATION.

Ventilator supply strategies for HCPs guidance
Tomorrow, FDA will issue an immediately in effect guidance to provide a policy for expanding the availability of ventilators and accessories as well as other respiratory devices during the COVID-19 pandemic.

Confidential

From: Kahn, Jeremy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1B98D36D2C1F4AE795140B68DE7B37F7-JEREMY.KAHN]
Sent: 3/19/2020 5:22:33 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]
CC: Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]
Subject: Two COVID-19 Press Releases for Tonight or Tomorrow
Attachments: 20200318-PR--Hand Sanitizer Guidance FINAL.docx; 20200319--PR--REMS Guidance FINAL.docx

Keagan/Erika-
Flagging two HHS cleared COVID-19 press releases on hand sanitizers and REMS that are awaiting release once the guidances post. SH and AA cleared their quotes.

Please let me know ASAP if you have any concerns.

Thank you,
--Jeremy

Jeremy Kahn
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel 301-796-8671
jeremy.kahn@fda.hhs.gov

From: Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]
Sent: 3/19/2020 7:33:34 PM
To: Tom Polen [tom_polen@bd.com]
Subject: Re: Your Support in Validation of Nasal Swabs & Addressing Testing Bottlenecks - White House Follow-up

(b)(5)

Sent from my iPhone

On Mar 19, 2020, at 7:28 PM, Tom Polen <tom_polen@bd.com> wrote:

Hi Keagan, Spoke with Jeff Shuren, he was extremely helpful and all is addressed. No need for follow-up.
Thanks,
Tom

Tom Polen
Chief Executive Officer and President
BD
1 Becton Drive , Franklin Lakes, NJ 07417
tel: 201-847-3176 mobile: **(b)(6)**
email: tom_polen@bd.com website: www.bd.com

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Thursday, March 19, 2020 3:19 PM
To: Tom Polen <tom_polen@bd.com>
Cc: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Re: Your Support in Validation of Nasal Swabs & Addressing Testing Bottlenecks - White House Follow-up

(b)(5)

Thanks,
Keagan

Sent from my iPhone

On Mar 19, 2020, at 2:48 PM, Tom Polen <tom_polen@bd.com> wrote:

Steve,

(b)(5)

Please feel free to call me directly with any questions/concerns. My cell is **(b)(6)**

Tom

Tom Polen
Chief Executive Officer and President
BD
1 Becton Drive , Franklin Lakes, NJ 07417
tel: 201-847-3176 mobile:(b)(6)
email: tom polen@bd.com website: www.bd.com

<Group study suggested for FDA approval 3-17-20 FDA_RMS.docx>

From: Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]
Sent: 3/20/2020 7:40:36 AM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
CC: Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: Re: SWABS

(b)(5)

Sent from my iPhone

On Mar 20, 2020, at 5:52 AM, Hahn, Stephen <SH1@fda.hhs.gov> wrote:

(b)(5)

Steve

From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Date: March 19, 2020 at 5:40:08 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: FW: SWABS

(b)(5)

Brett P. Giroir, MD
ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
(b)(6)

From: Dave Hickey <Dave Hickey@bd.com>
Date: March 19, 2020 at 2:54:51 PM EDT
To: Lauren Silvis <lrsilvis@gmail.com>
Subject: FW: Your Support in Validation of Nasal Swabs & Addressing Testing Bottlenecks - White House Follow-up

(b)(5)

<image001.jpg>

Dave Hickey
President, Integrated Diagnostic Solutions

Dave.Hickey@bd.com

(b)(6)

t: 4103164121
(b)(6)

bd.com

From: Tom Polen <tom polen@bd.com>
Sent: Thursday, March 19, 2020 2:48 PM
To: Elizabeth Woody <elizabeth woody@bd.com>; Dave Hickey <Dave Hickey@bd.com>
Subject: FW: Your Support in Validation of Nasal Swabs & Addressing Testing Bottlenecks - White House Follow-up

Tom Polen
Chief Executive Officer and President
BD
1 Becton Drive , Franklin Lakes, NJ 07417
tel: 201-847-3176 mobile: (b)(6)
email: tom polen@bd.com website: www.bd.com

From: Tom Polen
Sent: Thursday, March 19, 2020 2:47 PM
To: 'SH1@fda.hhs.gov' <SH1@fda.hhs.gov>; 'Keagan.Lenihan@fda.hhs.gov' <Keagan.Lenihan@fda.hhs.gov>
Subject: Your Support in Validation of Nasal Swabs & Addressing Testing Bottlenecks - White House Follow-up

Steve,

(b)(5)

Tom

Tom Polen
Chief Executive Officer and President
BD
1 Becton Drive , Franklin Lakes, NJ 07417
tel: 201-847-3176 mobile: 443-850-0016
email: tom polen@bd.com website: www.bd.com

****

IMPORTANT MESSAGE FOR RECIPIENTS IN THE U.S.A.:
This message may constitute an advertisement of a BD group's products or services or a solicitation of interest in them. If this is such a message and you would like to opt out of receiving future advertisements or solicitations from this BD group, please forward this e-mail to optoutbygroup@bd.com. [BD.v1.0]
****

****

Corporate Headquarters Mailing Address: BD (Becton, Dickinson and Company) 1 Becton Drive Franklin Lakes, NJ 07417 U.S.A.

<Group study suggested for FDA approval 3-17-20 FDA_RMS.docx>

From: Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]
Sent: 3/20/2020 7:51:36 AM
To: Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]
CC: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
Subject: Re: alternatives to make chloroquine and otehr COVID-19 drugs available before approval

Steve- maybe we could do a call after the task force meeting if you don't get dragged into something else? Let us know when you might have time over there and I can conference us all in for a quick huddle.

Sent from my iPhone

On Mar 19, 2020, at 7:23 PM, Amin, Stacy <Stacy.Amin@fda.hhs.gov> wrote:

In case you find this helpful —

From: Beers, Donald <Donald.Beers@fda.hhs.gov>
Date: March 19, 2020 at 5:51:24 PM EDT
To: Amin, Stacy <Stacy.Amin@fda.hhs.gov>, Raza, Mark <Mark.Raza@fda.hhs.gov>, Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>
Cc: Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>
Subject: alternatives to make chloroquine and otehr COVID-19 drugs available before approval

Stacy, Mark, and Amanda,

(b)(5)

(b)(5)

(b)(5)

Don

Donald O. Beers
Senior Counsel
Food and Drug Division
Office of General Counsel
Department of Health and Human Services
Donald.Beers@fda.hhs.gov
White Oak Bldg. 31 Room 4406
301-796-8542

From: Caccomo, Stephanie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=950C32CEBC4B4F80B302C50CF31C8524-STEPHANIE.C]
Sent: 3/20/2020 4:14:07 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: Automatic reply: Chloroquine

I am currently working on the FDA's COVID-19 response and may be delayed in responding to your email. Please text me at (b)(6) if you need me urgently.

Thank you!
Stephanie Caccomo

From: Cristinzio, Dayle [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B5A8DC4E587946FA938714A962DF4246-DAYLE.CRIST]
Sent: 3/20/2020 4:57:30 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]
CC: Lynch, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d24ee4a4fc6241f48110d6b35e6704ed-Sarah.Lynch]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; McWilliams, Carly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]; Fritsch, Beth F. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3625ad3bfbe743b6bf659324fa39dc5a-FRITSCHB]; Morin, Steve [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e7ada1e856e450989eca925efcf201a-MORINS]
Subject: RE: FDA Stakeholder Update - March 20, 2020

Pressed send too fast. Couple more items below.

Catholic Health, Buffalo, NY – Participated on a call with Mark Sullivan, CEO of Catholic Health. Mr. Sullivan expressed concerns about the availability of COVID-19 diagnostics and reagents. He was specifically interested in the availability of a point of care diagnostic. Coordinated response with CDRH.
American Hospital Association (AHA) - Answered a question about CLIA for AHA. AHA's CLIA question should be directed to CMS.
American Society of Health-System Pharmacy (ASHP)
1. ASHP surveyed its members to assess the status of supplies and availability of medical masks, including surgical-type masks, N-95 respirators, or other masks used in healthcare settings, during the current COVID-19 pandemic. (see attached)
2. Pharmacy Organization's Joint Policy Recommendations to Combat the COVID-19 Pandemic (attached)

Dayle Lewis Cristinzio
Director, Stakeholder Engagement
Office of External Affairs
U.S. Food and Drug Administration
(t) 301.796.8898 | (m) **(b)(6)**
dayle.cristinzio@fda.hhs.gov

From: Cristinzio, Dayle
Sent: Friday, March 20, 2020 4:56 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Cc: Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; 'Fritsch, Beth F.' <beth.fritsch@fda.hhs.gov>; Morin, Steve <Steve.Morin@fda.hhs.gov>
Subject: FW: FDA Stakeholder Update - March 20, 2020

Stakeholder Updates from today:
Talked with CDRH Comms shop to brainstorm new ideas to outreach to the academic medical centers and hospitals/hospital systems on testing and PPE. We are working out a list of groups that need personal touches and language to use in the conversations. Colin – maybe you can help with this one as I know you've done some outreach in the past on this area. CDRH is very protective of their relationships and worried about crossover.
We also suggested a stakeholder call with hospital systems to talk through some of the testing and PPE shortage questions they have. Getting some desperate calls from hospital CEOs funneled to us through the American Hospital Association about test availability and the EUA process and think hearing from us would be useful.

Had good phone conversations with the following:
Personal Care Products Council – Very happy with the hand sanitizers guidance and fast turnaround.
Consumer Healthcare Products Association – Thanks us for putting out the statement on NSAIDS/COVID-10 and also appreciated the hand sanitizer guidance.
American Hospital Association – continue to talk to them daily
American Association for Critical Care Nurses – Appreciate Agency reaching out to AACCN – and they will push out information to their members
American College of Emergency Physicians – Reported field issues with Metered Dose Inhalers and information was also sent to Drug Shortages.
American College of Obstetrics and Gynecology – report that they will push information out to their members.
American Dental Association – Washington State ordered all dental offices to close for two weeks due to shortage of PPE. Dental offices are worried about future supplies.
American Medical Association – Appreciated information being sent in a single email and they report they will push information out to their members
National Consumers League – appreciate the consolidated information.

And sent email updates to the following groups:

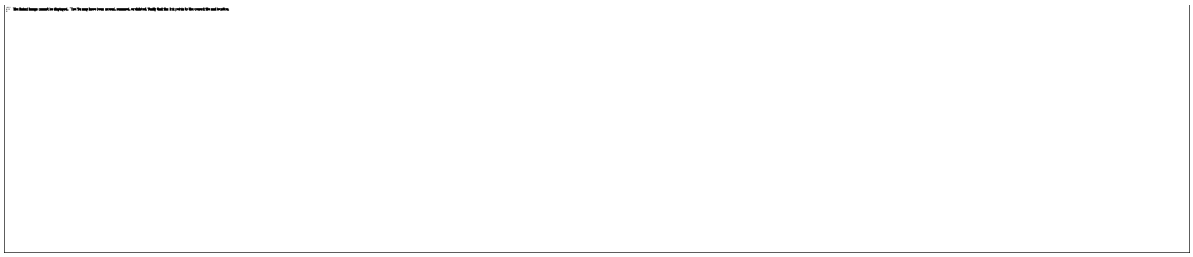
American Nurses Association
Infectious Disease Society of America
American Association of Nurse Practitioners
American Cancer Society
American Academy of Pediatrics
American Academy of Physician Assistants
American Diabetes Association
American Geriatric Society
American Heart Association
American Hospital Association
American Lung Association
American Pharmacists Association
American Public Health Association
American Thoracic Society
Association Society of Health-System Pharmacists
Gerontological Society for America
National Association of Chain Drug Stores
National Community Pharmacists Association
Society of Infectious Disease Pharmacists
Federation of American Hospitals [FAH]
Children's Hospital Association
Greater New York Hospital Association
Catholic Health Association
Association of Academic Health Centers

Also, our stakeholder newsletter went out this afternoon to our 84,000 subscribers. Scroll down to read it.

Dayle Lewis Cristinzio
Director, Stakeholder Engagement
Office of External Affairs
U.S. Food and Drug Administration
(t) 301.796.8898 | (m) (b)(6)
dayle.cristinzio@fda.hhs.gov

From: U.S. Food and Drug Administration <fda@info.fda.gov>
Sent: Friday, March 20, 2020 1:47 PM
To: Chenjo, Lakeecha <Lakeecha.Chenjo@fda.hhs.gov>
Subject: FDA Stakeholder Update - March 20, 2020

If your email program has trouble displaying this email, view it as a web page.



March 20, 2020

Dear Colleague,
FDA's *Stakeholder Engagement Staff* works to provide you with up-to-date information to further our commitment to advance public health and well-being.

Coronavirus Disease 2019 (COVID-19)

Announcements

- **March 20, 2020** - FDA provides guidance on production of alcohol-based hand sanitizer to help boost supply, protect public health
- **March 20, 2020** - FDA allows expanded use of devices to monitor patients' vital signs remotely
- **March 19, 2020** - FDA advises patients on use of non-steroidal anti-inflammatory drugs (NSAIDs) for COVID-19
- **March 19, 2020** - FDA Continues to Facilitate Development of Treatments
- **March 19, 2020** - Blood Donations
- **March 19, 2020** - Coronavirus (COVID-19) Frequently Asked Questions has now been translated into Spanish
- **March 18, 2020** - FDA Focuses on Safety of Regulated Products While Scaling Back Domestic Inspections

Draft and Final Guidances

- **March 19, 2020** - Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19)
- **March 19, 2020** - Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During a Pandemic
- **March 18, 2020** - FDA Issues Guidance for Conducting Clinical Trials
- **March 17, 2020** - Temporary Policy Regarding Preventive Controls and FSVP Food Supplier Verification Onsite Audit Requirements During the COVID-19 Public Health Emergency

Drug Shortages

The FDA continues to take steps to monitor the supply chain. The Drug Shortage Staff within the FDA's Center for Drug Evaluation and Research (CDER) has asked manufacturers to evaluate their entire supply chain, including active pharmaceutical ingredients, finished dose forms, and any components that may be impacted in

any area of the supply chain due to the COVID-19 outbreak. For the latest information from the FDA on COVID-19 see our website at: Coronavirus Disease 2019 (COVID-19).

To report a drug shortage, please contact the CDER Drug Shortage Staff below

Report a Drug Shortage

FDA Announcements

FDA requires new health warnings for cigarette packages and advertisements

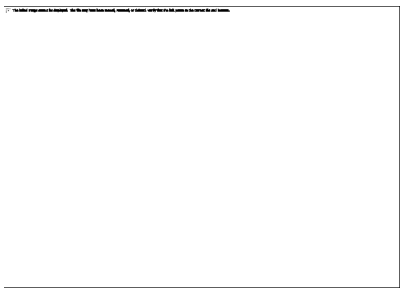
The FDA issued a final rule to require new health warnings on cigarette packages and in cigarette advertisements. The warnings feature textual statements with photo-realistic color images depicting some of the lesser-known, but serious health risks of cigarette smoking, including impact to fetal growth, cardiac disease, diabetes and more. [03/17/2020]

FDA Finalizes Guidance for Industry on Applications for Drugs with Inadequate Generic Competition

The FDA finalized guidance for industry, "Competitive Generic Therapies" (CGTs), which describes the process that generic drug applicants should follow to request designation of a drug as a CGT and the criteria for that designation. The final guidance provides information on actions the FDA may take to expedite development and review of Abbreviated New Drug Applications (ANDAs) for drugs designated as CGTs and explains how the FDA implements the statutory provisions providing for a 180-day exclusivity period for certain first-approved applicants who submit ANDAs for CGTs. [03/13/2020]

FDA Guidance Document

Restricted Delivery Systems: Flow Restrictors for Oral Liquid Drug Products Guidance for Industry by May 18, 2020

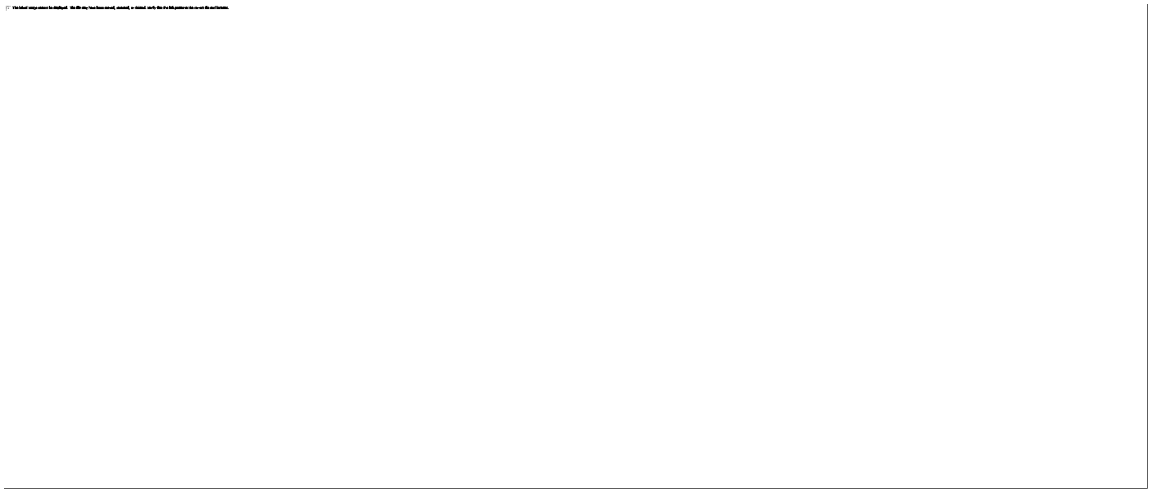


This guidance provides recommendations regarding the use of restricted delivery systems, to limit unintentional ingestion of oral liquid drug products (e.g., oral solution, oral suspension) by children. The recommendations in this guidance apply broadly to oral liquid drug and biological products. Accordingly, this guidance is intended for manufacturers of oral liquid drug and biological products.

Submit Online Comment

Consumer Updates

Where and How to Dispose of Unused Medicines



Is your medicine cabinet full of expired drugs or medications you no longer use? Your medicine is for you. What's safe for you might be harmful for someone else. You can dispose of your expired, unwanted, or unused medicines through a drug take back program — or you can do it at home

Drug Take Back Programs

The U.S. Drug Enforcement Administration (DEA) sponsors National Prescription Drug Take Back Day in communities nationwide. Many communities also have their own drug take back programs. Check with your local law enforcement officials to find a location near you or with the DEA to find a DEA-authorized collector in your community. You can also check with your pharmacist. Some pharmacies have mail-back programs and disposal kiosks for unused medicines.

How to Dispose of Medicines at Home

When a take-back option is not readily available, there are two ways to dispose of prescription and over-the counter (OTC) medicine, depending on the drug.

About Us

The FDA Stakeholder Engagement Staff reside within the Office of the Commissioner and support the FDA mission by engaging with Patient and Health Professional Organizations, Consumer Groups, Trade Associations, Think Tanks and other external stakeholders. We encourage and support active engagement from external stakeholders related to policy that impacts human and animal medical products, cosmetics, tobacco, nutrition and food safety that promote health and healthy living.

Email FDA Stakeholder Engagement Staff

U.S. Food and Drug Administration
10903 New Hampshire Avenue, Silver Spring, MD 20993
1-888-INFO-FDA (1-888-463-6332)

From: Felberbaum, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4819A643CA2945CDB1A2631B83E69673-MICHAEL.FEL]
Sent: 3/20/2020 5:17:05 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Guram, Jeet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ef73bea97e2b477b847ea302c4730ccf-Gurjeet.Gur]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
CC: Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
Subject: RE: Chloroquine

I can check with CDER and OCC.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Friday, March 20, 2020 5:05 PM
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: RE: Chloroquine

If CDER is ok with that I am.

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Sent: Friday, March 20, 2020 5:02 PM
To: Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: RE: Chloroquine

Much appreciated.

I can link/reference in any follow-up inquiries once out.

(b)(5)

From: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Sent: Friday, March 20, 2020 4:44 PM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: RE: Chloroquine

Here is the latest draft of CDC's "information for clinicians" that they shared with us that's likely going up later today. Michael I'll connect you with the person we've been working with at CDC to see if he can put you in touch with their comms person. I don't believe NIH is putting out anything regarding chloroquine.

--
Jeet Guram, M.D.
Senior Advisor, Office of the Commissioner
Food and Drug Administration
+1 (202) 230-0451 | jeet.guram@fda.hhs.gov

U.S. FOOD & DRUG ADMINISTRATION

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Friday, March 20, 2020 4:35 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Subject: RE: Chloroquine

Michael –
Just seeing this. +Jeet for CDC and NIH input
Thanks
Anand

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Friday, March 20, 2020 4:14 PM
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: RE: Chloroquine

Hopefully the guidelines go up today, I think they are literally ironing them out now, so we should reference.

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Sent: Friday, March 20, 2020 4:08 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: RE: Chloroquine

Thanks. I'll run by OCC **(b)(5)** **(b)(5)** Anand, I believe you're working with one or both of them on this – can you ask them to have their comms folks working on this connect with me? I can reach out separately but it will be a shot in the dark.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Friday, March 20, 2020 4:01 PM
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: RE: Chloroquine

Like it

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Sent: Friday, March 20, 2020 3:59 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: Chloroquine

Following up on a request from LC. We have not been directly discussing approval status, rather sharing our press release (excerpt below) and the transcript from the WH briefing from yesterday with reporters who ask, and clarifying that it's immediately available for off-label use. I understand that CDC (and maybe NIH) is doing something larger around the state of knowledge of the drug so that prescribers can make an informed decision about off-label use. We haven't gotten any additional follow-up that has been handled differently than above, but I can run the highlighted sentence by

(b)(5)

Michael Felberbaum
Senior Advisor

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

From: Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]
Sent: 3/20/2020 7:20:05 PM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
Subject: Re: South Dakota Call

Yes.

Sent from my iPhone

On Mar 20, 2020, at 7:07 PM, Hahn, Stephen <SH1@fda.hhs.gov> wrote:

Keagan, would you ask someone from Brett's group to respond?
Thanks
S

Sent from my iPad

Begin forwarded message:

From: "Southern, Tim" <Tim.Southern@state.sd.us>
Date: March 20, 2020 at 6:46:41 PM EDT
To: "Hahn, Stephen" <SH1@fda.hhs.gov>, "Stenzel, Timothy" <Timothy.Stenzel@fda.hhs.gov>, "Urban, Lori - RD, Washington, DC" <lori.urban@usda.gov>, "Giroir, Brett (OS)" <(b)(6)>
Cc: FDA Commissioner <Stephen.Hahn@fda.hhs.gov>, "Becker, Scott | APHL" <Scott.Becker@aphl.org>, "Malsam-Rysdon, Kim" <Kim.Malsam-Rysdon@state.sd.us>, Governor of South Dakota <GovernorNoem@state.sd.us>
Subject: RE: South Dakota Call

Good evening.

The South Dakota Public Health Laboratory has had difficulties securing critical supplies for SARS-CoV-2 testing; our orders to manufacturers and the IRR are delayed – sometimes indefinitely – and have also been cancelled. Unfortunately, we could not secure the bare minimum supplies needed to continue testing this week and had to stop SARS-CoV-2 testing for two days. SDPHL is the only laboratory in the South Dakota to provide this critical testing service so the impact was significant. Governor Noem is a strong advocate for the SDPHL and she was able secure critical supplies on Wednesday (3/18) from the IRR which allowed SARS-CoV-2 testing to resume on Thursday (3/19), but we will face a critical shortage again by early next week.

Also of concern, critical supplies for SARS-CoV-2 testing were allocated to at least one facility in South Dakota that does not provide SARS-CoV-2 testing. It was my understanding that resource allocation was put in place to ensure critical testing supplies go to the laboratories that need those supplies the most, like our nation's public health laboratories. My experiences this week make me question federal processes for allocation of critical SARS-CoV-2 testing supplies.

I recognize that FDA is one partner of many in this very large response, and that some of what I mentioned above may not be controlled or even influenced by the FDA. I ask that you continue to advocate for our public health laboratory system so that we can get the supplies we need to provide SARS-CoV-2 testing.

Thank you for your time. I will follow up with Tim Stenzel this evening by phone.

Tim

Tim Southern, PhD, D(ABMM)
Public Health Laboratory Director | *Division of Administration*
SOUTH DAKOTA DEPARTMENT OF HEALTH
605.773.3368 | 615 E 4th Street, Pierre | doh.sd.gov

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Friday, March 20, 2020 4:48 PM
To: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Southern, Tim <Tim.Southern@state.sd.us>; Urban, Lori - RD, Washington, DC <lori.urban@usda.gov>; Giroir, Brett (OS) <(b)(6)>
Cc: FDA Commissioner <Stephen.Hahn@fda.hhs.gov>
Subject: RE: [EXT] South Dakota Call

Brett,
There are some problems with reagent orders being cancelled. Can you help?
Thx
S

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Date: March 20, 2020 at 5:28:16 PM EDT
To: Southern, Tim <Tim.Southern@state.sd.us>, Urban, Lori - RD, Washington, DC <lori.urban@usda.gov>
Cc: Hahn, Stephen <SH1@fda.hhs.gov>, FDA Commissioner <Stephen.Hahn@fda.hhs.gov>
Subject: RE: South Dakota Call

Hi Dr. Southern,

On the phone with Gov. Noem and understand you didn't get some reagents you ordered. Can we jump on a call again tonight?

My cell is (b)(6)

Best,
Tim

Timothy T. Stenzel, MD, PhD
Director, OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality

Center for Devices and Radiological Health
U.S. Food and Drug Administration
Timothy.Stenzel@fda.hhs.gov
Jennifer Campbell
Administrative Assistant

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Sent: Wednesday, March 18, 2020 5:52 PM
To: Southern, Tim <Tim.Southern@state.sd.us>; Urban, Lori - RD, Washington, DC <lori.urban@usda.gov>
Subject: RE: South Dakota Call

Tonight is good.

Look forward to it.

Best,
Tim

Timothy T. Stenzel, MD, PhD
Director, OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality

Center for Devices and Radiological Health
U.S. Food and Drug Administration
Timothy.Stenzel@fda.hhs.gov
Jennifer Campbell
Administrative Assistant

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

From: Southern, Tim <Tim.Southern@state.sd.us>
Sent: Wednesday, March 18, 2020 5:44 PM
To: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Urban, Lori - RD, Washington, DC <lori.urban@usda.gov>
Subject: RE: South Dakota Call

Yes, sir.

You were on a call today with APHL. Joanne Bartkus (MNPHL) asked a good question about using the new FDA process for state approval of local SARS-CoV-2 testing programs. We are being given the authority but we have limited

information about process. I believe I understand the process now but I want to touch base quickly with you. Let's plan for a quick call. Not sure about time yet…still with the Sec. of Health right now.

Tim

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Sent: Wednesday, March 18, 2020 4:01 PM
To: Urban, Lori - RD, Washington, DC <lori.urban@usda.gov>
Cc: Southern, Tim <Tim.Southern@state.sd.us>
Subject: RE: [EXT] South Dakota Call

Hi Dr. Southern. Can we connect at 6 pm eastern or later?

My cell is **(b)(6)**

Best,
Tim

Timothy T. Stenzel, MD, PhD
Director, OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality

Center for Devices and Radiological Health
U.S. Food and Drug Administration
Timothy.Stenzel@fda.hhs.gov
Jennifer Campbell
Administrative Assistant

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

From: Urban, Lori - RD, Washington, DC <lori.urban@usda.gov>
Sent: Wednesday, March 18, 2020 4:46 PM
To: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Cc: Tim.Southern@state.sd.us
Subject: South Dakota Call

Dr. Stenzel –
I apologize. The South Dakota leadership joined right after you disconnected.

Dr. Southern, whom heads the SD Labs had questions. I am connecting him with you.
If you could connect with him, we do not need to reschedule a call.

I appreciate your help! Thank you!

<image005.jpg>

Lori Urban

Senior Advisor, Rural Development
United States Department of Agriculture
Rural Utilities Service #5138 South Building
1400 Jefferson Dr. SW, Washington DC 20250
Cell: (b)(6) Desk: (202) 720-1910

From: Felberbaum, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4819A643CA2945CDB1A2631B83E69673-MICHAEL.FEL]
Sent: 3/20/2020 7:40:50 PM
To: Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Guram, Jeet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ef73bea97e2b477b847ea302c4730ccf-Gurjeet.Gur]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
Subject: RE: FYI - Fauci

That works for me. OK with others?

Michael Felberbaum
Senior Advisor

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

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Date: March 20, 2020 at 7:39:04 PM EDT
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Guram, Jeet <Jeet.Guram@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: RE: FYI - Fauci

(b)(5)

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Sent: Friday, March 20, 2020 7:34 PM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: RE: FYI - Fauci

I think if asked, we'll need to say something like the following, if asked about this **(b)(5)**

(b)(5)

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Friday, March 20, 2020 7:27 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: RE: FYI - Fauci

Haven't heard anything about this concept **(b)(5)**

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Friday, March 20, 2020 7:21 PM
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Shah, Anand <Anand.Shah@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: Re: FYI - Fauci

Anand?

Sent from my iPhone

On Mar 20, 2020, at 7:13 PM, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov> wrote:

On CBS Evening News:

"I was just speaking to the Commissioner of FDA, together with Dr. Birx, about having an online system where people can actually get on and have a doctor make the determination whether or not they should be put on (hydroxychloroquine) but also have the capability of collecting information."

I'm not familiar with what he's talking about, but I'm sure we're going to have to (at some point) provide more detail – and since he mentioned it publicly, likely before we're able to roll out something larger.

Michael
Michael Felberbaum
Senior Advisor

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

<image013.png>

<image014.jpg>

<image015.jpg>

<image016.jpg>

<image017.jpg>

<image018.jpg>

From: Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]
Sent: 3/21/2020 7:27:29 AM
To: Beckham, Tammy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8b3c038e4917469dbb5666f0464192b3-HHS-Tammy.B]
CC: Harder, Kristina (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7a27fdbe16947fcb4a0c7caad82aa32-HHS-Kristin]; Kellogg, Rachel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6dc3e53a06f5451cad9facbb50d54576-HHS-Rachel.]
Subject: Re: South Dakota Call

Thx

Sent from my iPhone

On Mar 20, 2020, at 10:36 PM, Beckham, Tammy (HHS/OASH) <(b)(6) wrote:

FDA responded to them today.
Tammy

From: Harder, Kristina (HHS/IOS) <(b)(6)
Sent: Friday, March 20, 2020 8:11 PM
To: Beckham, Tammy (HHS/OASH) <Tammy.Beckham@hhs.gov>; Kellogg, Rachel (HHS/OASH) (b)(6)
Cc: Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: South Dakota Call

Tammy and Rachel – is this your team?

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Friday, March 20, 2020 7:21 PM
To: Harder, Kristina (HHS/IOS) <(b)(6)>
Subject: Fwd: South Dakota Call

Can you pls help with this?

Sent from my iPhone

Begin forwarded message:

From: "Hahn, Stephen" <SH1@fda.hhs.gov>
Date: March 20, 2020 at 7:07:11 PM EDT
To: "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>
Subject: Fwd: South Dakota Call

Keagan, would you ask someone from Brett's group to respond?
Thanks
S

Sent from my iPad

Begin forwarded message:

From: "Southern, Tim" <[redacted]>
Date: March 20, 2020 at 6:46:41 PM EDT
To: "Hahn, Stephen" <SH1@fda.hhs.gov>, "Stenzel, Timothy" <Timothy.Stenzel@fda.hhs.gov>, "Urban, Lori - RD, Washington, DC" <lori.urban@usda.gov>, "Giroir, Brett (OS)" [redacted]
Cc: FDA Commissioner [redacted], "Becker, Scott | APHL" <Scott.Becker@aphl.org>, "Malsam-Rysdon, Kim" <Kim.Malsam-Rysdon@state.sd.us>, Governor of South Dakota <GovernorNoem@state.sd.us>
Subject: RE: South Dakota Call

Good evening.

The South Dakota Public Health Laboratory has had difficulties securing critical supplies for SARS-CoV-2 testing; our orders to manufacturers and the IRR are delayed – sometimes indefinitely – and have also been cancelled. Unfortunately, we could not secure the bare minimum supplies needed to continue testing this week and had to stop SARS-CoV-2 testing for two days. SDPHL is the only laboratory in the South Dakota to provide this critical testing service so the impact was significant. Governor Noem is a strong advocate for the SDPHL and she was able secure critical supplies on Wednesday (3/18) from the IRR which allowed SARS-CoV-2 testing to resume on Thursday (3/19), but we will face a critical shortage again by early next week.

Also of concern, critical supplies for SARS-CoV-2 testing were allocated to at least one facility in South Dakota that does not provide SARS-CoV-2 testing. It was my understanding that resource allocation was put in place to ensure critical testing supplies go to the laboratories that need those supplies the most, like our nation's public health laboratories. [redacted]

I recognize that FDA is one partner of many in this very large response, and that some of what I mentioned above may not be controlled or even influenced by the FDA. I ask that you continue to advocate for our public health laboratory system so that we can get the supplies we need to provide SARS-CoV-2 testing.

Thank you for your time. I will follow up with Tim Stenzel this evening by phone.

Tim

Tim Southern, PhD, D(ABMM)
Public Health Laboratory Director | *Division of Administration*
SOUTH DAKOTA DEPARTMENT OF HEALTH
605.773.3368 | 615 E 4th Street, Pierre | doh.sd.gov

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Friday, March 20, 2020 4:48 PM
To: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Southern, Tim <[redacted]>; Urban, Lori - RD, Washington, DC <lori.urban@usda.gov>; Giroir, Brett (OS) <[redacted]

Cc: FDA Commissioner <Stephen.Hahn@fda.hhs.gov>
Subject: RE: [EXT] South Dakota Call

Brett,
There are some problems with reagent orders being cancelled. Can you help?
Thx
S

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Date: March 20, 2020 at 5:28:16 PM EDT
To: Southern, Tim <[redacted (b)(6)]>, Urban, Lori - RD, Washington, DC <lori.urban@usda.gov>
Cc: Hahn, Stephen <SH1@fda.hhs.gov>, FDA Commissioner <Stephen.Hahn@fda.hhs.gov>
Subject: RE: South Dakota Call

Hi Dr. Southern,

On the phone with Gov. Noem and understand you didn't get some reagents you ordered. Can we jump on a call again tonight?

My cell is [redacted (b)(6)]

Best,
Tim

Timothy T. Stenzel, MD, PhD
Director, OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality

Center for Devices and Radiological Health
U.S. Food and Drug Administration
Timothy.Stenzel@fda.hhs.gov
Jennifer Campbell
Administrative Assistant

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Sent: Wednesday, March 18, 2020 5:52 PM
To: Southern, Tim <Tim.Southern@state.sd.us>; Urban, Lori - RD, Washington, DC <lori.urban@usda.gov>
Subject: RE: South Dakota Call

Tonight is good.

Look forward to it.

Best,
Tim

Timothy T. Stenzel, MD, PhD
Director, OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality

Center for Devices and Radiological Health
U.S. Food and Drug Administration
Timothy.Stenzel@fda.hhs.gov
Jennifer Campbell
Administrative Assistant

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

From: Southern, Tim <Tim.Southern@state.sd.us>
Sent: Wednesday, March 18, 2020 5:44 PM
To: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Urban, Lori - RD, Washington, DC <lori.urban@usda.gov>
Subject: RE: South Dakota Call

Yes, sir.

You were on a call today with APHL. Joanne Bartkus (MNPHL) asked a good question about using the new FDA process for state approval of local SARS-CoV-2 testing programs. We are being given the authority but we have limited information about process. I believe I understand the process now but I want to touch base quickly with you. Let's plan for a quick call. Not sure about time yet…still with the Sec. of Health right now.

Tim

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Sent: Wednesday, March 18, 2020 4:01 PM
To: Urban, Lori - RD, Washington, DC <lori.urban@usda.gov>
Cc: Southern, Tim <Tim.Southern@state.sd.us>
Subject: RE: [EXT] South Dakota Call

Hi Dr. Southern. Can we connect at 6 pm eastern or later?

My cell is **(b)(6)**

Best,
Tim

Timothy T. Stenzel, MD, PhD
Director, OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality

Center for Devices and Radiological Health
U.S. Food and Drug Administration
Timothy.Stenzel@fda.hhs.gov
Jennifer Campbell
Administrative Assistant

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

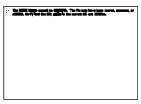
CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

From: Urban, Lori - RD, Washington, DC <lori.urban@usda.gov>
Sent: Wednesday, March 18, 2020 4:46 PM
To: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Cc: Tim.Southern@state.sd.us
Subject: South Dakota Call

Dr. Stenzel –
I apologize. The South Dakota leadership joined right after you disconnected.

Dr. Southern, whom heads the SD Labs had questions. I am connecting him with you.
If you could connect with him, we do not need to reschedule a call.

I appreciate your help! Thank you!



Lori Urban
Senior Advisor, Rural Development
United States Department of Agriculture
Rural Utilities Service #5138 South Building
1400 Jefferson Dr. SW, Washington DC 20250
Cell: (b)(6) Desk: (202) 720-1910

From: Caliguiri, Laura [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AA086F2D6C0346C49E996932D86AC62E-LAURA.CALIG]
Sent: 3/21/2020 5:27:44 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: RE: First rapid point-of-care coronavirus test gets FDA emergency use authorization

Been waiting on clearance, Brad pinged several times and I just re-upped **(b)(5)**

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Saturday, March 21, 2020 5:26 PM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: RE: First rapid point-of-care coronavirus test gets FDA emergency use authorization

Where are the tweets? Why didn't they go together?

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Saturday, March 21, 2020 5:25 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: RE: First rapid point-of-care coronavirus test gets FDA emergency use authorization

PR went out.

Stephanie Caccomo
Press Officer

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

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Saturday, March 21, 2020 5:24 PM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: FW: First rapid point-of-care coronavirus test gets FDA emergency use authorization

Did these go out?

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Saturday, March 21, 2020 5:15 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: Fwd: First rapid point-of-care coronavirus test gets FDA emergency use authorization

Tweets?

From: POLITICO Pro Health Care <politicoemail@politicopro.com>

Date: March 21, 2020 at 12:01:47 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: First rapid point-of-care coronavirus test gets FDA emergency use authorization

First rapid point-of-care coronavirus test gets FDA emergency use authorization

By David Lim

03/21/2020 12:00 PM EDT

The FDA has given emergency authorization for a rapid point-of-care coronavirus test that can deliver results in 45 minutes instead of hours, the test's manufacturer said Sunday.

The test could prove to be a critical development for hospitals that have struggled to get timely results from coronavirus tests now in use, which rely on a technique called real-time polymerase chain reaction that can take several hours to run.

By contrast, many point-of-care tests — for conditions such as flu or strep infection — can be processed quickly at a doctor's office. The point-of-care coronavirus test is made by Cepheid and runs on the company's GeneXpert System.

There are nearly 5,000 of the systems in the United States, the company said in a statement touting its technology as a tool to help alleviate the growing demand for coronavirus testing.

"An accurate test delivered close to the patient can be transformative — and help alleviate the pressure that the emergence of the 2019-nCoV outbreak has put on healthcare facilities that need to properly allocate their respiratory isolation resources," said David Persing, Cepheid's chief medical and technology officer.

Health providers to date have been shipping patient specimens to sophisticated labs to test. As a result, they have been waiting three to four days for commercial laboratories to report whether a patient has tested positive for the virus.

American Hospital Association President Rick Pollack told reporters Saturday that without readily available coronavirus tests, hospitals are "simply burning up [personal protective equipment] at unsustainable rates."

"If we had the tests and got the results quickly, we can free up PPE and hospital beds for those that really need the care," Pollack said.

An FDA spokesperson confirmed the agency granted an EUA to Cepheid.

To view online:
https://subscriber.politicopro.com/health-care/whiteboard/2020/03/first-rapid-point-of-care-coronavirus-test-gets-fda-emergency-use-authorization-3978294

Arlington, VA 22209
USA .

From: Caliguiri, Laura [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AA086F2D6C0346C49E996932D86AC62E-LAURA.CALIG]
Sent: 3/21/2020 5:31:05 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: RE: First rapid point-of-care coronavirus test gets FDA emergency use authorization

And appreciate his feedback an **(b)(5)**

(b)(5)

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Saturday, March 21, 2020 5:30 PM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: RE: First rapid point-of-care coronavirus test gets FDA emergency use authorization

Laura – work with Hahn on that, I am fine with that process.

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Sent: Saturday, March 21, 2020 5:29 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: RE: First rapid point-of-care coronavirus test gets FDA emergency use authorization

Can we agree **(b)(5)**

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Saturday, March 21, 2020 5:28 PM
To: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: RE: First rapid point-of-care coronavirus test gets FDA emergency use authorization

(b)(5)

From: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>
Sent: Saturday, March 21, 2020 5:25 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: RE: First rapid point-of-care coronavirus test gets FDA emergency use authorization

I sent these tweets up minutes ago.

Brad Kimberly
Director, Social Media

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-1002 | Cell: **(b)(6)**
brad.kimberly@fda.hhs.gov

FDA U.S. FOOD & DRUG ADMINISTRATION

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Saturday, March 21, 2020 5:24 PM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: FW: First rapid point-of-care coronavirus test gets FDA emergency use authorization

Did these go out?

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Sent: Saturday, March 21, 2020 5:15 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: Fwd: First rapid point-of-care coronavirus test gets FDA emergency use authorization

Tweets?

From: POLITICO Pro Health Care <politicoemail@politicopro.com>
Date: March 21, 2020 at 12:01:47 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: First rapid point-of-care coronavirus test gets FDA emergency use authorization

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By David Lim

03/21/2020 12:00 PM EDT

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By contrast, many point-of-care tests — for conditions such as flu or strep infection — can be processed quickly at a doctor's office. The point-of-care coronavirus test is made by Cepheid and runs on the company's GeneXpert System.

There are nearly 5,000 of the systems in the United States, the company said in a statement touting its technology as a tool to help alleviate the growing demand for coronavirus testing.

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“If we had the tests and got the results quickly, we can free up PPE and hospital beds for those that really need

the care," Pollack said.

An FDA spokesperson confirmed the agency granted an EUA to Cepheid.

To view online:
https://subscriber.politicopro.com/health-care/whiteboard/2020/03/first-rapid-point-of-care-coronavirus-test-gets-fda-emergency-use-authorization-3978294

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This email was sent to sh1@fda.hhs.gov by:
POLITICO, LLC
1000 Wilson Blvd.
Arlington, VA 22209
USA .

From: HHS Office of Public Affairs [hhsopa@hhs.gov]
Sent: 3/21/2020 6:27:55 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: HHS funds Phase 2/3 clinical trial for potential treatment for COVID-19

News Release

U.S. Department of Health and Human Services

202-205-8117
asprmedia@hhs.gov
www.hhs.gov/news
Twitter @SpoxHHS

FOR IMMEDIATE RELEASE
Saturday, March 21, 2020

HHS funds Phase 2/3 clinical trial for potential treatment for COVID-19

An antibody medicine being evaluated to treat severe cases of coronavirus disease 2019 (COVID-19) will receive additional support from the U.S. Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response (ASPR) under an existing partnership with Regeneron Pharmaceuticals of Tarrytown, New York.

The Biomedical Advanced Research and Development Authority (BARDA) within ASPR will provide support for a U.S. Phase 2/3 clinical trial to evaluate Kevzara as a potential treatment for severely ill COVID-19 patients. Currently, Kevzara is approved by the U.S. Food and Drug Administration for the treatment of rheumatoid arthritis. Kevzara was developed under a collaboration between Regeneron and Sanofi; the companies continue to collaborate on studying Kevzara for COVID-19, with Regeneron leading U.S.-based trials and Sanofi leading trials outside the U.S.

"We are working at a record pace with our private sector partners to speed development of therapeutic treatments for people with COVID-19," said BARDA Director Rick A. Bright, PhD. "By repurposing a currently approved product, we may be able to expedite development and make treatments available quickly."

Patients with COVID-19 are at risk of developing life-threatening respiratory failure, which may be mediated in part by elevated levels of a series of pro-inflammatory molecules, including interleukin-6 (IL-6). Kevzara is a fully-human monoclonal antibody that binds to the IL-6 receptor on normal cells and may improve patient outcomes by decreasing the severe inflammatory response.

The role of IL-6 is supported by preliminary uncontrolled data from a Chinese trial of a different IL-6 agent, which showed rapid reductions in fever in all patients and improvements in oxygenation. The Phase 2/3 clinical trial will determine if Kevzara can be used as a safe and effective therapy to reduce the amount of time that a person infected with the novel coronavirus remains ill. The first part of the trial will evaluate the impact of Kevzara on fever and patients' need for supplemental oxygen. The second, larger part of the trial will evaluate the improvement in longer-term outcomes, including whether it can prevent death and reduce the need for mechanical ventilation, supplemental oxygen, and/or hospitalization.

This partnership with Regeneron is among the first to be issued by BARDA with funding from the H.R.6074 – Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 that was passed by the U.S. Congress and signed by President Trump on March 6, 2020.

HHS continues to work across the U.S. government, including with the Department of Defense, to review potential products from public and private sectors to identify promising candidates that could detect, protect against, or treat COVID-19 for development and FDA approval/clearance.

In addition to this adaptive Phase 2/3 clinical trial with Kevzara, one other HHS-funded trial of an investigational COVID-19 treatment is ongoing. The National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), is sponsoring a randomized controlled clinical trial to evaluate the safety and efficacy of the investigational antiviral remdesivir in hospitalized adults.

"Proven treatment options for COVID-19 are urgently needed. This trial of Kevzara is critical to inform doctors on treatment options for COVID-19," said HHS Secretary Alex Azar. "The close collaboration between BARDA, the FDA, and Regeneron to initiate this trial as soon as possible again demonstrates the speed at which we are responding to this pandemic."

HHS divisions, including NIH and ASPR, are supporting the development of multiple diagnostic tests, vaccines, and potential therapeutic treatments for COVID-19. BARDA continues to seek partners for COVID-19 medical countermeasures, and offers multiple ways to submit proposals for potential new products or technologies.

About HHS, ASPR, and BARDA

HHS works to enhance and protect the health and well-being of all Americans, providing for effective health and human services and fostering advances in medicine, public health, and social services. The mission of ASPR is to save lives and protect Americans from 21st century health security threats. Within ASPR, BARDA invests in the innovation, advanced research and development, acquisition, and manufacturing of medical countermeasures – vaccines, drugs, therapeutics, diagnostic tools, and non-pharmaceutical products needed to combat health security threats. To date, 54 BARDA-supported products have achieved regulatory approval, licensure or clearance.

###

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From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 3/21/2020 6:34:30 PM
To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
Subject: RE: for IMMEDIATE review: ventilator PR

Ha! Excellent.

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Saturday, March 21, 2020 6:34 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: for IMMEDIATE review: ventilator PR

Yes, PR is much, much better.

Stephanie Caccomo
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk 301.348 1956
Cell (b)(6)
stephanie.caccomo@fda.hhs.gov

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Saturday, March 21, 2020 6:28 PM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: RE: for IMMEDIATE review: ventilator PR

Did we (b)(5) ?

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Saturday, March 21, 2020 6:09 PM
To: CDRH COVID19 Leadership Team <CDRHCOVID19@fda.hhs.gov>; OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>; Mednick, David <David.Mednick@fda.hhs.gov>; Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Krueger, Angela C <Angela.Krueger@fda.hhs.gov>; 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>
Cc: Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: for IMMEDIATE review: ventilator PR

Hi folks—
Major revisions to the ventilator PR going today, I appreciate your urgent review in next hour.

OF NOTE- (b)(5) (b)(5) Please help me in keeping this PR as lay person friendly as possible, while keeping it technically accurate. Thank you.

I appreciate your edits in sharepoint, but I'm copying whole PR below for awareness.

(b)(5)

(b)(5)

Stephanie Caccomo
Press Officer

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

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 3/21/2020 7:45:42 PM
To: Caliguiri, Laura (Laura.Caliguiri@fda.hhs.gov) [Laura.Caliguiri@fda.hhs.gov]
Subject: FW: FDA 2019-nCOV SITREP - 21 March 2020
Attachments: 42_2019-nCoV Outbreak_FDA SITREP_21 March 2020.docx

Do we have slimmed down version for Joe?

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Saturday, March 21, 2020 7:44 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Sigg, Jim <Jim.Sigg@fda.hhs.gov>; Hebert, Angelique A. <Angelique.Hebert@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Tootle, William <William.Tootle@fda.hhs.gov>; Carter, Lionel <Lionel.Carter@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Solomon, Steven M <Steven.Solomon@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rogers, Michael <Michael.Rogers@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>; Abdoo, Mark <Mark.Abdoo@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Branch, Tiffany <Tiffany.Branch@fda.hhs.gov>; Tse, Tania <Tania.Tse@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Musser, Steven M <Steven.Musser@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Throckmorton, Douglas C <Douglas.Throckmorton@fda.hhs.gov>; Solberg, Tim <Tim.Solberg@fda.hhs.gov>; Tyler, James <James.Tyler@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>
Cc: Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Tyler, James <James.Tyler@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Malais, Tanya <Tanya.Malais@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; O'Callaghan, Kathryn <Kathryn.OCallaghan@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>; Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Ross, Bruce <Bruce.Ross@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Measer, Gregory <Gregory.Measer@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Rubinstein, Wendy <Wendy.Rubinstein@fda.hhs.gov>; Helms Williams, Emily <Emily.HelmsWilliams@fda.hhs.gov>
Subject: RE: FDA 2019-nCOV SITREP - 21 March 2020

Hi,

Attached for your situational awareness is the 21 March FDA 2019-nCoV SITREP.

Please do not share outside of FDA and consider restricting further internal distribution to those involved in the response as much of this information is very sensitive, close hold, internal as identified in the attached document.

Many thanks for your continued support. -Michael

From: Gross, Karas [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0B6D3DC4EE4B415D86EC634C536453B6-KARA.GROSS]
Sent: 3/21/2020 8:39:12 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: FW: Compassionate Use still on Gilead website

See below. Where are you seeing an announcement?

From: Black, Jennifer <Jennifer.Black@fda.hhs.gov>
Sent: Saturday, March 21, 2020 7:00 PM
To: Gross, Karas <Karas.Gross@fda.hhs.gov>
Subject: Compassionate Use still on Gilead website

There is no press anywhere that EA is stopping and compassionate use for remdesivir is still listed on Gilead's website, but it was last updated 2/26/2020, here: https://www.gilead.com/purpose/advancing-global-health/covid-19

From Webpage:

"Compassionate Use

Gilead is working with government and non-government organizations and regulatory authorities to provide remdesivir to patients with COVID-19 for emergency treatment in the absence of any approved treatment options.

Compassionate use requests must be submitted by a patient's treating physician. Gilead is currently assessing requests on an individual basis and require, at a minimum, that the patient be hospitalized with confirmed COVID-19 infection with significant clinical manifestations.

Access to Remdesivir and Future Study

Gilead is mapping out options to make access to investigational remdesivir more widely available through appropriate channels for emergency use should it demonstrate the potential to be a safe and effective treatment option based on the results of preliminary clinical trials.

Gilead is also in discussions with regulatory agencies to determine the most appropriate pathway for submitting remdesivir for approval for the treatment of COVID-19 in the event the trial results are positive.

Finally, Gilead is in discussion with multiple organizations regarding the potential for future trials.

For More Information:

Please contact Gilead via email with any questions by clicking here.

Last Updated: February 26, 2020"

Jennifer R. Black, J.D.
Congressional Affairs Specialist

Office of Legislation
U.S. Food and Drug Administration
Tel: 301-796-9607
jennifer.black@fda.hhs.gov

From: Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]
Sent: 3/21/2020 8:50:04 PM
To: Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]
Subject: Re: Compassionate Use still on Gilead website

They flagged for us.

Sent from my iPhone

On Mar 21, 2020, at 8:39 PM, Gross, Karas <Karas.Gross@fda.hhs.gov> wrote:

See below. Where are you seeing an announcement?

From: Black, Jennifer <Jennifer.Black@fda.hhs.gov>
Sent: Saturday, March 21, 2020 7:00 PM
To: Gross, Karas <Karas.Gross@fda.hhs.gov>
Subject: Compassionate Use still on Gilead website

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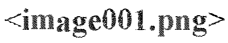
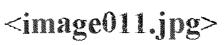
Last Updated: February 26, 2020"

Jennifer R. Black, J.D.
Congressional Affairs Specialist

Office of Legislation
U.S. Food and Drug Administration
Tel: 301-796-9607
jennifer.black@fda.hhs.gov





From: Sheehy, Janice [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F45A6C96F5274724A1BE5970EB648FF7-JSHEEHY]
Sent: 3/22/2020 7:53:18 AM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
CC: Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]
Subject: FW: Information for WHTF March 22.docx
Attachments: Information for WHTF March 22.docx

Will one of you be sharing this with SH?

From: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Sent: Sunday, March 22, 2020 7:44 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Cc: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: Information for WHTF March 22.docx

Good Morning,

Attached is information for the TF meeting today. Includes info on ventilator guidance and chloroquine supply. CCI is in red

Thanks,

Carly

From: Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]
Sent: 3/22/2020 8:41:59 AM
To: Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
CC: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]
Subject: Re: Need some help and I figure I should start going through you now

Thx.

Sent from my iPhone

On Mar 22, 2020, at 8:36 AM, Shah, Anand <Anand.Shah@fda.hhs.gov> wrote:

I just spoke with him – thanks

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Saturday, March 21, 2020 7:47 PM
To: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: RE: Need some help and I figure I should start going through you now

Thanks Jeff. Anand, can you get back to Mayo?

From: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Sent: Saturday, March 21, 2020 5:52 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: Re: Need some help and I figure I should start going through you now

Where they should go is to healthcare facilities that have seen a high volume of infected patients for a reasonable period of time as patients who are early in their infection may not yet have developed antibodies. **(b)(5)**

(b)(5)

Jeff

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Date: March 21, 2020 at 5:40:22 PM EDT
To: Marks, Peter <Peter.Marks@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: FW: Need some help and I figure I should start going through you now

Is this **(b)(5)**

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Saturday, March 21, 2020 5:07 PM

To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: Need some help and I figure I should start going through you now

Senator Klobuchar contacted me about some needs for the Mayo Clinic Lab as they develop a serologic test for COVID-19.
They need blood samples from people who have been infected with the virus within the last 10 days. Not sure who can provide the samples.
Mayo Clinic Lab Director
Dr. Farugia
(b)(6)

The other heads up is that the University of Minnesota will be submitting a EUA for their own LDT.

Thanks
Steve

From: Caccomo, Stephanie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=950C32CEBC4B4F80B302C50CF31C8524-STEPHANIE.C]
Sent: 3/22/2020 12:33:46 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Guram, Jeet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ef73bea97e2b477b847ea302c4730ccf-Gurjeet.Gur]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; McWilliams, Carly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: talkers for today's pressser
Attachments: WHTF-3.22.20.docx; topline responsive language_3.22.20.docx

Two docs—

Talking points if he needs them (not sure what topic is, so focused on all FDA activities)

Responsive talking points, that include **(b)(5)**

Anand/Jeet—does basic language or **(b)(5)** look ok?

Stephanie Caccomo
Press Officer

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

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 3/22/2020 5:51:34 PM
To: Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
Subject: FW: COVID-19 Serologic Tests

Team working together cross center. Examples I will start forwarding you to message on. Thanks!

From: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Sent: Sunday, March 22, 2020 5:41 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: COVID-19 Serologic Tests

Peter,

Kudos to you on the work you are doing to help treat patients with COVID-19. I appreciate the importance of identifying patients with an antibody response to the virus. Under a new policy we issued earlier this week, developers of serologic tests do not need to get authorization from the FDA to market these tests if they have completed their validation, notified us of their intent via email, and included certain statements in their labeling. For those Test developers who have met those criteria, we post their names on our website. I will send you the link to the webpage in a separate email.

(b)(5)

Please let me know if there is anything we at CDRH can do to help.

Jeff

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 3/22/2020 7:24:29 PM
To: Shuy, Bryan (OS/ASPR/IO) [Bryan.Shuy@hhs.gov]
Subject: RE: [EXTERNAL] Breakthrough technology to control virus spread (Synexis)

(b)(5)

-----Original Message-----
From: Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>
Sent: Sunday, March 22, 2020 7:02 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: [EXTERNAL] (b)(4)

(b)(5)

-----Original Message-----
From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Sunday, March 22, 2020 6:49 PM
To: Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>
Subject: RE: [EXTERNAL] (b)(4)

(b)(5)

-----Original Message-----
From: Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>
Sent: Sunday, March 22, 2020 6:47 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: [EXTERNAL] (b)(4)

(b)(5)

-----Original Message-----
From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Sunday, March 22, 2020 6:44 PM
To: Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>
Subject: RE: [EXTERNAL] (b)(4)

Thanks for heads up. Whats the (b)(6)?

-----Original Message-----
From: Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>
Sent: Sunday, March 22, 2020 6:40 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: FW: [EXTERNAL] (b)(4)

(b)(5)

-----Original Message-----
From: COVIDMail <(b)(6)>
Sent: Sunday, March 22, 2020 6:17 PM
To: Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>
Subject: FW: [EXTERNAL] (b)(4)

Bryan,

To follow up on our phone conversation, please see below. Would you mind sending an email back to us here at (b)(6) once you have further information regarding this offer?

Thanks!

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

From: Michael, Molly A. EOP/WHO <(b)(6)>
Sent: Sunday, March 22, 2020 3:34 PM
To: COVIDMail <(b)(6)>
Cc: Williams, Michael B. EOP/WHO <(b)(6)>
Subject: FW: [EXTERNAL] Breakthrough technology to control virus spread (b)(4)

Please see below!

-----Original Message-----
From: John Myers <(b)(6)>
Sent: Sunday, March 22, 2020 9:50 AM
To: Michael, Molly A. EOP/WHO <(b)(6)>
Cc: James Lee <(b)(6)>
Subject: [EXTERNAL] (b)(6)

Molly, thanks for taking my call this morning. I appreciate you bringing this to the attention of the President or the appropriate individual he designates to follow up.
My cell is (b)(6). Our chief scientist is James Lee ((b)(6) jlee@s(b)(6).com) who is the most knowledgeable about the technology and the product. Attached is the (b)(4) website.

Mr President,

We believe we have a game changer to control the spread of the Coronavirus. A Company I am involved with,

(b)(4)

(b)(4)

As you've said in your daily briefings, the US has the most innovative private sector in the world and you believe they will help combat and defeat this deadly virus. I'm confident that your team when they review Synexis results will agree this technology can be part of the solution.

Finally, thank you Mr President for all you are doing to safeguard our Country. We've known each other for more than 25 years and I've never been more proud of our relationship than now.
God bless and God speed.

John Myers

>https://protect2.fireeye.com/url?k=81d2d260-dd87dbb0-81d2e35f-0cc47a6a52de-b2641add1edb3f6c&u=https://protect2.fireeye.com/url?k=52b3114b-0ee70837-52b32074-0cc47adc5fa2-c02ef0434332c50d&u=https://protect2.fireeye.com/url?k=ad5773b8-f1036ac4-ad574287-0cc47adc5fa2-0499de4af1804380&u=https://synexis.com/<

Sent from my iPad

From: Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]
Sent: 3/23/2020 8:16:52 AM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
Subject: Re: Update 1.2: Schedule for Monday, March 23rd

Whatever works with schedule. 11:30 is great.

Sent from my iPhone

On Mar 23, 2020, at 8:10 AM, Hinton, Denise <Denise.Hinton@fda.hhs.gov> wrote:

Janice asked for 1130 so would you like 1100 or 1130?

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Monday, March 23, 2020 7:24 AM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: Fwd: Update 1.2: Schedule for Monday, March 23rd

Task force is at 4pm today. So 11 am AEG?

Sent from my iPhone

Begin forwarded message:

From: "Hahn, Stephen" <SH1@fda.hhs.g●v>
Date: March 23, 2020 at 6:46:32 AM EDT
To: "Olivarria, Frank" <Frank.Olivarria@fda.hhs.g●v>
Cc: "Sheehy, Janice" <Janice.Sheehy@fda.hhs.g●v>, "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>, "Shah, Anand" <Anand.Shah@fda.hhs.g●v>, "Rom, Colin" <C●lin.R●m@fda.hhs.g●v>, "Copeland, Jakea" <Jakea.C●peland@fda.hhs.g●v>
Subject: RE: Update 1.2: Schedule for Monday, March 23rd

Or also move AEG to 11 and we can do the media prep from 12 to 1:30?
Thanks

From: Olivarria, Frank <Frank.Olivarria@fda.hhs.g●v>
Date: March 22, 2020 at 10:49:45 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.g●v>
Cc: Sheehy, Janice <Janice.Sheehy@fda.hhs.g●v>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.g●v>, Shah, Anand <Anand.Shah@fda.hhs.g●v>, Rom, Colin <C●lin.R●m@fda.hhs.g●v>, Copeland, Jakea <Jakea.C●peland@fda.hhs.g●v>
Subject: RE: Update 1.2: Schedule for Monday, March 23rd

2020.03.23 Background from WH TF Meeting, has been updated since the 10:39 PM message:

Denise: *one edit re: ventilator guidance, below:*

- <!--[if !supportLists]--><!--[endif]-->***Ventilator supply strategies for HCPs guidance***

FDA will issued an immediately in effect guidance on March 22 to provide a policy for expanding the availability of ventilators and accessories as well as other respiratory devices during the COVID-19 pandemic.

Attached (updated doc).

From: Olivarria, Frank
Sent: Sunday, March 22, 2020 10:39 PM
To: Hahn, Stephen (SH1@fda.hhs.gov) <SH1@fda.hhs.gov>
Cc: Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: Update 1: Schedule for Monday, March 23rd

Updates in green.

Your first call is scheduled for 7:10 AM: *Quick Touch Point: Media[Stephanie Caccomo will call your cell] (your first in-person will be at 10:30 AM at HHS, you will be at HHS until 2 PM, when you depart for the WH, and you will return back to HHS by 7:50 PM for Remote Media Interview with Tucker Carson [from the HHS Studio])*

7:10-7:15 am Quick Touch Point: Media
Note: Materials attached. POC: Stephanie Caccomo will call you (her number is: (b)(6))

7:15-7:30 am Telecon: Radio Interview - Boston radio: The Kuhner show
*Note: Materials attached, same as 7:10 AM: Quick Touch Point: Media call. You are to call: Brittney Jennings: (**(b)(6)**, NLT 7:15 AM*

7:30-7:45 am Telecon: Radio Interview - Steve Gruber Show, Flint, Michigan
*Note: Materials attached, same as 7:10 AM: Quick Touch Point: Media call. You are to call: Ivey: **(b)(6)** **(b)(6)** NLT 7:30 AM*

7:45-7:55 am Telecon: Radio Interview - Bloomdaddy (David), Pittsburgh, Host: BLOOMDADDY (DAVID)
*Note: Materials attached, same as 7:10 AM: Quick Touch Point: Media call. You are to call: **(b)(6)** (back up just in case): **(b)(6)**, NLT 7:45 AM*

8:00-8:30 am TELECON ONLY: Commissioner's Daily Check-In
*Note: Dial-In (1-877-465-7975,,, **(b)(6)** #)*

10:00 am Uber to HHS

10:30-12:00 pm Media Prep: Tucker Carlson Interview
Note: Location – HHS Studio (pending confirmation from Laura, otherwise will be in FDA Suite). Materials attached, same as 7:10 AM: Quick Touch Point: Media call.

10:00-12:00 pm HOLD: White House Buffer

12:00-1:00 pm COVID-19 AED Meeting
Note: Dial-In (1-877-465-7975,, (b)(6)#)

2:00 pm Travel to WH

2:00-2:30 pm Telecon: Weekly CFSAN Meeting with the Commissioner
Note: Agenda attached. Dial-In (1-877-465-7975,,, (b)(6)#). You will take this call en route to the WH, however we are attempting to move the call up to 1:15 PM to avoid you having to take this en route – will text you and Colin if this changes.

2:30-3:00 pm Clear White House Security

3:00-3:30 pm Telecon: Senator Richard Durbin and Commissioner Hahn
Note: You will take this call at the WH, so avoid taking it en route to the WH. Materials attached, additional TP's on COVID-19 forthcoming. Dial-In (1-888-913-9943,, (b)(6)#).

3:30-4:00 pm Telecon: Bi-Weekly Check-In: AAbernethy / Dr. Hahn

3:50 pm Walk to WHSR for WHTF Meeting

4:00-5:00 pm White House Coronavirus Task Force Meeting
Note: Agenda and seating chart forthcoming. Janice will forward once received.

5:00 pm Travel to TBD (HHS or Residence)

6:00-6:30 pm Daily Check-In
Note: Dial-In (1-877-465-7975)

7:15 pm Travel to HHS (from residence, if not already at HHS)

7:45 pm Walk to HHS Studio

8:00-8:30 pm Interview (Remote): Tucker Carlson
Note: Materials attached, same as 7:10 AM: Quick Touch Point: Media call. The interview will be for

---

Reading Material(s):
1. *nCoV Outbreak SITREP: March 22, 2020*, attached
2. 2020.03.23 Background from WH TF Meeting, attached

Calendar Snapshot:
<image001.png>

All Materials: LINK

From: Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]
Sent: 3/23/2020 8:57:47 AM
To: Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]
CC: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]
Subject: Re: [EXTERNAL] Re: McKesson Action Items

Great work Suzanne!

Sent from my iPhone

On Mar 23, 2020, at 8:48 AM, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov> wrote:

(b)(5)

Suzanne B. Schwartz, MD, MBA
Deputy Director (& Acting Office Director) Office of Strategic Partnerships & Technology Innovation
Center for Devices and Radiological Health (CDRH)
Office of Strategic Partnerships and Technology Innovation (OST)
U.S. Food and Drug Administration
WO66, Room 5410
Tel: 301-796-6937
Cell: (b)(6)
Suzanne.Schwartz@fda.hhs.gov
<image002.png>
<image003.jpg>

<image004.jpg>

<image005.jpg>

<image006.jpg>

<image007.jpg>
Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

From: McComb, Stanton <(b)(6)>
Sent: Monday, March 23, 2020 8:20 AM
To: Ryan Holleran <(b)(6)>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
Cc: Bowen, Patrick A <Patrick.Bowen@fda.hhs.gov>; Rachael Baitel <(b)(6)>; Mango, Paul (OS) <Paul.Mango@hhs.gov>; (b)(6); DeBorde, Kevin <(b)(6)>; Slone, Pete <(b)(6)>; Haywood, Deborah <(b)(6)>
Subject: RE: [EXTERNAL] Re: McKesson Action Items

Ryan:

I just spoke with our agent. The product is still there for us. I never told him to ship last night, hoping that you guys might change your mind.

And, yes, Ryan, Deborah can take it from here and coordinate the execution of this order, we just need something in writing authorizing us to do so under these flexible conditions set forth by Suzanne.

Thanks, Stanton

From: Ryan Holleran <(b)(6)>
Sent: Monday, March 23, 2020 8:16 AM
To: Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
Cc: McComb, Stanton <(b)(6)>; Bowen, Patrick A <Patrick.Bowen@fda.hhs.gov>; Rachael Baitel <rbaitel@usaid.gov>; Mango, Paul (OS) <Paul.Mango@hhs.gov>; (b)(6); DeBorde, Kevin <(b)(6)>; Slone, Pete <(b)(6)>; Haywood, Deborah <(b)(6)>
Subject: Re: [EXTERNAL] Re: McKesson Action Items

This is great news. (b)(4)

Stanton - Let us know if this has not been released. I know we owe you some logistical items. Can I list Deborah Haywood as the primary contact?

Ryan

On Mon, Mar 23, 2020 at 6:21 AM Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov> wrote:

Stanton,

(b)(4)

Suzanne B. Schwartz, MD, MBA
Deputy Director (& Acting Office Director) Office of Strategic Partnerships & Technology Innovation (OST)
Center for Devices & Radiological Health
US Food & Drug Administration
Office: 301-796-6937
Mobile: (b)(6)

From: McComb, Stanton <(b)(6)>
Date: March 22, 2020 at 9:33:18 PM EDT
To: Ryan Holleran <(b)(6)>, Bowen, Patrick A <Patrick.Bowen@fda.hhs.gov>, Rachael Baitel <(b)(6)>, Mango, Paul (OS) <Paul.Mango@hhs.gov>, (b)(6) <(b)(6)>, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
Cc: DeBorde, Kevin <(b)(6)>, Slone, Pete <(b)(6)>, Haywood, Deborah <(b)(6)>
Subject: RE: [EXTERNAL] Re: McKesson Action Items

Including Suzanne Schwartz per Ryan's last email. Hello Suzanne. Thank you for your consideration of these issues. Regards, Stanton McComb, McKesson

From: McComb, Stanton
Sent: Sunday, March 22, 2020 9:31 PM
To: Ryan Holleran <(b)(6)>; patrick.bowen@fda.hhs.gov; Rachael Baitel <(b)(6)>; Paul Mango (paul.mango@hhs.gov) <paul.mango@hhs.gov> (b)(6)
Cc: DeBorde, Kevin <(b)(6)>; Slone, Pete <(b)(6)>; Haywood, Deborah <(b)(6)>
Subject: RE: [EXTERNAL] Re: McKesson Action Items

Dear Paul, Rachael, Dennis, Patrick, and Ryan:

(b)(4)

Thank you,

Stanton

From: Ryan Holleran <(b)(6)>
Sent: Sunday, March 22, 2020 8:31 PM
To: McComb, Stanton <(b)(6)>; patrick.bowen@fda.hhs.gov
Cc: (b)(6) DeBorde, Kevin <(b)(6)>; Slone, Pete <(b)(6)>
Subject: Re: [EXTERNAL] Re: McKesson Action Items

Stanton - Adding @patrick.bowen@fda.hhs.gov. Thank your for your patience here, we went very high up in the FDA. The summary is that this can be imported, however they would need to be relabeled before distribution.

> Considering the status of this particular shipment, if the product is not able to be relabeled prior to importation into the U.S., the product will need to be relabeled in the U.S. prior to distribution.

What is McKesson's capacity or ability to do this?

I promise you we're setting up a process for FDA approval/authorization to happen before we start organizing pickup moving forward.

Ryan

Surgical masks provide protection against large droplets, splashes or sprays of bodily or hazardous fluids. They do not provide the wearer with reliable protection from inhaling smaller airborne particles and are not considered respiratory protection. FDA regulates surgical masks as Class II devices and assesses them for liquid barrier protection among other things.

FDA recognizes the urgent need for face masks in the setting of the COVID-19 pandemic due to increased use and shortages in their availability.

FDA does not object to the marketing and distribution of face masks in the healthcare setting without prior 510(k) clearance if the product is labeled in the following manner:

1. It states it may be used when FDA cleared masks are unavailable;
2. It recommends against use in a surgical setting or where significant exposure to liquid bodily or other hazardous fluids may be expected;
3. It makes no claims of antimicrobial or antiviral protection;
4. It makes no claims of infection prevention or reduction;
5. It makes no claims regarding flammability
6. The labeling contains a list of the body contacting materials.
7. The mask is not labeled as a "surgical mask"; rather it may be labeled as a "face mask"

In addition, FDA does not intend to object to marketing of masks that meet the above criteria even if they are manufactured at facilities that do not meet 21 CFR 820.

Considering the status of this particular shipment, if the product is not able to be relabeled prior to importation into the U.S., the product will need to be relabeled in the U.S. prior to distribution.

Best,

Best,

Ryan

On Sun, Mar 22, 2020 at 5:57 PM McComb, Stanton <(b)(6)> wrote:

Ryan, ASAP:

- Note, we just sent you the invoice.
- We need the FDA release of some sort for those Mexican masks.

- (b)(4)

From: Ryan Holleran <(b)(6)>
Sent: Sunday, March 22, 2020 5:54 PM
To: McComb, Stanton <(b)(6)>
Subject: Re: [EXTERNAL] Re: McKesson Action Items

Thank you Stanton. I am including this screenshot in my brief to the procurement team. Please send any and all information (including the invoice est. for the masks) if you get it. Shipping stuff over at 7. Sorry for any fire drills.

Ryan

On Sun, Mar 22, 2020 at 3:21 PM McComb, Stanton <(b)(6)> wrote:

They are working on it. It looks like it is actually 3.6 million kilograms. I have a summary pasted below but I am getting more specific details that fit your requirements.

CN stands for China. MY stands for Malaysia. CBM equals Cubic Meters and CS stands for Cases. We are pretty confident that all of the items within these categories are on your list.

<image001.png>

From: Ryan Holleran <(b)(6)>
Sent: Sunday, March 22, 2020 3:05 PM
To: McComb, Stanton <(b)(6)>
Subject: Re: [EXTERNAL] Re: McKesson Action Items

(b)(4)

On Sun, Mar 22, 2020 at 3:01 PM McComb, Stanton <(b)(6)> wrote:

Ok, thanks

From: Ryan Holleran <(b)(6)>
Sent: Sunday, March 22, 2020 2:55 PM
To: McComb, Stanton <(b)(6)>
Cc: (b)(6) Bashore, Elizabeth <(b)(6)>; Haywood, Deborah <(b)(6)>
Subject: Re: [EXTERNAL] Re: McKesson Action Items

Stanton and team - outstanding items are being worked on, on our end, including shipping destination for the invoice, and FDA guidance; we've initiated review of this mask manufacturer.

FAQs on Shortages of Surgical Masks and Gowns

The FDA is collaborating with manufacturers of personal protective equipment (PPE) to help facilitate mitigation strategies related to the COVID-19 outbreak. The FDA's door is open, and we are available to collaborate with stakeholders.

To help alleviate supply pressures, the FDA may consider expedited review of manufacturing site changes or premarket submissions—manufacturers of PPE (particularly surgical masks and surgical or isolation gowns) may contact FDA regarding plans to increase availability of these products to the U.S. market. https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/faqs-shortages-surgical-masks-and-gowns

FDA Emergency Use Authorization for COVID-related PPE and test kits

https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ppe

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On Sun, Mar 22, 2020 at 1:31 PM McComb, Stanton <Stanton.McComb@mckesson.com> wrote:

Dear Jerry:

When you know, can you let us (me and those copied here) know who, in Mexico, will be picking up the products so that we can confirm their identity at time of transfer?

Thank you,

Stanton McComb

From: Ryan Holleran <(b)(6)>
Sent: Sunday, March 22, 2020 12:50 PM
To: McComb, Stanton <(b)(6)>
Cc: Rachael Baitel <(b)(6)>; robert.charrow@hhs.gov; Slone, Pete <(b)(6)>; Gibney, Kelly <(b)(6)>; Birken, Andy <(b)(6)>; Paul Mango (paul.mango@hhs.gov) <paul.mango@hhs.gov>; (b)(6) Haywood, Deborah <(b)(6)>
Subject: Re: [EXTERNAL] Re: McKesson Action Items

Adding Jerry from FEMA logistics. See below please.

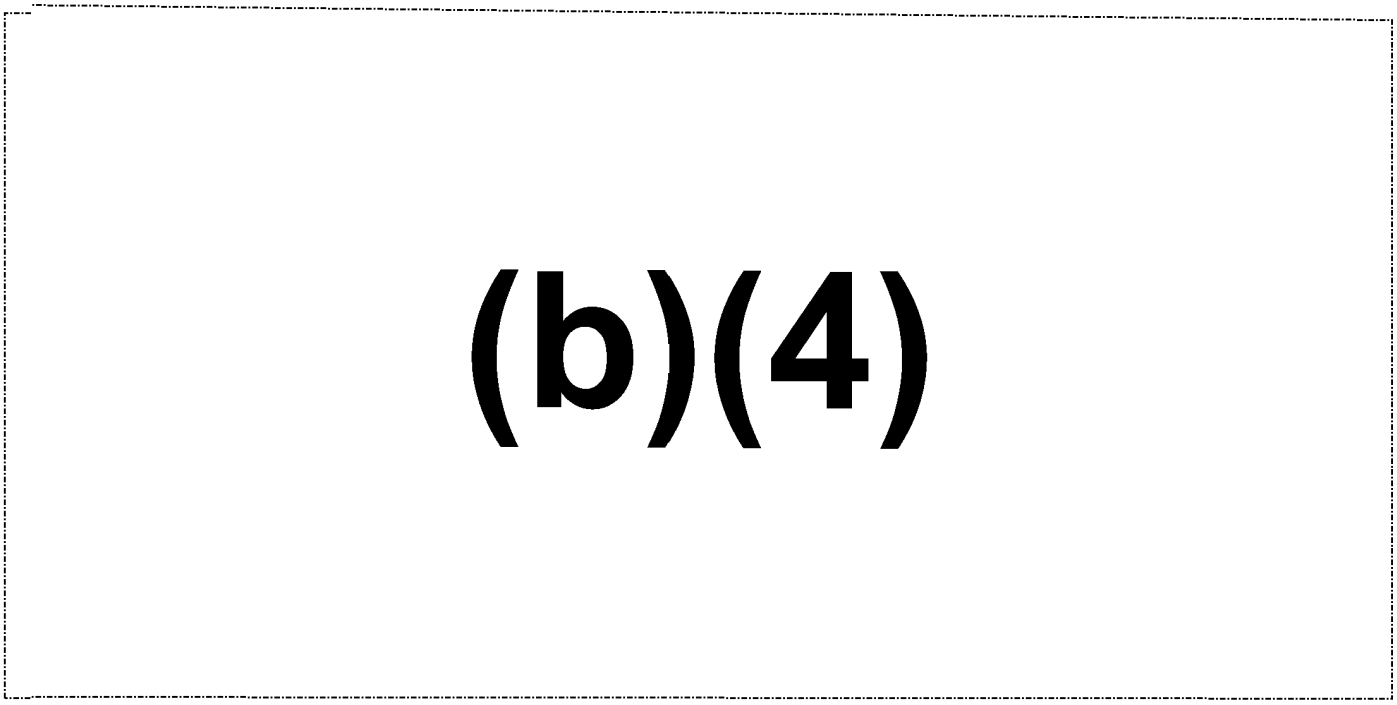
On Sun, Mar 22, 2020 at 12:45 PM McComb, Stanton <(b)(6)> wrote:

Ryan:

Here are the answers to your questions:

- (b)(4)

• Dimensions:



Ryan

On Sun, Mar 22, 2020 at 11:56 AM Rachael Baitel <(b)(6)> wrote:

Dennis is calling you now. What's the best number to reach you?

On Sun, Mar 22, 2020 at 11:53 AM McComb, Stanton (b)(6) wrote:

Hi Rachael:

I am waiting for word from you to "hit go." Can we catch up very briefly by phone now; can I call you?

Thanks, Stanton

From: Rachael Baitel <(b)(6)>
Sent: Sunday, March 22, 2020 11:45 AM
To: McComb, Stanton <(b)(6)>
Cc: robert.charrow@hhs.gov; Slone, Pete <(b)(6)>; Gibney, Kelly <(b)(6)>; Birken, Andy <(b)(6)>; Paul Mango (paul.mango@hhs.gov) <paul.mango@hhs.gov>; (b)(6)
Subject: [EXTERNAL] Re: McKesson Action Items

CAUTION: This email was sent from an EXTERNAL source. Use caution when clicking links or opening attachments.

Hi Stanton, Just checking in on the offers. Let me know where we stand. We're ready to make a decision.

On Sun, Mar 22, 2020 at 7:06 AM McComb, Stanton <Stanton.McComb@mckesson.com> wrote:

Good morning Rachael:

I am sorry to bother you first thing in the morning, but I have not heard back from you on either of the opportunities below. We have time on the second opportunity, but I am afraid that we may run out of time on the first offer and lose that chance to get 1 million surgical masks from Mexico. Do you have any sense for what you guys might want to do here? I told them that I would have an answer by 8AM. If you don't think you are going to buy these masks, please let me know so that we can cut them lose and allow them to flow to Europe.

Thank you, Stanton McComb, McKesson

From: McComb, Stanton
Sent: Saturday, March 21, 2020 6:40 PM
To: Rachael Baitel <(b)(6)>
Cc: robert.charrow@hhs.gov; Pete Slone ((b)(6)) <(b)(6)>; Gibney, Kelly <Kelly.Gibney@McKesson.com>; Birken, Andy <Andy.Birken@McKesson.com>; Paul Mango (paul.mango@hhs.gov) <paul.mango@hhs.gov>; (b)(6)
Subject: McKesson Action Items

Dear Racheal:

We have two opportunities for your immediate consideration.

Surgical Masks from Mexico

(b)(4)

We have attached several documents that will support the manufacturer and the products in question.

Accelerate PPE for McKesson and Its Non-Acute Providers, e.g. Nursing Homes

(b)(4)

Rachael, I know that there is a lot here, so thank you for taking the time to read through all of this and help our country. We appreciate your assistance and leadership.

Regards,

Stanton McComb

From: Gibney, Kelly <(b)(6)>
Sent: Saturday, March 21, 2020 5:55 PM
To: McComb, Stanton <(b)(6)>
Subject: Face Masks

Stanton- the following are the details on the surgical masks.

(b)(4)

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Cell: (b)(6)

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Cell: (b)(6)

--
Ryan Holleran
(b)(6)
LinkedIn

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Ryan Holleran
(b)(6)
LinkedIn

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Ryan Holleran
(b)(6)
LinkedIn

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Ryan Holleran
(b)(6)
LinkedIn

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Ryan Holleran
(b)(6)
LinkedIn

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Ryan Holleran
(b)(6)
LinkedIn

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Ryan Holleran
(b)(6)
LinkedIn

From: Caccomo, Stephanie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=950C32CEBC4B4F80B302C50CF31C8524-STEPHANIE.C]
Sent: 3/23/2020 9:05:18 AM
To: Guram, Jeet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ef73bea97e2b477b847ea302c4730ccf-Gurjeet.Gur]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; McWilliams, Carly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]
Subject: RE: Media Prep

Got it...adding to our toplines. Thanks!

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

-----Original Message-----
From: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Sent: Monday, March 23, 2020 9:03 AM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Subject: RE: Media Prep

(b)(5)

--
Jeet Guram, M.D.
Senior Advisor, Office of the Commissioner Food and Drug Administration
+1 (202) 230-0451 | jeet.guram@fda.hhs.gov

-----Original Message-----
From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Monday, March 23, 2020 8:39 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Subject: RE: Media Prep

On it

Stephanie Caccomo

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

-----Original Message-----
From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Monday, March 23, 2020 8:23 AM
To: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Cc: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: Media Prep

Can we get these before 10 pls?
From SH:

I'll need high level stats on hydroxychloroquine availability for the prep.

Also need some specific examples of regulatory flexibility to feed the press

Sent from my iPhone

From: Caccomo, Stephanie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=950C32CEBC4B4F80B302C50CF31C8524-STEPHANIE.C]
Sent: 3/23/2020 9:08:37 AM
To: Guram, Jeet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ef73bea97e2b477b847ea302c4730ccf-Gurjeet.Gur]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; McWilliams, Carly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]
Subject: RE: Media Prep
Attachments: topline responsive language_3.22.20.docx

Some updated language copied below, plus added to attached.

(b)(5)

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

-----Original Message-----
From: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Sent: Monday, March 23, 2020 9:03 AM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Subject: RE: Media Prep

(b)(5)

--
Jeet Guram, M.D.
Senior Advisor, Office of the Commissioner Food and Drug Administration
+1 (202) 230-0451 | jeet.guram@fda.hhs.gov

-----Original Message-----
From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Monday, March 23, 2020 8:39 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Subject: RE: Media Prep

On it

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Press Officer
Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: 301 348 1956
Cell: (b)(6)
stephanie.caccomo@fda.hhs.gov

-----Original Message-----
From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Monday, March 23, 2020 8:23 AM
To: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Cc: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: Media Prep

Can we get these before 10 pls?
From SH:

I'll need high level stats on hydroxychloroquine availability for the prep.

Also need some specific examples of regulatory flexibility to feed the press

Sent from my iPhone

From: Caliguiri, Laura [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AA086F2D6C0346C49E996932D86AC62E-LAURA.CALIG]
Sent: 3/23/2020 1:01:08 PM
To: Guram, Jeet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ef73bea97e2b477b847ea302c4730ccf-Gurjeet.Gur]; McWilliams, Carly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
CC: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]
Subject: RE: Media Prep

I can send forward two minutes

-----Original Message-----
From: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Sent: Monday, March 23, 2020 12:58 PM
To: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: RE: Media Prep

Stephanie is going to run our chloroquine points by Mary Beth Clarke to make sure we're including all the latest info (Stephanie lmk if I can help).

--
Jeet Guram, M.D.
Senior Advisor, Office of the Commissioner Food and Drug Administration
+1 (202) 230-0451 | jeet.guram@fda.hhs.gov

-----Original Message-----
From: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Sent: Monday, March 23, 2020 12:56 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: RE: Media Prep

I can compile. Laura, please send the ORA piece when you can. I will compile jeet's talking points, and what stephanie sent this morning along with materials I sent last night. Am I missing anything?

-----Original Message-----
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Sent: Monday, March 23, 2020 12:55 PM
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Subject: RE: Media Prep

Does someone have all of this compiled for his WH meeting? Can someone send to me pls in the larger document?

Also, Laura, add the ORA piece we have been working on too. Thanks.

-----Original Message-----
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Subject: RE: Media Prep

(b)(5)

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Senior Advisor, Office of the Commissioner Food and Drug Administration
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Stephanie Caccomo
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Cc: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: Media Prep

Can we get these before 10 pls?
From SH:

I' ll need high level stats on hydroxychloroquine availability for the prep.

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Sent from my iPhone

From: Felberbaum, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4819A643CA2945CDB1A2631B83E69673-MICHAEL.FEL]
Sent: 3/23/2020 1:43:43 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
Subject: RE: For NYT

Yes, that works for me. Sorry – hit send before added the drug names.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Monday, March 23, 2020 1:41 PM
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: RE: For NYT

How is the below? Or a version of it.

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Sent: Monday, March 23, 2020 1:33 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: For NYT

Stephanie said she mentioned this inquiry to you … does this work for you?

The FDA has been working on therapeutics from the beginning of this outbreak and has been keeping the White House, including the President, apprised along the way about our efforts to support the development of a number of therapies, including Hydroxychloroquine and Chloroquine . As always, the FDA works closely with the White House on all COVID-19 announcements.

From: McWilliams, Carly [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B68C7458214244D08424FD441FEA4FDA-CARLYLE.MCW]
Sent: 3/23/2020 1:44:48 PM
To: Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Guram, Jeet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ef73bea97e2b477b847ea302c4730ccf-Gurjeet.Gur]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]
CC: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: RE: Media Prep

Rather than email me everything, I uploaded in sharepoint: please add there so we can do this quickly.

http://sharepoint.fda.gov/orgs/OC-OCET/OCETdocs/nCoV/Shared%20Documents/WH%20Daily%20Task%20Force%20Talking%20Points%20and%20Background/2020.03.23%20Background%20from%20WH%20Task%20Force%20Meeting%20final%20(002).docx

-----Original Message-----
From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Sent: Monday, March 23, 2020 1:14 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Prep

(b)(5)

-----Original Message-----
From: Felberbaum, Michael
Sent: Monday, March 23, 2020 1:08 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Prep

Jeet -- if you can follow-up on the chain with Mary Beth on this topic with those points, that would be greatly appreciated.

-----Original Message-----
From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Monday, March 23, 2020 1:05 PM
To: Guram, Jeet <Jeet.Guram@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: RE: Media Prep

WE need to turnaround on some of this stuff in the next hour. So pls hustle. I know you all are, thanks!

-----Original Message-----
From: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Sent: Monday, March 23, 2020 12:58 PM
To: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: RE: Media Prep

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Jeet Guram, M.D.
Senior Advisor, Office of the Commissioner Food and Drug Administration
+1 (202) 230-0451 | jeet.guram@fda.hhs.gov

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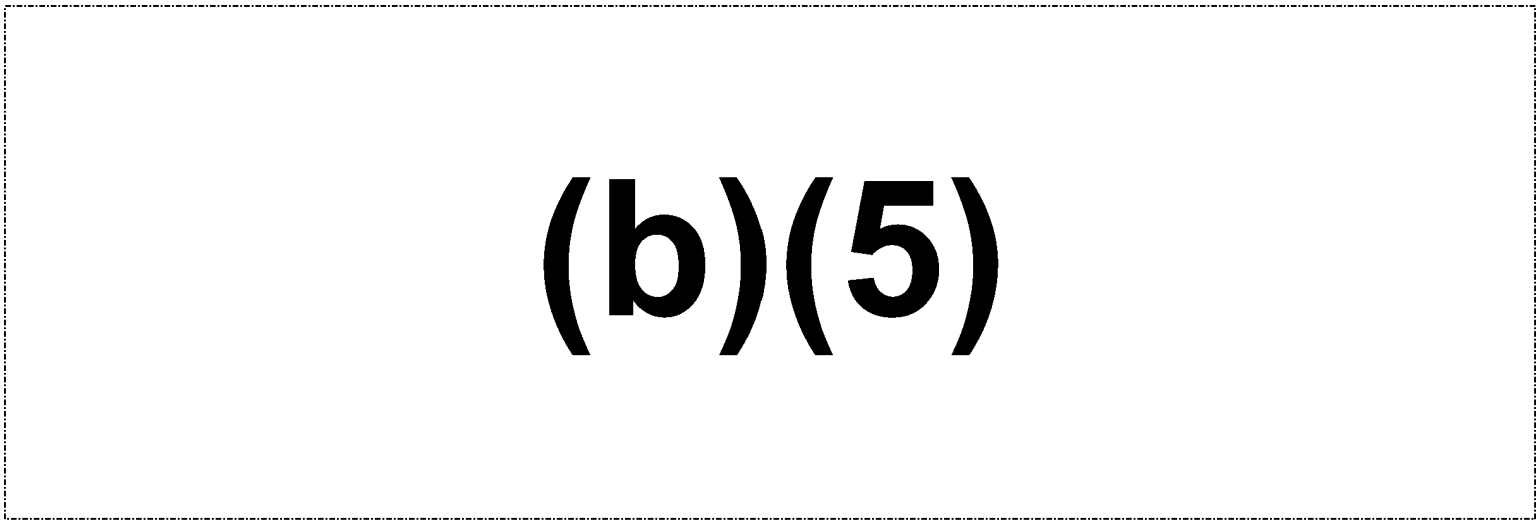
Subject: RE: Media Prep



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Jeet Guram, M.D.
Senior Advisor, Office of the Commissioner Food and Drug Administration
+1 (202) 230-0451 | jeet.guram@fda.hhs.gov

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On it

Stephanie Caccomo
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Sent: 3/23/2020 2:03:07 PM
To: Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]
Subject: RE: FDA Ventilator Guidance Talkers

(b)(5)

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Sent: Monday, March 23, 2020 1:47 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: FDA Ventilator Guidance Talkers

(b)(5)

(b)(5)

Laura Caliguiri
Associate Commissioner for External Affairs

Office of External Affairs
U.S. Food and Drug Administration
Tel: 301 796-8546
Laura.Caliguiri@fda.hhs.gov

From: Rom, Colin [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F59636221F4340D697DBD43EE27255FB-COLIN.ROM]
Sent: 3/23/2020 2:27:20 PM
To: McWilliams, Carly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Guram, Jeet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ef73bea97e2b477b847ea302c4730ccf-Gurjeet.Gur]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]
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Printing off now

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From: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Sent: Monday, March 23, 2020 2:27 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: FW: Media Prep

With Keagan this time.

-----Original Message-----
From: McWilliams, Carly
Sent: Monday, March 23, 2020 2:26 PM
To: Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: RE: Media Prep

Updated with Washington examiner tp

-----Original Message-----
From: McWilliams, Carly
Sent: Monday, March 23, 2020 2:16 PM
To: Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: RE: Media Prep

Laura, I don't know what's going on with VPN but your email with talkers are not coming through. Can you please put in document and send ASAP to Keagan and colin, ccing the rest of us for awareness.

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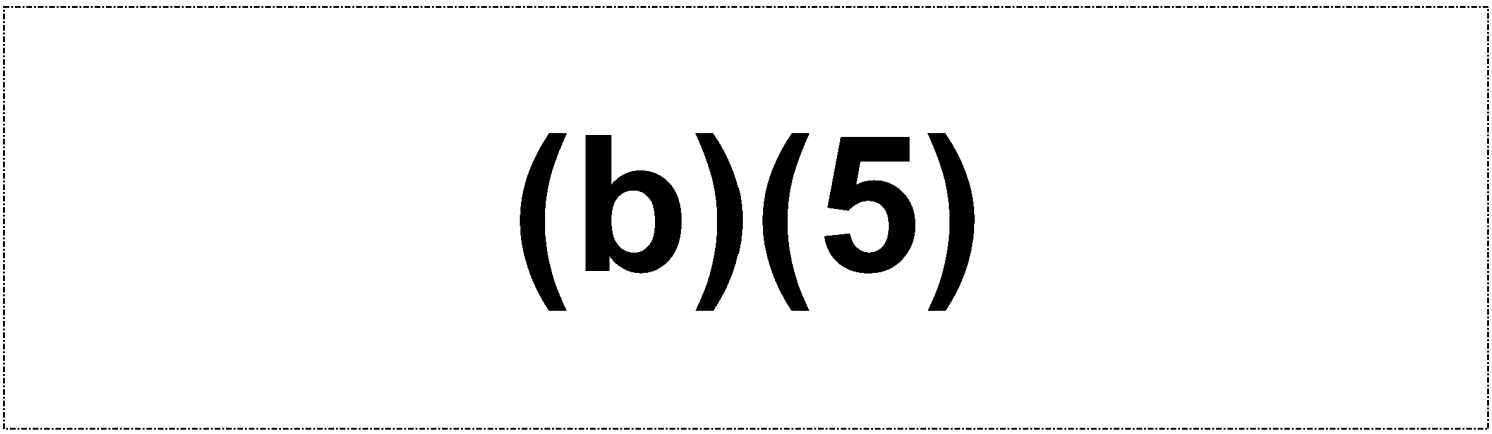
Sent: Monday, March 23, 2020 1:58 PM
To: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: RE: Media Prep

Thanks! And here is what Stephanie sent this morning in regards to Dr. Hahn's question about examples of regulatory flexibility:

(b)(5)



--
Jeet Guram, M.D.
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Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
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I will put in. thanks!

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To: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
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Subject: RE: Media Prep

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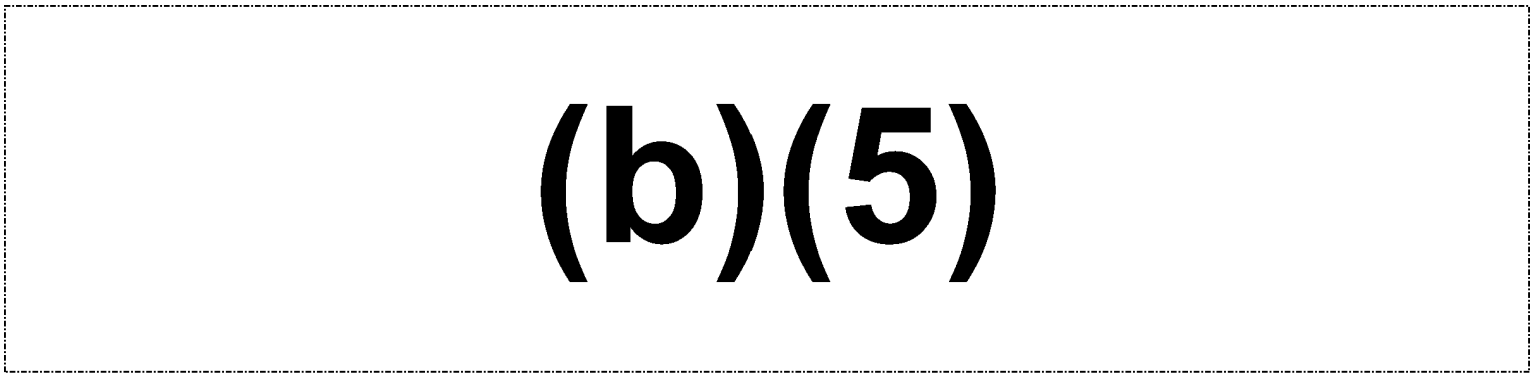

--
Jeet Guram, M.D.
Senior Advisor, Office of the Commissioner Food and Drug Administration
+1 (202) 230-0451 | jeet.guram@fda.hhs.gov

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Stephanie is going to run our chloroquine points by Mary Beth Clarke to make sure we're including all the latest info (Stephanie lmk if I can help).

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Senior Advisor, Office of the Commissioner Food and Drug Administration
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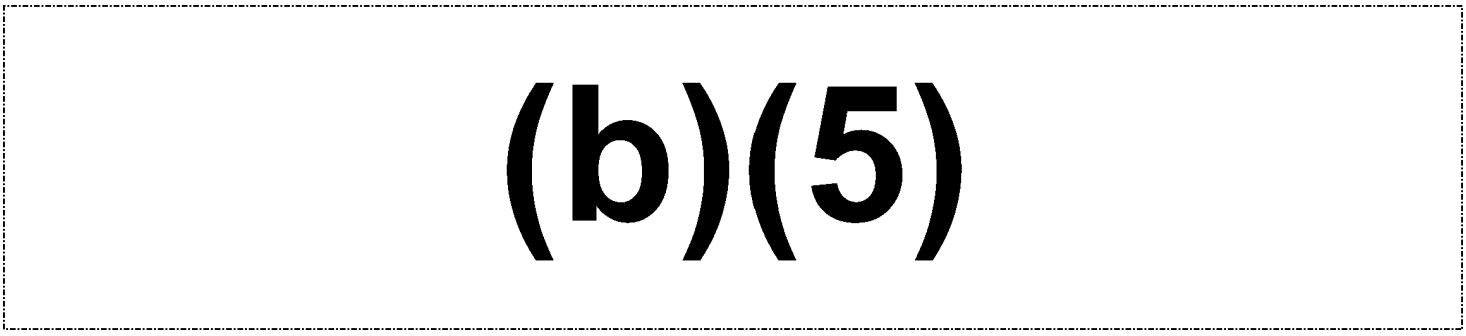

(b)(6)

--
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-----Original Message-----
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Sent: Monday, March 23, 2020 8:39 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Subject: RE: Media Prep

On it

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

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Cc: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: Media Prep

Can we get these before 10 pls?
From SH:

I'll need high level stats on hydroxychloroquine availability for the prep.

Also need some specific examples of regulatory flexibility to feed the press

Sent from my iPhone

From: Rom, Colin [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F59636221F4340D697DBD43EE27255FB-COLIN.ROM]
Sent: 3/23/2020 3:01:02 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: RE: Media Prep

Will do

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Subject: RE: Media Prep

Colin, pls show him these

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Sent: Monday, March 23, 2020 2:28 PM
To: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
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Thank you!

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Laura, I don't know what's going on with VPN but your email with talkers are not coming through. Can you please put in document and send ASAP to Keagan and colin, ccing the rest of us for awareness.

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Subject: RE: Media Prep

Thanks! And here is what Stephanie sent this morning in regards to Dr. Hahn's question about examples of regulatory flexibility:

(b)(5)

--
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(b)(5)

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Press Officer
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Office of External Affairs
U.S. Food and Drug Administration
Desk: 301 348 1956
Cell: (b)(6)
stephanie.caccomo@fda.hhs.gov

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Sent: 3/23/2020 5:09:55 PM
To: Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; McWilliams, Carly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]; Guram, Jeet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ef73bea97e2b477b847ea302c4730ccf-Gurjeet.Gur]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]
Subject: RE: Media Prep

Can I see final?

-----Original Message-----
From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Sent: Monday, March 23, 2020 3:49 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: RE: Media Prep

Not talkers below just context we have the statement content and working now

-----Original Message-----
From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Monday, March 23, 2020 3:46 PM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: RE: Media Prep

(b)(5) ..pls work on the talkers I sent below. What is ORA comfortable with. That is fine for responsive to media.

-----Original Message-----
From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Sent: Monday, March 23, 2020 3:22 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: RE: Media Prep

Just to be clear the examiner piece conflates many things that don't follow the process/make sense. Regardless, this was the overall ORA feedback on this when it originally came up

(b)(5)

-----Original Message-----
From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Monday, March 23, 2020 3:10 PM

To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
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(b)(5)

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He wants more on the Washington examiner piece. Pls see what you can get from John Verbaten. John said **(b)(5)** **(b)(5)** All good messaging.

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Laura, I don't know what's going on with VPN but your email with talkers are not coming through. Can you please put in document and send ASAP to Keagan and colin, ccing the rest of us for awareness.

-----Original Message-----
From: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Sent: Monday, March 23, 2020 1:58 PM
To: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>

Subject: RE: Media Prep

Thanks! And here is what Stephanie sent this morning in regards to Dr. Hahn's question about examples of regulatory flexibility:

(b)(5)

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Jeet Guram, M.D.
Senior Advisor, Office of the Commissioner Food and Drug Administration
+1 (202) 230-0451 | jeet.guram@fda.hhs.gov

-----Original Message-----
From: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Sent: Monday, March 23, 2020 1:57 PM
To: Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: RE: Media Prep

I will put in. thanks!

-----Original Message-----
From: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Sent: Monday, March 23, 2020 1:56 PM
To: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: RE: Media Prep

I don't think I can access the sharepoint site - here are the latest TPs on chloroquine though if y'all could add these above the table:

(b)(5)

--
Jeet Guram, M.D.
Senior Advisor, Office of the Commissioner Food and Drug Administration
+1 (202) 230-0451 | jeet.guram@fda.hhs.gov

-----Original Message-----
From: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Sent: Monday, March 23, 2020 1:55 PM
To: Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: RE: Media Prep

Just reminder that we need these in 10 mins. Is that an issue?

-----Original Message-----
From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Monday, March 23, 2020 1:05 PM
To: Guram, Jeet <Jeet.Guram@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: RE: Media Prep

WE need to turnaround on some of this stuff in the next hour. So pls hustle. I know you all are, thanks!

-----Original Message-----
From: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Sent: Monday, March 23, 2020 12:58 PM
To: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: RE: Media Prep

Stephanie is going to run our chloroquine points by Mary Beth Clarke to make sure we're including all the latest info (Stephanie lmk if I can help).

--
Jeet Guram, M.D.
Senior Advisor, Office of the Commissioner Food and Drug Administration
+1 (202) 230-0451 | jeet.guram@fda.hhs.gov

-----Original Message-----
From: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Sent: Monday, March 23, 2020 12:56 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: RE: Media Prep

I can compile. Laura, please send the ORA piece when you can. I will compile jeet's talking points, and what stephanie sent this morning along with materials I sent last night. Am I missing anything?

-----Original Message-----
From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Monday, March 23, 2020 12:55 PM
To: Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Subject: RE: Media Prep

Does someone have all of this compiled for his WH meeting? Can someone send to me pls in the larger document?

Also, Laura, add the ORA piece we have been working on too. Thanks.

-----Original Message-----
From: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Sent: Monday, March 23, 2020 9:03 AM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Subject: RE: Media Prep

How about this for chloroquine:

(b)(5)

(b)(5)

--
Jeet Guram, M.D.
Senior Advisor, Office of the Commissioner Food and Drug Administration
+1 (202) 230-0451 | jeet.guram@fda.hhs.gov

-----Original Message-----
From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Monday, March 23, 2020 8:39 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Subject: RE: Media Prep

On it

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

-----Original Message-----
From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Monday, March 23, 2020 8:23 AM
To: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Cc: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: Media Prep

Can we get these before 10 pls?
From SH:

I'll need high level stats on hydroxychloroquine availability for the prep.

Also need some specific examples of regulatory flexibility to feed the press

Sent from my iPhone

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 3/23/2020 5:22:21 PM
To: Hamel, Joseph (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b90f78a9c02426eb8d62bd1ad9117b8-HHS-Joseph.]
Subject: FW: Vizient Recommendations re: chloroquine & hydroxychloroquine
Attachments: Vizient Recommendations re Chloroquine and hydroxychloroquine supply 0323.pdf

FYI

From: Krilow,Shoshana <shoshana.krilow@vizientinc.com>
Sent: Monday, March 23, 2020 2:39 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Kistner,Daniel <Daniel.Kistner@vizientinc.com>
Subject: Vizient Recommendations re: chloroquine & hydroxychloroquine

Hi Keagan,

I know you are aware of the recent spike in demand for chloroquine (6482%) and hydroxychloroquine (2196%) since they have been identified as potential treatments to COVID-19. For example, prior to COVID-19 we would see on average about **(b)(4)** tablets of hydroxychloroquine purchased a day by our members while last week we saw an average of about **(b)(4)** a day ordered with only about 12% of orders being fulfilled. While many manufacturers are coming to market to make chloroquine and hydroxychloroquine it will take weeks and, until then, the market will survive on the products that are in the channel. Unfortunately, we are hearing more and more of prophylaxis and unnecessary refill scripts being written and filled which is keeping that product potentially off the shelves of hospitals to treat COVID-19 confirmed cases.

As a follow-up to our President and CEO, Byron Jobe, meeting with the Vice President and Administrator Verma, we wanted to pass along additional recommendations (attached) regarding how to mitigate any shortage related to these drugs by making sure the product is being used for FDA-approved indications and in the hospital setting as much as possible to treat patients who are positive for COVID-19. We are also sharing these with the Vice President's office.

Happy to answer any questions you may have. Thank you, and the Commissioner, for all of your work. We know these are trying times and we hope we can be helpful to you.

Shoshana

Shoshana Krilow
VP, Public Policy & Government Relations

T (202) 354-2607
M **(b)(6)**
shoshana.krilow@vizientinc.com

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Washington, DC 20001
vizientinc.com

prohibited. If this e-mail has been transmitted to you in error, please notify and return the original message to the sender immediately at the above listed address. Thank you for your cooperation.

From: Krilow,Shoshana [shoshana.krilow@vizientinc.com]
Sent: 3/23/2020 5:41:00 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Kistner,Daniel [Daniel.Kistner@vizientinc.com]
Subject: Re: Vizient Recommendations re: chloroquine & hydroxychloroquine

You are welcome and thanks!

Sent from my iPhone

On Mar 23, 2020, at 5:22 PM, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov> wrote:

Thank you for this. Appreciate the information and I will pass it along.

From: Krilow,Shoshana <shoshana.krilow@vizientinc.com>
Sent: Monday, March 23, 2020 2:39 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Kistner,Daniel <Daniel.Kistner@vizientinc.com>
Subject: Vizient Recommendations re: chloroquine & hydroxychloroquine

Hi Keagan,

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As a follow-up to our President and CEO, Byron Jobe, meeting with the Vice President and Administrator Verma, we wanted to pass along additional recommendations (attached) regarding how to mitigate any shortage related to these drugs by making sure the product is being used for FDA-approved indications and in the hospital setting as much as possible to treat patients who are positive for COVID-19. We are also sharing these with the Vice President's office.

Happy to answer any questions you may have. Thank you, and the Commissioner, for all of your work. We know these are trying times and we hope we can be helpful to you.

Shoshana

Shoshana Krilow
VP, Public Policy & Government Relations

T (202) 354-2607
M **(b)(6)**
shoshana.krilow@vizientinc.com

Vizient

799 9th St NW Ste 21●
Washington, DC 2●●●1
vizientinc.c●m

From: Caccomo, Stephanie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=950C32CEBC4B4F80B302C50CF31C8524-STEPHANIE.C]
Sent: 3/23/2020 8:00:40 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; McWilliams, Carly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]
CC: Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]
Subject: RE: MARYLAND

Nevada, Maryland, Washington state, NY

Stephanie Caccomo
Press Officer

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

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Monday, March 23, 2020 8:00 PM
To: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Cc: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: Re: MARYLAND

No. 4th.

Sent from my iPhone

On Mar 23, 2020, at 7:51 PM, McWilliams, Carly <Carly.McWilliams@fda.hhs.gov> wrote:

This is the first state beside ny?

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Monday, March 23, 2020 7:14 PM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Subject: FW: MARYLAND

To add to the talkers

From: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Sent: Monday, March 23, 2020 7:12 PM
To: Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: MARYLAND

Maryland has notified us that they plan to take advantage of being a state that authorizes laboratory developed tests for COVID-19.

Jeff

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 3/24/2020 8:17:11 PM
To: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Patrizia Cavazzoni (Patrizia.Cavazzoni@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]; Throckmorton, Douglas C [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdc411a0b9be442daec5172d411e2fd3-THROCKMORTO]
Subject: FW: Vizient Recommendations re: chloroquine & hydroxychloroquine
Attachments: Vizient Recommendations re Chloroquine and hydroxychloroquine supply 0323.pdf

(b)(5)

From: Krilow,Shoshana <shoshana.krilow@vizientinc.com>
Sent: Monday, March 23, 2020 2:39 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Kistner,Daniel <Daniel.Kistner@vizientinc.com>
Subject: Vizient Recommendations re: chloroquine & hydroxychloroquine

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Happy to answer any questions you may have. Thank you, and the Commissioner, for all of your work. We know these are trying times and we hope we can be helpful to you.

Shoshana

Shoshana Krilow
VP, Public Policy & Government Relations

T (202) 354-2607
M (b)(6)
shoshana.krilow@vizientinc.com

Vizient
799 9th St NW Ste 210
Washington, DC 20001
vizientinc.com

To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
Subject: For your discussion with Joe tomorrow
Attachments: Rapid Clinician impressions from Oracle COVID 032320docx.docx; Objective_032420aa.docx

I will send to him as well.

Steve and Joe – (b)(5)

(b)(3) 42 USC 247d-6b(d), (b)(5)

(b)(3) 42 USC 247d-6b(d), (b)(5)

From: Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]
Sent: 3/25/2020 8:47:50 AM
To: Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]
CC: Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Guram, Jeet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ef73bea97e2b477b847ea302c4730ccf-Gurjeet.Gur]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
Subject: Re: FYI: Oracle to partner with Trump administration to collect data on unproven drugs to treat covid-19 - The Washington Post

Think that makes sense.

Sent from my iPhone

On Mar 25, 2020, at 8:10 AM, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov> wrote:

Thank you. Assuming we don't have anything we can share with reporters at this moment beyond what we cleared previously, which is:

We are actively working with our federal health partners as well as academic medical centers on the COVID-19 response and collecting data in a variety of ways about potential therapies. We will share additional information when available.

Michael Felberbaum
Senior Advisor

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

From: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
Date: March 25, 2020 at 6:24:30 AM EDT
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: Re: FYI: Oracle to partner with Trump administration to collect data on unproven drugs to treat covid-19 - The Washington Post

For visibility, here is the NYT article about it.

https://www.nytimes.com/2020/03/24/us/politics/trump-oracle-coronavirus-chloroquine.html?searchResultPosition=1

Oracle Providing White House With Software to Study Unproven Coronavirus Drugs

The online platform could allow physicians to upload patient data on how malaria drugs perform on coronavirus patients.

www.nytimes.com

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Sent: Tuesday, March 24, 2020 11:25 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: FYI: Oracle to partner with Trump administration to collect data on unproven drugs to treat covid-19 - The Washington Post

https://www.washingtonpost.com/politics/oracle-to-partner-with-trump-administration-to-collect-data-on-use-of-antimalarial-drugs-to-treat-covid-19/2020/03/24/ecbb8b76-6de2-11ea-b148-e4ce3fbd85b5_story.html

Oracle to partner with Trump administration to collect data on unproven drugs to treat covid-19

A series of conversations President Trump has had with tech billionaire Larry Ellison have helped convince him that two old anti-malarial drugs may be game-changing treatments for covid-19, the disease caused by the novel coronavirus, according to four people familiar with the conversations.

Trump has said he has “a good feeling” about the drugs based on anecdotal reports, even though there is scant data showing they benefit people with covid-19. Now, Ellison — who recently held a high-profile fundraiser for Trump — has helped arrange a partnership between Oracle, the software company he co-founded, and the federal government to crowdsource that idea by collecting data in real time from doctors trying out those and other unproven drugs on covid-19 patients.

While the anti-malarial drugs are also being tested in clinical trials, the primary purpose of Oracle's new website and mobile app is to help gather information on patients prescribed the medications outside of trials and more quickly assess whether the drugs — or any others that may emerge as possible treatments — are effective against covid-19, for which there is no proven treatment. The company plans to donate the site to the government.

Chloroquine and hydroxychloroquine are approved for malaria, so doctors can prescribe them for other illnesses. Some are trying them on patients with covid-19 based on anecdotal reports that they are sometimes helpful. The Oracle technology is meant to help the government collect data "in real time" and faster than in traditional Food and Drug Administration clinical trials, said one person familiar with the discussions, who spoke on the condition of anonymity because he was not authorized to speak publicly.

Oracle declined requests to comment for this story.

The administration is also exploring whether it will offer bonus payments to doctors who use the technology. This raises ethical concerns among some health officials, who fear that will further promote the use of unproven drugs, according to a person familiar with the plans, who also spoke on the condition of anonymity because he was not authorized to share the conversations. Some of the president's top health officials have urged the government to proceed with randomized clinical trials to ensure they have definitive data about what does and does not work, several senior administration officials said.

The White House did not respond to multiple requests for comment.

Trump's conversations with Ellison have played a significant role in the president's recent statements during daily White House coronavirus briefings and on Twitter pushing the anti-malarials, according to four people familiar with the conversations, who spoke on the condition of anonymity because they were not authorized to share them.

The president's recent statements underscore his desire for a quick fix to the rapidly escalating pandemic that has infected more than 53,000 Americans and killed upward of 600. They have also resulted in shortages of chloroquine and hydroxychloroquine for patients who need them for other uses. Even in private, the president has dismissed concerns from doctors that the drugs are not adequately tested, saying it is a dire situation and he wants people to have options, say senior officials.

Last week, shortly after Trump's initial conversations with Ellison, he convened several top health officials and aides in an Oval Office meeting to discuss whether the government could expedite approval of chloroquine, hydroxychloroquine and remdesivir, an antiviral that has not been approved for any use but is currently being scrutinized in several late-stage trials.

The meeting included FDA Commissioner Stephen Hahn, Centers for Disease Control and Prevention Director Robert Redfield and Anthony S. Fauci, director of the National Institute

of Allergy and Infectious Diseases, among others, according to people familiar with the gathering.

The officials pushed back on the idea, urging the president to wait for the results of randomized clinical trials that meet the FDA's standards.

But Health and Human Services Secretary Alex Azar, who had been asked by Trump earlier that day to find legal authority to immediately approve the drugs, told the president he had conferred with his lawyers and had options for immediate approval if Trump wanted them, including emergency authorities granted to the health secretary.

A senior administration official said Azar was not advocating for immediate approval but presenting the president with options he had requested.

The other officials in the room were stunned at the suggestion and urged Trump to rely on the clinical trials.

Trump ultimately stood down, but still turned to Ellison and Oracle to build a website to collect data on the drugs' efficacy outside of official clinical trials, and he has continued to push the drugs as possible treatments in daily briefings.

Ellison is heavily involved in health care, in addition to software. He launched a wellness company called Sensei and is a major shareholder in Quark Pharmaceuticals, which develops therapeutics based on gene discovery. He also funded a cancer institute at the University of Southern California led by Los Angeles doctor David Agus, who has been involved in discussions with the administration.

Joshua Sharfstein, vice dean for public health practice and community engagement at the Johns Hopkins Bloomberg School of Public Health, said he had heard few details about the Oracle website but was unenthused based on what he knew.

"It sounds like a very poor substitute for a well-designed clinical trial," said Sharfstein, who was FDA deputy commissioner during the Obama administration. He added that a trial could be conducted quickly without a large number of patients.

The fastest, best way to know whether something works is to randomly assign patients to treatments and then see what happens, he said. "Otherwise, it's hard to know whether something works."

Trump has repeatedly talked up the malaria drugs from the White House podium. He has cited a small study of 36 patients in France that administered chloroquine and an antibiotic called azithromycin. "HYDROXYCHLOROQUINE & AZITHROMYCIN, taken together, have a real chance to be one of the biggest game changers in the history of medicine," Trump tweeted Saturday.

"I feel like I feel, as the expression goes, what do we have to lose? Because, you know, I feel very, I feel very good about it," Trump said during a White House briefing Saturday.

Fauci interjected to say the president was right to have hope, but he urged caution in placing too much faith in the drugs without proper data.

“Many of the things that you hear out there are what I had called anecdotal reports. They may be true, but they’re anecdotal,” Fauci said. “So the only thing that I was saying is that if you really want definitively to know if something works, that you’ve got to do the kind of trial that you get, the good information. The president is talking about hope for people. And it’s not an unreasonable thing to hope for people.”

Medical and health experts have raised concerns that the president is pushing unproven treatments, leading people to try to obtain the drug. After hearing the president’s remarks, an Arizona man ingested chloroquine phosphate, a fish tank cleaner, in an effort to prevent covid-19, and died shortly after. His wife also ingested the substance and has been hospitalized.

“When the president comes in and says that he has a feeling that something is going to work very well, he makes it much harder to do that science,” said Ashish Jha, a professor at Harvard University and director of the Harvard Global Health Institute. “He makes it much harder for us to learn and figure out which treatments are going to work.”

On Tuesday, the state of New York was scheduled to begin testing chloroquine and hydroxychloroquine as treatments for covid-19.

From: Olivarria, Frank [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C180721DB774423F99990DD86E67057C-FRANK.OLIVA]
Sent: 3/25/2020 10:46:14 AM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
CC: Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Copeland, Jakea [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7fe05ed233c42b68be990b12ae2c8c8-Jakea.Copel]
Subject: RE: CDRH 1:1 Topic Check: FDA request of ADx

Understood - thank you!

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, March 25, 2020 10:45 AM
To: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Cc: Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: CDRH 1:1 Topic Check: FDA request of ADx

Think he is talking with Jeff daily so ok to wait till next week.

From: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Sent: Wednesday, March 25, 2020 10:28 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Cc: Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: CDRH 1:1 Topic Check: FDA request of ADx

Hi Keagan, Colin -

Yesterday morning's check-in with CDRH was canceled as SH's request. The next scheduled meeting for CDRH is not until next week, Tuesday. **Ok for this item SH provided to wait until Tuesday**? Or, if it is pressing, we can bump another check in to get CDRH on sooner.

Frank

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Tuesday, March 24, 2020 6:38 PM
To: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: Fwd: FDA request of ADx

For our next CDRH 1:1 call

From: Van Meter, Susan <SVanMeter@AdvaMeddx.org>
Date: March 20, 2020 at 6:41:16 PM EDT
To: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Cc: Bryant, Doug <dbryant@quidel.com>, FDA Commissioner <Stephen.Hahn@fda.hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Whitaker, Scott <SWhitaker@AdvaMed.org>, Trunzo,

Janet <JTrunzo@AdvaMed.org>
Subject: RE: FDA request of ADx

Jeff and Tim –

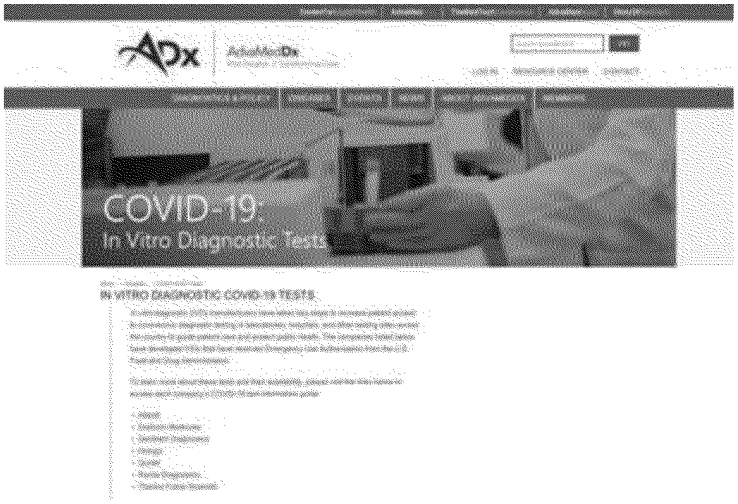
Our member companies are standing up their individual COVID-19 landing pages to provide information the agency has requested relative to the availability of EUA tests, production schedules, etc.

Further, as promised, we have created a single point of entry for anyone interested in information about all of the available IVD EUA tests via a new COVID-19 page on the AdvaMedDx site, accessible via the AdvaMed and the AdvaMedDx home pages and via this link: https://dx.advamed.org/diseases/vitro-diagnostic-covid-19-tests

The page will be updated frequently to keep pace with the FDA EUA landing page. We hope this is useful to you and a place to which you can direct visitors to the agency web site and stakeholder who otherwise reach out to the agency for information on IVD EUA.

A snapshot of our landing page is below.

Best regards,
Susan



From: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Sent: Tuesday, March 17, 2020 7:04 PM
To: Van Meter, Susan <SVanMeter@AdvaMeddx.org>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Cc: Bryant, Doug <dbryant@guidel.com>; FDA Commissioner <Stephen.Hahn@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Whitaker, Scott <SWhitaker@AdvaMed.org>; Trunzo, Janet <JTrunzo@AdvaMed.org>
Subject: RE: FDA request of ADx

This is very helpful. Thank you very much.

Best regards,

Jeff

From: Van Meter, Susan <SVanMeter@AdvaMeddx.org>
Date: March 17, 2020 at 6:26:34 PM EDT
To: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Cc: Bryant, Doug <dbryant@guidel.com>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, FDA Commissioner <Stephen.Hahn@fda.hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Whitaker, Scott <SWhitaker@AdvaMed.org>, Trunzo, Janet <JTrunzo@AdvaMed.org>
Subject: RE: FDA request of ADx

Tim, most certainly. I'll reach out as soon as it is live.
Regards,
Susan

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Sent: Tuesday, March 17, 2020 6:21 PM
To: Van Meter, Susan <SVanMeter@AdvaMeddx.org>
Cc: Bryant, Doug <dbryant@guidel.com>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; FDA Commissioner <Stephen.Hahn@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Whitaker, Scott <SWhitaker@AdvaMed.org>; Trunzo, Janet <JTrunzo@AdvaMed.org>
Subject: RE: FDA request of ADx

Thank you Susan and AdvaMed, This is very helpful. I defer to Jeff for any other thoughts. Could you let us know once the Advamed website for this is active?

Thank you very much.

Best,
Tim

Timothy T. Stenzel, MD, PhD
Director, OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality

Center for Devices and Radiological Health
U.S. Food and Drug Administration
Timothy.Stenzel@fda.hhs.gov
Jennifer Campbell
Administrative Assistant

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

From: Van Meter, Susan <SVanMeter@AdvaMeddx.org>
Sent: Tuesday, March 17, 2020 6:17 PM
To: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Cc: Bryant, Doug <dbryant@guidel.com>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; FDA Commissioner <Stephen.Hahn@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Whitaker, Scott <SWhitaker@AdvaMed.org>; Trunzo, Janet <JTrunzo@AdvaMed.org>
Subject: RE: FDA request of ADx

Hi Tim –

Today AdvaMedDx communicated to all board member companies and later to our full membership the FDA request for companies with a COVID-19 EUA to establish on their web sites dedicated pages to communicate publicly inventory availability, production schedule and all other data elements you indicated in your note to me earlier today.

While acknowledging potential challenges / lack of applicability of certain elements, I encouraged member companies with COVID-19 EUAs to accommodate this request as best they can, as rapidly and thoroughly as is practicable.

AdvaMedDx will dedicate a section on our web site that will serve as a central location for this information, in coming days. That is, we will provide a consolidated list of IVD manufacturer COVID-19 webpages. We are hopeful that will also be helpful to the agency. **(b)(5)**

(b)(5)

Scott, Doug and I thank you for the opportunity to be helpful and thank you all for the work you are doing around the clock for patients and public health.

Regards,
Susan

Susan Van Meter
Executive Director
AdvaMedDx
701 Pennsylvania Avenue, Suite 800
Washington, DC 20004
Direct: (202) 434-7250
Cell **(b)(6)**
svanmeter@advameddx.org

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Sent: Tuesday, March 17, 2020 9:19 AM
To: Van Meter, Susan <SVanMeter@AdvaMeddx.org>
Cc: Bryant, Doug <dbryant@guidel.com>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; FDA Commissioner <Stephen.Hahn@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: RE: FDA request of ADx

Hi Susan,

Thanks for reaching back out and for the quick call we just had. I understand Dr. Hahn is joining your meeting today and so have copied him. This is just a start. Please comment or edit as needed or wanted.

At a high level, this is the ask:

(b)(5)

At the moment, the testing items of greatest need are:

Swabs
Transport media
Extraction reagents
Controls
PCR reagents
Test kits
Instruments

Best,
Tim

Timothy T. Stenzel, MD, PhD
Director, OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality

Center for Devices and Radiological Health
U.S. Food and Drug Administration
Timothy.Stenzel@fda.hhs.gov
Jennifer Campbell
Administrative Assistant

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

From: Van Meter, Susan <SVanMeter@AdvaMeddx.org>
Sent: Tuesday, March 17, 2020 8:46 AM
To: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Cc: Bryant, Doug <dbryant@quidel.com>
Subject: FDA request of ADx

Tim -
Doug and I connected a short while ago on the request Jeff and you sent to me late yesterday.

(b)(5)

We want to step up in a way that is effective and practical.

We will speak later this morning with our executive committee.

My cell is: (b)(6)

Regards,
Susan

Susan Van Meter
AdvaMedDx

From: Maynard, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1CAB5888CA99495880D8220C67476F8E-MAYNARDJ]
Sent: 3/25/2020 1:44:16 PM
To: Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Hunter, Nina L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8005f93bd66a4dfc83ebdaa67d9fd33b-NLH]
Subject: Remdesivir orphan drug designation

Gilead, the sponsor of remdesivir, has requested withdrawal of their orphan drug designation. On FDA's public orphan designation website, it now says that remdesivir's designation status for treatment of COVID-19 is designated/withdrawn (https://www.accessdata.fda.gov/scripts/opdlisting/oopd/listResult.cfm). If you have any questions, please let me know.

Thank you, Janet

Janet Maynard, MD, MHS
Office of Orphan Products Development, Director

U.S. Food and Drug Administration
Office of Clinical Policy and Programs
Office of the Commissioner
Tel: (301) 796-2978
Janet.Maynard@fda.hhs.gov

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 3/25/2020 6:19:37 PM
To: Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
CC: Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: RE: Follow-up on Fraud/Fish Drug

He is presenting at WH Friday. We need to have something by then.

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Sent: Wednesday, March 25, 2020 5:51 PM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Follow-up on Fraud/Fish Drug

Taking SH off –

We have not received information from centers on CTAP and I just checked with the JIC rep coordinating and they center reps have not yet provided any content for building website. Friday seems unlikely.

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Wednesday, March 25, 2020 5:44 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Follow-up on Fraud/Fish Drug

Is that happening Friday? We just heard from CBER the blood donor guidance is going Friday, which is a big deal and we were hoping to do a media call on Friday.

Stephanie Caccomo
Press Officer

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

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, March 25, 2020 5:41 PM
To: Hahn, Stephen <SH1@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>

Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Follow-up on Fraud/Fish Drug

(b)(5) My two cents.

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Wednesday, March 25, 2020 5:39 PM
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: Re: Follow-up on Fraud/Fish Drug

This is so great, Michael. Thank you. I have a call with 5000 doctors on Saturday. Let's think about high level messages that I can give them during my opening remarks. The call is being arranged by Administrator Verma at CMS and I think it's a terrific opportunity to connect with the front line.
Similarly, I'll be on a call with the hospitals (again through CMS) on Monday. It's another opportunity to get our message out.
Steve

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Date: March 25, 2020 at 1:53:22 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: Follow-up on Fraud/Fish Drug

Hi Dr. Hahn,

I wanted to follow up with you for your awareness about the work our entire communications shop has done/is doing to promote the Consumer Update we issued yesterday, entitled Beware of Fraudulent Coronavirus Tests, Vaccines and Treatments, which includes warnings on fake tests and fish tank drug. I'm including the entire document below if you'd like to take a look.

(b)(5)

We are hopeful this will continue to help amplify our message in this area.

Thanks,

Michael

Beware of Fraudulent Coronavirus Tests, Vaccines and Treatments

While many Americans are sheltering at home to help "flatten the curve" and slow the spread of coronavirus disease (also called COVID-19), they might be tempted to buy or use questionable products that claim to help diagnose, treat, cure, and even prevent COVID-19.

Because COVID-19 has never been seen in humans before, there are currently no vaccines to prevent or drugs to treat COVID-19 approved by the U.S. Food and Drug Administration (FDA). The FDA is working with vaccine and drug manufacturers to develop new vaccines for and find drugs to treat COVID-19 as quickly as possible. Meanwhile, some people and companies are trying to profit from this pandemic by selling unproven and illegally marketed products that make false claims, such as being effective against the coronavirus.

These fraudulent products that claim to cure, treat, or prevent COVID-19 haven't been evaluated by the FDA for safety and effectiveness and might be dangerous to you and your family.

The FDA is particularly concerned that these deceptive and misleading products might cause Americans to delay or stop appropriate medical treatment, leading to serious and life-threatening harm. It's likely that the products do not do what they claim, and the ingredients in them could cause adverse effects and could interact with, and potentially interfere with, essential medications.

The FDA has also seen unauthorized fraudulent test kits for COVID-19 being sold online. Currently, the only way to be tested for COVID-19 is to talk to your health care provider. The FDA has not authorized any test that is available to purchase for testing yourself at home for COVID-19. You will risk unknowingly spreading COVID-19 or not getting treated appropriately if you use an unauthorized test. The FDA knows that having a home test for COVID-19 would be very helpful and is actively working with test developers on this. But currently the FDA has not authorized any home test for COVID-19.

There Are No Vaccines or Medicines for COVID-19, Yet

The FDA **is working with medical product developers** to rapidly advance the development and availability of vaccines and treatments for COVID-19. Although there are investigational COVID-19 vaccines and treatments being studied in clinical trials, these products are in the early stages of development. They haven't yet been fully tested for safety or effectiveness, or received FDA approval.

Fraudulent COVID-19 products can come in many varieties, including dietary supplements and other foods, as well as products claiming to be tests, drugs, medical devices, or vaccines.

The FDA has been working with retailers to remove dozens of misleading products from store shelves and online. The agency will continue to monitor social media and online marketplaces promoting and selling fraudulent COVID-19 products.

Recently, the FDA and the Federal Trade Commission issued warning letters to seven companies for selling fraudulent COVID-19 products. The products cited include teas, essential oils, tinctures, and colloidal silver.

The FDA is actively monitoring for any firms marketing products with fraudulent COVID-19 diagnostic, prevention and treatment claims. The FDA is exercising its authority to protect consumers from firms selling unauthorized products with false or misleading claims. The FDA may send warning letters, or pursue seizures or injunctions against people, products, or companies that violate the law. We are also increasing our enforcement at ports of entry to ensure that fraudulent products do not enter the country through our borders.

In addition, the FDA is monitoring complaints of fake coronavirus treatments and tests. Consumers and health care professionals can help by reporting suspected fraud to the FDA's Health Fraud Program or the Office of Criminal Investigations.

How to Protect Yourself and Your Family From Coronavirus Fraud

The FDA advises consumers to be cautious of websites and stores selling products that claim to prevent, treat or cure COVID-19. There are no FDA-approved products to prevent COVID-19. Products marketed for veterinary use, or "for research use only," or otherwise not for human consumption, have not been evaluated for safety and should never be used by humans. For example, the FDA is aware of people trying to prevent COVID-19 by taking a product called chloroquine phosphate, which is sold to treat parasites in aquarium fish. Products for veterinary use or for "research use only" may have adverse effects, including serious illness and death, when taken by people. Don't take any form of chloroquine unless it has been prescribed for you by your health care provider and obtained from legitimate sources.

Here are some tips to identify false or misleading claims.

- Be suspicious of products that claim to treat a wide range of diseases.
- Personal testimonials are no substitute for scientific evidence.

- Few diseases or conditions can be treated quickly, so be suspicious of any therapy claimed as a "quick fix."
- If it seems too good to be true, it probably is.
- "Miracle cures," which claim scientific breakthroughs or contain secret ingredients, are likely a hoax.
- Know that you can't test yourself for coronavirus disease.

If you have symptoms of COVID-19, follow the Centers for Disease Control and Prevention's guidelines, and speak to your medical provider. Your health care provider will advise you about whether you should get tested and the process for being tested in your area.

If you have a question about a treatment or test found online, talk to your health care provider or doctor. If you have a question about a medication, call your pharmacist or the FDA.

The FDA's Division of Drug Information (DDI) will answer almost any drug question. DDI pharmacists are available by email, druginfo@fda.hhs.gov, and by phone, 1-855-543-DRUG (3784) and 301-796-3400.

The sale of fraudulent COVID-19 products is a threat to the public health. If you are concerned about the spread of COVID-19, talk to your health care provider and follow the advice of FDA's federal partners about how to prevent the spread of this illness.

Michael Felberbaum
Senior Advisor

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-8548 / Cel: **(b)(6)**
michael.felberbaum@fda.hhs.gov

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 3/25/2020 6:32:08 PM
To: Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]
CC: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]
Subject: RE: Follow-up on Fraud/Fish Drug

I am managing. Wait on reaching out to Keith. I will connect you tomorrow.

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Sent: Wednesday, March 25, 2020 6:26 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Subject: RE: Follow-up on Fraud/Fish Drug

OK **(b)(5)**

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, March 25, 2020 6:23 PM
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Subject: RE: Follow-up on Fraud/Fish Drug

I doubt it.

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Sent: Wednesday, March 25, 2020 6:20 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
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Cc: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Subject: RE: Follow-up on Fraud/Fish Drug

Keith is building it, we will have to be quick for turnaround on how we roll this out. WH putting us in a tough spot.

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I still have nothing from the centers on CTAP, and am told the website will NOT be ready for Friday.

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To: Hahn, Stephen <SH1@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
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We had a media briefing held and postponed a couple of times for calendar. **(b)(5)**

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Stephanie Caccomo
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: 301.348.1956
Cell **(b)(6)**
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Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: Follow-up on Fraud/Fish Drug

Hi Dr. Hahn,

I wanted to follow up with you for your awareness about the work our entire communications shop has done/is doing to promote the Consumer Update we issued yesterday, entitled Beware of Fraudulent Coronavirus Tests, Vaccines and Treatments, which includes warnings on fake tests and fish tank drug. I'm including the entire document below if you'd like to take a look.

(b)(5)

We are hopeful this will continue to help amplify our message in this area.

Thanks,

Michael

Beware of Fraudulent Coronavirus Tests, Vaccines and Treatments

While many Americans are sheltering at home to help "flatten the curve" and slow the spread of coronavirus disease (also called COVID-19), they might be tempted to buy or use questionable products that claim to help diagnose, treat, cure, and even prevent COVID-19.

Because COVID-19 has never been seen in humans before, there are currently no vaccines to prevent or drugs to treat COVID-19 approved by the U.S. Food and Drug Administration (FDA). The FDA is working with vaccine and drug manufacturers to develop new vaccines for and find drugs to treat COVID-19 as quickly as possible. Meanwhile, some people and companies are trying to profit from this pandemic by selling unproven and illegally marketed products that make false claims, such as being effective against the coronavirus.

These fraudulent products that claim to cure, treat, or prevent COVID-19 haven't been evaluated by the FDA for safety and effectiveness and might be dangerous to you and your family.

The FDA is particularly concerned that these deceptive and misleading products might cause Americans to delay or stop appropriate medical treatment, leading to serious and life-threatening harm. It's likely that the products do not do what they claim, and the ingredients in them could cause adverse effects and could interact with, and potentially interfere with, essential medications.

The FDA has also seen unauthorized fraudulent test kits for COVID-19 being sold online. Currently, the only way to be tested for COVID-19 is to talk to your health care provider. The FDA has not authorized any test that is available to purchase for testing yourself at home for COVID-19. You will risk unknowingly spreading COVID-19 or not getting treated appropriately if you use an unauthorized test. The FDA knows that having a home test for COVID-19 would be very helpful and is actively working with test developers on this. But currently the FDA has not authorized any home test for COVID-19.

There Are No Vaccines or Medicines for COVID-19, Yet

The FDA **is working with medical product developers** to rapidly advance the development and availability of vaccines and treatments for COVID-19. Although there are investigational COVID-19 vaccines and treatments being studied in

clinical trials, these products are in the early stages of development. They haven't yet been fully tested for safety or effectiveness, or received FDA approval.

Fraudulent COVID-19 products can come in many varieties, including dietary supplements and other foods, as well as products claiming to be tests, drugs, medical devices, or vaccines.

The FDA has been working with retailers to remove dozens of misleading products from store shelves and online. The agency will continue to monitor social media and online marketplaces promoting and selling fraudulent COVID-19 products.

Recently, the FDA and the Federal Trade Commission issued warning letters to seven companies for selling fraudulent COVID-19 products. The products cited include teas, essential oils, tinctures, and colloidal silver.

The FDA is actively monitoring for any firms marketing products with fraudulent COVID-19 diagnostic, prevention and treatment claims. The FDA is exercising its authority to protect consumers from firms selling unauthorized products with false or misleading claims. The FDA may send warning letters, or pursue seizures or injunctions against people, products, or companies that violate the law. We are also increasing our enforcement at ports of entry to ensure that fraudulent products do not enter the country through our borders.

In addition, the FDA is monitoring complaints of fake coronavirus treatments and tests. Consumers and health care professionals can help by reporting suspected fraud to the FDA's Health Fraud Program or the Office of Criminal Investigations.

How to Protect Yourself and Your Family From Coronavirus Fraud

The FDA advises consumers to be cautious of websites and stores selling products that claim to prevent, treat or cure COVID-19. There are no FDA-approved products to prevent COVID-19. Products marketed for veterinary use, or "for research use only," or otherwise not for human consumption, have not been evaluated for safety and should never be used by humans. For example, the FDA is aware of people trying to prevent COVID-19 by taking a product called chloroquine phosphate, which is sold to treat parasites in aquarium fish. Products for veterinary use or for "research use only" may have adverse effects, including serious illness and death, when taken by people. Don't take any form of chloroquine unless it has been prescribed for you by your health care provider and obtained from legitimate sources.

Here are some tips to identify false or misleading claims.

- Be suspicious of products that claim to treat a wide range of diseases.
- Personal testimonials are no substitute for scientific evidence.
- Few diseases or conditions can be treated quickly, so be suspicious of any therapy claimed as a "quick fix."
- If it seems too good to be true, it probably is.
- "Miracle cures," which claim scientific breakthroughs or contain secret ingredients, are likely a hoax.
- Know that you can't test yourself for coronavirus disease.

If you have symptoms of COVID-19, follow the Centers for Disease Control and Prevention's guidelines, and speak to your medical provider. Your health care provider will advise you about whether you should get tested and the process for being tested in your area.

If you have a question about a treatment or test found online, talk to your health care provider or doctor. If you have a question about a medication, call your pharmacist or the FDA.

The FDA's Division of Drug Information (DDI) will answer almost any drug question. DDI pharmacists are available by email, druginfo@fda.hhs.gov, and by phone, 1-855-543-DRUG (3784) and 301-796-3400.

The sale of fraudulent COVID-19 products is a threat to the public health. If you are concerned about the spread of COVID-19, talk to your health care provider and follow the advice of FDA's federal partners about how to prevent the spread of this illness.

Michael Felberbaum
Senior Advisor

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


FDA
U.S. FOOD & DRUG
ADMINISTRATION

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 3/25/2020 6:43:06 PM
To: Ashley, Donald [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40241a76230349cbb195ab1721092196-Donald.Ashl]
Subject: FW: Restriction of Hydroxychloroquine Exports
Attachments: Indian Export Statement 3-25-20 final.pdf

Is there assessment true? We were more worried about **(b)(4)**

From: Schiller, Lowell <Lowell.Schiller@fda.hhs.gov>
Sent: Wednesday, March 25, 2020 6:40 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Abdoo, Mark <Mark.Abdoo@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: FW: Restriction of Hydroxychloroquine Exports

FYI

From: Jeff Francer <Jeffrey.Francer@accessiblemeds.org>
Sent: Wednesday, March 25, 2020 5:58 PM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Schiller, Lowell <Lowell.Schiller@fda.hhs.gov>
Subject: Restriction of Hydroxychloroquine Exports

Hi Anna and Lowell,

We are working with our member companies and sister association in India to respond to the Indian government's announcement last night that it is restricting exports of hydroxychloroquine. The good news is that the restrictions that have been put into place by the Indian government exempt exports of the drug under existing export licenses. This exemption should allow most Indian exports of hydroxychloroquine to the U.S. for existing contracts to continue. In addition, the export limitation exempts exports of hydroxychloroquine on humanitarian grounds.

We are also providing this information to DPC, State, Commerce, and USTR. We believe that it may make sense for the administration to work with the Government of India to ensure access to the U.S. for clinical trial / expanded access use under humanitarian grounds.

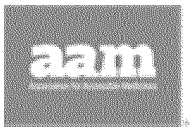
I am in close contact with our sister association in India and our member companies that are based in India. Please let me know if AAM can help facilitate dialog on this issue or if you would like to discuss this with me further. I'm happy to speak at any time (mobile number below) and have attached our reactive public statement for any media questions.

I hope you are doing ok and staying safe.

Best,

Jeff

Jeffrey K. Francer
INTERIM CEO & GENERAL COUNSEL
Association for Accessible Medicines (AAM)
Mobile (b)(6) E • jeffrey.francer@accessiblemeds.org
601 NEW JERSEY AVE., NW • SUITE 850 • WASHINGTON, DC 20001
/accessiblemeds



Your Generics & Biosimilars Industry

From: Flanagan, Keith [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=15DCAAB5C1EA4007ADBC43E9ACD413A6-KEITH.FLANA]
Sent: 3/25/2020 8:16:32 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Shreeve, Chris [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=571674b26ca64f578288f39264470299-Christine.K]; Bugin, Kevin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=735d396f29ce480a88de9e6c2b0f424e-BUGINK]
Subject: RE: Follow-up on Fraud/Fish Drug

Thanks, will do. Copying my CDER colleagues Chris and Kevin for their awareness.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, March 25, 2020 8:06 PM
To: Flanagan, Keith <Keith.Flanagan@fda.hhs.gov>
Subject: Re: Follow-up on Fraud/Fish Drug

Thank you Keith. Let me know if we can provide Comms folks to help with website or other components of Comms materials.

Sent from my iPhone

On Mar 25, 2020, at 7:17 PM, Flanagan, Keith <Keith.Flanagan@fda.hhs.gov> wrote:

And I in return am sorry to bother you.
I have good CDER-CBER CTAP talking points, we're scrubbing exact operational details (per WH's request) + clinical trial ## for accuracy. Team is working on that right now + overnight. I expect draft to be ready for review by JW and Peter Marks ~ mid day tomorrow.
I have been focused on your CTAP talkers, don't know timing of website. I'd be surprised if website was up Friday, though.

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Sorry to bother you, checking in (b)(5)

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Subject: Follow-up on Fraud/Fish Drug

Hi Dr. Hahn,

I wanted to follow up with you for your awareness about the work our entire communications shop has done/is doing to promote the Consumer Update we issued yesterday, entitled Beware of Fraudulent Coronavirus Tests, Vaccines and Treatments, which includes warnings on fake tests and fish tank drug. I'm including the entire document below if you'd like to take a look.

(b)(5)

We are hopeful this will continue to help amplify our message in this area.

Thanks,

Michael

Beware of Fraudulent Coronavirus Tests, Vaccines and Treatments

While many Americans are sheltering at home to help "flatten the curve" and slow the spread of coronavirus disease (also called COVID-19), they might be tempted to buy or use questionable products that claim to help diagnose, treat, cure, and even prevent COVID-19.

Because COVID-19 has never been seen in humans before, there are currently no vaccines to prevent or drugs to treat COVID-19 approved by the U.S. Food and Drug Administration (FDA). The FDA is working with vaccine and drug manufacturers to develop new vaccines for and find drugs to treat COVID-19 as quickly as possible. Meanwhile, some people and companies are trying to profit from this pandemic by selling unproven and illegally marketed products that make false claims, such as being effective against the coronavirus.

These fraudulent products that claim to cure, treat, or prevent COVID-19 haven't been evaluated by the FDA for safety and effectiveness and might be dangerous to you and your family.

The FDA is particularly concerned that these deceptive and misleading products might cause Americans to delay or stop appropriate medical treatment, leading to serious and life-threatening harm. It's likely that the products do not do what they claim, and the ingredients in them could cause adverse effects and could interact with, and potentially interfere with, essential medications.

The FDA has also seen unauthorized fraudulent test kits for COVID-19 being sold online. Currently, the only way to be tested for COVID-19 is to talk to your health care provider. The FDA has not authorized any test that is available to purchase for testing yourself at home for COVID-19. You will risk unknowingly spreading COVID-19 or not getting treated appropriately if you use an unauthorized test. The FDA knows that having a home test for COVID-19 would be very helpful and is actively working with test developers on this. But currently the FDA has not authorized any home test for COVID-19.

There Are No Vaccines or Medicines for COVID-19, Yet

The FDA **is working with medical product developers** to rapidly advance the development and availability of vaccines and treatments for COVID-19. Although there are investigational COVID-19 vaccines and treatments being studied in clinical trials, these products are in the early stages of development. They haven't yet been fully tested for safety or effectiveness, or received FDA approval.

Fraudulent COVID-19 products can come in many varieties, including dietary supplements and other foods, as well as products claiming to be tests, drugs, medical devices, or vaccines.

The FDA has been working with retailers to remove dozens of misleading products from store shelves and online. The agency will continue to monitor social media and online marketplaces promoting and selling fraudulent COVID-19 products.

Recently, the FDA and the Federal Trade Commission issued warning letters to seven companies for selling fraudulent COVID-19 products. The products cited include teas, essential oils, tinctures, and colloidal silver.

The FDA is actively monitoring for any firms marketing products with fraudulent COVID-19 diagnostic, prevention and treatment claims. The FDA is exercising its authority to protect consumers from firms selling unauthorized products with false or misleading claims. The FDA may send warning letters, or pursue seizures or injunctions against people, products, or companies that violate the law. We are also increasing our enforcement at ports of entry to ensure that fraudulent products do not enter the country through our borders.

In addition, the FDA is monitoring complaints of fake coronavirus treatments and tests. Consumers and health care professionals can help by reporting suspected fraud to the FDA's Health Fraud Program or the Office of Criminal Investigations.

How to Protect Yourself and Your Family From Coronavirus Fraud

The FDA advises consumers to be cautious of websites and stores selling products that claim to prevent, treat or cure COVID-19. There are no FDA-approved products to prevent COVID-19. Products marketed for veterinary use, or "for research use only," or otherwise not for human consumption, have not been evaluated for safety and should never be used by humans. For example, the FDA is aware of people trying to prevent COVID-19 by taking a product called chloroquine phosphate, which is sold to treat parasites in aquarium fish. Products for veterinary use or for "research use only" may have adverse effects, including serious illness and death, when taken by people. Don't take any form of chloroquine unless it has been prescribed for you by your health care provider and obtained from legitimate sources.

Here are some tips to identify false or misleading claims.

- Be suspicious of products that claim to treat a wide range of diseases.
- Personal testimonials are no substitute for scientific evidence.
- Few diseases or conditions can be treated quickly, so be suspicious of any therapy claimed as a "quick fix."
- If it seems too good to be true, it probably is.
- "Miracle cures," which claim scientific breakthroughs or contain secret ingredients, are likely a hoax.
- Know that you can't test yourself for coronavirus disease.

If you have symptoms of COVID-19, follow the Centers for Disease Control and Prevention's guidelines, and speak to your medical provider. Your health care provider will advise you about whether you should get tested and the process for being tested in your area.

If you have a question about a treatment or test found online, talk to your health care provider or doctor. If you have a question about a medication, call your pharmacist or the FDA.

The FDA's Division of Drug Information (DDI) will answer almost any drug question. DDI pharmacists are available by email, druginfo@fda.hhs.gov, and by phone, 1-855-543-DRUG (3784) and 301-796-3400.

The sale of fraudulent COVID-19 products is a threat to the public health. If you are concerned about the spread of COVID-19, talk to your health care provider and follow the advice of FDA's federal partners about how to prevent the spread of this illness.

Michael Felberbaum
Senior Adviser

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

<image001.png>

<image002.jpg>

<image003.jpg>

<image004.jpg>

<image005.jpg>

<image006.jpg>

From: Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]
Sent: 3/25/2020 8:54:45 PM
To: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
Subject: Fwd: FDA_Imported-Non-NIOSH-letter.pdf
Attachments: FDA_Imported-Non-NIOSH-letter.pdf; ATT00001.htm

Does this mean we aren't accepting Chinese masks?

Sent from my iPhone

Begin forwarded message:

From: John Bardis <JBardis@cooler.com>
Date: March 25, 2020 at 8:27:44 PM EDT
To: "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>
Subject: FDA_Imported-Non-NIOSH-letter.pdf

From: Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]
Sent: 3/25/2020 9:13:25 PM
To: Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]
Subject: Fwd: fyi, preparing to issue: COVID-19 Daily Roundup
Attachments: 2020.03.25_Final.docx; ATT00001.htm

You sending these to joe too? I would cut and paste text into an email.

Sent from my iPhone

Begin forwarded message:

From: "Caccomo, Stephanie" <Stephanie.Caccomo@fda.hhs.gov>
Date: March 25, 2020 at 9:03:37 PM EDT
To: OMA-Notifications <OMA-Notifications@fda.hhs.gov>
Cc: OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>, 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>
Subject: fyi, preparing to issue: COVID-19 Daily Roundup

Hi! Preparing to issue today's daily roundup.

-Stephanie

From: Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]
Sent: 3/26/2020 7:33:28 AM
To: Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]
CC: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
Subject: Re: CDRH response update

This is extremely helpful. Thank you.

Sent from my iPhone

On Mar 26, 2020, at 6:52 AM, Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov> wrote:

Dr Hahn,

Below please find a list of CDRH's emergency response actions from yesterday as well as anticipated actions in the coming 48 hours.

March 25, 2020 actions

- Ventilators:
  - CDRH issued a blanket **EUA** for ventilators, anesthesia gas machines modified for use as ventilators, and positive pressure breathing devices modified for use as ventilators (collectively referred to as "ventilators"), ventilator tubing connectors, and ventilator accessories. Manufacturers and other stakeholders may submit a request to FDA under the process outlined in the EUA to have their device(s) added to the EUA.
  - CDRH authorized an **EUA** for Beijing Aeonmed Co., Ltd., Beijing, China, for an unapproved ventilator model VG70 that NY state has purchased. The ventilators will be imported next week.
  - A CDRH subject matter expert worked with the FEMA ventilator surprise chain task force to facilitate the availability of a splitter to enable a single ventilator to support multiple patients at one time.
  - CDRH authorized an **EUA** for the Prisma Health 3D printed Ventilator Expansion Splitter (VESper) that allows one ventilator to be used on more than one patient.
  - CDRH met with multiple stakeholders developing creative solutions to a potential ventilator shortage.

(b)(5)

- PPE
  - CDRH published **Guidance** on "Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency."
- Diagnostics:
  - CDRH held a Town Hall/Webinar with 1,000 participants during which we provided an overview of the March 16th guidance on diagnostics and answered questions from labs.
  - CDRH authorized **EUAs** for SARS-CoV-2 diagnostics from Avellino Labs and Perkin Elmer. Avellino labs notified FDA and was offering their test under the policy outlined in the Feb. 29th guidance.
  - We now have 18 authorized diagnostics and over 100 notifications from developers offering tests under the Feb 29th/March 16th guidance.

Anticipated actions in the next 48 hours

(b)(5)

- CDRH intends to publish Guidance on gowns. The guidance will address appropriate labeling for these products during the COVID-19 public health emergency without requiring 510(k) submission and clearance
- CDRH intends to publish Guidance on "Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency." The guidance will address appropriate labeling for these products during the COVID-19 public health emergency without requiring 510(k) submission and clearance.

Elizabeth

Elizabeth Hillebrenner
Associate Director for Scientific and Regulatory Programs

Center for Devices and Radiological Health
Office of the Center Director
U.S. Food and Drug Administration
Tel: 301-796-6346
elizabeth.hillebrenner@fda.hhs.gov

From: Caccomo, Stephanie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=950C32CEBC4B4F80B302C50CF31C8524-STEPHANIE.C]
Sent: 3/26/2020 7:46:50 AM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: RE: CDRH response update

Yes please!!!

Stephanie Caccomo
Press Officer

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

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Thursday, March 26, 2020 7:46 AM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: Re: CDRH response update

Agreed. (b)(5)

Sent from my iPhone

On Mar 26, 2020, at 7:40 AM, Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov> wrote:

Got it—thanks for saying something. We had a chat about providing below to SH, Carly and me. Will be very helpful going forward.

Stephanie Caccomo
Press Officer

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

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Thursday, March 26, 2020 7:33 AM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: Fwd: CDRH response update

Sent from my iPhone

Begin forwarded message:

From: "Hillebrenner, Elizabeth J" <Elizabeth.Hillebrenner@fda.hhs.gov>
Date: March 26, 2020 at 6:52:03 AM EDT

To: "Hahn, Stephen" <SH1@fda.hhs.gov>
Cc: "Shuren, Jeff" <Jeff.Shuren@fda.hhs.gov>, "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>, "Shah, Anand" <Anand.Shah@fda.hhs.gov>, "Rom, Colin" <Colin.Rom@fda.hhs.gov>
Subject: CDRH response update

Dr Hahn,

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(b)(5)

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(b)(5)

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Elizabeth

Elizabeth Hillebrenner
Associate Director for Scientific and Regulatory Programs

Center for Devices and Radiological Health
Office of the Center Director
U.S. Food and Drug Administration
Tel: 301-796-6346
elizabeth.hillebrenner@fda.hhs.gov

Sent: 3/26/2020 10:16:24 AM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
Subject: Narrative
Attachments: Narrative Talkers 03222020_759pm.docx

Steve – here is the most up to date

From: Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]
Sent: 3/27/2020 7:03:05 AM
To: Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]
Subject: Fwd: Convalescent Plasma
Attachments: Convalescent Plasma Q and A draft 032720.docx; ATT00001.htm; Plasma Process Draft 032720.pptx; ATT00002.htm

See attachments, do we need to adjust talkers?

Sent from my iPhone

Begin forwarded message:

From: "Marks, Peter" <Peter.Marks@fda.hhs.gov>
Date: March 27, 2020 at 6:55:13 AM EDT
To: "Hahn, Stephen" <SH1@fda.hhs.gov>, "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>
Cc: "Tierney, Julia" <Julia.Tierney@fda.hhs.gov>, "McNeill, Lorrie" <Lorrie.McNeill@fda.hhs.gov>
Subject: Convalescent Plasma

Dear Commissioner,

The questions you asked last night were great and thought provoking. It is already clear that the demand for this is going to be quite significant. I only wish we were closer than being about a week away from delivering units as part of the program. My apologies for that, but we worked as fast as possible through a number of issues that came up getting in the way.

After thinking about it overnight, I thought that it would be good to build out your Q and A further. Please see the attached. Also attaching a slide with a summary of the current workflow for the programs for your reference. I think that explaining what the therapy is and also reviewing the contours of what is in place and being put in place could be very helpful.

Perhaps you could give me a call? **(b)(6)** Thanks

Best Regards,
Peter

From: Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]
Sent: 3/27/2020 8:34:42 AM
To: Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; McWilliams, Carly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]
Subject: Fwd: CDRH response update - 3/27

Reactive for presser.

Sent from my iPhone

Begin forwarded message:

From: "Hahn, Stephen" <SH1@fda.hhs.gov>
Date: March 27, 2020 at 8:14:28 AM EDT
To: "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>
Subject: Fwd: CDRH response update - 3/27

(b)(5)

Thanks
Steve

From: Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
Date: March 27, 2020 at 6:44:04 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>
Cc: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: CDRH response update - 3/27

Dr. Hahn,
Below is CDRH's update of actions taken yesterday and anticipated soon.
Elizabeth

March 26, 2020 actions

- General:
  - CDRH posted information on our website regarding use of digital communication methods with healthcare providers.
  - FDA entered into an MOU with the Department of Veterans Affairs and the National Institutes of Health, National Institute of Allergy and Infectious Diseases (NIH/NIAID), and is working with America Makes, the National Additive Manufacturing Innovation Institute, to facilitate connections between patients and healthcare providers, local manufacturers with capabilities, and designs for needed medical products. This MOU provides a framework for collaboration intended to facilitate regulatory and basic science innovation with 3D printing technologies to respond to COVID-19.
  - CDRH met with the Defense Logistics Agency (DLA). The DLA is looking to have the Army procure components and manufacturer products that are on the FEMA needs list.
- Ventilators:

- More than 60 EUAs under review.
- CDRH initiated calls with Zoll, DoD, and Hamilton to discuss the potential for bringing their closed-loop control ventilators under the umbrella EUA approved yesterday.

- PPE
  - More than 20 EUAs and pre-EUAs under review.
  - CDRH was alerted that Tesla was importing Philips respirators from China for use in the U.S. They were temporarily held up at the border, but Philips provided documentation for import.
- Diagnostics:
  - 49 EUAs and over 200 pre-EUAs under review.
  - CDRH authorized an **EUA** for BGI Genomics SARS-CoV-2 diagnostic test. BGI's test is high throughput, was already being sold for clinical use following notification to FDA under the March 16th guidance, and will be scaled to 700k tests/week.
  - CDRH authorized an amendment to Quest's **EUA** to decrease the number of targets in each test, resulting in an increase in the number of patient specimens that can be processed.
  - We now have 19 authorized diagnostics and over 100 notifications from developers offering tests under the Feb 29th/March 16th guidance.

Anticipated actions in the next 48 hours

- CDRH anticipates authorizing an EUA for E.G. Battelle's N95 reprocessing and decontamination system.
- CDRH anticipates expanding the EUA for NIOSH-approved respirators such that manufacturers have to opt out rather than opt in to the policy and to include reusable respirators
- CDRH anticipates authorizing an EUA for Luminex's molecular diagnostic. The Luminex test is high throughput and can be scaled to 50k tests/week.
- CDRH anticipates authorizing an EUA for Abbott's Point of Care diagnostic.
- CDRH anticipates authorizing an umbrella EUA for all laboratories who notified FDA and began running validated tests under the Feb 29th/March 16th guidance. Similar to the umbrella EUA for ventilators, laboratories may submit their validation data to FDA and have their device(s) added to the umbrella EUA. This will be more efficient than individual EUAs from each of the >100 laboratories operating in this space. UNC has already submitted their data and we anticipate listing them as the first lab under this umbrella EUA.
- ~~CDRH anticipates authorizing an EUA for multiple models of Molekule Air for light and filtration based disinfection of room air.~~ CDRH is reassessing this EUA due to concerns the device could push virus into the air.
- CDRH is working with the Commissioner's Office to initiate discussions about FEMA procurement of thermometers.
- CDRH will engage with MedSun hospitals and hospital associations through our Network of Experts to obtain information about shortages of medical devices that are considered "essential" to providing care for patients in intensive care settings with the COVID-19 infection.
- CDRH intends to publish Guidance on gowns, gloves and face shields. The guidance will address appropriate labeling for these products during the COVID-19 public health emergency without requiring 510(k) submission and clearance
- CDRH intends to publish Guidance on "Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency." The guidance will address appropriate labeling for these products during the COVID-19 public health emergency without requiring 510(k) submission and clearance.

Elizabeth Hillebrenner
Associate Director for Scientific and Regulatory Programs
Center for Devices and Radiological Health
Office of the Center Director
U.S. Food and Drug Administration
Tel: 301-796-6346
elizabeth.hillebrenner@fda.hhs.gov

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: https://www.research.net/s/cdrhcustomerservice?ID=2000&S=E.

From: Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]
Sent: 3/27/2020 9:37:03 AM
To: Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]
Subject: Fwd: Sterigenics Sterilization Capacity urgently needed
Attachments: image001.png; ATT00001.htm; Sterigenics response March 25 2020.pdf; ATT00002.htm

Is this true? Won't matter with FEMA thing, right?

Sent from my iPhone

Begin forwarded message:

From: "Hahn, Stephen" <SH1@fda.hhs.gov>
Date: March 27, 2020 at 9:26:47 AM EDT
To: "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>
Subject: Fwd: Sterigenics Sterilization Capacity urgently needed

I thought this was resolved. Could you check with Brian Harrison?
Thanks
S

From: Kelly, Liam <liam.kelly@teleflex.com>
Date: March 26, 2020 at 8:38:55 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Sterigenics Sterilization Capacity urgently needed

Dear Dr Hahn,

Thank you for your continued efforts on behalf of patients as we continue to combat COVID-19.

I will be brief, the response from Cobb County has been very disappointing. They are only allowing for a limited reopening of the Sterigenics facility and for the sterilization of PPE only. We need sterilization capacity for critical Medical Devices and we need it immediately.

I respectfully ask you and your team to revisit the discussion with Cobb County. I attach the response from Sterigenics for your reference.

Thanks again for your help,

Liam

Liam Kelly
President and C.E.O.

P: +1.610.225.6808 | M: + (b)(6)
E: liam.kelly@teleflex.com

Teleflex
550 E. Swedesford Road, Suite 400, Wayne, PA 19087

Teleflex.com

From: Liam Kelly <liam.kelly@teleflex.com>
Date: Wednesday, March 18, 2020 at 8:37 AM
To: "Hahn, Stephen" <sh1@fda.hhs.gov>
Subject: Re: From the Office of Vince Forlenza, BD

Dear Dr Hahn,
Thank you for your attention to the sterilization issue. This will assist companies like Teleflex who are seeing increased demand for products needed to treat COVID-19 patients. Without this capacity we may have a supply issue which could impact patient care. It is in times of crisis that almost always brings out the best in people, companies and agencies. We should learn and make it every day life!
On a separate but related topic, I would like to make you aware of an effort that Teleflex is working on pertaining to a Point of Care, fully portable solution for the rapid identification of the presence of the novel coronavirus in respiratory secretions. We are in contact with BARDA and are submitting an application later today (BAA-20-100-SOL-0002, AOI #4.1C: Diagnostic Assay for detection of COVID-19 disease). **(b)(5)**

(b)(5)

Unlike the present solutions where samples are collected remotely and then transported to a central lab facility where the molecular assay is performed, our intention is to greatly reduce the overall process time by elimination of the sample transportation interval. Our intention is to provide a means of performing a highly sensitive assay at the time and place of sample collection. The system will consist of an off-mains, battery powered miniature detection unit capable of performing a proprietary assay technology on specific target nucleotide sequences in accordance with CDC guidelines, including control sequences for appropriate test result interpretation. Included in the kit will be all supporting equipment associated with the manipulation of the sample and the reagent materials. Potentially, this kit could be self-contained in a rugged suitcase-like enclosure designed for transportation and use in urgent, remote and rural locations. Although the system is designed for simplicity, pipetting skills and understanding of sterile technique will be required by the operator. This is a field deployable system which detects pathogen viral RNA specific to the COVID-19 virus within 45 minutes from sample collection. Each individual system is expected to be capable of processing up to 40 specimens per 24hr period.
In addition to the lab system, reagents and consumable /single use disposable materials will be provided separately as individually pouched kits capable of supporting two assays. The kits will be packaged as multiples in cartons designed for transportation an use in field deployed scenarios.
We are highly dedicated to doing all that we can to support the immediate needs of potential COVID-19 patients and the containment strategies associated.
Best wishes and keep safe,
Liam

Liam Kelly
President and C.E.O.

P: +1.610.225.6808 | M: **(b)(6)**
E: liam.kelly@teleflex.com

Teleflex
550 E. Swedesford Road, Suite 400, Wayne, PA 19087

Teleflex.com

From: "Hahn, Stephen" <sh1@fda.hhs.gov>
Date: Tuesday, March 17, 2020 at 4:29 PM
To: Vincent Forlenza <vincent_forlenza@bd.com>
Cc: Tom Polen <tom_polen@bd.com>, Scott Whitaker <SWhitaker@AdvaMed.org>, Elizabeth Woody <elizabeth_woody@bd.com>, "Shuren, Jeff" <Jeff.Shuren@fda.hhs.gov>, "Patel, Chaitali"

<chaitali.patel@fda.hhs.gov>, Liam Kelly <liam.kelly@teleflex.com>, "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>
Subject: Re: From the Office of Vince Forlenza, BD

Dear Mr. Forlenza,
Thank you very much for your letter. I appreciated having the opportunity to hear from you on today's call. I am copying my Chief of Staff, Keagan Lenihan, who will follow up with you.
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From: Vincent Forlenza <vincent_forlenza@bd.com>
Date: March 17, 2020 at 4:05:06 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Tom Polen <tom_polen@bd.com>, Whitaker, Scott <SWhitaker@AdvaMed.org>, Elizabeth Woody <elizabeth_woody@bd.com>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Patel, Chaitali <Chaitali.Patel@fda.hhs.gov>, liam.kelly@teleflex.com <liam.kelly@teleflex.com>
Subject: From the Office of Vince Forlenza, BD

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 3/27/2020 9:37:07 AM
To: Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]
Subject: Fwd: Sterigenics Sterilization Capacity urgently needed
Attachments: image001.png; ATT00001.htm; Sterigenics response March 25 2020.pdf; ATT00002.htm

Is this true? Won't matter with FEMA thing, right?

Sent from my iPhone

Begin forwarded message:

From: "Hahn, Stephen" <SH1@fda.hhs.gov>
Date: March 27, 2020 at 9:26:47 AM EDT
To: "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>
Subject: Fwd: Sterigenics Sterilization Capacity urgently needed

I thought this was resolved. Could you check with Brian Harrison?
Thanks
S

From: Kelly, Liam <liam.kelly@teleflex.com>
Date: March 26, 2020 at 8:38:55 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Sterigenics Sterilization Capacity urgently needed

Dear Dr Hahn,

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Thanks again for your help,

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Teleflex.com

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Subject: From the Office of Vince Forlenza, BD

From: Felberbaum, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4819A643CA2945CDB1A2631B83E69673-MICHAEL.FEL]
Sent: 3/27/2020 10:03:58 AM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; McWilliams, Carly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: CTAP/Plasma For Today
Attachments: CTAP One-Pager 03272020.docx; WH Presser TPs 03272020 903am.docx

Hi – putting us all on the same chain here.

Attaching updated WH press talkers – incorporates SH input.

Also attaching jazzed up CTAP one-pager for meeting with Jared/Hope – open to input.

Thanks!

Michael

Michael Felberbaum
Senior Adviser

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

From: Guram, Jeet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EF73BEA97E2B477B847EA302C4730CCF-GURJEET.GUR]
Sent: 3/27/2020 10:25:08 AM
To: McWilliams, Carly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
Subject: RE: Talkers for today
Attachments: WH Presser TPs 03272020 903am.docx; CTAP One-Pager 03272020.docx

On the efficacy of convalescent plasma and immune globulin? I haven't seen anything more specific than what's in these TPs.

--
Jeet Guram, M.D.
Senior Advisor, Office of the Commissioner
Food and Drug Administration
+1 (202) 230-0451 | jeet.guram@fda.hhs.gov

From: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Sent: Friday, March 27, 2020 10:18 AM
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Subject: RE: Talkers for today

Keagan, do the talking points for the TF need to be different than the ones Michael drafted? Also, jeet do you have any info on efficacy?

From: Felberbaum, Michael
Sent: Friday, March 27, 2020 10:14 AM
To: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: RE: Talkers for today

I just sent press briefing talkers and the one-pager for the meeting with Jared/Hope. Carly and Colin were both copied.

If there's anything additional needed, please let us know, but if ones for WHTF, we'll need assistance on those.

From: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Sent: Friday, March 27, 2020 10:12 AM
To: Rom, Colin <Colin.Rom@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: RE: Talkers for today

Looping in mf and SC as they are drafting most.

From: Rom, Colin
Sent: Friday, March 27, 2020 10:12 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Subject: Talkers for today

Dr Hahn just asked for talkers by noon today so he can review before he gets to WH. I realize this is very short turnaround time but wanted to flag

From: Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]
Sent: 3/27/2020 10:53:49 AM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
Subject: Re: Sterigenics Sterilization Capacity urgently needed

Yes. Will pass along.

Sent from my iPhone

On Mar 27, 2020, at 10:48 AM, Hahn, Stephen <SH1@fda.hhs.gov> wrote:

Should this go to Exec Sec for a response?
Thanks
S

From: Kelly, Liam <liam.kelly@teleflex.com>
Date: March 26, 2020 at 8:38:55 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Sterigenics Sterilization Capacity urgently needed

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From: Liam Kelly <liam.kelly@teleflex.com>
Date: Wednesday, March 18, 2020 at 8:37 AM
To: "Hahn, Stephen" <sh1@fda.hhs.gov>
Subject: Re: From the Office of Vince Forlenza, BD

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From: "Hahn, Stephen" <sh1@fda.hhs.gov>
Date: Tuesday, March 17, 2020 at 4:29 PM
To: Vincent Forlenza <vincent_forlenza@bd.com>
Cc: Tom Polen <tom_polen@bd.com>, Scott Whitaker <SWhitaker@AdvaMed.org>, Elizabeth Woody <elizabeth_woody@bd.com>, "Shuren, Jeff" <Jeff.Shuren@fda.hhs.gov>, "Patel, Chaitali" <chaitali.patel@fda.hhs.gov>, Liam Kelly <liam.kelly@teleflex.com>, "Lenihan, Keagan"

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Subject: From the Office of Vince Forlenza, BD

<image001.png>

Vincent A. Forlenza
Executive Chairman

BD
1 Becton Drive, Franklin Lakes, NJ 07417 USA MC: 097
Office: 201-847-7306 Fax: 201-847-5361
Email: Vincent.Forlenza@bd.com Website: www.BD.com

<Sterigenics response March 25 2020.pdf>

From: Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]
Sent: 3/27/2020 10:54:06 AM
To: Tobias, Lindsay [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a4766773c717470bbc55d204b5f067b2-Lindsay.Sto]
Subject: Fwd: Sterigenics Sterilization Capacity urgently needed
Attachments: image001.png; ATT00001.htm; Sterigenics response March 25 2020.pdf; ATT00002.htm

Exec sec pls.

Sent from my iPhone

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Date: March 27, 2020 at 10:48:12 AM EDT
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On a separate but related topic, I would like to make you aware of an effort that Teleflex is working on pertaining to a Point of Care, fully portable solution for the rapid identification of the presence of the novel coronavirus in respiratory secretions. We are in contact with BARDA and are submitting an application later today (BAA-20-100-SOL-0002, AOI #4.1C: Diagnostic Assay for detection of COVID-19 disease). **(b)(5)**
(b)(5)
Unlike the present solutions where samples are collected remotely and then transported to a central lab facility where the molecular assay is performed, our intention is to greatly reduce the overall process time by elimination of the sample transportation interval. Our intention is to provide a means of performing a highly sensitive assay at the time and place of sample collection. The system will consist of an off-mains, battery powered miniature detection unit capable of performing a proprietary assay technology on specific target nucleotide sequences in accordance with CDC guidelines, including control sequences for appropriate test result interpretation. Included in the kit will be all supporting equipment associated with the manipulation of the sample and the reagent materials. Potentially, this kit could be self-contained in a rugged suitcase-like enclosure designed for transportation and use in urgent, remote and rural locations. Although the system is designed for simplicity, pipetting skills and understanding of sterile technique will be required by the operator. This is a field deployable system which detects pathogen viral RNA specific to the COVID-19 virus within 45 minutes from sample collection. Each individual system is expected to be capable of processing up to 40 specimens per 24hr period.
In addition to the lab system, reagents and consumable /single use disposable materials will be provided separately as individually pouched kits capable of supporting two assays. The kits will be packaged as multiples in cartons designed for transportation an use in field deployed scenarios.
We are highly dedicated to doing all that we can to support the immediate needs of potential COVID-19 patients and the containment strategies associated.
Best wishes and keep safe,
Liam

Liam Kelly
President and C.E.O.

P: +1.610.225.6808 | M: + **(b)(6)**
E: liam.kelly@teleflex.com

Teleflex
550 E. Swedesford Road, Suite 400, Wayne, PA 19087

Teleflex.com

From: "Hahn, Stephen" <sh1@fda.hhs.gov>
Date: Tuesday, March 17, 2020 at 4:29 PM
To: Vincent Forlenza <vincent_forlenza@bd.com>
Cc: Tom Polen <tom_polen@bd.com>, Scott Whitaker <SWhitaker@AdvaMed.org>, Elizabeth Woody

<elizabeth_woody@bd.com>, "Shuren, Jeff" <Jeff.Shuren@fda.hhs.gov>, "Patel, Chaitali" <chaitali.patel@fda.hhs.gov>, Liam Kelly <liam.kelly@teleflex.com>, "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>
Subject: Re: From the Office of Vince Forlenza, BD

Dear Mr. Forlenza,
Thank you very much for your letter. I appreciated having the opportunity to hear from you on today's call. I am copying my Chief of Staff, Keagan Lenihan, who will follow up with you.
Steve

From: Vincent Forlenza <vincent_forlenza@bd.com>
Date: March 17, 2020 at 4:05:06 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Tom Polen <tom_polen@bd.com>, Whitaker, Scott <SWhitaker@AdvaMed.org>, Elizabeth Woody <elizabeth_woody@bd.com>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Patel, Chaitali <Chaitali.Patel@fda.hhs.gov>, liam.kelly@teleflex.com <liam.kelly@teleflex.com>
Subject: From the Office of Vince Forlenza, BD

From: Olivarria, Frank [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C180721DB774423F99990DD86E67057C-FRANK.OLIVA]
Sent: 3/27/2020 10:00:35 PM
To: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
CC: Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]
Subject: Materials: Stakeholder Call
Attachments: 1200-1-Remarks-CMS-SH Doctors call.1 20020328.docx; 1200-2-Run of Show-CMS COVID-19 Lessons from the Front Lines - Therapeutics 03282020_V3.docx

Dr. Hahn mentioned he wanted these printed, and also inquired on the Administrator's attendance to this from HHS. Colin confirmed the Administrator will not be joining this call from HHS, she is joining from home – I imagine SH will as well, not sure that someone can print for him in this case. Attaching here for easier reference in case someone is covering this.

These have been provided to Dr. Hahn in his schedule email.

Frank

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Friday, March 27, 2020 10:45 AM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Cc: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Subject: RE: HOLD: Stakeholder Call

I'll need the final printed. I think I should probably go to HHS for the call if Seema is planning to be there. Colin, can you find out about that?
Thanks
Steve

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Date: March 27, 2020 at 10:13:27 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>
Cc: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Subject: RE: HOLD: Stakeholder Call

Thank you

Janice - I will staff the call with Steve tomorrow.

Colin – can you please work on TP with Dayle (OEA) including toppers for Steve and me? Focus is on therapy, but we can touch on diagnostics, vax, and PPE. OEA can build from the attached document and include any potential announcements from today (blood; convalescent, etc).

Thanks,
Anand

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Friday, March 27, 2020 9:26 AM
To: Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Cc: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Subject: RE: HOLD: Stakeholder Call

Thanks, Janice

From: Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>
Date: March 27, 2020 at 9:25:31 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>
Cc: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Subject: RE: HOLD: Stakeholder Call

Hi, please note we're now holding two hours for the CMS stakeholder call on Saturday (12-2pm). Thanks! -j

-----Original Appointment-----
From: CMS Administrator <CMSAdministrator@cms.hhs.gov>
Sent: Thursday, March 26, 2020 10:13 AM
To: CMS Administrator; CMS SV1; Brookes, Brady (CMS); Good-Cohn, Meredith (CMS); Perez-Rivera, Diana (CMS); Czekai, Alina (CMS); Couch, Marion (CMS); Shah, Anand; Hahn, Stephen; Rom, Colin
Subject: HOLD: Stakeholder Call
When: Saturday, March 28, 2020 12:00 PM-2:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: #Pending

From: Caliguiri, Laura [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AA086F2D6C0346C49E996932D86AC62E-LAURA.CALIG]
Sent: 3/28/2020 7:55:42 AM
To: Bonner, Maria K. EOP/WHO [Maria.K.Bonner@who.eop.gov]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Williams, James H. EOP/WHO [(b)(6)]
Subject: RE: Daily Roundup March 27, 2020

Will do!

From: Bonner, Maria K. EOP/WHO <Maria.K.Bonner@who.eop.gov>
Sent: Friday, March 27, 2020 10:53 PM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Williams, James H. EOP/WHO [(b)(6)]
Subject: Re: Daily Roundup March 27, 2020

Hi Laura — Going forward, can you put James Williams on these distros? No need to include me. Thanks!

Maria K. Bonner
Special Assistant to the President
The Domestic Policy Council
The White House

This record is not identified as a copy or for convenience of reference. As such it remains a segregable presidential record under 44 U.S.C. § 2201(2)(B)(iv). To the extent this email involves the requesting or submitting of advice, legal workproduct, or presidential communications, availability of this record is subject to any rights, defenses, or privileges which the United States or any agency or person may invoke pursuant to 44 U.S.C. § 2205(2) and further restricted pursuant to 44 U.S.C. § 2204(a)(5).

On Mar 27, 2020, at 8:44 PM, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov> wrote:

>https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-daily-roundup-march-27-2020<

FDA NEWS RELEASE

Coronavirus (COVID-19) Update: Daily Roundup March 27, 2020

For Immediate Release:

March 27, 2020

The U.S. Food and Drug Administration today announced the following actions taken in its ongoing response effort to the COVID-19 pandemic:

- The FDA is working closely with manufacturers to make sure that they continue to notify the agency of any permanent discontinuance or interruption of drug and biological product manufacturing in a timely manner. Today, the agency published guidance for immediate implementation about the importance of these notifications, the timelines for drug and biologic manufacturers to follow when notifying the FDA, and the details for manufacturers to provide about the discontinuance or interruption in manufacturing. Along with the requirements in the statute and implementing regulations, the guidance requests that applicants and manufacturers provide additional details

and follow additional procedures to make sure the FDA has the specific information it needs to help prevent or mitigate shortages.

- The FDA issued a Consumer Update, Food Safety and Availability During the Coronavirus Pandemic, to describe the many ways the agency is working to help ensure the foods you, your family, and your pets eat are safe and available.

- The FDA issued a letter to stakeholders about the imminent threat to the health of consumers who may take chloroquine phosphate products used to treat disease in aquarium fish, thinking the products are interchangeable with FDA-approved drugs (used to treat malaria and certain other conditions in humans) that are being studied as a COVID-19 treatment for humans. Chloroquine products sold for aquarium use have not been evaluated by the FDA to determine whether they are safe, effective, properly manufactured, and adequately labeled for use in fish--let alone humans.

- Diagnostics update to date: During the COVID-19 pandemic, the FDA has worked with more than 220 test developers who have said they will be submitting emergency use authorizations (EUA) requests to FDA for tests that detect the virus. To date, 19 emergency use authorizations have been issued for diagnostic tests. Additionally, the FDA has been notified that more than 110 laboratories have begun testing under the policies set forth in our COVID-19 Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency Guidance. The FDA also continues to keep its COVID-19 Diagnostics FAQ up to date.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

###

Laura Caliguiri
Associate Commissioner for External Affairs

Office of External Affairs
U.S. Food and Drug Administration
Tel: 301 796-8546
Laura.Caliguiri@fda.hhs.gov

<image001.png>

<image002.jpg>

<image003.jpg>

<image004.jpg>

<image005.jpg>

<image006.jpg>

From: McWilliams, Carly [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B68C7458214244D08424FD441FEA4FDA-CARLYLE.MCW]
Sent: 3/28/2020 1:51:22 PM
To: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Guram, Jeet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ef73bea97e2b477b847ea302c4730ccf-Gurjeet.Gur]
CC: Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Copeland, Jakea [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7fe05ed233c42b68be990b12ae2c8c8-Jakea.Copel]
Subject: task force 3/28
Attachments: 2020.03.28 WHTF.docx

Appreciate the feedback colin!

Attached are materials I put together today for task force, please let me know if there is anything missing that needs to be included. thanks to jeet for connecting me on cder materials. I included talking points from cder on **(b)(5)** as I know many members are hearing about this.

From: Rom, Colin <Colin.Rom@fda.hhs.gov>
Sent: Saturday, March 28, 2020 12:57 PM
To: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Subject: Re: Tomorrow?

Nothing specific for this afternoon unless someone has heard anything different. Yesterday's talkers were very helpful to update on everything potentially moving within the agency this week and early next week

---

From: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Date: March 27, 2020 at 8:58:51 PM EDT
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>, Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Subject: Tomorrow?

Does commissioner need anything specific for task force? Dayle is leading on talkers for cms call.

From: Caccomo, Stephanie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=950C32CEBC4B4F80B302C50CF31C8524-STEPHANIE.C]
Sent: 3/28/2020 3:55:31 PM
To: Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]
Subject: RE: NYTimes--need FDA to update asap

Got it. Will clean up and send back to HHS. Mark edits on top, Stacy at the end.

(b)(5) In addition to NYT, waiting on a few other stories as well.

Stephanie Caccomo
Press Officer

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

From: Raza, Mark <Mark.Raza@fda.hhs.gov>
Sent: Saturday, March 28, 2020 3:52 PM
To: Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Subject: RE: NYTimes--need FDA to update asap

Please us Stacy's edits on the last few paragraphs.

From: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Sent: Saturday, March 28, 2020 3:50 PM
To: Raza, Mark <Mark.Raza@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Subject: RE: NYTimes--need FDA to update asap

Crossed emails with Mark. We had similar edits so feel free to take his language if you prefer it.

From: Raza, Mark <Mark.Raza@fda.hhs.gov>
Sent: Saturday, March 28, 2020 3:49 PM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Subject: RE: NYTimes--need FDA to update asap

(b)(5)

(b)(5)

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Saturday, March 28, 2020 2:47 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>
Subject: RE: NYTimes--need FDA to update asap

How about below, it's a bit long, but it's most of what we sent Sheila, plus (b)(5)
(b)(5)

(b)(5)

(b)(5)

Stephanie Caccomo
Press Officer

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

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Saturday, March 28, 2020 2:44 PM
To: Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>
Cc: Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Stecker, Judy (OS) <Judy.Stecker@hhs.gov>; Harrison, Brian (OS) <Brian.Harrison@hhs.gov>; McKeogh, Katherine (OS) <Katherine.McKeogh@hhs.gov>; Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>; Charrow, Robert (OS) <Robert.Charrow@hhs.gov>
Subject: Re: NYTimes--need FDA to update asap

Stephanie, can you connect with OCC and work through?

Sent from my iPhone

On Mar 28, 2020, at 2:36 PM, Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@hhs.gov> wrote:

https://www.nytimes.com/2020/03/28/us/testing-coronavirus-pandemic.html

Team FDA– (b)(5)

(b)(5)

I know you work with Sheila Kaplan of the times, but Michael Shear was the lead, so we should send to both him and Sheila. Michael.Shear@nytimes.com

When do you think we could have this statement by?

Hoping we can get it updated before the print paper version.

Thank you,

Caitlin B. Oakley
Deputy Assistant Secretary, National Spokesperson
Office of the Assistant Secretary for Public Affairs
U.S. Department of Health and Human Services
caitlin.oakley@hhs.gov
DRAFT PRE-DECISIONAL DELIBERATIVE

Dr. Stephen Hahn's first day as F.D.A. commissioner came just six weeks before Mr. Azar declared a public health emergency on Jan. 31. A radiation oncologist and researcher who helped turn around MD Anderson in Houston, one of the nation's leading cancer centers, Dr. Hahn had come to Washington to oversee a sprawling federal agency that regulates everything from lifesaving therapies to dog food.

But overnight, his mission — to manage 15,000 employees in a culture defined by precision and caution — was upended. A pathogen that Mr. Trump would later call the "invisible enemy" was hurtling toward the United States. It would fall to the newly arrived Dr. Hahn to help build a huge national capacity for testing by academic and private labs.

Instead, under his leadership, the F.D.A. became a significant roadblock, according to current and former officials as well as researchers and doctors at laboratories around the country.

Private-sector tests were supposed to be the next tier after the C.D.C. fulfilled its obligation to jump-start screening at public labs. In other countries hit hard by the coronavirus, governments acted quickly to speed tests to their populations. In South Korea, for example, regulators in early February summoned executives from 20 medical manufacturers, easing rules as they demanded tests.

But Dr. Hahn took a cautious approach. He was not proactive in reaching out to manufacturers, and instead deferred to his scientists, following the F.D.A.'s often cumbersome methods for approving medical screening.

Even the nation's public health labs were looking for the F.D.A.'s help. "We are now many weeks into the response with still no diagnostic or surveillance test available outside of C.D.C. for the vast majority of our member laboratories," Scott Becker, chief executive of the Association of Public Health Laboratories, wrote to Mr. Hahn in late February. "We believe a more expeditious route is needed at this time."

Ironically, it was Mr. Azar's emergency declaration that established the rules Dr. Hahn insisted on following. Designed to make it easier for drugmakers to pursue vaccines and other therapies during a crisis, such a declaration lets the F.D.A. speed approvals that could otherwise take a year or more.

But the emergency announcement created a new barrier for hospitals and laboratories that wanted to create their own tests to diagnose the coronavirus. Usually, they faced minimal federal regulation. But once Mr. Azar took action, they were subject to an F.D.A. process called an "emergency use authorization."

Even though researchers around the country quickly began creating tests that could diagnose Covid-19, many said they were hindered by the F.D.A.'s approval process. The new tests sat unused at labs around the country.

Stanford was one of them. Researchers at the world-renowned university had a working test by February, based on protocols published by the W.H.O. The organization had already deliveredmore than 250,000 of the

German-designed tests to 70 laboratories around the world, and doctors at the Stanford lab wanted to be prepared for a pandemic.

“Even if it didn’t come, it would be better to be ready than not to be ready,” said Dr. Benjamin Pinsky, the lab’s medical director.

But in the face of what he called “relatively tight” rules at the F.D.A., Dr. Pinsky and his colleagues decided against even trying to win permission. The Stanford clinical lab would not begin testing coronavirus samples until early March, when Dr. Hahn finally relaxed the rules.

From: Caccomo, Stephanie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=950C32CEBC4B4F80B302C50CF31C8524-STEPHANIE.C]
Sent: 3/28/2020 5:12:40 PM
To: Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]
Subject: RE: NYTimes--need FDA to update asap

Thanks, will send forward.

Stephanie Caccomo
Press Officer

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

From: Raza, Mark <Mark.Raza@fda.hhs.gov>
Sent: Saturday, March 28, 2020 5:11 PM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Subject: RE: NYTimes--need FDA to update asap

I think it's ok.

(b)(5)

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Saturday, March 28, 2020 4:52 PM
To: Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Subject: FW: NYTimes--need FDA to update asap

What do you think of additions below?

(b)(5)

(b)(5)

Stephanie Caccomo
Press Officer

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

From: Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>
Sent: Saturday, March 28, 2020 4:44 PM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Cc: Stecker, Judy (OS) <Judy.Stecker@hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Harrison, Brian (OS) <Brian.Harrison@hhs.gov>; McKeogh, Katherine (OS) <Katherine.McKeogh@hhs.gov>; Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>; Charrow, Robert (OS) <Robert.Charrow@hhs.gov>; Steele, Danielle (OS) <Danielle.Steele@hhs.gov>
Subject: Re: NYTimes--need FDA to update asap

Thanks for your work on this!

(b)(5)

Thanks

Sent from my iPhone

On Mar 28, 2020, at 4:05 PM, Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov> wrote:

hi—see below, we can cut down to the first two paragraphs, but what we sent to Sheila might not have been shared with the team, so there may be value in sharing below (b)(5) tomorrow.

(b)(5)

(b)(5)

Stephanie Caccomo
Press Officer

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

From: Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov>
Sent: Saturday, March 28, 2020 2:47 PM
To: Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>
Cc: Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Harrison, Brian (OS) <Brian.Harrison@hhs.gov>; McKeogh, Katherine (OS) <Katherine.McKeogh@hhs.gov>; Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>; Charrow, Robert (OS) <Robert.Charrow@hhs.gov>; Steele, Danielle (OS) <Danielle.Steele@hhs.gov>
Subject: Re: NYTimes--need FDA to update asap

Adding Danielle as well.

Sent from my iPhone

On Mar 28, 2020, at 2:35 PM, Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@hhs.gov> wrote:

https://www.nytimes.com/2020/03/28/us/testing-coronavirus-pandemic.html

Team FDA—See story that just published on testing. While there are many things we wish they would correct, it's urgent that they correct this part about the PHE creating extra barriers.

Could FDA please work up a statement asap about why it's wrong?

I know you work with Sheila Kaplan of the times, but Michael Shear was the lead, so we should send to both him and Sheila. Michael.Shear@nytimes.com

When do you think we could have this statement by?

Hoping we can get it updated before the print paper version.

Thank you,

Caitlin B. Oakley
Deputy Assistant Secretary, National Spokesperson
Office of the Assistant Secretary for Public Affairs
U.S. Department of Health and Human Services
caitlin.oakley@hhs.gov
DRAFT PRE-DECISIONAL DELIBERATIVE

Dr. Stephen Hahn's first day as F.D.A. commissioner came just six weeks before Mr. Azar declared a public health emergency on Jan. 31. A radiation oncologist and researcher who helped turn around MD Anderson in

Houston, one of the nation's leading cancer centers, Dr. Hahn had come to Washington to oversee a sprawling federal agency that regulates everything from lifesaving therapies to dog food.

But overnight, his mission — to manage 15,000 employees in a culture defined by precision and caution — was upended. A pathogen that Mr. Trump would later call the "invisible enemy" was hurtling toward the United States. It would fall to the newly arrived Dr. Hahn to help build a huge national capacity for testing by academic and private labs.

Instead, under his leadership, the F.D.A. became a significant roadblock, according to current and former officials as well as researchers and doctors at laboratories around the country.

Private-sector tests were supposed to be the next tier after the C.D.C. fulfilled its obligation to jump-start screening at public labs. In other countries hit hard by the coronavirus, governments acted quickly to speed tests to their populations. In South Korea, for example, regulators in early February summoned executives from 20 medical manufacturers, easing rules as they demanded tests.

But Dr. Hahn took a cautious approach. He was not proactive in reaching out to manufacturers, and instead deferred to his scientists, following the F.D.A.'s often cumbersome methods for approving medical screening.

Even the nation's public health labs were looking for the F.D.A.'s help. "We are now many weeks into the response with still no diagnostic or surveillance test available outside of C.D.C. for the vast majority of our member laboratories," Scott Becker, chief executive of the Association of Public Health Laboratories, wrote to Mr. Hahn in late February. "We believe a more expeditious route is needed at this time."

Ironically, it was Mr. Azar's emergency declaration that established the rules Dr. Hahn insisted on following. Designed to make it easier for drugmakers to pursue vaccines and other therapies during a crisis, such a declaration lets the F.D.A. speed approvals that could otherwise take a year or more.

But the emergency announcement created a new barrier for hospitals and laboratories that wanted to create their own tests to diagnose the coronavirus. Usually, they faced minimal federal regulation. But once Mr. Azar took action, they were subject to an F.D.A. process called an "emergency use authorization."

Even though researchers around the country quickly began creating tests that could diagnose Covid-19, many said they were hindered by the F.D.A.'s approval process. The new tests sat unused at labs around the country.

Stanford was one of them. Researchers at the world-renowned university had a working test by February, based on protocols published by the W.H.O. The organization had already deliveredmore than 250,000 of the German-designed tests to 70 laboratories around the world, and doctors at the Stanford lab wanted to be prepared for a pandemic.

"Even if it didn't come, it would be better to be ready than not to be ready," said Dr. Benjamin Pinsky, the lab's medical director.

But in the face of what he called "relatively tight" rules at the F.D.A., Dr. Pinsky and his colleagues decided against even trying to win permission. The Stanford clinical lab would not begin testing coronavirus samples until early March, when Dr. Hahn finally relaxed the rules.

From: Felberbaum, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4819A643CA2945CDB1A2631B83E69673-MICHAEL.FEL]
Sent: 3/29/2020 8:30:12 AM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: Re: FOR CONCURRENT JIC/OCC REVIEW BY 8:30 AM, SUNDAY 3/29: ASPR Press Release on hydroxychloroquine sulfate and chloroquine phosphate donations/EUA

Thanks.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Date: March 29, 2020 at 7:47:28 AM EDT
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: Re: FOR CONCURRENT JIC/OCC REVIEW BY 8:30 AM, SUNDAY 3/29: ASPR Press Release on hydroxychloroquine sulfate and chloroquine phosphate donations/EUA

EUa was signed late last night. Deliver is like noon today.

Sent from my iPhone

On Mar 28, 2020, at 9:40 PM, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov> wrote:

Hi all –

We have been working with ASPR on a draft press release regarding the issuance of the EUAs for hydroxychloroquine sulfate and chloroquine phosphate donations to the Strategic National Stockpile – which I understand may happen later tonight or early tomorrow.

Given the timing, I'm seeking concurrent JIC/OCC review (I'm also including a few others SMEs that have been working on this for their review – but CDER, please make sure to share with others I may have missed).

Please make edits in SharePoint **by 8:30 AM SUNDAY, MARCH 29**: http://sharepoint.fda.gov/orgs/OC-OCET/OCETdocs/nCoV/Shared%20Documents/JIC%20-%20FDA%20IMG/Press/For%20clearance/HHS%20accepts%201%20million%20doses%20of%20chloroquine%20as%20possible%20treatment%20for%20COVID-v9%20FDA.docx

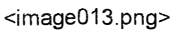
JIC SOCIAL: Here are a couple of tweets for consideration:

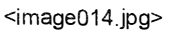
(b)(5)

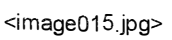
Thanks,

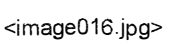
Michael
Michael Felberbaum
Senior Advisor

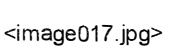
Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-9548 / Cell: **(b)(6)**
michael.felberbaum@fda.hhs.gov

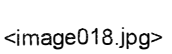












(b)(5)

(b)(5)

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 3/29/2020 10:13:57 AM
To: Guram, Jeet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ef73bea97e2b477b847ea302c4730ccf-Gurjeet.Gur]
Subject: CTAP One-Pager 03272020.docx
Attachments: CTAP One-Pager 03272020.docx; ATT00001.txt

Michael made it a little more Comms friendly in this version.

From: Rebello, Heidi [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2834CE193CA949799EF063E34A2CFA0B-HEIDI.REBEL]
Sent: 3/29/2020 12:22:36 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: Senator Paul email (to flip to SH)
Attachments: Senator Paul.docx; International Journal of AntiMicrobial Agents.pdf; Letter from Dr. Zelenko.pdf

Email to Senator Paul + 2 attachments

From: Rebello, Heidi [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2834CE193CA949799EF063E34A2CFA0B-HEIDI.REBEL]
Sent: 3/29/2020 12:25:38 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: Congressman Diaz-Balart email (to flip to SH)
Attachments: Cong. Diaz-Balart.docx; International Journal of AntiMicrobial Agents.pdf; Letter from Dr. Zelenko.pdf

Email to Congressman Diaz-Balart + 2 attachments

From: Olivarria, Frank [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C180721DB774423F99990DD86E67057C-FRANK.OLIVA]
Sent: 3/29/2020 5:17:49 PM
To: Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]
CC: Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: RE: Request to send email from SH1 to Senator Paul and Congressman Diaz-Balart
Attachments: COVID-19 research material for your review and input; COVID-19 research material for your review and input

Completed. Attached are copies of the emails sent.

Thank you,
Frank

From: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Sent: Sunday, March 29, 2020 1:52 PM
To: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Cc: Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: Request to send email from SH1 to Senator Paul and Congressman Diaz-Balart

Hi Frank,
Keagan would like you to send an email on behalf of the Commissioner to Senator Paul and a separate email to Congressman Diaz, both from his SH1 inbox. The first attachment provides background/original request from Keagan. The second attachment is the text for the email to Senator Paul and you will need to attach the 2 PDFs to the email (in the order they are in now). The email for Congressman Diaz-Balart is third attachment and you will need to attach the same 2 PDFs to the Congressman's email, also in same order they are here. Let me know if you need any clarity and thanks so much.

I believe Janice may be waiting on the email address for Senator Paul. Here is Congressman Mario Diaz-Balart's: mariohr3920@mail.house.gov.

I recommend the subject line of the emails to be:
COVID-19 research material for your review and input

From: Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]
Sent: 3/29/2020 10:24:15 PM
To: McBride, Maren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]
CC: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Tyler, James [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddb047ff73e640b29259d7ca22611e67-James.Tyler]; Tootle, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0900da296e4a474da740ef1c47e6f1bd-William.Too]
Subject: Re: Background for your 8:30

Maren- pls trim down to VERY top level.

Sent from my iPhone

On Mar 29, 2020, at 10:20 PM, McBride, Maren <Maren.McBride@fda.hhs.gov> wrote:

Hi Commissioner—

Below is some funding background for your meeting with the Secretary tomorrow at 8:30 on the Supplemental. Overall,

(b)(5)

(b)(5)

From: Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]
Sent: 3/30/2020 12:40:50 PM
To: Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]
Subject: Fwd: Sterigenics Sterilization Capacity urgently needed
Attachments: image001.png; ATT00001.htm; Sterigenics response March 25 2020.pdf; ATT00002.htm

Is it worth a call to Gov too?

Sent from my iPhone

Begin forwarded message:

From: "Hahn, Stephen" <SH1@fda.hhs.gov>
Date: March 30, 2020 at 12:19:20 PM EDT
To: "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>
Subject: Fwd: Sterigenics Sterilization Capacity urgently needed

Is there any update?

From: Kelly, Liam <liam.kelly@teleflex.com>
Date: March 26, 2020 at 8:38:55 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Sterigenics Sterilization Capacity urgently needed

Dear Dr Hahn,

Thank you for your continued efforts on behalf of patients as we continue to combat COVID-19.

I will be brief, the response from Cobb County has been very disappointing. They are only allowing for a limited reopening of the Sterigenics facility and for the sterilization of PPE only. We need sterilization capacity for critical Medical Devices and we need it immediately.

I respectfully ask you and your team to revisit the discussion with Cobb County. I attach the response from Sterigenics for your reference.

Thanks again for your help,

Liam

Liam Kelly
President and C.E.O.

P: +1.610.225.6808 | M: + **(b)(6)**
E: liam.kelly@teleflex.com

Teleflex
550 E. Swedesford Road, Suite 400, Wayne, PA 19087

Teleflex.com

From: Liam Kelly <liam.kelly@teleflex.com>
Date: Wednesday, March 18, 2020 at 8:37 AM
To: "Hahn, Stephen" <sh1@fda.hhs.gov>
Subject: Re: From the Office of Vince Forlenza, BD

Dear Dr Hahn,
Thank you for your attention to the sterilization issue. This will assist companies like Teleflex who are seeing increased demand for products needed to treat COVID-19 patients. Without this capacity we may have a supply issue which could impact patient care. It is in times of crisis that almost always brings out the best in people, companies and agencies. We should learn and make it every day life!
On a separate but related topic, I would like to make you aware of an effort that Teleflex is working on pertaining to a Point of Care, fully portable solution for the rapid identification of the presence of the novel coronavirus in respiratory secretions. We are in contact with BARDA and are submitting an application later today (BAA-20-100-SOL-0002, AOI #4.1C: Diagnostic Assay for detection of COVID-19 disease). **(b)(5)**
(b)(5)
Unlike the present solutions where samples are collected remotely and then transported to a central lab facility where the molecular assay is performed, our intention is to greatly reduce the overall process time by elimination of the sample transportation interval. Our intention is to provide a means of performing a highly sensitive assay at the time and place of sample collection. The system will consist of an off-mains, battery powered miniature detection unit capable of performing a proprietary assay technology on specific target nucleotide sequences in accordance with CDC guidelines, including control sequences for appropriate test result interpretation. Included in the kit will be all supporting equipment associated with the manipulation of the sample and the reagent materials. Potentially, this kit could be self-contained in a rugged suitcase-like enclosure designed for transportation and use in urgent, remote and rural locations. Although the system is designed for simplicity, pipetting skills and understanding of sterile technique will be required by the operator. This is a field deployable system which detects pathogen viral RNA specific to the COVID-19 virus within 45 minutes from sample collection. Each individual system is expected to be capable of processing up to 40 specimens per 24hr period.
In addition to the lab system, reagents and consumable /single use disposable materials will be provided separately as individually pouched kits capable of supporting two assays. The kits will be packaged as multiples in cartons designed for transportation an use in field deployed scenarios.
We are highly dedicated to doing all that we can to support the immediate needs of potential COVID-19 patients and the containment strategies associated.
Best wishes and keep safe,
Liam

Liam Kelly
President and C.E.O.

P: +1.610.225.6808 | M: + **(b)(6)**
E: liam.kelly@teleflex.com

Teleflex
550 E. Swedesford Road, Suite 400, Wayne, PA 19087

Teleflex.com

From: "Hahn, Stephen" <sh1@fda.hhs.gov>
Date: Tuesday, March 17, 2020 at 4:29 PM
To: Vincent Forlenza <vincent_forlenza@bd.com>
Cc: Tom Polen <tom_polen@bd.com>, Scott Whitaker <SWhitaker@AdvaMed.org>, Elizabeth Woody <elizabeth_woody@bd.com>, "Shuren, Jeff" <Jeff.Shuren@fda.hhs.gov>, "Patel, Chaitali" <chaitali.patel@fda.hhs.gov>, Liam Kelly <liam.kelly@teleflex.com>, "Lenihan, Keagan"

<Keagan.Lenihan@fda.hhs.gov>
Subject: Re: From the Office of Vince Forlenza, BD

Dear Mr. Forlenza,
Thank you very much for your letter. I appreciated having the opportunity to hear from you on today's call. I am copying my Chief of Staff, Keagan Lenihan, who will follow up with you.
Steve

From: Vincent Forlenza <vincent_forlenza@bd.com>
Date: March 17, 2020 at 4:05:06 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Tom Polen <tom_polen@bd.com>, Whitaker, Scott <SWhitaker@AdvaMed.org>, Elizabeth Woody <elizabeth_woody@bd.com>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Patel, Chaitali <Chaitali.Patel@fda.hhs.gov>, liam.kelly@teleflex.com <liam.kelly@teleflex.com>
Subject: From the Office of Vince Forlenza, BD

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 3/30/2020 12:40:55 PM
To: Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]
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To: "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>
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Thanks again for your help,

Liam

Liam Kelly
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E: liam.kelly@teleflex.com

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Teleflex.com

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Subject: Re: From the Office of Vince Forlenza, BD

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(b)(5)
Unlike the present solutions where samples are collected remotely and then transported to a central lab facility where the molecular assay is performed, our intention is to greatly reduce the overall process time by elimination of the sample transportation interval. Our intention is to provide a means of performing a highly sensitive assay at the time and place of sample collection. The system will consist of an off-mains, battery powered miniature detection unit capable of performing a proprietary assay technology on specific target nucleotide sequences in accordance with CDC guidelines, including control sequences for appropriate test result interpretation. Included in the kit will be all supporting equipment associated with the manipulation of the sample and the reagent materials. Potentially, this kit could be self-contained in a rugged suitcase-like enclosure designed for transportation and use in urgent, remote and rural locations. Although the system is designed for simplicity, pipetting skills and understanding of sterile technique will be required by the operator. This is a field deployable system which detects pathogen viral RNA specific to the COVID-19 virus within 45 minutes from sample collection. Each individual system is expected to be capable of processing up to 40 specimens per 24hr period.
In addition to the lab system, reagents and consumable /single use disposable materials will be provided separately as individually pouched kits capable of supporting two assays. The kits will be packaged as multiples in cartons designed for transportation an use in field deployed scenarios.
We are highly dedicated to doing all that we can to support the immediate needs of potential COVID-19 patients and the containment strategies associated.
Best wishes and keep safe,
Liam

Liam Kelly
President and C.E.O.

P: +1.610.225.6808 | M: + **(b)(6)**
E: liam.kelly@teleflex.com

Teleflex
550 E. Swedesford Road, Suite 400, Wayne, PA 19087

Teleflex.com

From: "Hahn, Stephen" <sh1@fda.hhs.gov>
Date: Tuesday, March 17, 2020 at 4:29 PM
To: Vincent Forlenza <vincent_forlenza@bd.com>
Cc: Tom Polen <tom_polen@bd.com>, Scott Whitaker <SWhitaker@AdvaMed.org>, Elizabeth Woody <elizabeth_woody@bd.com>, "Shuren, Jeff" <Jeff.Shuren@fda.hhs.gov>, "Patel, Chaitali"

<chaitali.patel@fda.hhs.gov>, Liam Kelly <liam.kelly@teleflex.com>, "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>
Subject: Re: From the Office of Vince Forlenza, BD

Dear Mr. Forlenza,
Thank you very much for your letter. I appreciated having the opportunity to hear from you on today's call. I am copying my Chief of Staff, Keagan Lenihan, who will follow up with you.
Steve

From: Vincent Forlenza <vincent_forlenza@bd.com>
Date: March 17, 2020 at 4:05:06 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Tom Polen <tom_polen@bd.com>, Whitaker, Scott <SWhitaker@AdvaMed.org>, Elizabeth Woody <elizabeth_woody@bd.com>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Patel, Chaitali <Chaitali.Patel@fda.hhs.gov>, liam.kelly@teleflex.com <liam.kelly@teleflex.com>
Subject: From the Office of Vince Forlenza, BD

From: Anderson, Erika [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=98606928B9A64EDFB25ABA1E3573FDFE-ERANDERS]
Sent: 3/30/2020 1:12:49 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: RE: Sterigenics Sterilization Capacity urgently needed

Not at this time

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Monday, March 30, 2020 12:41 PM
To: Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Subject: Fwd: Sterigenics Sterilization Capacity urgently needed

Is it worth a call to Gov too?

Sent from my iPhone

Begin forwarded message:

From: "Hahn, Stephen" <SH1@fda.hhs.gov>
Date: March 30, 2020 at 12:19:20 PM EDT
To: "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>
Subject: Fwd: Sterigenics Sterilization Capacity urgently needed

Is there any update?

From: Kelly, Liam <liam.kelly@teleflex.com>
Date: March 26, 2020 at 8:38:55 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Sterigenics Sterilization Capacity urgently needed

Dear Dr Hahn,

Thank you for your continued efforts on behalf of patients as we continue to combat COVID-19.

I will be brief, the response from Cobb County has been very disappointing. They are only allowing for a limited reopening of the Sterigenics facility and for the sterilization of PPE only. We need sterilization capacity for critical Medical Devices and we need it immediately.

I respectfully ask you and your team to revisit the discussion with Cobb County. I attach the response from Sterigenics for your reference.

Thanks again for your help,

Liam

Liam Kelly
President and C.E.O.

P: +1.610.225.6808 | M: + (b)(6)
E: liam.kelly@teleflex.com

Teleflex
550 E. Swedesford Road, Suite 400, Wayne, PA 19087

Teleflex.com

From: Liam Kelly <liam.kelly@teleflex.com>
Date: Wednesday, March 18, 2020 at 8:37 AM
To: "Hahn, Stephen" <sh1@fda.hhs.gov>
Subject: Re: From the Office of Vince Forlenza, BD

Dear Dr Hahn,
Thank you for your attention to the sterilization issue. This will assist companies like Teleflex who are seeing increased demand for products needed to treat COVID-19 patients. Without this capacity we may have a supply issue which could impact patient care. It is in times of crisis that almost always brings out the best in people, companies and agencies. We should learn and make it every day life!
On a separate but related topic, I would like to make you aware of an effort that Teleflex is working on pertaining to a Point of Care, fully portable solution for the rapid identification of the presence of the novel coronavirus in respiratory secretions. We are in contact with BARDA and are submitting an application later today (BAA-20-100-SOL-0002, AOI #4.1C: Diagnostic Assay for detection of COVID-19 disease). (b)(5)
(b)(5)
Unlike the present solutions where samples are collected remotely and then transported to a central lab facility where the molecular assay is performed, our intention is to greatly reduce the overall process time by elimination of the sample transportation interval. Our intention is to provide a means of performing a highly sensitive assay at the time and place of sample collection. The system will consist of an off-mains, battery powered miniature detection unit capable of performing a proprietary assay technology on specific target nucleotide sequences in accordance with CDC guidelines, including control sequences for appropriate test result interpretation. Included in the kit will be all supporting equipment associated with the manipulation of the sample and the reagent materials. Potentially, this kit could be self-contained in a rugged suitcase-like enclosure designed for transportation and use in urgent, remote and rural locations. Although the system is designed for simplicity, pipetting skills and understanding of sterile technique will be required by the operator. This is a field deployable system which detects pathogen viral RNA specific to the COVID-19 virus within 45 minutes from sample collection. Each individual system is expected to be capable of processing up to 40 specimens per 24hr period.
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Best wishes and keep safe,
Liam

Liam Kelly
President and C.E.O.

P: +1.610.225.6808 | M: (b)(6)
E: liam.kelly@teleflex.com

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From: "Hahn, Stephen" <sh1@fda.hhs.gov>
Date: Tuesday, March 17, 2020 at 4:29 PM
To: Vincent Forlenza <vincent forlenza@bd.com>
Cc: Tom Polen <tom polen@bd.com>, Scott Whitaker <SWhitaker@AdvaMed.org>, Elizabeth Woody <elizabeth woody@bd.com>, "Shuren, Jeff" <Jeff.Shuren@fda.hhs.gov>, "Patel, Chaitali" <chaitali.patel@fda.hhs.gov>, Liam Kelly <liam.kelly@teleflex.com>, "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>
Subject: Re: From the Office of Vince Forlenza, BD

Dear Mr. Forlenza,
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Steve

From: Vincent Forlenza <vincent forlenza@bd.com>
Date: March 17, 2020 at 4:05:06 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Tom Polen <tom polen@bd.com>, Whitaker, Scott <SWhitaker@AdvaMed.org>, Elizabeth Woody <elizabeth woody@bd.com>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Patel, Chaitali <Chaitali.Patel@fda.hhs.gov>, liam.kelly@teleflex.com <liam.kelly@teleflex.com>
Subject: From the Office of Vince Forlenza, BD

From: Caliguiri, Laura [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AA086F2D6C0346C49E996932D86AC62E-LAURA.CALIG]
Sent: 3/30/2020 5:41:22 PM
To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
CC: Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]
Subject: RE: Abbot POC talkers.docx

+ Heidi, minus SH had a hard time multitasking to what he actually read but Heidi, I think we can pull the latter part below for tweets and together can figure out

---

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Monday, March 30, 2020 4:17 PM
To: Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: Abbot POC talkers.docx

See below and attached.

Abbot POC talkers:

Hospitals without walls, expanding the healthcare workforce, patients over paperwork and expanding telehealth

These are game changing in my opinion and will facilitate the care of patients in the is time of urgent need

Many thanks to President Trump's leadership and the incredible efforts of Secretary Azar and Administrator Verma.

As the FDA Commissioner, I am very proud of my staff's work in the last few months to help expedite the availability of testing in this country.

I am also incredibly appreciative of private industry's ingenuity and willingness to work with us to quickly develop and distribute these tests.

A real game changer has been the authorization of point of care tests, especially the Abbott point of care tests.

A point of care test is a test that gives you results right where you are getting your care—a hospital, an emergency department, an urgent care center, a drive by testing site.

Just like a doctor tests for the flu or strep in the doctor's office—and shares your results quickly—now we can do the same for coronavirus.

Without point of care testing, patients would have to wait for their doctors to send their sample to a laboratory, which took some time.

Now, with point of care tests available from Abbott and others, a doctor can give their patients the results in the same visit. And plan for appropriate treatment, if needed.

I am excited about these point of care tests being available now—a patient can hear from their doctor in as little as 5 minutes with their results. That is patient-centered care at its core.

I am proud of FDA staff for working quickly with Abbott as well. Normally, these types of tests can take months to develop. Abbott developed this test in a matter of weeks and we worked with them to rapidly get the test authorized.

Abbott shared that they will begin delivering tests next week and is ramping up to 50,000 tests each day. This will greatly help get tests where they are needed to patients across the country.

The most innovative and safe products come from industry and government taking an all hands on deck approach—just like in this case. Abbott and FDA worked together to get a fast, reliable and accurate test to market.

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 3/31/2020 7:40:37 AM
To: Danielle Steele (Danielle.Steele@hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=634b96dc13cf48f3971ce676b65e952f-HHS-Daniell]
Subject: CTAP
Attachments: CTAP_print_combined_v5_3.30.20.pdf; CTAP-handout-1col-draft3.pdf

For AMAs countermeasure conversation today. These are internal documents only.

From: Cohen, Kenneth [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44F565B739EA4879BDC516CAF2E136BC-KENNETH.COH]
Sent: 3/31/2020 9:00:50 AM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Schiller, Lowell [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77949b06919e4f91aa788e9a616c50c7-Lowell.Schi]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Roth, Lauren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52bfd08572694f269a20c508f3c04a03-Lauren.Roth]; Steele, Danielle (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=634b96dc13cf48f3971ce676b65e952f-HHS-Daniell]; Agnew, Ann (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=daa06163025f427aa913c47cafaf6589-HHS-Ann.Agn]; Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Stecker, Judy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e205440400ab4f629be1faccfe0846fc-HHS-Judy.St]; Mango, Paul (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2fe1932caf0249d2a0c6af5fb82c9ec5-HHS-Paul.Ma]; Malliou, Ekaterini (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c57996fad6db44ecba5ab5c1dacf7e0a-HHS-Ekateri]
CC: Hawkins, Jamar (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bd7c1a4031647ce89237aef4deb5d89-HHS-jamar.h]; Horska, Katerina (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70fcf3bd050a4050931f28d7bf5f5f0f-HHS-Katerin]; Rooths, Tarita [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9ea3aa705bda4ff98b5043488cc9688f-TRooths]; Helmanis, Lisa M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4345183932aa42a99c9adb79dfc1ba4b-LHELMANI]
Subject: COVID-19 FDA Guidance Tracker, March 31, 2020

Documents under OMB review

(No documents to report.)

Documents under HHS review

(No documents to report.)

Under Development in FDA

New to Tracker

(1) CBER, FRDTS #2020-297, SPS # 00433795, Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products

- Provides blood establishments that collect blood or blood components, including Source Plasma, with FDA's revised donor deferral recommendations for individuals with increased risk for transmitting human immunodeficiency virus infection.

(2) CBER, 2020-173, 00433796, Revised Recommendations to Reduce the Risk of Transfusion-Transmitted Malaria

- Provides blood establishments that collect blood and blood components with FDA's recommendations to reduce the risk of transfusion-transmitted malaria.

(3) CFSAN, 2020-306, 00433797, Temporary Policy Regarding Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments During the COVID-19 Public Health Emergency

- Provides flexibility regarding menu labeling requirements covered under the menu labeling provisions of section 403(q)(5)(H) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) during the COVID-19 pandemic.

On Previous Tracker

(4) CVM, 2020-298, 00433692, Guidance on the Conduct and Review of Studies to Support New Animal Drug Development during the COVID-19 Pandemic

- Provides general considerations to assist sponsors conducting studies to support new animal drug development to ensure the safety of animals and their owners and study personnel, maintain compliance with good laboratory practice regulations and good clinical practice, and maintain the scientific integrity of the data during the COVID-19 pandemic.

(5) CBER, 2020-265, 00433113, Alternative Procedures for Blood and Blood Components During the Coronavirus Disease (COVID-19) 2019 Public Health Emergency

- Discusses exceptions or alternative procedures to existing requirements that FDA considers acceptable regarding blood, blood components or blood products, during the COVID-19 Public Health Emergency.

(b)(5)

Link to All Posted COVID-19-Related FDA Guidance Documents for Industry, FDA Staff, and Other Stakeholders

https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders

DELIBERATIVE, INTERNAL, PRE-DECISIONAL

Kenneth R. Cohen, MHSA, MPP
Director, Regulations Policy and Management Staff
Office of Policy
301-796-7001

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 3/31/2020 9:15:20 AM
To: 'Hahn, Stephen' [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Guram, Jeet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ef73bea97e2b477b847ea302c4730ccf-Gurjeet.Gur]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
CC: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: RE: Please send to me
Attachments: CTAP-handout-1col-draft3.pdf

Here is the 1 about the program.

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Tuesday, March 31, 2020 9:03 AM
To: Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: Please send to me

The 3 pager CTAP document
Page 1 the bullet points about the program
Pages 2-3 graphics of pipeline

The Secretary wants this and it may get disseminated - so we need to make sure there is not CCI present. When can you get this to me?
Thanks
Steve

From: Kahn, Jeremy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1B98D36D2C1F4AE795140B68DE7B37F7-JEREMY.KAHN]
Sent: 3/31/2020 5:38:44 PM
To: Jungman, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5238a0caec064ba8b5d598115bc4f99f-Elizabeth.J]; Jensen, Valerie E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e940a2d8ae47461296d03872f74d9a6a-JENSENV]; Clarke, Mary Beth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b0124a15b9344d8483929470fefa403a-CLARKEM]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
CC: Sipes, Grail [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ccee8d18ee1f4a36885078f780c2f2f8-SIPESG]; Roberts, Rosemary [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b7838eab964e4ca1a7d703876d08411b-ROBERTSR]
Subject: RE: posting on website -hydroxychloroquine and chloroquine

Thanks all. Adding the edited language to the daily report. OCC will review as part of that process.

Thanks,
Jeremy

Jeremy Kahn, M.A.
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 301-796-8671
jeremy.kahn@fda.hhs.gov

From: Jungman, Elizabeth <Elizabeth.Jungman@fda.hhs.gov>
Date: March 31, 2020 at 5:35:12 PM EDT
To: Jensen, Valerie E <Valerie.Jensen@fda.hhs.gov>, Kahn, Jeremy <Jeremy.Kahn@fda.hhs.gov>, Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Cc: Sipes, Grail <Grail.Sipes@fda.hhs.gov>, Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>
Subject: RE: posting on website -hydroxychloroquine and chloroquine

Great thanks

Elizabeth Jungman
Director, Office of Regulatory Policy
Center for Drug Evaluation & Research, FDA
240-402-1563 (work)
240-278-6021 (work cell)

From: Jensen, Valerie E <Valerie.Jensen@fda.hhs.gov>
Date: March 31, 2020 at 5:06:29 PM EDT
To: Jungman, Elizabeth <Elizabeth.Jungman@fda.hhs.gov>, Kahn, Jeremy <Jeremy.Kahn@fda.hhs.gov>, Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Cc: Sipes, Grail <Grail.Sipes@fda.hhs.gov>, Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>
Subject: RE: posting on website -hydroxychloroquine and chloroquine

Thanks EJ (b)(5)

(b)(5)

From: Jungman, Elizabeth <Elizabeth.Jungman@fda.hhs.gov>
Sent: Tuesday, March 31, 2020 3:53 PM
To: Jensen, Valerie E <Valerie.Jensen@fda.hhs.gov>; Kahn, Jeremy <Jeremy.Kahn@fda.hhs.gov>; Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Cc: Sipes, Grail <Grail.Sipes@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>
Subject: RE: posting on website -hydroxychloroquine and chloroquine

Val: (b)(5)

(b)(5)

Elizabeth Jungman
Director, Office of Regulatory Policy
Center for Drug Evaluation & Research, FDA
240-402-1563 (work)
240-278-6021 (work cell)

From: Jensen, Valerie E <Valerie.Jensen@fda.hhs.gov>
Sent: Tuesday, March 31, 2020 3:49 PM
To: Kahn, Jeremy <Jeremy.Kahn@fda.hhs.gov>; Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Cc: Sipes, Grail <Grail.Sipes@fda.hhs.gov>; Jungman, Elizabeth <Elizabeth.Jungman@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>
Subject: RE: posting on website -hydroxychloroquine and chloroquine

Made some edits below – Thanks!

From: Kahn, Jeremy <Jeremy.Kahn@fda.hhs.gov>
Sent: Tuesday, March 31, 2020 3:40 PM
To: Jensen, Valerie E <Valerie.Jensen@fda.hhs.gov>; Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Cc: Sipes, Grail <Grail.Sipes@fda.hhs.gov>; Jungman, Elizabeth <Elizabeth.Jungman@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>
Subject: RE: posting on website -hydroxychloroquine and chloroquine

Proposing this for daily round-up today. Due ASAP. Feel free to propose edits.

(b)(5)

Jeremy Kahn
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel 301-796-8671
jeremy.kahn@fda.hhs.gov

From: Jensen, Valerie E <Valerie.Jensen@fda.hhs.gov>
Sent: Tuesday, March 31, 2020 3:09 PM
To: Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Cc: Sipes, Grail <Grail.Sipes@fda.hhs.gov>; Kahn, Jeremy <Jeremy.Kahn@fda.hhs.gov>; Jungman, Elizabeth

<Elizabeth.Jungman@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>
Subject: RE: posting on website -hydroxychloroquine and chloroquine

(b)(5) Thanks!

From: Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>
Sent: Tuesday, March 31, 2020 3:03 PM
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Cc: Sipes, Grail <Grail.Sipes@fda.hhs.gov>; Kahn, Jeremy <Jeremy.Kahn@fda.hhs.gov>; Jungman, Elizabeth <Elizabeth.Jungman@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Jensen, Valerie E <Valerie.Jensen@fda.hhs.gov>
Subject: RE: posting on website -hydroxychloroquine and chloroquine

The highlighted section looks like fairly standard language and is okay, but I'm adding in Val so she can weigh in.

(b)(5)

Mary Beth

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Sent: Tuesday, March 31, 2020 2:52 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Cc: Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>; Sipes, Grail <Grail.Sipes@fda.hhs.gov>; Kahn, Jeremy <Jeremy.Kahn@fda.hhs.gov>
Subject: RE: posting on website -hydroxychloroquine and chloroquine

This is the first we are hearing of this.

We have a previously cleared response but would need CDER to let us know if there's anything to share in addition to the below and our language on allowing compounding of these drugs. Adding Jeremy who has been working on drug shortages.

(b)(5)

Michael

Michael Felberbaum
Senior Adviser

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

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Tuesday, March 31, 2020 2:49 PM
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Cc: Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>; Sipes, Grail <Grail.Sipes@fda.hhs.gov>
Subject: FW: posting on website -hydroxychloroquine and chloroquine

Do we have comms for when this goes up?

From: Helms Williams, Emily <Emily.HelmsWilliams@fda.hhs.gov>
Sent: Tuesday, March 31, 2020 2:41 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: FW: posting on website -hydroxychloroquine and chloroquine

FYI re: hydroxychloroquine and chloroquine shortages. I've highlighted some key info in the email chain below.

From: Cunningham, Courtney C. <CourtneyC.Cunningham@fda.hhs.gov>
Sent: Tuesday, March 31, 2020 2:31 PM
To: Helms Williams, Emily <Emily.HelmsWilliams@fda.hhs.gov>
Cc: McLatchy, Johanna <Johanna.McLatchy@fda.hhs.gov>
Subject: FW: posting on website -hydroxychloroquine and chloroquine

Hi Emily,
Wanted to share this info with you below. DSS plans to post hydroxychloroquine and chloroquine shortages on their webpage today. Please let me know if you want any additional information.

Thanks,
Courtney

Courtney (Carpenter) Cunningham, MPH
CDER Liaison
OEP|Executive Operations Staff
301.796.4487 |(c **(b)(6)**
CourtneyC.Cunningham@fda.hhs.gov

From: Jensen, Valerie E <Valerie.Jensen@fda.hhs.gov>
Sent: Tuesday, March 31, 2020 2:23 PM
To: Rawlings, Kimberly <Kimberly.Rawlings@fda.hhs.gov>

Cc: Cunningham, Courtney C. <CourtneyC.Cunningham@fda.hhs.gov>
Subject: posting on website -hydroxychloroquine and chloroquine

Hi Kim, just wanted to make sure you know we posted hydroxychloroquine and chloroquine on our shortage website. This is due to the multiple reports that patients are not able to get their Rxs filled for rheumatologic conditions and although all the manufacturers are ramping up, this shows who has availability and we will continue to update and we also understand the posting will enable 503b outsourcers to assist with additional supplies as well.
Thanks, - Val

CAPT Valerie Jensen R.Ph.
Associate Director
CDER Drug Shortage Staff, FDA
Building #22/Room 6204
10903 New Hampshire Avenue
Silver Spring, MD 20993
Phone 301-796-0737
Fax 301-796-9887

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 3/31/2020 8:15:25 PM
To: Alex Azar II [AMA2@hhs.gov]
CC: Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]
Subject: COVID-19 Vitals_31 March 2020.docx
Attachments: COVID-19 Vitals_31 March 2020.docx; ATT00001.txt

FDA Vitals for Today

From: Flowers, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9418B62EC07642D7BC53C564E008F5CE-SUSAN.FLOWE]
Sent: 4/1/2020 1:24:46 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: Background for Medical Device Telecon - 1:30 p.m.
Attachments: Hahn tps industry call 20200401.docx

Background material:

Please find dial-in details for the FDA Team below as well as the current list of participants from industry. Also attached are Dr. Hahn's opening remarks.

Agenda:
Dr. Hahn opening remarks (5 min)
Question/Answers (10 min)

FDA-AdvaMed Conference Call
Wednesday, April 1, 2020
1:30pm ET

Leader Toll-Free Dial-In Number:
Leader International Dial-In Number:
Conference ID:

(b)(6)

FDA Participants
Dr. Stephen Hahn, Commissioner
Dr. Malvina Eydelman, Director of Opthlamic, Respiratory and ENT, CDRH
Dr. James Lee, Assistant Director, Respiratory, CDRH

Company Participants
Jan Makela, President and CEO, Imaging; GE Healthcare
John Groetelaars, President & CEO; Hill-Rom
John Liddicoat, EVP & President - Americas Region; Medtronic
Vitor Rocha, Chief Executive Officer; Philips
Michael Farrell, Chief Executive Officer; ResMed Corp.
Gaurav Agarwal, President and CEO; Vyaire

AdvaMed Staff
Scott Whitaker, President & CEO
Chris White, COO and General Counsel
Janet Trunzo, SVP, Technology and Regulatory
Greg Crist, Chief Advocacy Officer
Brian O'Connor, Chief of Staff
Nancy Jackson, Executive Office

From: Copeland, Jakea [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D7FE05ED233C42B68BE990B12AE2C8C8-JAKEA.COPEL]
Sent: 4/1/2020 1:51:05 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
CC: Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]
Subject: FW: Materials: WHTF 04.01.2020
Attachments: COVID-19 Vitals_31 March 2020.docx; 2020.04.01 WHTF.docx; 2020.04.01 FDA COVID Related News.docx; Serology Plan.docx

Hi Keagan/Colin,

Is there someone available to print these documents for Dr. Hahn? If needed, I can send them to the printer.

Jakea

From: Copeland, Jakea
Sent: Wednesday, April 1, 2020 1:48 PM
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Subject: Materials: WHTF 04.01.2020

Good Afternoon Dr. Hahn,

Attached are the 4 documents for today's WHTF meeting:

1. COVID-Vitals 03.31.2020 document
2. Detailed rundown of center activities
3. Media document of press on COVID-19
4. Serology Plan

Thank you,
Jakea

Jakea Copeland
Immediate Office, Office of the Commissioner
U.S. Food and Drug Administration
Desk Phone: (301) 796-7050
Email: Jakea.Copeland@fda.hhs.gov


FDA
U.S. FOOD & DRUG
ADMINISTRATION

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 4/1/2020 2:17:25 PM
To: Helms Williams, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=873be46f1b1a4d2b8df3fe67137cbdc8-HELMSWILLIA]
Subject: RE: Biweekly Oversight Call summary

Very helpful. Thanks.

From: Helms Williams, Emily <Emily.HelmsWilliams@fda.hhs.gov>
Sent: Wednesday, April 1, 2020 2:11 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: Biweekly Oversight Call summary

The oversight t-con only lasted about 10 minutes. Gemma Flamberg, Kara, Jon Hodnette and I were on the line. Jon reported the following:

(b)(5)

If you need any additional info, please let me know.

Emily C. Helms Williams
Senior Advisor, Office of the Chief of Staff

Office of the Commissioner
U.S. Food and Drug Administration
Tel: 301-796-3381
Emily.HelmsWilliams@fda.hhs.gov

FDA U.S. FOOD & DRUG ADMINISTRATION

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 4/1/2020 2:55:11 PM
To: Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]
Subject: RE: NYT follow-up

Did you follow up with JW here?

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Sent: Wednesday, April 1, 2020 2:53 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: RE: NYT follow-up

Bumping to the top of your inbox.

From: Felberbaum, Michael
Sent: Wednesday, April 01, 2020 8:34 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: NYT follow-up

Hi Keagan,

We worked with CDER and others on a response to NYT about the chloroquine/hydroxychloroquine EUA. This is cleared but we need input on the language as noted below.

Do you want to check with SH on this?

As a reminder, here is the relevant part of their questions: Do you agree with the characterization that Mr. Azar told Dr. Hahn to make the change, granting the EUA that was announced yesterday, or that he would do it himself? If that is not an accurate characterization, how would you describe the process by which the FDA gave the EUA after Dr. Hahn said during one of the task force press briefings, that there was not yet evidence that it worked for Covid-19.

Proposed Response:

(b)(5)

(b)(5)

Thanks,

Michael

Michael Felberbaum
Senior Advisor

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

From: Felberbaum, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4819A643CA2945CDB1A2631B83E69673-MICHAEL.FEL]
Sent: 4/1/2020 3:11:36 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
Subject: RE: NYT follow-up

(b)(5)

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, April 01, 2020 3:10 PM
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: RE: NYT follow-up

I am good then.

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Sent: Wednesday, April 1, 2020 2:58 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: RE: NYT follow-up

Yes, CDER was OK with it and I did speak with JW.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, April 01, 2020 2:55 PM
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: RE: NYT follow-up

Was CDER ok with this response?

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Sent: Wednesday, April 1, 2020 2:53 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: RE: NYT follow-up

Bumping to the top of your inbox.

From: Felberbaum, Michael
Sent: Wednesday, April 01, 2020 8:34 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: NYT follow-up

Hi Keagan,

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Do you want to check with SH on this?

As a reminder, here is the relevant part of their questions: Do you agree with the characterization that Mr. Azar told Dr. Hahn to make the change, granting the EUA that was announced yesterday, or that he would do it himself? If that is not an accurate characterization, how would you describe the process by which the FDA gave the EUA after Dr. Hahn said during one of the task force press briefings, that there was not yet evidence that it worked for Covid-19.

Proposed Response:

(b)(5)

Thanks,

Michael

Michael Felberbaum
Senior Advisor

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

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 4/1/2020 6:39:23 PM
To: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]
Subject: FW: FasterCures/Milken Institute Follow-up
Attachments: Expedited_Therapy_Proposal_Expanded_2020_03_29.pdf

In case this is helpful.

From: Dianna Dunne (ddunne@milkeninstitute.org) <ddunne@milkeninstitute.org>
Sent: Wednesday, April 1, 2020 5:52 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Esther Krofah (ekrofah@milkeninstitute.org) <ekrofah@milkeninstitute.org>
Subject: FasterCures/Milken Institute Follow-up

Keagan – attached are a set of ideas and recommendations that we received on how to quickly deploy antibody treatment. These are well-supported from the below researchers. This was also sent over to Gary Disbrow at BARDA. As I know you are extremely busy, let us know if these type of recommendations should be sent directly to a point person on the FDA team. I have cc'd Esther Krofah, Executive Director of FasterCures, A Center of the Milken Institute, if you and others have any questions.

Contributors:
Dr. Thomas Cahill, MD, Ph.D. is the Founder and Managing Partner of Newpath Management, L.P. Dr. Cahill received both his M.D. and Ph.D. from Duke University. His Ph.D. work, with Professor Robert Lefkowitz (Nobel Laureate), focused on studying cellular receptors and their signaling to inform novel drug development and discovery.

Dr. Benjamin Cravatt, Ph.D. is a Professor of Chemistry at The Scripps Research Institute in La Jolla, California and a member of the National Academy of Sciences. He is a founder of Vividion Therapeutics, Abide Therapeutics, and Activx Biosciences. Considered a co-inventor of activity-based proteomics and a substantial contributor to research on the endocannabinoid system, Cravatt is a prominent figure in the field of chemical biology.

Lynn R. Goldman, M.D., M.S., M.P.H. is the Michael and Lori Milken Dean and Professor of Environmental and Occupational Health at the Milken Institute School of Public Health at the George Washington University. She is a member of the National Academy of Medicine, the National Research Council Strategic Planning Group, and the NIH National Advisory Environmental Health Sciences Council.

Dr. Akiko Iwasaki, Ph.D. is a Waldemar von Zedtwitz Professor of Immunobiology at Yale University School of Medicine, and a Howard Hughes Medical Institute Investigator. She is a member of the National Academy of Sciences, and a member of the National Academy of Medicine. She has discovered molecular mechanisms underlying innate and adaptive antiviral immunity, and is a pioneer of novel vaccine strategies.

Dr. Michael Z. Lin, M.D., Ph.D. is Associate Professor of Neurobiology, Bioengineering, and Chemical and Systems Biology at Stanford University. A NIH Pioneer Award recipient, Dr. Lin develops protein-based tools for molecular imaging and control of gene and viral therapy.

Dr. David Liu, Ph.D. is Professor of Chemistry and Chemical Biology at Harvard University, Vice-Chair of the Faculty at the Broad Institute of MIT and Harvard, and a Howard Hughes Medical Institute Investigator. He is a founder of Editas Medicine, Beam Therapeutics, Pairwise Plants, Exo Therapeutics, and Prime Medicine. Liu is a pioneer in gene editing and protein engineering, and developed both base editing and prime editing technologies.

Dr. Michael Rosbash, Ph.D. is the 2017 Nobel laureate in Physiology or Medicine, a member of the National Academy of Sciences, a Professor of Biology at Brandeis University, and a Howard Hughes Medical Institute Investigator. Rosbash is a pioneer of chronobiology, the study of how living systems sense and respond to time.

Dr. Stuart Schreiber, Ph.D. is a Professor of Chemistry and Chemical Biology at Harvard University and co-Founder of the Broad Institute. He is a member of the National Academy of Sciences, and a founder of Vertex Pharmaceuticals, Ariad Pharmaceuticals, Infinity Pharmaceuticals, Forma Therapeutics, H3 Biomedicine and Jnana Therapeutics. Schreiber co-pioneered the field of chemical biology.

Dr. Edward Scolnick, M.D. is the former Head of Research and Development at Merck and a core investigator at the Broad Institute of MIT and Harvard. While at Merck, Scolnick oversaw the development of 28 FDA-approved drugs and vaccines, including statins, HIV protease inhibitors, and Gardasil. He also made seminal discoveries on the nature of genes that cause cancer in humans before beginning his 22-year career at Merck.

Dr. Jonathan W. Simons, M.D. is the CEO and President of the Prostate Cancer Foundation. Simons a molecular oncologist who previously was the Founding Director of the Winship NCI Cancer Center at Emory University, and currently co-directs the PCF-Veterans Administration Precision Oncology Program for Prostate Cancer.

Dr. Ramnik Xavier, M.D., Ph.D. is Professor of Medicine at Harvard Medical School, former Chief of Gastroenterology at Massachusetts General Hospital, and a core institute member of the Broad Institute of MIT and Harvard. He has discovered molecular mechanisms underlying innate and adaptive immunity, as well as causes of Crohn's disease, ulcerative colitis, inflammatory bowel disease, and autoimmunity.

Dianna Dunne
Head of Government Affairs
Milken Institute | 730 15th Street, NW
Washington, DC 20005
+1 202-336-8931

From: Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]
Sent: 4/2/2020 4:45:06 PM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
Subject: Re: FDA Letter

Think Jeff emailed us about this last night and this am. They are looking at it, but heard from them for the first time yesterday I think.

Sent from my iPhone

On Apr 2, 2020, at 4:41 PM, Hahn, Stephen <SH1@fda.hhs.gov> wrote:

From: Bill de Blasio [(b)(6)]
Date: April 2, 2020 at 12:25:19 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Re: FDA Letter

Commissioner, please confirm that you received this. Thanks, Bill

Sent from my BlackBerry 10 smartphone.

From: Bill de Blasio
Sent: Wednesday, April 1, 2020 9:55 PM
To: SH1@FDA.HHS.GOV
Subject: Fw: FDA Letter (Clean)

Commissioner, really appreciate your responsiveness. Mitch Katz will get you the medical data you need. Let me know if there are any questions or concerns. I can be reached anytime at [(b)(6)] Thanks, Bill

Sent from my BlackBerry 10 smartphone.

From: Kayla Arslanian [(b)(6)]
Sent: Wednesday, April 1, 2020 9:50 PM
To: Bill Deblasio
Subject: FDA Letter (Clean)

Dr. Stephen M. Hahn, M.D.
Commissioner, Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

April 1, 2020

Dr. Hahn,

I write to you regarding New York City's urgent need for ventilators to manage the current and, more importantly, the coming influx of patients with COVID-19.

Specifically, I request that you approve the Emergency Use Authorization (EUA) application for the automatic resuscitator called the Spiro Wave. This device would provide a critical emergency alternative to ICU ventilators. We are asking for extraordinarily expedited action because of the unprecedented times we are living through.

New York City continues to be disproportionately impacted by this global pandemic, with over 45,000 positive cases of COVID-19 and over 1,000 deaths to date. While we appreciate the resources that the federal government has made available thus far, our need continues to quickly outpace our resources and the City faces constant shortfalls of critical supplies. Right now, we need 400 ventilators by April 5th and another 2,500 to 3,000 to make it through next week.

Approval of an EUA would allow the Spiro Wave to be quickly distributed throughout New York City and the nation, and help build desperately needed capacity during this crisis. Completed units will be coming off the line as early as Friday, meaning that approval this week will save lives. This would not only augment our current resources but would also allow medical professionals to treat more patients in the coming weeks, which are projected to be increasingly challenging.

Further, the Spiro Wave was designed by a consortium of leading experts to operate a manual resuscitator safely and reliably. The design has been evolving in response to clinical feedback until as recently as this past weekend. Moreover, the device has also been reviewed by our public hospital clinicians and they have requested to use it as soon as possible.

The need for available material and personnel increases by the day as COVID-19 spreads throughout the country. The World Health Organization (WHO) and the Centers for Disease Control (CDC) estimates indicate that in the next 30 days, there will be a national shortage of ventilators in the range of 150,000 to 300,000 units.

I urge you to expedite the EUA for the Spiro Wave automatic resuscitator so that New York City and cities across the country can access this life saving resource. The decisions we make now will result in lives saved.

Sincerely,

Bill de Blasio

From: Felberbaum, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4819A643CA2945CDB1A2631B83E69673-MICHAEL.FEL]
Sent: 4/2/2020 8:12:25 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Block, Molly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e32ca68078848889751e7ec26910142-Molly.Block]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
CC: McWilliams, Carly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]
Subject: RE: No 'magic pill': The fight over unproven drugs for coronavirus

Bumping to top of box:

This is the quote —

"Accelerating the investigation of products that could potentially benefit people affected by the COVID-19 pandemic is one of the FDA's highest priorities. The FDA began working directly with federal health partners, academia and industry to advance medical countermeasures against COVID-19 quickly after the emergence of this virus. Through the Coronavirus Treatment Acceleration Program, we continue to work across all sectors to expedite the development of numerous, innovative potential prevention and treatment approaches. We are also looking at pragmatic and expedited ways to make these products available to patients, while still ensuring the FDA's standards are met. We want to help patients by expediting promising treatments and are committed to maximizing our regulatory flexibility and proactively bringing the best innovators together to ensure we are getting the right treatments to the right patients at the right time."

Michael Felberbaum
Senior Advisor

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

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Date: April 2, 2020 at 7:27:48 PM EDT
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>, Block, Molly <Molly.Block@fda.hhs.gov>, Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Cc: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Subject: RE: No 'magic pill': The fight over unproven drugs for coronavirus

Planning to share this quote, which is from the CTAP announcement:

(b)(5)

Please let me know if you have any concerns ASAP.

From: Felberbaum, Michael
Sent: Thursday, April 02, 2020 7:20 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Block, Molly <Molly.Block@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Cc: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Subject: FW: No 'magic pill': The fight over unproven drugs for coronavirus

FYI on the story below – I've just reached out to the reporter, who never came to us for comment on this story, which is very unfortunate. She's giving us an opportunity to provide comment and said she'd also add in some info about the CTAP program, which she wrote about earlier this week. I'm working something up to share now.

From: POLITICO Pro Health Care <politicoemail@politicopro.com>
Sent: Thursday, April 02, 2020 7:06 PM
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: No 'magic pill': The fight over unproven drugs for coronavirus

No 'magic pill': The fight over unproven drugs for coronavirus

By Sarah Owermohle

04/02/2020 07:04 PM EDT

The Food and Drug Administration's rush to greenlight unproven malaria medicines to fight the coronavirus may derail clinical trials of other potential cures for the deadly virus.

Right now, dozens of potential therapies — from antivirals to antibodies taken from the blood of coronavirus survivors — are being tested in people. The first results from these studies could come within months if drugmakers enroll the thousands of patients needed to complete the research.

But with the malaria drugs chloroquine and hydroxychloroquine available by prescription from any doctor, and the president touting them as coronavirus treatments at his daily briefings, enlisting volunteers to enroll in clinical trials of other potential therapies may be a tough sell.

Researchers are concerned that clear answers on the efficacy of dozens of other medicines, which will only

come from clinical trials, could be delayed by the fervor. Online hype of the malaria drugs, along with the president's endorsement, is already fueling drug shortages. The FDA added both chloroquine and hydroxychloroquine to its shortage list this week, after prescriptions spiked as much 7,000 percent in March.

The Trump administration is also considering authorizing another unproven coronavirus treatment for emergency use. The drug, a Japanese flu medicine called Avigan, has been publicly endorsed by Japanese Prime Minister Shinzo Abe. But it is not approved by the FDA, and the agency has rejected it in the past over concerns about side effects.

An emergency authorization from the FDA could clear the way for off-label use before U.S. clinical trials even begin — raising the question of how research could catch up.

"We have to use science to save ourselves, not hunches," said Mildred Solomon, president of the bioethics thinktank Hastings Center. "If we lead people into a frenzy of stockpiling something they've got their hopes in, how are we ever going to get the knowledge we need to get ourselves out of this problem?"

Only by running randomized clinical trials of experimental treatments will scientists and doctors find a cure for the coronavirus, says Holly Fernandez Lynch, a bioethicist at the University of Pennsylvania. Such trials are the gold standard for getting answers, because doctors cannot cherry-pick who gets a dose of the drug being studied or which results to share.

Drugmakers are also struggling to balance ongoing clinical trials of experimental coronavirus treatments with the flood of requests for emergency access to those potential therapies. Gilead, which developed the experimental antiviral drug remdesivir, said late last month that it would temporarily stop granting requests for compassionate use, a pathway to access experimental medicines outside of clinical trials.

"In recent weeks, there has been an exponential increase in compassionate use requests," the company said, adding that the system was not designed for use in a pandemic. "Enrollment in clinical trials is the primary way to access remdesivir to generate critical data that inform the appropriate use of this investigational medicine."

It is not clear whether remdesivir or other potential therapies are effective against the coronavirus. The data for chloroquine and hydroxychloroquine is limited and mixed. Small early studies out of France have been questioned because of how scientists analyzed their results — and the lead researcher's history of manipulating data. One subsequent Chinese study found no benefit at all, while another, posted online this week but not peer-reviewed, suggests that hydroxychloroquine speeds recovery in patients with mild symptoms.

Regulators in other nations are treading cautiously when it comes to potential coronavirus drugs. Chloroquine and hydroxychloroquine should only be used to treat the virus in clinical trials and in severe cases, the European Medicines Agency said in a statement this week. The European counterpart to the FDA noted that both compounds can have serious side effects, particularly when combined with other drugs.

The Trump administration's push to make experimental therapies widely available for use outside of clinical trials have earned swift criticism from patient groups accusing the FDA of folding to political pressure. In one case, the group Patients Over Pharma has publicly urged FDA Commissioner Stephen Hahn to act based on the best science rather than political calculus.

Reports of chloroquine and hydroxychloroquine shortages across the country also raises the question of who should be prioritized to receive a medicine that has been around for years. Some have likened the potential quandary to how health care providers are using ventilators and who should be prioritized in those situations. But the comparison doesn't quite match up, said one senior HHS official who points to early data and big questions about the drugs' effectiveness.

"If it's about ventilators, there is no question in my mind what the positive benefit is," the official said. "Here, I do agree that there is an issue of triage and who gets access and who doesn't — but I'm still not convinced it matters."

Representatives for HHS Assistant Secretary for Preparedness and Response Robert Kadlec, who manages the national stockpile that will dole out the now millions of chloroquine pills in the supply, did not respond to questions about how the agency would prioritize certain groups or balance between trials and off-label use.

Even with the infusion of donated pills into the government's stockpile, the federal attention on chloroquine has fueled shortages already happening around the country, said David Karp, a Texas doctor and president-elect of the American College of Rheumatology, a group of providers that treats people with lupus and arthritis — who have used the drugs for years to manage their symptoms.

Interest in the drugs soared once they were discussed on the White House briefing stage. "Very quickly the supply in local pharmacies went down to zero," Karp said, adding that pharmacies and hospitals all over the country have struggled to secure supplies. "I haven't talked to any rheumatologist who hasn't had a patient call their office and say 'I can't find any of my medication."

"With it being in the news, suddenly people say 'I should get this so in case I need it, I have it,'" said American College of Physicians president Robert McLean, a rheumatologist who has prescribed the drug for years to treat lupus and arthritis. The doctors' group sent a letter to Trump late Monday warning of low supplies fueled by the coronavirus frenzy.

"There is clearly a looming shortage," said McLean.

Sen. Elizabeth Warren (D-Mass.) wrote to Hahn on Thursday demanding answers on how the agency will stem shortages.

There is also concern among doctors and researchers about how quickly potential risks, unknown side effects or just ineffectiveness could be sorted out with off-label use that does not feed central databases or published trials.

Drugmakers are shielded from liability if their products end up not working or causing harm through a measure activated when the president declared a public health emergency, known as the PREP Act. One of the ways to get that shield is an emergency use nod from the FDA. Discussions about the PREP Act and potential emergency authorizations had been going on for at least a week before the Sunday announcement, one official said.

Health experts warn that even if chloroquine and hydroxychloroquine work against Covid-19 — and many have questioned the data so far — no one medicine will be the answer to an outbreak that has already killed more than 30,000 worldwide and infected at least 174,000 in the U.S. alone.

"We still are going to have to do physical distancing. That is the proven method here, not a magic pill," said Solomon.

But even as health officials around the president — like top infectious disease doctor Anthony Fauci — have warned that social distancing guidelines may need to stay in place much longer, the president has been optimistic about reopening the economy. By Sunday, Trump scaled back from a hope that distancing would be over by Easter, saying instead that tactics should stay in place through April. Some states, like Virginia, have put rules in place until June.

"Quite frankly if you look across infectious disease history, its extremely rare that we 'defeat' a virus," said longtime rheumatologist McLean. "You learn how to manage it."

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 4/2/2020 8:57:42 PM
To: Alex Azar II [AMA2@hhs.gov]
CC: Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]
Subject: COVID-19 Vitals_02 April 2020.docx
Attachments: COVID-19 Vitals_02 April 2020.docx; ATT00001.txt

Today's Vitals Report

From: Nalubola, Ritu [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3103228E5EBA458F9C2AA1A846D25C7C-PNALUBOL]
Sent: 4/3/2020 8:14:36 AM
To: Hunt, Michie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7815b5291a944498653374dada35d91-HUNTM]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Throckmorton, Douglas C [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdc411a0b9be442daec5172d411e2fd3-THROCKMORTO]; Clarke, Mary Beth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b0124a15b9344d8483929470fefa403a-CLARKEM]; Jensen, Valerie E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e940a2d8ae47461296d03872f74d9a6a-JENSENV]; Shreeve, Chris [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=571674b26ca64f578288f39264470299-Christine.K]; Fuchs, Elissa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e76c3f1f5f2d4ad281bc5b05ad9a0cd4-Elissa.Fuch]; Rosenberg, Matthew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c27759625f414830a7d9510eef02fc74-ROSENBERGMA]; Schick, Andreas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce65e11cf29b486b99da49528c348cd8-Andreas.Sch]
CC: Louati, Claudia (FSN)* [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c682e89ffbb049c6be95d65e2eeb04eb-Claudia.Lou]; Kweder, Sandra L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3dcee61a387b4de49117ed8a0a80eea5-KWEDER]; Lutter, Randall [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=868b21db20e3456ab4e1b3109b56c23f-Randall.Lut]; Mullin, Theresa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=816f51c336a9449db257955b88720bdd-TMullin]
Subject: RE: notes from EU call
Attachments: RE: FDA & HMA/EMA taskforce TC on Drug Shortages - COVID-19 updates and FDA report presentation

Hi all – Follow-up to Wednesday's call –

Thanks for making the time for this exchange with EU colleagues esp. during this hectic time! Attached note that we sent to partners on this side (along with the article that Michie provided) – Claudia will circle back with Michie if we get any questions. We'll keep you posted of EU updates so you can consider need for/value of future such exchanges with this HMA Task Force group.

Have a restful weekend.
Ritu

From: Hunt, Michie
Sent: Wednesday, April 1, 2020 5:52 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Throckmorton, Douglas C <Douglas.Throckmorton@fda.hhs.gov>; Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>; Jensen, Valerie E <Valerie.Jensen@fda.hhs.gov>; Nalubola, Ritu <Ritu.Nalubola@fda.hhs.gov>; Kweder, Sandra L <Sandra.Kweder@fda.hhs.gov>; Louati, Claudia (FSN)* <Claudia.Louati@fda.hhs.gov>; Shreeve, Chris <Christine.Kuethe@fda.hhs.gov>; Fuchs, Elissa <Elissa.Fuchs@fda.hhs.gov>; Rosenberg, Matthew <Matthew.Rosenberg@fda.hhs.gov>; Schick, Andreas <Andreas.Schick@fda.hhs.gov>
Subject: FW: notes from EU call

Keagan,

I asked Elissa Fuchs to take notes on the EU call/presentation. These are attached if you are interested. They have not been reviewed or edited but on first read look pretty comprehensive to me.

I will put them in SharePOint in case any of you have comments, edits, or additions.

Michie

From: Fuchs, Elissa <Elissa.Fuchs@fda.hhs.gov>
Sent: Wednesday, April 01, 2020 11:39 AM
To: Shreeve, Chris <Christine.Kuethe@fda.hhs.gov>; Bernstein, Jessica <Jessica.Bernstein@fda.hhs.gov>; Hunt, Michie <Michie.Hunt@fda.hhs.gov>
Subject: notes from EU call

Hi All,
Here are my notes from the EU call. At times it was hard to hear, so please fill in gaps as appropriate.

Thanks,
Elissa

Elissa Fuchs
Health Communications Specialist

Office of Communications, Division of Public Education and Outreach
Center for Drug Evaluation and Research
Office: (301) 796-3213 Mobile: **(b)(6)**
elissa.fuchs@fda.hhs.gov

U.S. FOOD & DRUG ADMINISTRATION

From: James Thomas (b)(6)
Sent: 4/3/2020 12:33:51 PM
To: Hunt, Michie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7815b5291a944498653374dada35d91-HUNTM]; Ashley, Donald [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40241a76230349cbb195ab1721092196-Donald.Ashl]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Lee, Amy * [Amy.Lee@fda.hhs.gov]; Demske, Gregory E (OIG) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4929aff1bf44ec3bbca993ed7cf4290-HHS-Gregory]; smhahn (b)(6) anthony.fauci (b)(6) birxd@ (b)(6) ; scott.gottlieb (b)(6) castro.lisam (b)(6) Grimm, Christi A (OIG) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f016a8789314dae984d5e4c5942161e-HHS-Christi]; Adams, Jerome (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=302991451fc341bf9a7ffa53eba3f81c-HHS-Jerome.]
CC: Stephen E. Broden (b)(6) ; Revchildressjr (b)(6) ; wrandyshort (b)(6)
Subject: Re: Hydroxychloroquine Chloroquine Phosphate 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 C...

Dear Michie Hunt and Attorney Richard Ashley, Gregory Demske, Surgeon General, Dr Hahn, Dr Fauci et al,

By way of introduction, a group of pastors and physicians, scientists and researchers working together on these issues revealed that there was a National Security Threat because the United States Department of defense medication APIs[1] were made in China: the US could not make PCN, Cipro and Doxy[2] as well as many other medications within the United States. The FDA was informed (in early 2019), the Surgeon General and military representatives (in June 2019). Please note, it might have been an obligation of AmerisourceBergen and other Distributors who supply the military, not this group of pastors, the black healthcare coalition, and physicians, to inform the military that source ingredients are not made within the United States. Shortages and tainted medications may preferentially kill Black Americans and Native Americans.

Now attention regarding COVID-19 is required to note the CDC's, the FDA's as well as other's missteps, in refusing to allow early treatment of the people of the United States with Hydroxychloroquine (HCQ) and in preventing access to this medication by independent physicians, is and has been harming our patients. Governors and the Attorney General's office of States such as NJ, are putting in harmful orders which will make this epidemic worse by limiting treatment with HCQ until late in the course of illness and only after a faulty test turns positive. This disease is going to preferentially affect Black Americans, the elderly, hypertensives and diabetics. Black Americans are dying at a rate of three times that of others in some areas. (Please provide the data.) Native Americans as well.

Recent searches of the FDA Drug Shortage Database revealed that there were no overt shortages for Hydroxychloroquine (HCQ) or Chloroquine (CQ) according to the FDA's own shortage resource criteria as of 30 March 2020. Yet, HCQ no longer seems to be available at pharmacies, especially independent pharmacies and smaller hospitals. It seems that the distributors such as AmerisourceBergen, Cardinal Health/CVS and McKesson are not providing lists of amounts of medications available but simply saying it is unavailable to the pharmacies and physicians on the front lines. We need to know who is hoarding the medication within the government, within the distribution chain and within the hospital associations. Also, new regulations from the State Attorney Generals, Governors and Pharmacy Boards seem to be attempting to make it impossible for physicians to dispense hydroxychloroquine for early

[1] Active Pharmaceutical Ingredients
[2] PCN (Penicillin), Cipro (Ciprofloxacin), Doxy (Doxycycline)

treatment.[3] Delaying this early treatment for only use as a late treatment is inhumane, especially since the medication works best when given early in the infection and those who will benefit most from early treatment, the elderly, police, healthcare workers cannot access this early treatment at this time.

Would you please consider providing a real time heat map of where the HCQ or CQ is located within the United States and its territories? The physicians will benefit from being able to locate small amounts for each of their patient; each patient, if treated early, may require on average one 200mg HCQ pill per week and will hopefully not need larger amounts and/or other scarce resources. Such a small amount per week has the potential to keep many patients out of the hospital and off the ventilators. A portion of lung damage from Covid-19 may be permanent and early HCQ may prevent permanent damage and viral shedding /spread. We must give the patients and their physicians such an option and allow patients and physicians the freedom to make this decision. We must not tie the ability to prescribe the HCQ/CQ medication to a faulty nasal PCR test that will not be positive until too late in the disease to treat with HCQ alone. We must not force the patients to line up to get tested in places where the testing methods may transmit the disease while falsely indicating the patient is negative. No double blinded placebo-controlled studies comparing the Nasal PCR test to early treatment, has been done and no double-blind evaluation of the possibility that Nasal PCR testing spreads the disease has been done. No documentation/quantification of shedding of the virus from stool or other bodily fluids has been made by the CDC/NIH/FDA yet numerous studies have shown decreased shedding when being treated with HCQ/CQ; not allowing early treatment of police, healthcare workers, food handlers and many others perhaps should be considered in light of the data.

Therefore, the following is requested:

1. Please provide real time mechanisms for physicians to obtain this medication for the high-risk people in the community, especially in rural areas.
2. Please do not tie the physicians hands by mandating that HCQ only be given after the faulty PCR tests turns positive very late in infection.
3. Please do not force the public to have the nasal swab PCR test or even encourage the public to take nasal PCR tests that may provide a false sense of security (read negative early in disease) and even spread the disease.
4. After treatment with HCQ, decreased viral shedding has been documented. Consider mandatory low dose early treatment of healthcare workers and police as well as first responders. PCR test check should not be required prior to early treatment but could show viral shedding is not seen post treatment. Nasal PCR testing could be used to show a patient is not shedding by PCR after HCQ treatment and should no longer have to be quarantined while taking HCQ once a week.
5. Viral infection, unchecked, may take 42 days to build up enough to turn a nasal PCR test positive yet the IGM/IGG tests may turn positive much earlier. There is little to no downside to early treatment with HCQ 200 mg po each week in early asymptomatic patients (e.g. the USS Theodore Roosevelt Sailors).

a. Please do not advocate nasal testing … please consider encourage treating and if needed testing with the plasma or blood IGM/IgG test

b. No double-blind placebo-controlled studies have been done on the nasal testing and it could spread the disease. Please discontinue nasal testing during a pandemic until the double blinded study has been completed showing it does not spread the Covid-19 disease.

6. Low dose HCQ treatment every week or moving to every other week may protect against permanent lung and other organ damage as well as resurgence. IGG antibody presence may indicated no need for further treatment for that strain unless a mutation is noted. Low dose HCQ should protect against subsequent waves of the virus or mutations since it acts to prevent replication and intracellular entry and should slow the spread and severity of new Covid-19 strains of the disease in the near future.

[3] https://urldefense.proofpoint.com/v2/url?u=https-3A__www.nj.gov_governor_news_news_562020_20200330c.shtml&d=DwMFAw&c=n4nxo_3wbMT6jcMjwPfD0w&r=W_Q5TMVNHzfP_XQIbVWYok_hEKQ02h9xYMjp_L7C_4IE&m=V4W3xkvFKf4vBJ2wVBZ3I9-cgIQTZRC90EXfBR21is4&s=GHFcOoR4cBbzO9znUJ_i7thY_oFSdKEasScYPsLmzQc&e=

7. Please provide data from Serology testing (lgM/lgG). The CDC/NIH does not seem to be collecting or distributing data from Serology laboratories around the country. Please provide this serology information urgently in real-time or with frequent updates.
8. Dual- Agents and intelligence services, corporations or foreign governments may be being provided this information. We ask for protection in what should be an effort for all countries and agencies to help each other and seems to be politicized which is overtly harming the American people. Please consider asking that all dual-citizen or those who help foreign intelligence services or members who do not put the people of the United States first, be asked to reveal themselves and remove themselves from the US Government payrolls and organizations.
9. Please provide the controlled studies that shows how many days after confirmed early infection with Covid-19 the PCR nasal test turns positive with greater than 90% sensitivity and specificity.

Physicians are trying to prescribe hydroxychloroquine/chloroquine phosphate for their patients. It has been found that if HCQ was given early (with only a clinical diagnosis of infection and also given early to family contacts), no patients who has received 200mg HCQ per week have had to be hospitalized or been placed on a ventilator or had permanent sequelae. At this relative low and infrequent dose, it will likely be very cost effective and beneficial to give the medication early, prior to the PCR test turning positive in high risk individuals such as those over 50 years of age and individuals valuable to society's infrastructure like truck drivers, police, healthcare workers, military as well as those on ACE inhibitors, spironolactone, ARB's and Diabetics.

Those fortunate enough to develop antibodies are willing to be tested in order to donate their plasma but the IGM/IGG serology laboratories throughout the united states cannot be located easily. Please provide on the CDC website the result of the serology testing data.

We remain grateful for your consideration in this time of national trouble. HCQ has been proven to be an effective treatment in the later stages of Covid-19. But low dose early treatment has also been proving to be an effective mitigator of disease.
Truck drivers who the nation depends upon to stock the supermarkets. Prohibition of truckers travel could adversely affect many millions. First responders and people who are in harm's way will have a very high exposure to the virus within a short time and a low dose, protective, regimen should be instituted to keep them functioning during the pandemic and for their and the public's protection.

Chloroquine Phosphate is better than delayed treatment, is FDA approved for malaria treatment/prophylaxis and is safe in shorter term dosages HCQ is FDA approved in much higher doses for other indications including Rheumatoid arthritis. Academic centers may be better suited to manage the slightly higher side effect profile of Chloroquine Phosphate and outpatient community physicians may be best suited to utilize hydroxychloroquine(HCQ), safe even in pregnancy. Please consider providing real time information on the availably of both medications from Amerisource Bergen/Cardinal health and McKesson as well as hospitals (AHA) and Pharmacies (group organizations, CVS/Walgreens/Kmart and other small independent pharmacies) as soon as possible. Each day that goes by many Americans are dying and we hope those who have not allowed physicians to utilize hydroxychloroquine in early treatment will remain both financially and ethically responsible to the people of the United States and their physicians, especially those who have given or are about to give their lives because of the actions and inactions as above.

More references will be added with an updated letter soon to follow.

[1] Active Pharmaceutical Ingredients
[1] PCN (Penicillin), Cipro (Ciprofloxacin), Doxy (Doxycycline)
[1] https://urldefense.proofpoint.com/v2/url?u=https-3A www.nj.gov governor news news 562020 20200330c.shtml&d=DwMFAw&c=n4nxo 3wbMT6jcMjwPfD0w&r=W ●5TMVNHzfP X●lbVWYok hEK●02h9xYMjp L7C 4lE&m=V4W3xkvFKf4vBJ2wVBZ3l9-cgl●TZRC90EXfBR21is4&s=GHFcOoR4cBbzO9znUJ i7thY oFSdKEasScYPsLmz●c&e=

Grateful for your time and consideration. We are not suicidal and pray that the God (of Abraham Isaac and Jacob) protects us all.

Kind Regards,

Jim Thomas
(b)(6)

From: James Thomas <(b)(6)>
Date: Monday, March 16, 2020 at 9:18 AM
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)>, "Revchildressjr (b)(6)" <Revchildressjr (b)(6)> <wrandyshort (b)(6)>
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

Dear Michie Hunt and Attorney Richard Ashley, Gregory Demske, et al,

We now have evidence that of the kickbacks between the hospital CEOs and GPOs. Please request the contracts between and among the GPOs and other organizations.

We are now nearing a state of panic in the USA that is not necessary and will be counterproductive to isolate those away from necessary medications and help. We wish you the best and encourage each one of you to speak with your personal independent physician urgently. Trying to get these low cost generics meds readily available will be difficult if there is limited ability to move about and even help the elderly. Inaction or lockdown will preferentially kill the vulnerable elderly.

70% or more of the United States population has likely already been or will be exposed or infected with Covid-19 virus. There is no shame. Treatment in its early phase of infection with low dose Hydroxychloroquine/ Plaquenil seems to have overnight anecdotal symptom improvement as below. Many physicians, lawmakers and members of the judiciary recognize this possibility and have already started taking low dose hydroxychloroquine themselves. It is suggested that a low dose Hydroxychloroquine regimen be considered by a patient and their independent physician as an early treatment possibility, even long before the test is positive which could take 20-30 days or more after initial exposure and long before severe symptoms occur.
A 7 pill (6 week) and 14 pill (8 week) very low dose 200mg Hydroxychloroquine regimens are outlined within the document for consideration as a very early treatment considerations which do not preclude other treatment options. **It is up to a patient and their individual physician to decide how they should utilize this medication which is already FDA approved for over 70 years for other indications at much higher doses.**

Intravenous Remdesivir over 10 days does not seem to be an early treatment option but may be a late infection option if a patient and their physician insist on waiting as much as 30 or more days until the Covid-19 test is positive before treating.

How bad is it going to look when we find that congressmen, members of the judiciary and physicians all began this low dose regimen of hydroxychloroquine and locked their patients and people of the Untied States in their houses to die… already infected with the virus to get sick enough to only be helped by Gilead and Joe Grogan's Remdesivir.

https://1drv.ms/w/s!Akio3mRvXSI0mC1kpv_FpG_MJ5M6

Good Luck, and may the God (of Abraham Isaac and Jacob) protect us all.

Kind Regards,

Jim Thomas

(b)(6)

From: James Thomas (b)(6)
Date: Thursday, March 5, 2020 at 6:31 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) "Revchildressjr (b)(6) <Revchildressjr (b)(6) <wrandyshort@ (b)(6)
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

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/

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PubMed Mobile will be replaced by the new PubMed in early March. Click here to try the new PubMed!

↓ 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

(b)(6)

From: James Thomas (b)(6)
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), "Revchildressjr (b)(6) <Revchildressjr (b)(6)
<wrandyshort (b)(6)
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.**

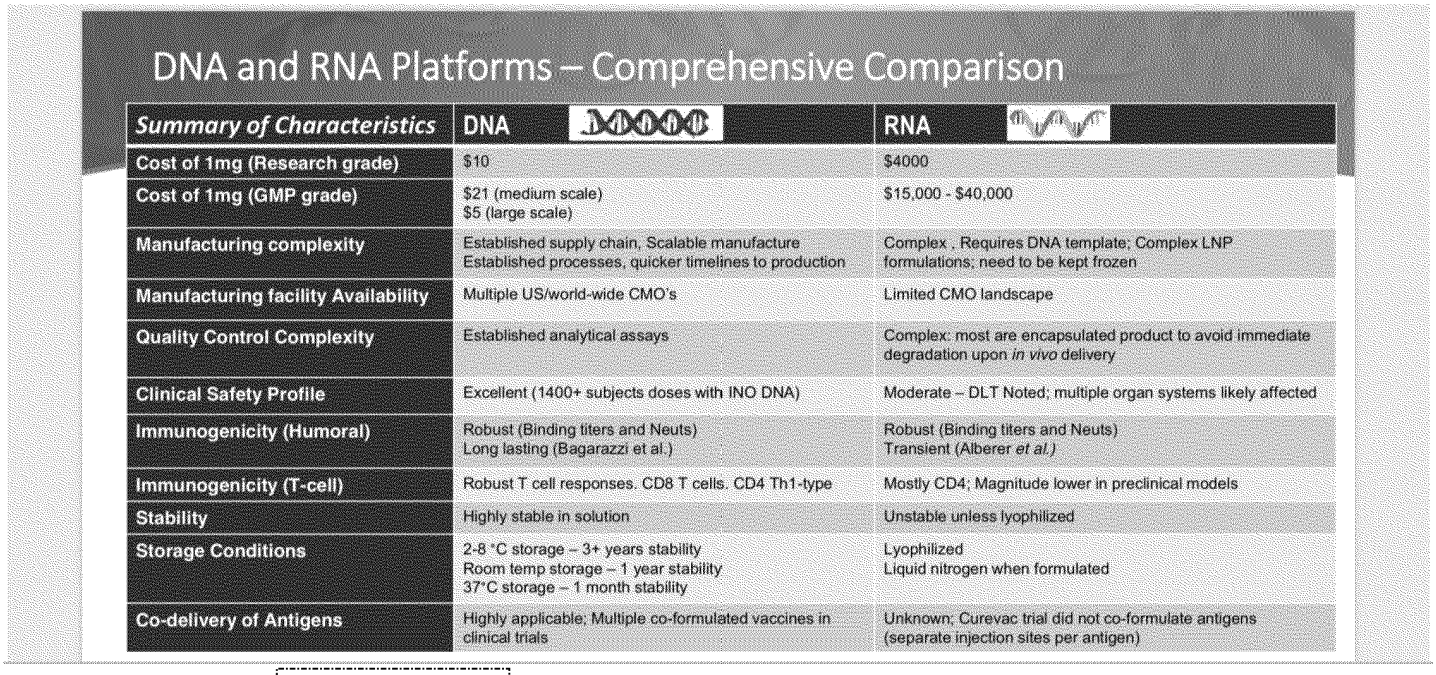
Please tell us who you are passing this information and if you are not, please suggest who we should communicate with regarding each of these topics to those who can and are willing to make a timely difference. We are patriots and not suicidal. We ask that anyone in this email chain who has "dual citizenship" 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

(b)(6)



DNA and RNA Platforms – Comprehensive Comparison

Summary of Characteristics	DNA	RNA
Cost of 1mg (Research grade)	$10	$4000
Cost of 1mg (GMP grade)	$21 (medium scale) $5 (large scale)	$15,000 - $40,000
Manufacturing complexity	Established supply chain, Scalable manufacture Established processes, quicker timelines to production	Complex , Requires DNA template; Complex LNP formulations; need to be kept frozen
Manufacturing facility Availability	Multiple US/world-wide CMO's	Limited CMO landscape
Quality Control Complexity	Established analytical assays	Complex: most are encapsulated product to avoid immediate degradation upon *in vivo* delivery
Clinical Safety Profile	Excellent (1400+ subjects doses with INO DNA)	Moderate – DLT Noted; multiple organ systems likely affected
Immunogenicity (Humoral)	Robust (Binding titers and Neuts) Long lasting (Bagarazzi et al.)	Robust (Binding titers and Neuts) Transient (Alberer *et al.)*
Immunogenicity (T-cell)	Robust T cell responses. CD8 T cells. CD4 Th1-type	Mostly CD4; Magnitude lower in preclinical models
Stability	Highly stable in solution	Unstable unless lyophilized
Storage Conditions	2-8 °C storage – 3+ years stability Room temp storage – 1 year stability 37°C storage – 1 month stability	Lyophilized Liquid nitrogen when formulated
Co-delivery of Antigens	Highly applicable; Multiple co-formulated vaccines in clinical trials	Unknown; Curevac trial did not co-formulate antigens (separate injection sites per antigen)

From: James Thomas (b)(6)
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), "Revchildressjr (b)(6) <Revchildressjr (b)(6)
<wrandyshort (b)(6)
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://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://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 (b)(6)
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 <(b)(6)>
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)>, "Revchildressjr (b)(6) <Revchildressjr@aol.com>, <wrandyshort (b)(6)>
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

(b)(6)

From: "Hunt, Michie" <Michie.Hunt@fda.hhs.gov>
Date: Monday, April 15, 2019 at 1:48 PM
To: James Thomas (b)(6)
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

FDA U.S. FOOD & DRUG ADMINISTRATION

From: James Thomas [(b)(6)]
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
[(b)(6)]

From: James Thomas [(b)(6)]
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)] "Revchildressjr [(b)(6)] <Revchildressjr@aol.com>, [(b)(6)]
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.

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 Jerseyan'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 hosptials 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

AHIP is interesting

Problems at the FDA and HHS are documented and longstanding

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.

http://www.puncturemovie.com/wp-content/themes/Romix/pdfs/group-purchasing-government-accountablity.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 A ctivitiesAccording 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://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
(b)(6)

Sent: 4/4/2020 10:34:40 AM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
Subject: Trial/CTAP info
Attachments: CDER_Public_Numbers_Trials_Development_Master_List_For_FDA_4_2_2020.xlsx; 4-3-2020_COVID Therapeutics.docx; CTAP_print_outline_combined_V10_4.2.20.pdf; CTAP VS REGULAR.docx

Sent: 4/4/2020 10:41:03 AM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
Subject: For today
Attachments: CDER_Public_Numbers_Trials_Development_Master_List_For_FDA_4_2_2020.xlsx; 4-3-2020_COVID Therapeutics.docx; CTAP_print_outline_combined_V10_4.2.20.pdf; CTAP VS REGULAR.docx

From: Guram, Jeet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EF73BEA97E2B477B847EA302C4730CCF-GURJEET.GUR]
Sent: 4/6/2020 12:26:08 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: RE: This am

No prob, and I assume so but let me check with Janet and Patrizia.

--
Jeet Guram, M.D.
Senior Advisor, Office of the Commissioner
Food and Drug Administration
+1 (202) 230-0451 | jeet.guram@fda.hhs.gov

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Monday, April 6, 2020 12:17 PM
To: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Subject: RE: This am

Thank you. Is CDER engaging with GSK and Vir?

From: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Sent: Monday, April 6, 2020 12:07 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: This am

I don't think I've gotten anything recently from her on that – the latest information I've received is in the CTAP therapeutics document from last week (attached), showing trials beginning in June and capacity at half a million to a million treatment courses by September; also page two mentions that if Lilly fails they will offer their antibody production facilities to Regeneron (their names are not mentioned though).

There has been news this morning about GSK and Vir also working on monoclonal antibodies: https://www.statnews.com/2020/04/06/glaxosmithkline-and-vir-aim-to-take-on-covid-19-with-antibodies-and-crispr/

--
Jeet Guram, M.D.
Senior Advisor, Office of the Commissioner
Food and Drug Administration
+1 (202) 230-0451 | jeet.guram@fda.hhs.gov

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Monday, April 6, 2020 12:02 PM
To: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Subject: This am

JW said she gave you a bunch of info and timelines on monoclonal antibodies and Regeneron. Is that in the CTAP doc?

From: Kraemer, John W [John.W.Kraemer@pfizer.com]
Sent: 4/7/2020 10:47:39 AM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: (b)(4)
Subject: FYI Pfizer HHS/FEMA RFI Response
Attachments: HHS-2020-RFI-COVID-19-1 Cover Letter FINAL.docx

Keagan,

Hope this note finds you well and wanted to share the attached cover letter Pfizer recently submitted in response to a joint HHS/FEMA RFI on manufacturing capacity related to COVID-19 for your information/awareness.

Pfizer has been working to prioritize and increase supply of as many critical medicines used for COVID-19 treatment as possible. In our response we have provided HHS and FEMA with information on our manufacturing capacity, inventory positions, potential roadblocks to increasing production, and FSS contract pricing where available. Pfizer takes seriously the presence of the novel coronavirus and we are collaborating with stakeholders in unprecedented ways including sharing data and offering manufacturing capabilities.

Pfizer has identified over (b)(4) medicines in our portfolio that are most relevant in today's situation for hospitals and affected patients, including over (b)(4) that are core to institutions providing patients supportive and critical care. Approximately (b)(4) In early March, our inventory could suppor (b)(4)

(b)(4)

Pfizer will remain committed to doing all we can to pursue these priorities throughout the duration of this crisis. We will continue to monitor the situation and adjust as necessary in order to ensure supply continuity of the critical hospital medications needed to treat COVID-19 patients, while ensuring the safety and well-being of our colleagues. We appreciate too the challenges this crisis presents to health care agencies and look forward to working closely to fulfill the expectations and needs of the patients we both serve.

I hope this note is helpful by way of information, and happy to answer any questions you may have.

Kind regards,

John

From: McWilliams, Carly [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B68C7458214244D08424FD441FEA4FDA-CARLYLE.MCW]
Sent: 4/7/2020 11:19:06 AM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: RE: Additional Background for diagnostics-

If it's not helpful, don't send, it is just an explanation of the types of test. If they don't need it, that's fine.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Tuesday, April 7, 2020 11:18 AM
To: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Additional Background for diagnostics-

Just not sure they need that level of detail.

Why put all the specifics of kinds of tests below?

From: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Sent: Tuesday, April 7, 2020 11:14 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Additional Background for diagnostics-

Without the list it is a two pager, still too long?

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Tuesday, April 7, 2020 11:12 AM
To: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Additional Background for diagnostics-

No way he is reading all of this…can we shorten?

From: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Sent: Tuesday, April 7, 2020 11:10 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: Additional Background for diagnostics-

For simplicity, I put this all together. I think this would be helpful to JG. I will have an updated list of diagnostics posted shortly.

Defining High Throughput

- As with many performance terms, there is no well accepted definition.
- High through put typically means that many samples can be run in parallel.
- Many EUA's are run on a 96 well plate format therefore you can run a **max of apx. 90 patient samples in one run**.
- Run times can vary widely depending on the technology the lab is using but **typically 3-4 hours per instrument is a good average**.
- If the lab adds automation and multiple instruments the throughput and time to result can be improved quickly.

Tests for Detection of the Novel Coronavirus (SARS-CoV-2)

Specimen collection

Regardless of the underlying technology, all tests begin with the collection of a specimen from a patient. Healthcare providers collect specimens from deep in the nose with Nasopharengeal (NP) swabs and from the tonsils and the back of the throat with Oralpharengeal (OP) swabs. Swabs are put into vials with a storage medium that keeps them stable, so the specimen won't break down during transport to the lab.

The Gates Foundation is studying whether nasal swabs that only reach the mid-turbinate part of the nose can produce valid results. This method for collecting a specimen is much easier for a patient to perform on their own and could open the door for self-collection.

Test Kits and Protocols

All tests contain a protocol that is validated end-to-end, which means that validation includes each step from sample collection through return of results. When a protocol is distributed in a kit, the kit includes most of the components necessary to run the test; however, most protocols require additional components not provided in the kit, such as platforms, general purpose reagents, and controls for verification. Platforms can be big machines that represent a substantial investment and can be used to run many different tests. While there are many different platforms available on the market for any given technology, such as Polymerase Chain Reaction (PCR) platforms, labs typically have only one or two such platforms. If a lab does not have the specific platform required by a protocol, they cannot run the test in the kit.

Tests for viruses like SARS-CoV-2 can be made using different technologies, such as antibody tests, antigen tests, and nucleic acid amplification tests described below.

Antibody Tests

Antibody tests identify the presence of antibodies made by the body's immune system in response to the SARS-CoV-2 infection. This type of test runs quickly and returns results within minutes, but it is only effective at detecting the body's immune response to SARS-CoV-2 after the virus has been present in the body for some time, and we do not yet know how long this is for SARS-CoV-2. Because this test is only effective an unknown period of time after an individual has been exposed to SARS-CoV-2, its performance characteristics to aid in medical decision making are unclear. Previous antibody tests for other infections have been used to confirm that a patient who is already showing clear symptoms of an infection and for monitoring the progression of infections in previously diagnosed individuals. At this time, an antibody test for SARS-CoV-2 cannot be used to determine that a person does not have the virus or whether or not a person should be quarantined without follow-up testing with a different type of test or a second antibody test some days later. Depending on the performance of an antibody test and depending on what we learn about the virus over time, a test of this type could be a useful tool to support the response to the pandemic, but this type of test alone may not be sufficient to rule out SARS-CoV-2 infection. Once a person is no longer infected, antibodies may remain in the body for an unknown period of time and could produce positive results even though the patient no longer has the infection.

Under the policy outlined in FDA's March 16, 2020 guidance, developers may distribute or run serology tests without an EUA if they have validated the test, notify FDA, and include key information in their labeling indicating the test cannot be

used for diagnosis or exclusion of infection. A list of serology tests offered under this policy is included in FDA's FAQ website.

Antigen Tests

Antigen tests identify the presence of proteins that are part of the SARS-CoV-2 virus. We have not yet seen any validated tests with this technology because such tests take a long time to develop. Once developed, this technology is inexpensive, and, based on our experience, we expect that it will produce results quickly. Performance of these tests tends to favor specificity over sensitivity. This means positives are likely true, but there will be more false negatives than there would be with a Nucleic Acid Amplification Test (NAAT). Depending on the performance of the test and the condition of the patient or degree of likely exposure, negative test results may require follow-up testing with a different type of test.

Nucleic Acid Amplification Tests (NAAT)

NAAT tests identify the presence of viral RNA from the SARS-CoV-2 virus. As viruses do not have DNA, the RNA is the virus's genetic code. This technology optimizes performance with respect to both sensitivity and specificity. This means that positives and negatives are both likely to be true. This type of test can take hours to run, and often this type of testing has to be done in special labs rather than a doctor's office. In some parts of the country, that can mean that samples have to be shipped, and getting results can take days.

Most NAAT tests use RNA extraction platforms, RNA extraction reagents, PCR platforms, and PCR reagents (also called primers and probes). Both the RNA extraction platform and the PCR platform must be installed in the lab. There are some platforms that combine both RNA extraction and PCR into a single platform (e.g., Roche, Hologic, Cepheid). The RNA extraction reagents and PCR reagents are consumable components. They are often sold separately and could be from separate manufacturers. As described above, the protocol defines exactly which platforms and reagents have been validated for use in the test and are therefore required to run the test. Components cannot be mixed and matched without validation.

During RNA extraction, extraction reagents purify and isolate the RNA from other biological material so that the RNA doesn't break down and become impossible to detect. Next, the RNA is loaded into plates with 96 or 384 wells. Some plate wells are reserved for each of three controls, all of which are needed to interpret results: a positive external control (viral RNA used to make sure the test is properly amplifying and detecting viral RNA), a negative control (water used to make sure there is no contamination), and a process control (human DNA used to make sure enzymes are working).

Plates with RNA extracted from patient specimens and controls are loaded into a PCR instrument, which is also called a thermocycler. Primers and probes are also loaded into the PCR instrument, and the instrument mixes these with each RNA specimen to produce reactions. Primers make copies of the RNA, which is called "amplification." Probes detect specific viral RNA sequences associated with SARS-CoV-2, called "targets." If a test is designed with multiple targets, samples from each patient must be loaded into separate wells for each target. Currently, FDA-authorized tests use two or three targets. Some single target tests are in development. They may be less sensitive, meaning they may miss identifying some positive specimens, but they will increase testing capacity by using fewer wells.

All authorized EUAs and notified LDTs for SARS-CoV-2 virus to date are based on this technology. FDA has many pre-EUAs for additional nucleic acid amplification tests and anticipates many additional EUAs in the coming weeks. FDA has authorized three tests that can be performed at a doctor's office or at the Point-of-Care without sending the specimen to a laboratory.

Lab Verification

Under CLIA, labs who run kits authorized by FDA are required to verify the performance of the test in their lab. This requires either known positive clinical specimens or viral material. In some cases this is provided with the kits, but in some cases it is not. Labs are reporting difficulty obtaining these materials, so FDA and CMS have provided flexibility to use DNA plasmids as an alternative during this emergency.

Supply Chain

FDA is hearing of labs having difficulty obtaining swabs and transport media, RNA extraction reagent kits, positive controls, and process controls. These are not provided with all test kits. FDA has reviewed other available data sources, such as data in prior test submissions for influenza, to identify other options that could work. FDA has posted options on our website in our FAQ. Developers may validate additional alternatives without an EUA. When they do, FDA asks that developers share their data with the agency informally and allow FDA to share what works in our online FAQ so that other labs do not need to perform studies to re-validate the same techniques.

Earlier, there were also issues obtaining reagents for CDC's test, but these have been resolved by CDC's qualification of lots produced and distributed by contract manufacturers IDT and Biosearch. All qualified lots are identified on CDC's website, which FDA has linked to through our FAQ.

SPONSOR	PRODUCT (link to authorization letter)	DESCRIPTION
DIAGNOSTICS		
Center for Disease Control and Prevention	CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel	• Developed by CDC and initially distributed to public health labs across the country • High throughput • Can only be run in high complexity labs
Wadsworth – New York State Public Health	New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel	• Developed by Wadsworth based on CDC's published protocol • Run in qualified labs across New York State • High throughput • Can only be run in high complexity labs
Roche Molecular Systems, Inc.	cobas® SARS-CoV-2 for use on the cobas® 6800/8800 Systems	• Commercially distributed as a kit to labs • High throughput • Can only be run in high complexity labs
Life Technologies (a part of Thermo Fisher Scientific, Inc.)	TaqPath™ COVID-19 Combo Kit, 100 Rxn, TaqPath™ COVID-19 Combo Kit, 1,000 Rxn	• Commercially distributed as a kit to labs • High throughput • Can only be run in high complexity labs

Laboratory Corporation of America	COVID-19 RT-PCR Test	• Developed and run in LabCorp labs only; not for broad lab distribution. • High throughput • Can only be run in high complexity labs
Hologic, Inc.	Panther Fusion SARS-CoV-2 Assay	• Reagents commercially distributed as a kit to labs • High throughput • Can only be run in high complexity labs
Quest Diagnostics Infectious Disease, Inc.	SARS-CoV-2 RNA, Qualitative Real-Time RT-PCR	• Developed and run in Quest labs only; not a kit for distribution. • High throughput • Can only be run in high complexity labs
Quidel Corporation	Lyra® SARS-CoV-2 Assay	• Reagents commercially distributed as a kit to labs • High throughput • Can only be run in high complexity labs
Abbott Molecular, Inc.	Abbott RealTime SARS-CoV-2 assay	• Reagents commercially distributed as a kit to labs • High throughput • Can only be run in high complexity labs
GenMark Diagnostics, Inc.	ePlex SARS-CoV-2 Test	• Reagents commercially distributed as a kit to labs • Can run up to 24 specimens at the same time • Can be run in a moderate or high complexity lab
DiaSorin Molecular LLC	Simplexa COVID-19 Direct	• Reagents commercially distributed as a kit to labs

		• Can run 1 specimen at a time • Can be run in a moderate or high complexity lab
Primerdesign Ltd.	Primerdesign Ltd COVID-19 genesig Real-Time PCR	• Reagents commercially distributed as a kit to labs • Requires separate RNA extraction kit and extraction platform not provided with reagents (GenoXtract) • High throughput • Can only be run in high complexity labs
Cepheid	Xpert Xpress SARS-CoV-2 test	• Reagents commercially distributed as a kit to labs • Can run up to 2,000 samples per day • Can be run in a clinical lab or at the Point of Care (POC) near the patient
Mesa Biotech Inc.	Accula SARS-CoV-2 Test	• Reagents commercially distributed as a kit to labs • Runs one specimen at a time • Can be run in a clinical lab or at the Point of Care (POC) near the patient
BioFire Defense, LLC	BioFire COVID-19 Test	• Reagents commercially distributed as a kit to labs • Can run 264 tests per day • Can be run in moderate or high complexity labs
PerkinElmer, Inc.	PerkinElmer New Coronavirus	• Reagents commercially distributed as a kit to labs

	Nucleic Acid Detection kit	• High throughput • Can only be run in a high complexity lab
Avellino Labs USA	AvellinoCoV2 test	• Developed and run in Avellino labs; not distributed to other labs • Run in a high complexity lab
BGI Genomics Co. Ltd.	Real-Time Fluorescent RT-PCR Kit for Detecting SARS-2019-nCoV	• Reagents commercially distributed as a kit to labs • High throughput • Can only be run in a high complexity lab
Luminex Molecular Diagnostics, Inc.	NxTAG CoV Extended Panel Assay	• Reagents commercially distributed as a kit to labs • High throughput • Can only be run in a high complexity lab
Abbott Diagnostics Scarborough, Inc.	ID NOW™ COVID-19	• Reagents commercially distributed as a kit • Requires a specific platform (ID NOW), of which there are 18,000 installed across the US • All-in-one; does not require separate RNA extraction kit • Runs one specimen at a time; each takes <13 minutes • Can be run in a clinical lab or at the Point of Care (POC) near the patient
NeuMoDx Molecular, Inc.	NeuMoDx SARS-CoV-2 Assay	• Reagents commercially distributed as a kit • Can run 288 or 96 samples at once, depending on the

		instrument, and takes 80 minutes per sample • Can be run in high and moderate complexity labs
QIAGEN GmbH	QIAstat-Dx Respiratory SARS-CoV-2 Panel	• Detects multiple other respiratory viral (17) and bacterial (3) organisms • Reagents commercially distributed as a kit to labs • Runs one specimen at a time and takes one hour • Can be run in high and moderate complexity labs
EUA for COVID-19 LDTs	Laboratory developed tests that are authorized are listed below and hyper link to letter granting inclusion under EUA	• Authorizes the use of LDTs that meet certain criteria. • Authorized tests can be used in the lab that developed the test and that is high complexity.
• Massachusetts General Hospital (Mass Gen) • Diagnostic Molecular Laboratory-Northwestern Medicine • Infectious Disease Diagnostics Laboratory-Children's Hospital of Philadelphia • Yale New Havel Hospital, Clinical Virology Laboratory		
Cellex Inc.	Serology Test qSARS-CoV-2 IgG/IgM Rapid Test	• The first serological test authorized under EUA. • Detects SARS-CoV-2 antibodies in blood. • Rapid test, provides results in 15-20 minutes.
Ipsum Diagnostics	COV-19 IDx assay	• Uses commercially available reagents • Can only be run in high complexity labs

Becton, Dickinson & Company (BD)	BioGX SARS-CoV-2 Reagents for BD MAX System	• Reagents commercially distributed as a kit to labs • Fully automated, 8 samples per hour • Can be run in moderate and high complexity labs
ScienCell Research Laboratories	ScienCell SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit	• Qualitative detection kit for nasal/oral/BAL • Testing is limited to laboratories certified to perform high complexity tests
Co-Diagnostics, Inc.	Logix Smart Coronavirus Disease 2019 (COVID-19) kit	• Qualitative detection of upper and lower respiratory tract fluids • Testing is limited to laboratories certified to perform higher complexity tests

From: Sheehy, Janice [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F45A6C96F5274724A1BE5970EB648FF7-JSHEEHY]
Sent: 4/7/2020 12:09:20 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
CC: Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]
Subject: **(b)(3) 42 USC 247d-6b(d), (b)(5)**
Attachments:

FYI below – I've hi-lited who this went to at FDA.

From: DLGDESK (HHS/ASPR/OPP) <DLGDESK@hhs.gov>
Sent: Tuesday, April 7, 2020 11:48 AM
To: Stannard, Paula (OS) <Paula.Stannard@hhs.gov>; Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>; Grigsby, Garrett G (OS) <Garrett.Grigsby@hhs.gov>; Kerr, Lawrence (OS) <Lawrence.Kerr@hhs.gov>; Chang, William (OS) <William.Chang@hhs.gov>; Sherman, Susan (OS) <Susan.Sherman@HHS.GOV>; Ray Gorrie, Jennifer (OS) <Jennifer.Ray-Gorrie@hhs.gov>; Strom, John (OS) <John.Strom@hhs.gov>; Patel, Anita (CDC) <bop1@cdc.gov>; Ethier, Kathleen A (CDC) <kbe0@cdc.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Collins, Francis S (NIH) <collinsf@od.nih.gov>; Fauci, Anthony S (NIH) <afauci@niaid.nih.gov>; Marston, Hilary D (NIH) <hilary.marston@nih.gov>; Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>; Yeskey, Kevin (OS) <Kevin.Yeskey@hhs.gov>; Bright, Rick (OS) <Rick.Bright@hhs.gov>; Disbrow, Gary (OS) <Gary.Disbrow@hhs.gov>; Lambert, Linda (OS) <Linda.Lambert@hhs.gov>; Adams, Steven A (CDC) <saa1@cdc.gov>; Gorman, Susan E (CDC) <spg4@cdc.gov>
Cc: Phillips, Sally (OS) <Sally.Phillips@hhs.gov>; DeBord, Kristin (OS) <Kristin.DeBord@hhs.gov>; Dodgen, Daniel (OS) <Daniel.Dodgen@HHS.GOV>; Meredith.L.Austin@usbordencg.mil; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Blatner@hhs.gov; Shirley, Mayo <Mayo.Shirley@fda.hhs.gov>; DLGDESK (HHS/ASPR/OPP) <DLGDESK@hhs.gov>
Subject: FOR REVIEW: **(b)(3) 42 USC 247d-6b(d), (b)(5)**

Dear Disaster Leadership Group Members and Colleagues:

Thank you for your participation in COVID-19 Disaster Leadership Group (DLG) Meetings **(b)(3) 42 USC 247d-6b(d), (b)(5)**

(b)(3) 42 USC 247d-6b(d), (b)(5)

(b)(3) 42 USC 247d-6b(d), (b)(5)

(b)(5)

(b)(5)

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Respectfully,

Dan

Daniel Dodgen, Ph.D.
Senior Advisor
Office of the Assistant Secretary for Preparedness and Response (ASPR)
Office of Strategy, Policy, Planning and Requirements (SPPR)

HEALTH AND HUMAN SERVICES (DHHS) | O'Neill House Office Building | 200 C Street SW | Washington, DC 20515
o. (202) 245-0719
Daniel.Dodgen@HHS.Gov | www.phe.gov

Sent: 4/7/2020 2:10:41 PM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
Subject: FW: HCQ and CQ EUA

Seems like there was some confusion, from her email below (b)(5)
(b)(5)

(b)(5) (b)(5)

(b)(5)

Best,
Jacqueline

From: Corrigan-Curay, Jacqueline <Jacqueline.Corrigan-Curay@fda.hhs.gov>
Sent: Tuesday, April 7, 2020 12:42 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: HCQ and CQ EUA

(b)(5) I spoke with Don about the issue of (b)(5)
(b)(5)
Below is his response. (b)(5)

From Don Beers

(b)(5)

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Tuesday, April 7, 2020 12:37 PM

To: Corrigan-Curay, Jacqueline <Jacqueline.Corrigan-Curay@fda.hhs.gov>
Subject: HCQ and CQ EUA

Hi Jacqueline,

(b)(3) 42 USC 247c-6b(d), (b)(5)

Thanks,
Keagan

From: Courtney, Brooke [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=261A2A3791E24E19B095AC0172485EBD-BROOKE.COUR]
Sent: 4/7/2020 8:29:34 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Clarke, Mary Beth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b0124a15b9344d8483929470fefa403a-CLARKEM]
Subject: RE: FOR REVIEW **(b)(3) 42 USC 247d-6b(d) , (b)(5)**

Yes, confirmed, CDER and OCS are reviewing and will provide any responses back to the DLG tomorrow.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Tuesday, April 07, 2020 6:24 PM
To: Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Subject: RE: FOR REVIEW **(b)(3) 42 USC 247d-6b(d) , (b)(5)**

Thanks ladies.

From: Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>
Sent: Tuesday, April 7, 2020 6:23 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Subject: RE: FOR REVIEW **(b)(3) 42 USC 247d-6b(d) , (b)(5)**

Brooke shared this earlier in the day. I think the response is underway, but Brooke can confirm.

Mary Beth

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Tuesday, April 7, 2020 6:21 PM
To: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Cc: Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>
Subject: FW: FOR REVIEW **(b)(3) 42 USC 247d-6b(d) , (b)(5)**

Brooke did you reach out for info on this?

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Tuesday, April 7, 2020 6:19 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: Fwd: FOR REVIEW **(b)(3) 42 USC 247d-6b(d) , (b)(5)**

See the HQ item below. Is Mary Beth aware?

From: DLGDESK (HHS/ASPR/OPP) <DLGDESK@hhs.gov>
Date: April 7, 2020 at 11:48:17 AM EDT
To: Stannard, Paula (OS) <Paula.Stannard@hhs.gov>, Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>, Grigsby, Garrett G (OS) <Garrett.Grigsby@hhs.gov>, Kerr, Lawrence (OS) <Lawrence.Kerr@hhs.gov>, Chang, William (OS) <William.Chang@hhs.gov>, Sherman, Susan (OS) <Susan.Sherman@HHS.GOV>, Ray Gorrie, Jennifer (OS) <Jennifer.Ray-Gorrie@hhs.gov>, Strom, John (OS) <John.Strom@hhs.gov>, Patel, Anita (CDC) <bop1@cdc.gov>, Ethier, Kathleen A (CDC) <kbe0@cdc.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>, Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>, Collins, Francis S (NIH)

<collinsf@od.nih.gov>, Fauci, Anthony S (NIH) <afauci@niaid.nih.gov>, Marston, Hilary D (NIH) <hilary.marston@nih.gov>, Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>, Yeskey, Kevin (OS) <Kevin.Yeskey@hhs.gov>, Bright, Rick (OS) <Rick.Bright@hhs.gov>, Disbrow, Gary (OS) <Gary.Disbrow@hhs.gov>, Lambert, Linda (OS) <Linda.Lambert@hhs.gov>, Adams, Steven A (CDC) <saa1@cdc.gov>, Gorman, Susan E (CDC) <spg4@cdc.gov>
Cc: Phillips, Sally (OS) <Sally.Phillips@hhs.gov>, DeBord, Kristin (OS) <Kristin.DeBord@hhs.gov>, Dodgen, Daniel (OS) <Daniel.Dodgen@HHS.GOV>, Meredith.L.Austin@usbordencg.mil <Meredith.L.Austin@usbordencg.mil>, Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>, Blatner@hhs.gov <Blatner@hhs.gov>, Shirley, Mayo <Mayo.Shirley@fda.hhs.gov>, DLGDESK (HHS/ASPR/SPPR) <DLGDESK@hhs.gov>
Subject: FOR REVIEW **(b)(3) 42 USC 247d-6b(d) , (b)(5)**

Dear Disaster Leadership Group Members and Colleagues:

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(b)(3) 42 USC 247d-6b(d) , (b)(5)

(b)(5)

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Respectfully,

Dan

Daniel Dodgen, Ph.D.
Senior Advisor
Office of the Assistant Secretary for Preparedness and Response (ASPR)
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HEALTH AND HUMAN SERVICES (DHHS) | O'Neill House Office Building | 200 C Street SW | Washington, DC 20515
o. (202) 245-0719
Daniel.Dodgen@HHS.Gov | www.phe.gov

From: Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]
Sent: 4/8/2020 8:35:43 AM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hahl
Subject: Re: FOR REVIEW (b)(3) 42 USC 247d-6b(d), (b)(5)

I believe Brooke Courtney gathers the info from the centers and sends it up. Will ask her to send what she provided.

Sent from my iPhone

On Apr 8, 2020, at 8:18 AM, Hahn, Stephen <SH1@fda.hhs.gov> wrote:

Who on our team is responsible for reviewing and can they provide us with briefing materials?
Thanks
S

From: DLGDESK (HHS/ASPR/OPP) <DLGDESK@hhs.gov>
Date: April 7, 2020 at 11:48:17 AM EDT
To: Stannard, Paula (OS) <Paula.Stannard@hhs.gov>, Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>, Grigsby, Garrett G (OS) <Garrett.Grigsby@hhs.gov>, Kerr, Lawrence (OS) <Lawrence.Kerr@hhs.gov>, Chang, William (OS) <William.Chang@hhs.gov>, Sherman, Susan (OS) <Susan.Sherman@HHS.GOV>, Ray Gorrie, Jennifer (OS) <Jennifer.Ray-Gorrie@hhs.gov>, Strom, John (OS) <John.Strom@hhs.gov>, Patel, Anita (CDC) <bop1@cdc.gov>, Ethier, Kathleen A (CDC) <kbe0@cdc.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>, Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>, Collins, Francis S (NIH) <collinsf@od.nih.gov>, Fauci, Anthony S (NIH) <afauci@niaid.nih.gov>, Marston, Hilary D (NIH) <hilary.marston@nih.gov>, Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>, Yeskey, Kevin (OS) <Kevin.Yeskey@hhs.gov>, Bright, Rick (OS) <Rick.Bright@hhs.gov>, Disbrow, Gary (OS) <Gary.Disbrow@hhs.gov>, Lambert, Linda (OS) <Linda.Lambert@hhs.gov>, Adams, Steven A (CDC) <saa1@cdc.gov>, Gorman, Susan E (CDC) <spg4@cdc.gov>
Cc: Phillips, Sally (OS) <Sally.Phillips@hhs.gov>, DeBord, Kristin (OS) <Kristin.DeBord@hhs.gov>, Dodgen, Daniel (OS) <Daniel.Dodgen@HHS.GOV>, Meredith.L.Austin@usbordencg.mil <Meredith.L.Austin@usbordencg.mil>, Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>, Blatner@hhs.gov <Blatner@hhs.gov>, Shirley, Mayo <Mayo.Shirley@fda.hhs.gov>, DLGDESK (HHS/ASPR/OPP) <DLGDESK@hhs.gov>
Subject: FOR REVIEW (b)(3) 42 USC 247d-6b(d), (b)(5)

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(b)(3) 42 USC 247d-6b(d), (b)(5)

(b)(3) 42 USC 247d-6b(d), (b)(5)

(b)(3) 42 USC 247d-6b(d), (b)(5)

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Daniel.Dodgen@HHS.Gov | www.phe.gov

<Release of SNS-Held Chloroquine and Hydroxychloroquine.docx>
<International MCM Sharing Policy Framework FINAL January 2014.pdf>

From: Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]
Sent: 4/8/2020 8:36:11 AM
To: Courtney, Brooke [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=261a2a3791e24e19b095ac0172485ebd-Brooke.Cour]
Subject:
Attachments:

(b)(3) 42 USC 247d-6b(d), (b)(5)

Can you pls pull together what you sent over for this data call and share it with me?

Sent from my iPhone

Begin forwarded message:

From: "Hahn, Stephen" <SH1@fda.hhs.gov>
Date: April 8, 2020 at 8:18:04 AM EDT
To: "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>
Subject: Fwd: **(b)(3) 42 USC 247d-6b(d), (b)(5)**

(b)(3) 42 USC 247d-6b(d), (b)(5)

Who on our team is responsible for reviewing and can they provide us with briefing materials?
Thanks
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From: DLGDESK (HHS/ASPR/OPP) <DLGDESK@hhs.gov>
Date: April 7, 2020 at 11:48:17 AM EDT
To: Stannard, Paula (OS) <Paula.Stannard@hhs.gov>, Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>, Grigsby, Garrett G (OS) <Garrett.Grigsby@hhs.gov>, Kerr, Lawrence (OS) <Lawrence.Kerr@hhs.gov>, Chang, William (OS) <William.Chang@hhs.gov>, Sherman, Susan (OS) <Susan.Sherman@HHS.GOV>, Ray Gorrie, Jennifer (OS) <Jennifer.Ray-Gorrie@hhs.gov>, Strom, John (OS) <John.Strom@hhs.gov>, Patel, Anita (CDC) <bop1@cdc.gov>, Ethier, Kathleen A (CDC) <kbe0@cdc.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>, Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>, Collins, Francis S (NIH) <collinsf@od.nih.gov>, Fauci, Anthony S (NIH) <afauci@niaid.nih.gov>, Marston, Hilary D (NIH) <hilary.marston@nih.gov>, Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>, Yeskey, Kevin (OS) <Kevin.Yeskey@hhs.gov>, Bright, Rick (OS) <Rick.Bright@hhs.gov>, Disbrow, Gary (OS) <Gary.Disbrow@hhs.gov>, Lambert, Linda (OS) <Linda.Lambert@hhs.gov>, Adams, Steven A (CDC) <saa1@cdc.gov>, Gorman, Susan E (CDC) <spg4@cdc.gov>
Cc: Phillips, Sally (OS) <Sally.Phillips@hhs.gov>, DeBord, Kristin (OS) <Kristin.DeBord@hhs.gov>, Dodgen, Daniel (OS) <Daniel.Dodgen@HHS.GOV>, Meredith.L.Austin@usbordencg.mil <Meredith.L.Austin@usbordencg.mil>, Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>, Blatner@hhs.gov <Blatner@hhs.gov>, Shirley, Mayo <Mayo.Shirley@fda.hhs.gov>, DLGDESK (HHS/ASPR/OPP) <DLGDESK@hhs.gov>
Subject: FOR REVIEW **(b)(3) 42 USC 247d-6b(d), (b)(5)**

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(b)(3) 42 USC 247d-6b(d), (b)(5)

(b)(3) 42 USC 247d-6b(d), (b)(5)

(b)(5)

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Respectfully,

Dan

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HEALTH AND HUMAN SERVICES (DHHS) | O'Neill House Office Building | 200 C Street SW | Washington, DC 20515
o. (202) 245-0719
Daniel.Dodgen@HHS.Gov | www.phe.gov

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 4/9/2020 7:40:08 PM
To: Alex Azar II [AMA2@hhs.gov]
CC: Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]
Subject: CovidVitals_09 APR 2020.docx
Attachments: CovidVitals_09 APR 2020.docx; ATT00001.txt

FDA Vitals for the day.

From: Cohen, Kenneth [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44F565B739EA4879BDC516CAF2E136BC-KENNETH.COH]
Sent: 4/9/2020 9:40:27 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Schiller, Lowell [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77949b06919e4f91aa788e9a616c50c7-Lowell.Schi]; Roth, Lauren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52bfd08572694f269a20c508f3c04a03-Lauren.Roth]; McWilliams, Carly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]
CC: Chesemore, Scott [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=056596add7954e548ce1c37485603421-Scott.Chese]; Rooths, Tarita [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9ea3aa705bda4ff98b5043488cc9688f-TRooths]
Subject: COVID-19-Related Guidance Documents Evening Report - April 9, 2020

A. Issued since yesterday's report: #30.

B. Comprehensive List of FDA COVID-19 Guidances Issued to Date (oldest to newest):

1. Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency (February 29, 2020, updated March 16, 2020)

2. Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (March 14, 2020, updated March 27, 2020)

3. Temporary Policy Regarding Preventive Controls and FSVP Food Supplier Verification Onsite Audit Requirements During the COVID-19 Public Health Emergency (March 17, 2020)

4. FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic (March 18, 2020, updated March 27, 2020)

5. Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During a Pandemic (March 19, 2020)

6. Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (March 19, 2020, updated March 27, 2020)

7. Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring During the Coronavirus Disease-2019 (COVID-19) Public Health Emergency (March 20, 2020)

8. Policy for Certain REMS Requirements During the COVID-19 Public Health Emergency Guidance for Industry and Health Care Professionals (March 22, 2020)

9. Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (March 22, 2020)

10. Temporary Policy for Manufacture of Alcohol for Incorporation Into Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19) (March 24, 2020, updated March 27, 2020)

11. Enforcement Policy Regarding Federal VCPR Requirements to Facilitate Veterinary Telemedicine During the COVID-19 Outbreak (CVM GFI #269) (March 24, 2020)

12. Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (March 25, 2020, Updated April 2, 2020)

13. Temporary Policy Regarding Nutrition Labeling of Certain Packaged Food During the COVID-19 Public Health Emergency (March 26, 2020)

14. Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing Under Section 506C of the FD&C Act Guidance for Industry (March 27, 2020)

15. Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (March 29, 2020)

16. Enforcement Policy for Gowns, Other Apparel, and Gloves During the Coronavirus Disease (COVID-19) Public Health Emergency (March 30, 2020)

17. Temporary Policy Regarding Nutrition Labeling of Standard Menu Items in Chain Restaurants and Similar Retail Food Establishments During the COVID-19 Public Health Emergency (April 1, 2020)

18. Alternative Procedures for Blood and Blood Components During the COVID-19 Public Health Emergency (April 2,2020)

19. Revised Recommendations to Reduce the Risk of Transfusion-Transmitted Malaria (April 2, 2020)

20. Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products (April 2, 2020)

21. Recommendations to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease and Variant Creutzfeldt-Jakob Disease by Blood and Blood Components (April 2, 2020)

22. Guidance on the Conduct and Review of Studies to Support New Animal Drug Development during the COVID-19 Public Health Emergency (CVM GFI #270) (April 3, 2020)

23. Temporary Policy Regarding Packaging and Labeling of Shell Eggs Sold by Retail Food Establishments During the COVID-19 Public Health Emergency (April 3, 2020)

24. Enforcement Policy for Clinical Electronic Thermometers During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (April 4, 2020)

25. Enforcement Policy for Infusion Pumps and Accessories During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (April 5, 2020)

26. Enforcement Policy for Remote Ophthalmic Assessment and Monitoring Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (April 6, 2020)

27. Enforcement Policy for Extracorporeal Membrane Oxygenation and Cardiopulmonary Bypass Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (April 6, 2020)

28. Temporary Policy Regarding Enforcement of 21 CFR Part 118 (the Egg Safety Rule) During the COVID-19 Public Health Emergency (April 6, 2020)

29. Investigational COVID-19 Convalescent Plasma (April 8, 2020)

30. Policy for the Temporary Use of Portable Cryogenic Containers Not in Compliance With 21 CFR 211.94(e)(1) For Oxygen and Nitrogen During the COVID-19 Public Health Emergency Guidance for Industry (April 9, 2020)

Kenneth R. Cohen, MHSA, MPP
Director, Regulations Policy and Management Staff
Office of Policy
301-796-7001
(b)(6) (mobile)

From: Cohen, Kenneth [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44F565B739EA4879BDC516CAF2E136BC-KENNETH.COH]
Sent: 4/12/2020 6:03:23 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Schiller, Lowell [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77949b06919e4f91aa788e9a616c50c7-Lowell.Schi]; Roth, Lauren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52bfd08572694f269a20c508f3c04a03-Lauren.Roth]; McWilliams, Carly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]
CC: OC OPPB OP RPMS [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f2e26c08c0a24020b0200a64ba43a096-OC OPPB OP]
Subject: COVID-19-Related Guidance Documents Evening Report - April 12, 2020

A. Issued since yesterday's report (No documents have posted since yesterday's report).
B. Comprehensive List of FDA COVID-19 Guidances Issued to Date (oldest to newest):

1. Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency (February 29, 2020, updated March 16, 2020)

2. Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (March 14, 2020, updated March 27, 2020)

3. Temporary Policy Regarding Preventive Controls and FSVP Food Supplier Verification Onsite Audit Requirements During the COVID-19 Public Health Emergency (March 17, 2020)

4. FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic (March 18, 2020, updated March 27, 2020)

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8. Policy for Certain REMS Requirements During the COVID-19 Public Health Emergency Guidance for Industry and Health Care Professionals (March 22, 2020)

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11. Enforcement Policy Regarding Federal VCPR Requirements to Facilitate Veterinary Telemedicine During the COVID-19 Outbreak (CVM GFI #269) (March 24, 2020)

12. Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (March 25, 2020, Updated April 2, 2020)

13. Temporary Policy Regarding Nutrition Labeling of Certain Packaged Food During the COVID-19 Public Health Emergency (March 26, 2020)

14. Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing Under Section 506C of the FD&C Act Guidance for Industry (March 27, 2020)

15. Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (March 29, 2020)

16. Enforcement Policy for Gowns, Other Apparel, and Gloves During the Coronavirus Disease (COVID-19) Public Health Emergency (March 30, 2020)

17. Temporary Policy Regarding Nutrition Labeling of Standard Menu Items in Chain Restaurants and Similar Retail Food Establishments During the COVID-19 Public Health Emergency (April 1, 2020)

18. Alternative Procedures for Blood and Blood Components During the COVID-19 Public Health Emergency (April 2,2020)

19. Revised Recommendations to Reduce the Risk of Transfusion-Transmitted Malaria (April 2, 2020)

20. Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products (April 2, 2020)

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23. Temporary Policy Regarding Packaging and Labeling of Shell Eggs Sold by Retail Food Establishments During the COVID-19 Public Health Emergency (April 3, 2020)

24. Enforcement Policy for Clinical Electronic Thermometers During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (April 4, 2020)

25. Enforcement Policy for Infusion Pumps and Accessories During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (April 5, 2020)

26. Enforcement Policy for Remote Ophthalmic Assessment and Monitoring Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (April 6, 2020)

27. Enforcement Policy for Extracorporeal Membrane Oxygenation and Cardiopulmonary Bypass Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (April 6, 2020)

28. Temporary Policy Regarding Enforcement of 21 CFR Part 118 (the Egg Safety Rule) During the COVID-19 Public Health Emergency (April 6, 2020)

29. Investigational COVID-19 Convalescent Plasma (April 8, 2020)

30. Policy for the Temporary Use of Portable Cryogenic Containers Not in Compliance With 21 CFR 211.94(e)(1) For Oxygen and Nitrogen During the COVID-19 Public Health Emergency Guidance for Industry (April 9, 2020)

31. Temporary Policy Regarding Non-Standard PPE Practices for Sterile Compounding by Pharmacy Compounders not Registered as Outsourcing Facilities During the COVID-19 Public Health Emergency (April 10, 2020)

Kenneth R. Cohen, MHSA, MPP
Director, Regulations Policy and Management Staff
Office of Policy
301-796-7001
(b)(6) (mobile)

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 4/13/2020 12:31:59 PM
To: Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]
Subject: RE: convalescent plasma announcement/ask/call to action

Thank you.

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Sent: Monday, April 13, 2020 12:24 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: convalescent plasma announcement/ask/call to action

Here is where we are:
Phone tag with OVP and have sent the following ask and you can share with Joe that it is with them and
We have a draft statement from the Commissioner on convalescent plasma which provides:

(b)(5)

Laura

Laura Caliguiri
Associate Commissioner for External Affairs

Office of External Affairs
U.S. Food and Drug Administration
Tel: 301 796-8546
Laura.Caliguiri@fda.hhs.gov

U.S. FOOD & DRUG ADMINISTRATION

From: Olivarria, Frank [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C180721DB774423F99990DD86E67057C-FRANK.OLIVA]
Sent: 4/13/2020 1:50:54 PM
To: Block, Molly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e32ca68078848889751e7ec26910142-Molly.Block]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Copeland, Jakea [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7fe05ed233c42b68be990b12ae2c8c8-Jakea.Copel]
CC: Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: RE: Media Holds for next week

Telecon: Murderboard Prep: TV Interviews scheduled for tomorrow, 4/14, 1:30-2:00 PM. Calendar invite sent.

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Monday, April 13, 2020 11:52 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

This wouldn't be for those radio hits. WH would like another murderboard before more TV this week.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Monday, April 13, 2020 11:47 AM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

Yes, when he agrees to media he agrees for the prep for them. Thanks. Does he really need them for radio though?

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Monday, April 13, 2020 11:46 AM
To: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

I believe so. Stephanie and Keagan have had discussions about regular comms prep for Dr. Hahn.

Stephanie - can you confirm?

From: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Sent: Monday, April 13, 2020 11:41 AM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

Has this additional calendar item (*murderboard prep tomorrow*) been approved by the Commissioner or COS?

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Monday, April 13, 2020 11:36 AM
To: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

And one more to add to the calendar.

30 minute murderboard prep tomorrow (whenever works for Dr. Hahn)
Invitees: Laura, Stephanie, Michael, Molly, Devin O'Malley

From: Block, Molly
Sent: Monday, April 13, 2020 10:41 AM
To: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

Second confirmed interview:

Tuesday, April 13
Time: 8:17 – 8:30 AM ET
Radio Show: Paul W. Smith
Host: Paul Smith
Media Market: Detroit, MI
Call-in number: **(b)(6)**
Back-up: **(b)(6)**

Topics: FDA's work supporting drugs and vaccines to fight coronavirus, including chloroquine and the use of blood products to help treat infected individuals. In the last week or so, FDA issued an emergency use authorization for the

first serology (antibody) test for COVID-19 to date and expanded national access to blood-related therapies for COVID-19 (aka convalescent plasma and hyperimmune globulin).

From: Block, Molly
Sent: Monday, April 13, 2020 10:29 AM
To: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

First confirmed interview:

Tuesday, April 13
Time: 8:02 – 8:15 AM ET
Radio Show: Morning Answer with Chris Stigall
Host: Chris Stigall
Media Market: Philadelphia
Call-in number: **(b)(6)**
Backup **(b)(6)**

Topics: DAs work to support drugs and vaccines to fight coronavirus, chloroquine, the hydroxychloroquine and ZPACK cocktail that some are claiming have saved their lives.

From: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Sent: Sunday, April 12, 2020 9:51 PM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

Hi Molly,

Here is where the holds for these media requests have landed:

Monday or Tuesday: 20 minutes (whenever) for an **interview with David Lim from Politico**

- Tuesday, 4/14, 1:10-1:30 PM

30 minute holds on **Tuesday and Thursday AM**: preferably before 10:00 AM if possible for **Radio**

- Tuesday, 4/14, 8:00-8:30 AM
- Thursday, 4/16, 8:30-9:00 AM

45 minutes on Friday for a **Pen & Pad with FDA beat reporters** (Stephanie and Michael are running point on this one)

- Friday, 4/17, 8:00-8:45 AM

Frank

From: Olivarria, Frank
Sent: Friday, April 10, 2020 6:58 PM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

Thank you! Will get these hold on the calendar.

Frank

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Friday, April 10, 2020 6:57 PM
To: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

Yes on Keagan.

From: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Sent: Friday, April 10, 2020 6:56 PM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

Thank you Molly, appreciate this. Have these calendar additions been cleared with the Commissioner or COS?

Frank

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Friday, April 10, 2020 6:54 PM
To: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: Media Holds for next week

Can I get the follow holds on Dr. Hahn's calendar for media next week:

Monday or Tuesday: 20 minutes (whenever) for an interview with David Lim from Politico

30 minute holds on Tuesday and Thursday AM: preferably before 10:00 AM if possible for Radio

45 minutes on Friday for a Pen & Pad with FDA beat reporters (Stephanie and Michael are running point on this one)

From: Caliguiri, Laura [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AA086F2D6C0346C49E996932D86AC62E-LAURA.CALIG]
Sent: 4/14/2020 10:26:45 AM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: FW: Media Holds for next week
Attachments: david lim talking points.docx

Re-upping 2 pages specific to reporter. If we need to set a time when we send direct, we can do that.

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Monday, April 13, 2020 9:20 PM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

Sorry, please use these for David Lim

Stephanie Caccomo
Press Officer

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

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Monday, April 13, 2020 9:19 PM
To: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

Separate document for politico. That is coming from Stephanie shortly as well.

From: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Sent: Monday, April 13, 2020 9:18 PM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

Understood. Same document to be used for politico? Checked my inbox, last indication was coming from Stephanie, we got radio talkers but not Fox or Politico.

TY

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Monday, April 13, 2020 9:14 PM
To: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

Yes – sorry. We're updating his talkers now. I'll have it shortly.

From: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Sent: Monday, April 13, 2020 9:06 PM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

Any materials for this?

Frank

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Monday, April 13, 2020 7:51 PM
To: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

And the details!

Show: "Fox & Friends"
LIVE INTERVIEW: 7:40 AM ET WITH STEVE DOOCY
TOPICS:
1.) EMERGENCY AUTHORIZATION OF MALARIA DRUGS FOR CORONAVIRUS
2.) WHAT ARE ANITBODY TESTS AND WHAT INFORMATION WILL THEY PROVIDE?
3.) FDA PROGRAM TO SPEED UP CORONAVIRUS THERAPIES

From: Block, Molly
Sent: Monday, April 13, 2020 7:50 PM
To: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

Last confirmation for tomorrow

7:40 – 7:47 am
Fox and Friends (live)
Remote studio van

I'm still waiting on the final details. Sorry!

From: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Sent: Monday, April 13, 2020 2:32 PM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

Excellent. Thank you.

Frank

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Monday, April 13, 2020 2:21 PM
To: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

Can confirm. Stephanie will have talkers this afternoon.

It'll either be a conference call or Stephanie will call Dr. Hahn and the reporter.

Molly

From: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Sent: Monday, April 13, 2020 2:05 PM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

Requesting confirmation/details on Tuesday, 4/14, 1:10-1:30 PM: **interview with David Lim from Politico**.

Please send any materials to me and Jakea.

Thank you,
Frank

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Sunday, April 12, 2020 9:59 PM
To: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

Thank you!

From: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Date: April 12, 2020 at 9:51:10 PM EDT
To: Block, Molly <Molly.Block@fda.hhs.gov>, Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>, Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>, Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

Hi Molly,

Here is where the holds for these media requests have landed:

Monday or Tuesday: 20 minutes (whenever) for an **interview with David Lim from Politico**

- Tuesday, 4/14, 1:10-1:30 PM

30 minute holds on **Tuesday and Thursday AM**: preferably before 10:00 AM if possible for **Radio**

- Tuesday, 4/14, 8:00-8:30 AM
- Thursday, 4/16, 8:30-9:00 AM

45 minutes on Friday for a **Pen & Pad with FDA beat reporters** (Stephanie and Michael are running point on this one)

- Friday, 4/17, 8:00-8:45 AM

Frank

From: Olivarria, Frank
Sent: Friday, April 10, 2020 6:58 PM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

Thank you! Will get these hold on the calendar.

Frank

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Friday, April 10, 2020 6:57 PM
To: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

Yes on Keagan.

From: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Sent: Friday, April 10, 2020 6:56 PM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

Thank you Molly, appreciate this. Have these calendar additions been cleared with the Commissioner or COS?

Frank

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Friday, April 10, 2020 6:54 PM
To: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: Media Holds for next week

Can I get the follow holds on Dr. Hahn's calendar for media next week:

Monday or Tuesday: 20 minutes (whenever) for an interview with David Lim from Politico

30 minute holds on Tuesday and Thursday AM: preferably before 10:00 AM if possible for Radio

45 minutes on Friday for a Pen & Pad with FDA beat reporters (Stephanie and Michael are running point on this one)

From: Block, Molly [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0E32CA68078848889751E7EC26910142-MOLLY.BLOCK]
Sent: 4/14/2020 11:15:32 AM
To: Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Copeland, Jakea [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7fe05ed233c42b68be990b12ae2c8c8-Jakea.Copel]
CC: Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: RE: Media Holds for next week

Last confirmation for Thursday radio:

Thursday, April 16
Time: 8:48 – 8:55 AM
Radio Show: The Ross Kaminsky Show (630 KHOW)
Host: Ross Kaminsky
Media Market: Denver, CO
Call-in number: (b)(6)
Back-up: (b)(6)

From: Block, Molly
Sent: Monday, April 13, 2020 1:25 PM
To: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

Thanks!

First confirmation for Thursday radio:

Thursday, April 16
Time: 8:35 – 8:45 AM ET
Radio Show: Morning News on 93.1FM WIBC
Host: Tony Katz
Media Market: Indianapolis, IN
Call-in number: (b)(6)
Back-up: (b)(6)

Topics: Chloroquine and any other medications as well as how the FDA is supporting the fight against COVID-19

From: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Sent: Monday, April 13, 2020 1:12 PM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <La ur a.Caliguiri@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

Will circle back with options.

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Monday, April 13, 2020 1:11 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <La ur a.Caliguiri@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

Thanks! Frank / Janice – is there time tomorrow to do this?

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Monday, April 13, 2020 11:59 AM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <La ur a.Caliguiri@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

Sounds good.

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Monday, April 13, 2020 11:52 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <La ur a.Caliguiri@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

This wouldn't be for those radio hits. WH would like another murderboard before more TV this week.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Monday, April 13, 2020 11:47 AM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rom, Colin

<Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

Yes, when he agrees to media he agrees for the prep for them. Thanks. Does he really need them for radio though?

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Monday, April 13, 2020 11:46 AM
To: Olivarria, Frank <Frank.●livarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

I believe so. Stephanie and Keagan have had discussions about regular comms prep for Dr. Hahn.

Stephanie - can you confirm?

From: Olivarria, Frank <Frank.●livarria@fda.hhs.gov>
Sent: Monday, April 13, 2020 11:41 AM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

Has this additional calendar item (*murderboard prep tomorrow*) been approved by the Commissioner or COS?

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Monday, April 13, 2020 11:36 AM
To: Olivarria, Frank <Frank.●livarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

And one more to add to the calendar.

30 minute murderboard prep tomorrow (whenever works for Dr. Hahn)
Invitees: Laura, Stephanie, Michael, Molly, Devin O'Malley

From: Block, Molly
Sent: Monday, April 13, 2020 10:41 AM
To: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

Second confirmed interview:

Tuesday, April 13
Time: 8:17 – 8:30 AM ET
Radio Show: Paul W. Smith
Host: Paul Smith
Media Market: Detroit, MI
Call-in number: (b)(6)
Back-up (b)(6)

Topics: FDA's work supporting drugs and vaccines to fight coronavirus, including chloroquine and the use of blood products to help treat infected individuals. In the last week or so, FDA issued an emergency use authorization for the first serology (antibody) test for COVID-19 to date and expanded national access to blood-related therapies for COVID-19 (aka convalescent plasma and hyperimmune globulin).

From: Block, Molly
Sent: Monday, April 13, 2020 10:29 AM
To: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

First confirmed interview:

Tuesday, April 13
Time: 8:02 – 8:15 AM ET
Radio Show: Morning Answer with Chris Stigall
Host: Chris Stigall
Media Market: Philadelphia
Call-in number: (b)(6)
Backup: (b)(6)

Topics: DAs work to support drugs and vaccines to fight coronavirus, chloroquine, the hydroxychloroquine and ZPACK cocktail that some are claiming have saved their lives.

From: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Sent: Sunday, April 12, 2020 9:51 PM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

Hi Molly,

Here is where the holds for these media requests have landed:

Monday or Tuesday: 20 minutes (whenever) for an **interview with David Lim from Politico**

- Tuesday, 4/14, 1:10-1:30 PM

30 minute holds on **Tuesday and Thursday AM**: preferably before 10:00 AM if possible for **Radio**

- Tuesday, 4/14, 8:00-8:30 AM
- Thursday, 4/16, 8:30-9:00 AM

45 minutes on Friday for a **Pen & Pad with FDA beat reporters** (Stephanie and Michael are running point on this one)

- Friday, 4/17, 8:00-8:45 AM

Frank

From: Olivarria, Frank
Sent: Friday, April 10, 2020 6:58 PM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

Thank you! Will get these hold on the calendar.

Frank

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Friday, April 10, 2020 6:57 PM
To: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

Yes on Keagan.

From: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Sent: Friday, April 10, 2020 6:56 PM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

Thank you Molly, appreciate this. Have these calendar additions been cleared with the Commissioner or COS?

Frank

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Friday, April 10, 2020 6:54 PM
To: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea

<Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: Media Holds for next week

Can I get the follow holds on Dr. Hahn's calendar for media next week:

Monday or Tuesday: 20 minutes (whenever) for an interview with David Lim from Politico

30 minute holds on Tuesday and Thursday AM: preferably before 10:00 AM if possible for Radio

45 minutes on Friday for a Pen & Pad with FDA beat reporters (Stephanie and Michael are running point on this one)

Sent: 4/14/2020 4:16:33 PM
To: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
CC: Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Torres, Melissa A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6c012e5b0aa843f78e818a92d82f8d1b-MAT]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]
Subject: RE: **(b)(5)**

(b)(5)

Thanks,
Keagan

From: Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
Sent: Tuesday, April 14, 2020 11:24 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Torres, Melissa A <Melissa.Torres@fda.hhs.gov>
Subject: RE: **(b)(5)**

Keagan,

The information that we provided yesterday is all we have **(b)(5)**
(b)(5)

Elizabeth

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Tuesday, April 14, 2020 8:04 AM
To: Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
Cc: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: Fwd: **(b)(5)**

Elizabeth- **(b)(5)**
(b)(5) Thanks.

Sent from my iPhone

Begin forwarded message:

From: "Grogan, Joseph J. EOP/WHO" <(b)(6)
Date: April 14, 2020 at 7:52:08 AM EDT
To: "Hahn, Stephen" <SH1@fda.hhs.gov>, "Rom, Colin" <Colin.Rom@fda.hhs.gov>
Cc: "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>
Subject: FW: (b)(5)

From: Kushner, Jared C. EOP/WHO (b)(6)
Sent: Monday, April 13, 2020 10:31 PM
To: Grogan, Joseph J. EOP/WHO (b)(6)
Cc: Boyd, Charlton J. EOP/WHO (b)(6) Campana, Alexandra D. EOP/WHO (b)(6)
Subject: RE (b)(5)

I went through these. (b)(5)
(b)(5)

JK

From: Grogan, Joseph J. EOP/WHO (b)(6)
Sent: Monday, April 13, 2020 8:13 PM
To: Kushner, Jared C. EOP/WHO (b)(6)
Cc: Boyd, Charlton J. EOP/WHO (b)(6) Campana, Alexandra D. EOP/WHO (b)(6)
Subject: FW: (b)(5)

Jared, see the list below (b)(5)

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Monday, April 13, 2020 3:05 PM
To: Hahn, Stephen <SH1@fda.hhs.gov>; Grogan, Joseph J. EOP/WHO (b)(6)
Subject: (b)(5)

Sir – attached are talkers I built with (b)(5)
(b)(5) I am still waiting to hear from CDER, but CDRH list is below.

(b)(4) (b)(5)

(b)(4) (b)(5)

Sent: 4/14/2020 4:32:57 PM
To: Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
CC: Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Torres, Melissa A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6c012e5b0aa843f78e818a92d82f8d1b-MAT]
Subject: RE: **(b)(5)**

Appreciate it.

From: Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
Sent: Tuesday, April 14, 2020 4:31 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Cc: Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Torres, Melissa A <Melissa.Torres@fda.hhs.gov>
Subject: RE: **(b)(5)**

Keagan,
The dx team is looking into this. Will be in touch.
Elizabeth

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Tuesday, April 14, 2020 4:25 PM
To: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Cc: Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Torres, Melissa A <Melissa.Torres@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
Subject: RE: **(b)(5)**

The Commissioner just called, FEMA volunteered to get the product out of China that we need. **(b)(5)**
(b)(5)
(b)(5) **(b)(4)**
(b)(4)
(b)(5) **(b)(5)**
(b)(5)

Thanks,
Keagan

From: Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
Sent: Tuesday, April 14, 2020 11:24 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Torres, Melissa A <Melissa.Torres@fda.hhs.gov>
Subject: RE: **(b)(5)**

Keagan,

The information that we provided yesterday is all we have (b)(5)

(b)(5)

Elizabeth

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Tuesday, April 14, 2020 8:04 AM
To: Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
Cc: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: Fwd (b)(5)

Elizabeth- (b)(5)

(b)(5)

Sent from my iPhone

Begin forwarded message:

From: "Grogan, Joseph J. EOP/WHO" <Joseph.J.Grogan@who.eop.gov>
Date: April 14, 2020 at 7:52:08 AM EDT
To: "Hahn, Stephen" (b)(6)@fda.hhs.gov>, "Rom, Colin" <Colin.Rom@fda.hhs.gov>
Cc: "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>
Subject: FW: (b)(5)

From: Kushner, Jared C. EOP/WHO <jck@who.eop.gov>
Sent: Monday, April 13, 2020 10:31 PM
To: Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>
Cc: Boyd, Charlton J. EOP/WHO <Charlton.J.Boyd@who.eop.gov>; Campana, Alexandra D. EOP/WHO <Alexandra.D.Campana2@who.eop.gov>
Subject: RE (b)(5)

I went through these (b)(5)
product, (b)(5)

JK

From: Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>
Sent: Monday, April 13, 2020 8:13 PM
To: Kushner, Jared C. EOP/WHO <jck@who.eop.gov>
Cc: Boyd, Charlton J. EOP/WHO <Charlton.J.Boyd@who.eop.gov>; Campana, Alexandra D. EOP/WHO <Alexandra.D.Campana2@who.eop.gov>
Subject: FW: (b)(5)

Jared, see the list below, (b)(5)

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Monday, April 13, 2020 3:05 PM
To: Hahn, Stephen (HHS/OS) <[redacted]@fda.hhs.gov>; Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>
Subject: (b)(5)

Sir – attached are talkers I built with (b)(5) (b)(5) I am still waiting to hear from CDER, but CDRH list is below.

(b)(4), (b)(5)

(b)(4), (b)(5)

From: Caliguiri, Laura [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AA086F2D6C0346C49E996932D86AC62E-LAURA.CALIG]
Sent: 4/15/2020 11:22:51 AM
To: Block, Molly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e32ca68078848889751e7ec26910142-Molly.Block]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]
CC: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Copeland, Jakea [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7fe05ed233c42b68be990b12ae2c8c8-Jakea.Copel]
Subject: RE: Confirming Need: Media Holds for next week

He has also been asked to do Anderson Cooper and Sanjay pretaping.

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Wednesday, April 15, 2020 11:21 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: Confirming Need: Media Holds for next week

Thanks!

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, April 15, 2020 11:18 AM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: Confirming Need: Media Holds for next week

Need to speak with him about it. Should see him very shortly.

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Wednesday, April 15, 2020 11:12 AM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: Confirming Need: Media Holds for next week

Can I confirm this with Washington Post?

From: Block, Molly
Sent: Wednesday, April 15, 2020 10:26 AM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: Confirming Need: Media Holds for next week

And we have a murder board session today so we can tune up some answers.

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Sent: Wednesday, April 15, 2020 10:25 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Block, Molly <Molly.Block@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: Confirming Need: Media Holds for next week

Testing was the ask

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, April 15, 2020 10:25 AM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Block, Molly <Molly.Block@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: Confirming Need: Media Holds for next week

I am in favor. Will call him about it. Can we make sure Steve can talk about testing?

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Sent: Wednesday, April 15, 2020 10:23 AM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: Confirming Need: Media Holds for next week

Ok for WaPO – 11:10-11:30 I know he has a likely hard stop at 11:30 and this cuts into a reoccurring mtg but recommend this strongly. This is moderated q & a w Bob Costa, opp to talk to American public on broad topics focusing on testing, therapies. **Can we confirm this?**

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Wednesday, April 15, 2020 9:51 AM
To: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>

Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: Confirming Need: Media Holds for next week

lsh – they won't give us more details until their 2:00 PM rundown meeting.

I've been told his interview would be in the first half of the show. Would be in the range of 5 – 9 minutes. Will have a remote studio.

From: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Sent: Wednesday, April 15, 2020 9:50 AM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: Confirming Need: Media Holds for next week

Has Hannity for tonight been confirmed? if so, please provide the finalized details.

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Tuesday, April 14, 2020 4:12 PM
To: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: Confirming Need: Media Holds for next week

9:00 – 9:30 pm. I should be getting better sense of timing soon.

There will be a remote van sent to his house for the taping.

From: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Sent: Tuesday, April 14, 2020 4:09 PM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: Confirming Need: Media Holds for next week

What time should the hold for Hannity be? Laura informed it is cleared by COS for addition to the calendar, but if we could have the time at least for now – or time range to get this on the calendar as a hold. We will move the murder board to tomorrow, as soon as some other WH Leg affairs items land.

Thank you,
Frank

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Tuesday, April 14, 2020 1:15 PM
To: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Sheehy, Janice

<Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: Confirming Need: Media Holds for next week

We really should have one before Hannity tomorrow night (in the process of getting that scheduled).

From: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Sent: Tuesday, April 14, 2020 1:12 PM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Block, Molly <Molly.Block@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: Confirming Need: Media Holds for next week

The Commissioner cannot participate in the murder board at 1:30p today.

I've been asked to reach out to evaluate the need for this additional time. Does Dr. Hahn need to do an additional murder board for TV media, or is this only if he feels he needs additional prep? Please advise.

Thank you,
Frank

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Monday, April 13, 2020 11:59 AM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

Sounds good.

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Monday, April 13, 2020 11:52 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

This wouldn't be for those radio hits. WH would like another murderboard before more TV this week.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Monday, April 13, 2020 11:47 AM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

Yes, when he agrees to media he agrees for the prep for them. Thanks. Does he really need them for radio though?

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Monday, April 13, 2020 11:46 AM
To: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

I believe so. Stephanie and Keagan have had discussions about regular comms prep for Dr. Hahn.

Stephanie - can you confirm?

From: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Sent: Monday, April 13, 2020 11:41 AM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

Has this additional calendar item (*murderboard prep tomorrow*) been approved by the Commissioner or COS?

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Monday, April 13, 2020 11:36 AM
To: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

And one more to add to the calendar.

30 minute murderboard prep tomorrow (whenever works for Dr. Hahn)
Invitees: Laura, Stephanie, Michael, Molly, Devin O'Malley

From: Block, Molly
Sent: Monday, April 13, 2020 10:41 AM
To: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

Second confirmed interview:

Tuesday, April 13

Time: 8:17 – 8:30 AM ET
Radio Show: Paul W. Smith
Host: Paul Smith
Media Market: Detroit, MI
Call-in number: (b)(6)
Back-up: (b)(6)

Topics: FDA's work supporting drugs and vaccines to fight coronavirus, including chloroquine and the use of blood products to help treat infected individuals. In the last week or so, FDA issued an emergency use authorization for the first serology (antibody) test for COVID-19 to date and expanded national access to blood-related therapies for COVID-19 (aka convalescent plasma and hyperimmune globulin).

From: Block, Molly
Sent: Monday, April 13, 2020 10:29 AM
To: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

First confirmed interview:

Tuesday, April 13
Time: 8:02 – 8:15 AM ET
Radio Show: Morning Answer with Chris Stigall
Host: Chris Stigall
Media Market: Philadelphia
Call-in number: (b)(6)
Backup: (b)(6)

Topics: DAs work to support drugs and vaccines to fight coronavirus, chloroquine, the hydroxychloroquine and ZPACK cocktail that some are claiming have saved their lives.

From: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Sent: Sunday, April 12, 2020 9:51 PM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

Hi Molly,

Here is where the holds for these media requests have landed:

Monday or Tuesday: 20 minutes (whenever) for an **interview with David Lim from Politico**

- Tuesday, 4/14, 1:10-1:30 PM

30 minute holds on **Tuesday and Thursday AM**: preferably before 10:00 AM if possible for **Radio**

- Tuesday, 4/14, 8:00-8:30 AM
- Thursday, 4/16, 8:30-9:00 AM

45 minutes on Friday for a **Pen & Pad with FDA beat reporters** (Stephanie and Michael are running point on this one)

- Friday, 4/17, 8:00-8:45 AM

Frank

From: Olivarria, Frank
Sent: Friday, April 10, 2020 6:58 PM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

Thank you! Will get these hold on the calendar.

Frank

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Friday, April 10, 2020 6:57 PM
To: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

Yes on Keagan.

From: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Sent: Friday, April 10, 2020 6:56 PM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

Thank you Molly, appreciate this. Have these calendar additions been cleared with the Commissioner or COS?

Frank

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Friday, April 10, 2020 6:54 PM
To: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie

<Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: Media Holds for next week

Can I get the follow holds on Dr. Hahn's calendar for media next week:

Monday or Tuesday: 20 minutes (whenever) for an interview with David Lim from Politico

30 minute holds on Tuesday and Thursday AM: preferably before 10:00 AM if possible for Radio

45 minutes on Friday for a Pen & Pad with FDA beat reporters (Stephanie and Michael are running point on this one)

From: Sheehy, Janice [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F45A6C96F5274724A1BE5970EB648FF7-JSHEEHY]
Sent: 4/15/2020 1:37:21 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]
Subject: RE: Confirming Need: Media Holds for next week

The testing call is at 2:10 pm

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, April 15, 2020 1:36 PM
To: Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>
Cc: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Subject: RE: Confirming Need: Media Holds for next week

Is the testing call in an hour.

From: Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>
Sent: Wednesday, April 15, 2020 1:31 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Subject: RE: Confirming Need: Media Holds for next week

Does SH need to be on this internal discussion or just you with OEA?

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, April 15, 2020 1:07 PM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: Confirming Need: Media Holds for next week

Ok, but we need to have an internal discussion first.

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Wednesday, April 15, 2020 12:53 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: Confirming Need: Media Holds for next week

Checking in on this. I've gotten two calls from the Post in the last 45 minutes

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From: Block, Molly
Sent: Wednesday, April 15, 2020 11:21 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Olivarria, Frank

<Frank.Olivarria@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: Confirming Need: Media Holds for next week

Thanks!

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, April 15, 2020 11:18 AM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: Confirming Need: Media Holds for next week

Need to speak with him about it. Should see him very shortly.

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Wednesday, April 15, 2020 11:12 AM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: Confirming Need: Media Holds for next week

Can I confirm this with Washington Post?

From: Block, Molly
Sent: Wednesday, April 15, 2020 10:26 AM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: Confirming Need: Media Holds for next week

And we have a murder board session today so we can tune up some answers.

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Sent: Wednesday, April 15, 2020 10:25 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Block, Molly <Molly.Block@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: Confirming Need: Media Holds for next week

Testing was the ask

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, April 15, 2020 10:25 AM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Block, Molly <Molly.Block@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: Confirming Need: Media Holds for next week

I am in favor. Will call him about it. Can we make sure Steve can talk about testing?

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Sent: Wednesday, April 15, 2020 10:23 AM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: Confirming Need: Media Holds for next week

Ok for WaPO – 11:10-11:30 I know he has a likely hard stop at 11:30 and this cuts into a reoccurring mtg but recommend this strongly. This is moderated q & a w Bob Costa, opp to talk to American public on broad topics focusing on testing, therapies. **Can we confirm this?**

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Wednesday, April 15, 2020 9:51 AM
To: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: Confirming Need: Media Holds for next week

lsh – they won't give us more details until their 2:00 PM rundown meeting.

I've been told his interview would be in the first half of the show. Would be in the range of 5 – 9 minutes. Will have a remote studio.

From: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Sent: Wednesday, April 15, 2020 9:50 AM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: Confirming Need: Media Holds for next week

Has Hannity for tonight been confirmed? if so, please provide the finalized details.

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Tuesday, April 14, 2020 4:12 PM
To: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Sheehy, Janice

<Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: Confirming Need: Media Holds for next week

9:00 – 9:30 pm. I should be getting better sense of timing soon.

There will be a remote van sent to his house for the taping.

From: Olivarria, Frank <Frank.●livarria@fda.hhs.gov>
Sent: Tuesday, April 14, 2020 4:09 PM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: Confirming Need: Media Holds for next week

What time should the hold for Hannity be? Laura informed it is cleared by COS for addition to the calendar, but if we could have the time at least for now – or time range to get this on the calendar as a hold. We will move the murder board to tomorrow, as soon as some other WH Leg affairs items land.

Thank you,
Frank

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Tuesday, April 14, 2020 1:15 PM
To: Olivarria, Frank <Frank.●livarria@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: Confirming Need: Media Holds for next week

We really should have one before Hannity tomorrow night (in the process of getting that scheduled).

From: Olivarria, Frank <Frank.●livarria@fda.hhs.gov>
Sent: Tuesday, April 14, 2020 1:12 PM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Block, Molly <Molly.Block@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: Confirming Need: Media Holds for next week

The Commissioner cannot participate in the murder board at 1:30p today.

I've been asked to reach out to evaluate the need for this additional time. Does Dr. Hahn need to do an additional murder board for TV media, or is this only if he feels he needs additional prep? Please advise.

Thank you,
Frank

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Monday, April 13, 2020 11:59 AM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Olivarria, Frank <Frank.●livarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>

Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

Sounds good.

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Monday, April 13, 2020 11:52 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

This wouldn't be for those radio hits. WH would like another murderboard before more TV this week.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Monday, April 13, 2020 11:47 AM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

Yes, when he agrees to media he agrees for the prep for them. Thanks. Does he really need them for radio though?

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Monday, April 13, 2020 11:46 AM
To: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

I believe so. Stephanie and Keagan have had discussions about regular comms prep for Dr. Hahn.

Stephanie - can you confirm?

From: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Sent: Monday, April 13, 2020 11:41 AM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

Has this additional calendar item (*murderboard prep tomorrow*) been approved by the Commissioner or COS?

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Monday, April 13, 2020 11:36 AM
To: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

And one more to add to the calendar.

30 minute murderboard prep tomorrow (whenever works for Dr. Hahn)
Invitees: Laura, Stephanie, Michael, Molly, Devin O'Malley

From: Block, Molly
Sent: Monday, April 13, 2020 10:41 AM
To: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

Second confirmed interview:

Tuesday, April 13
Time: 8:17 – 8:30 AM ET
Radio Show: Paul W. Smith
Host: Paul Smith
Media Market: Detroit, MI
Call-in number: **(b)(6)**
Back-up: **(b)(6)**

Topics: FDA's work supporting drugs and vaccines to fight coronavirus, including chloroquine and the use of blood products to help treat infected individuals. In the last week or so, FDA issued an emergency use authorization for the first serology (antibody) test for COVID-19 to date and expanded national access to blood-related therapies for COVID-19 (aka convalescent plasma and hyperimmune globulin).

From: Block, Molly
Sent: Monday, April 13, 2020 10:29 AM
To: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

First confirmed interview:

Tuesday, April 13
Time: 8:02 – 8:15 AM ET

Radio Show: Morning Answer with Chris Stigall
Host: Chris Stigall
Media Market: Philadelphia
Call-in number: (b)(6)
Backup (b)(6)

Topics: DAs work to support drugs and vaccines to fight coronavirus, chloroquine, the hydroxychloroquine and ZPACK cocktail that some are claiming have saved their lives.

From: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Sent: Sunday, April 12, 2020 9:51 PM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

Hi Molly,

Here is where the holds for these media requests have landed:

Monday or Tuesday: 20 minutes (whenever) for an **interview with David Lim from Politico**

- Tuesday, 4/14, 1:10-1:30 PM

30 minute holds on **Tuesday and Thursday AM**: preferably before 10:00 AM if possible for **Radio**

- Tuesday, 4/14, 8:00-8:30 AM
- Thursday, 4/16, 8:30-9:00 AM

45 minutes on Friday for a **Pen & Pad with FDA beat reporters** (Stephanie and Michael are running point on this one)

- Friday, 4/17, 8:00-8:45 AM

Frank

From: Olivarria, Frank
Sent: Friday, April 10, 2020 6:58 PM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

Thank you! Will get these hold on the calendar.

Frank

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Friday, April 10, 2020 6:57 PM

To: Olivarria, Frank <Frank.●livarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

Yes on Keagan.

From: Olivarria, Frank <Frank.●livarria@fda.hhs.gov>
Sent: Friday, April 10, 2020 6:56 PM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

Thank you Molly, appreciate this. Have these calendar additions been cleared with the Commissioner or COS?

Frank

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Friday, April 10, 2020 6:54 PM
To: Olivarria, Frank <Frank.●livarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: Media Holds for next week

Can I get the follow holds on Dr. Hahn's calendar for media next week:

Monday or Tuesday: 20 minutes (whenever) for an interview with David Lim from Politico

30 minute holds on Tuesday and Thursday AM: preferably before 10:00 AM if possible for Radio

45 minutes on Friday for a Pen & Pad with FDA beat reporters (Stephanie and Michael are running point on this one)

From: Abdoo, Mark [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCA42E5F1795433C9DF447F8F11BC80E-MARK.ABDOO]
Sent: 4/15/2020 1:58:07 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]
Subject: RE: AMA Call with Head of China's National Medical Products Administration

Thanks, Keagan.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, April 15, 2020 1:56 PM
To: Abdoo, Mark <Mark.Abdoo@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Subject: RE: AMA Call with Head of China's National Medical Products Administration

What we sent to WH is attached and below is additional info on things caught up in the export ban.

(b)(5)

(b)(5)

From: Abdoo, Mark <Mark.Abdoo@fda.hhs.gov>
Sent: Wednesday, April 15, 2020 9:53 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Subject: RE: AMA Call with Head of China's National Medical Products Administration

(b)(5)

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, April 15, 2020 9:32 AM
To: Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Abdoo, Mark <Mark.Abdoo@fda.hhs.gov>
Subject: RE: AMA Call with Head of China's National Medical Products Administration

Mark - **(b)(5)** **(b)(5)** I am fine with you staffing. Happy to send you the info we sent to their office to prep for the call.

From: Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Sent: Wednesday, April 15, 2020 9:29 AM
To: Abdoo, Mark <Mark.Abdoo@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: AMA Call with Head of China's National Medical Products Administration

I defer to Keagan about **(b)(5)**

From: Abdoo, Mark <Mark.Abdoo@fda.hhs.gov>
Sent: Wednesday, April 15, 2020 8:23 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Subject: AMA Call with Head of China's National Medical Products Administration

Keagan, Erika,
HHS/OGA is arranging a call between AMA and Jiao Hong, the head of China's National Medical Products Administration, to discuss China's regulations on the export of certain medical products. The date/time are still in flux, though the Secretary's office is pushing for tomorrow at 0730 EDT. Garrett has asked CDC staff in Beijing and me to join to help staff the call. Is this alright with you **(b)(5)** **(b)(5)**
Regards,
Abdoo

Mark Abdoo
Associate Commissioner for Global Policy and Strategy
Office of Policy, Legislation and International Affairs
U.S. Food and Drug Administration

From: Rom, Colin [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F59636221F4340D697DBD43EE27255FB-COLIN.ROM]
Sent: 4/15/2020 2:34:53 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: RE: Slightly Updated

Thank you will do

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, April 15, 2020 2:33 PM
To: Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Slightly Updated

Sounds good. Feel free to flag for me and just let me know what you are doing so I can support you if CDs reach out. Thanks.

From: Rom, Colin <Colin.Rom@fda.hhs.gov>
Sent: Wednesday, April 15, 2020 2:32 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: Slightly Updated

Ok sounds good. He expressly told me to go through you so wanted to make sure you saw

---

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, April 15, 2020 2:29 PM
To: Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Slightly Updated

Thank you. You are absolutely welcome to work with the Centers to do this if you prefer, you don't need to go through me.

From: Rom, Colin <Colin.Rom@fda.hhs.gov>
Sent: Wednesday, April 15, 2020 2:24 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: Slightly Updated

Perfect-- sent it along !

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, April 15, 2020 2:07 PM

To: Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: Slightly Updated

(b)(5)

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 4/15/2020 2:45:23 PM
To: McWilliams, Carly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]
Subject: RE: EUA for HCQ

Thanks!

From: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Sent: Wednesday, April 15, 2020 2:44 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: EUA for HCQ

https://www.fda.gov/media/136536/download

https://www.fda.gov/media/136538/download
From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, April 15, 2020 2:36 PM
To: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Subject: RE: EUA for HCQ

Do you have these fact sheets?
• Fact Sheet for Patients and Parent/Caregivers for EUA of Chloroquine Phosphate for treatment of COVID-19 in certain hospitalized patients
• Fact Sheet for Patients and Parent/Caregivers for EUA of Hydroxychloroquine sulfate for treatment of COVID-19 in certain hospitalized patients

From: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Sent: Wednesday, April 15, 2020 2:16 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: EUA for HCQ

Authorization letter to BARDA: https://www.fda.gov/media/136534/download
Therapeutics document
Allows hydroxychloroquine sulfate and chloroquine phosphate products donated to the Strategic National Stockpile (SNS) to be distributed and used for certain adolescent and adult patients hospitalized with COVID-19, as appropriate, when a clinical trial is not available or feasible. These drugs will be distributed from the SNS to states for doctors to prescribe to these patients.
• Fact Sheet for Patients and Parent/Caregivers for EUA of Chloroquine Phosphate for treatment of COVID-19 in certain hospitalized patients • Fact Sheet for Patients and Parent/Caregivers for EUA of Hydroxychloroquine sulfate for treatment of COVID-19 in certain hospitalized patients
From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, April 15, 2020 2:07 PM
To: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Subject: RE: EUA for HCQ

hydroxychloroquine

From: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Sent: Wednesday, April 15, 2020 2:06 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: EUA for HCQ

What is HCQ?

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, April 15, 2020 1:50 PM
To: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Subject: EUA for HCQ

Did we put something up on our website on this or did anything go out publicly? If so, can you send me whatever is public? Thanks.

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 4/15/2020 3:45:58 PM
To: Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
CC: Copeland, Jakea [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7fe05ed233c42b68be990b12ae2c8c8-Jakea.Copel]
Subject: RE: Conflict: Confirming Need: Media Holds for next week

Tomorrow am is the worst. We are going to need to go through it with him. I will try and do that after TF and report back.

From: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Sent: Wednesday, April 15, 2020 3:45 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Cc: Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: Conflict: Confirming Need: Media Holds for next week

Update: SH will now only get 10 mins, 10:45-10:55 AM with DC/CD's, OMA added additional time onto their hold for WaPo tomorrow, and also accounting for time to get to the HHS Studio.

I sent an email to Molly last week, 1:1 stressing the importance of including mic-up/setup time for interviews (thus my additional email today). This makes the calendar more chaotic than it already has become, hoping they can be better about this.

Frank

From: Olivarria, Frank
Sent: Wednesday, April 15, 2020 3:28 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Cc: Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: Conflict: Confirming Need: Media Holds for next week

The calendar is very ugly this week. Yes, absolutely... He can join for DC/CD meeting from 10:45-11:10 AM and drop off.

Frank

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, April 15, 2020 3:26 PM
To: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Cc: Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: Conflict: Confirming Need: Media Holds for next week

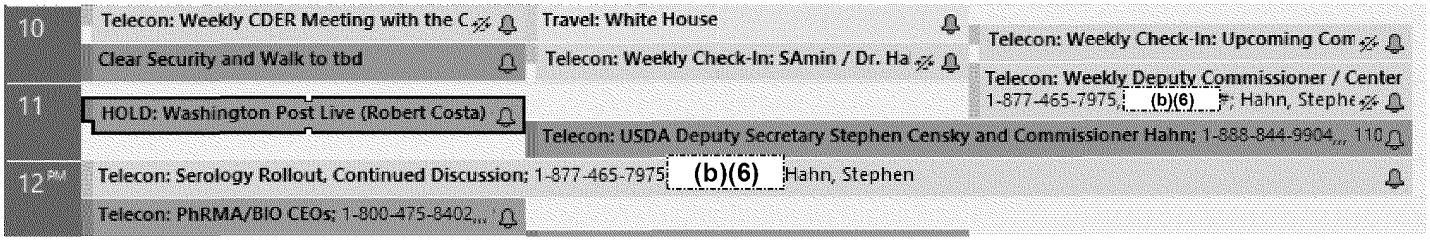
This is UGLY! Can he do the beginning of CD meeting?

From: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Sent: Wednesday, April 15, 2020 10:54 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Cc: Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: Conflict: Confirming Need: Media Holds for next week

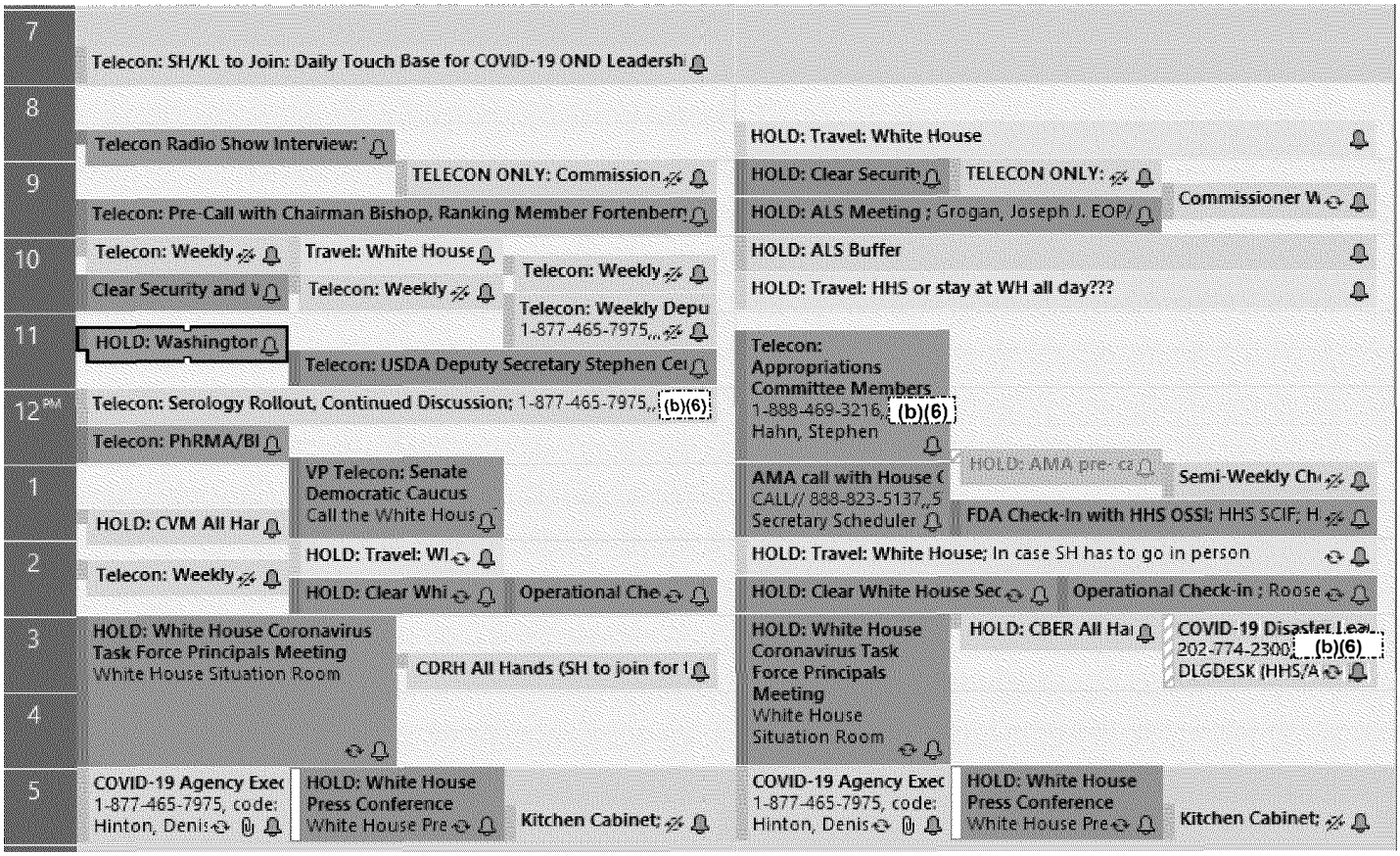
Keagan,

We're going to have to drop the Thursday "Weekly" DC/CD Meeting to make this work. Calendar is too full to move to another time, unless there are items we can drop on Thursday or Friday.

Conflict snapshot:



Thursday/Friday:



Frank

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, April 15, 2020 10:25 AM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Block, Molly <Molly.Block@fda.hhs.gov>; Olivarria, Frank

<Frank.Olivarria@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: Confirming Need: Media Holds for next week

I am in favor. Will call him about it. Can we make sure Steve can talk about testing?

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Sent: Wednesday, April 15, 2020 10:23 AM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: Confirming Need: Media Holds for next week

Ok for WaPO – 11:10-11:30 I know he has a likely hard stop at 11:30 and this cuts into a reoccurring mtg but recommend this strongly. This is moderated q & a w Bob Costa, opp to talk to American public on broad topics focusing on testing, therapies. **Can we confirm this?**

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Wednesday, April 15, 2020 9:51 AM
To: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: Confirming Need: Media Holds for next week

lsh – they won't give us more details until their 2:00 PM rundown meeting.

I've been told his interview would be in the first half of the show. Would be in the range of 5 – 9 minutes. Will have a remote studio.

From: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Sent: Wednesday, April 15, 2020 9:50 AM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: Confirming Need: Media Holds for next week

Has Hannity for tonight been confirmed? if so, please provide the finalized details.

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Tuesday, April 14, 2020 4:12 PM
To: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: Confirming Need: Media Holds for next week

9:00 – 9:30 pm. I should be getting better sense of timing soon.

There will be a remote van sent to his house for the taping.

From: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Sent: Tuesday, April 14, 2020 4:09 PM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: Confirming Need: Media Holds for next week

What time should the hold for Hannity be? Laura informed it is cleared by COS for addition to the calendar, but if we could have the time at least for now – or time range to get this on the calendar as a hold. We will move the murder board to tomorrow, as soon as some other WH Leg affairs items land.

Thank you,
Frank

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Tuesday, April 14, 2020 1:15 PM
To: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: Confirming Need: Media Holds for next week

We really should have one before Hannity tomorrow night (in the process of getting that scheduled).

From: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Sent: Tuesday, April 14, 2020 1:12 PM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Block, Molly <Molly.Block@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: Confirming Need: Media Holds for next week

The Commissioner cannot participate in the murder board at 1:30p today.

I've been asked to reach out to evaluate the need for this additional time. Does Dr. Hahn need to do an additional murder board for TV media, or is this only if he feels he needs additional prep? Please advise.

Thank you,
Frank

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Monday, April 13, 2020 11:59 AM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

Sounds good.

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Monday, April 13, 2020 11:52 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <La ur a.Caliguiri@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

This wouldn't be for those radio hits. WH would like another murderboard before more TV this week.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Monday, April 13, 2020 11:47 AM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <La ur a.Caliguiri@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

Yes, when he agrees to media he agrees for the prep for them. Thanks. Does he really need them for radio though?

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Monday, April 13, 2020 11:46 AM
To: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

I believe so. Stephanie and Keagan have had discussions about regular comms prep for Dr. Hahn.

Stephanie - can you confirm?

From: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Sent: Monday, April 13, 2020 11:41 AM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

Has this additional calendar item (*murderboard prep tomorrow*) been approved by the Commissioner or COS?

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Monday, April 13, 2020 11:36 AM
To: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea

<Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

And one more to add to the calendar.

30 minute murderboard prep tomorrow (whenever works for Dr. Hahn)
Invitees: Laura, Stephanie, Michael, Molly, Devin O'Malley

From: Block, Molly
Sent: Monday, April 13, 2020 10:41 AM
To: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

Second confirmed interview:

Tuesday, April 13
Time: 8:17 – 8:30 AM ET
Radio Show: Paul W. Smith
Host: Paul Smith
Media Market: Detroit, MI
Call-in number: **(b)(6)**
Back-up: **(b)(6)**

Topics: FDA's work supporting drugs and vaccines to fight coronavirus, including chloroquine and the use of blood products to help treat infected individuals. In the last week or so, FDA issued an emergency use authorization for the first serology (antibody) test for COVID-19 to date and expanded national access to blood-related therapies for COVID-19 (aka convalescent plasma and hyperimmune globulin).

From: Block, Molly
Sent: Monday, April 13, 2020 10:29 AM
To: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

First confirmed interview:

Tuesday, April 13
Time: 8:02 – 8:15 AM ET
Radio Show: Morning Answer with Chris Stigall
Host: Chris Stigall
Media Market: Philadelphia
Call-in number: **(b)(6)**
Backup: **(b)(6)**

Topics: DAs work to support drugs and vaccines to fight coronavirus, chloroquine, the hydroxychloroquine and ZPACK cocktail that some are claiming have saved their lives.

From: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Sent: Sunday, April 12, 2020 9:51 PM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

Hi Molly,

Here is where the holds for these media requests have landed:

Monday or Tuesday: 20 minutes (whenever) for an **interview with David Lim from Politico**

- Tuesday, 4/14, 1:10-1:30 PM

30 minute holds on **Tuesday and Thursday AM**: preferably before 10:00 AM if possible for **Radio**

- Tuesday, 4/14, 8:00-8:30 AM
- Thursday, 4/16, 8:30-9:00 AM

45 minutes on Friday for a **Pen & Pad with FDA beat reporters** (Stephanie and Michael are running point on this one)

- Friday, 4/17, 8:00-8:45 AM

Frank

From: Olivarria, Frank
Sent: Friday, April 10, 2020 6:58 PM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

Thank you! Will get these hold on the calendar.

Frank

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Friday, April 10, 2020 6:57 PM
To: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan

<Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

Yes on Keagan.

From: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Sent: Friday, April 10, 2020 6:56 PM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

Thank you Molly, appreciate this. Have these calendar additions been cleared with the Commissioner or COS?

Frank

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Friday, April 10, 2020 6:54 PM
To: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: Media Holds for next week

Can I get the follow holds on Dr. Hahn's calendar for media next week:

Monday or Tuesday: 20 minutes (whenever) for an interview with David Lim from Politico

30 minute holds on Tuesday and Thursday AM: preferably before 10:00 AM if possible for Radio

45 minutes on Friday for a Pen & Pad with FDA beat reporters (Stephanie and Michael are running point on this one)

From: Caliguiri, Laura [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AA086F2D6C0346C49E996932D86AC62E-LAURA.CALIG]
Sent: 4/15/2020 4:23:06 PM
To: Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; Block, Molly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e32ca68078848889751e7ec26910142-Molly.Block]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]
CC: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Copeland, Jakea [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7fe05ed233c42b68be990b12ae2c8c8-Jakea.Copel]
Subject: RE: Confirming Need: Media Holds for next week

My error Frank. Apologies.

From: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Sent: Wednesday, April 15, 2020 3:42 PM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: Confirming Need: Media Holds for next week

Thank you, Molly. This hold was for 11:10-11:30 AM – we really need to include prep/set-up time when requesting the holds. This takes an additional 10 mins away from his time with Dep. Commissioners/Center Directors tomorrow; I stressed the importance of this last week as well.

We'll update the calendar invite now.

Thank you,
Frank

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Wednesday, April 15, 2020 3:40 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: Confirming Need: Media Holds for next week

Frank, Janice and Jakea –

We are confirmed for Washington Post Live: Confronting COVID-19

Details:
11:10 – 11:30
Moderated Q&A with Bob Costa
Be in chair by 11:00 AM (in HHS TV Studio)

Let me know if you need any additional info!
Molly

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, April 15, 2020 1:07 PM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: Confirming Need: Media Holds for next week

Ok, but we need to have an internal discussion first.

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Wednesday, April 15, 2020 12:53 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: Confirming Need: Media Holds for next week

Checking in on this. I've gotten two calls from the Post in the last 45 minutes

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From: Block, Molly
Sent: Wednesday, April 15, 2020 11:21 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: Confirming Need: Media Holds for next week

Thanks!

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, April 15, 2020 11:18 AM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: Confirming Need: Media Holds for next week

Need to speak with him about it. Should see him very shortly.

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Wednesday, April 15, 2020 11:12 AM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: Confirming Need: Media Holds for next week

Can I confirm this with Washington Post?

From: Block, Molly
Sent: Wednesday, April 15, 2020 10:26 AM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: Confirming Need: Media Holds for next week

And we have a murder board session today so we can tune up some answers.

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Sent: Wednesday, April 15, 2020 10:25 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Block, Molly <Molly.Block@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: Confirming Need: Media Holds for next week

Testing was the ask

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, April 15, 2020 10:25 AM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Block, Molly <Molly.Block@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: Confirming Need: Media Holds for next week

I am in favor. Will call him about it. Can we make sure Steve can talk about testing?

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Sent: Wednesday, April 15, 2020 10:23 AM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: Confirming Need: Media Holds for next week

Ok for WaPO – 11:10-11:30 I know he has a likely hard stop at 11:30 and this cuts into a reoccurring mtg but recommend this strongly. This is moderated q & a w Bob Costa, opp to talk to American public on broad topics focusing on testing, therapies. **Can we confirm this?**

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Wednesday, April 15, 2020 9:51 AM
To: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: Confirming Need: Media Holds for next week

lsh – they won't give us more details until their 2:00 PM rundown meeting.

I've been told his interview would be in the first half of the show. Would be in the range of 5 – 9 minutes. Will have a remote studio.

From: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Sent: Wednesday, April 15, 2020 9:50 AM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: Confirming Need: Media Holds for next week

Has Hannity for tonight been confirmed? if so, please provide the finalized details.

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Tuesday, April 14, 2020 4:12 PM
To: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: Confirming Need: Media Holds for next week

9:00 – 9:30 pm. I should be getting better sense of timing soon.

There will be a remote van sent to his house for the taping.

From: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Sent: Tuesday, April 14, 2020 4:09 PM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: Confirming Need: Media Holds for next week

What time should the hold for Hannity be? Laura informed it is cleared by COS for addition to the calendar, but if we could have the time at least for now – or time range to get this on the calendar as a hold. We will move the murder board to tomorrow, as soon as some other WH Leg affairs items land.

Thank you,
Frank

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Tuesday, April 14, 2020 1:15 PM
To: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: Confirming Need: Media Holds for next week

We really should have one before Hannity tomorrow night (in the process of getting that scheduled).

From: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Sent: Tuesday, April 14, 2020 1:12 PM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Block, Molly <Molly.Block@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: Confirming Need: Media Holds for next week

The Commissioner cannot participate in the murder board at 1:30p today.

I've been asked to reach out to evaluate the need for this additional time. Does Dr. Hahn need to do an additional murder board for TV media, or is this only if he feels he needs additional prep? Please advise.

Thank you,
Frank

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Monday, April 13, 2020 11:59 AM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

Sounds good.

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Monday, April 13, 2020 11:52 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

This wouldn't be for those radio hits. WH would like another murderboard before more TV this week.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Monday, April 13, 2020 11:47 AM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <La ur a.Caliguiri@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

Yes, when he agrees to media he agrees for the prep for them. Thanks. Does he really need them for radio though?

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Monday, April 13, 2020 11:46 AM
To: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

I believe so. Stephanie and Keagan have had discussions about regular comms prep for Dr. Hahn.

Stephanie - can you confirm?

From: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Sent: Monday, April 13, 2020 11:41 AM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

Has this additional calendar item (*murderboard prep tomorrow*) been approved by the Commissioner or COS?

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Monday, April 13, 2020 11:36 AM
To: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

And one more to add to the calendar.

30 minute murderboard prep tomorrow (whenever works for Dr. Hahn)
Invitees: Laura, Stephanie, Michael, Molly, Devin O'Malley

From: Block, Molly
Sent: Monday, April 13, 2020 10:41 AM
To: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea

<Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

Second confirmed interview:

Tuesday, April 13
Time: 8:17 – 8:30 AM ET
Radio Show: Paul W. Smith
Host: Paul Smith
Media Market: Detroit, MI
Call-in number: **(b)(6)**
Back-up: **(b)(6)**

Topics: FDA's work supporting drugs and vaccines to fight coronavirus, including chloroquine and the use of blood products to help treat infected individuals. In the last week or so, FDA issued an emergency use authorization for the first serology (antibody) test for COVID-19 to date and expanded national access to blood-related therapies for COVID-19 (aka convalescent plasma and hyperimmune globulin).

From: Block, Molly
Sent: Monday, April 13, 2020 10:29 AM
To: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

First confirmed interview:

Tuesday, April 13
Time: 8:02 – 8:15 AM ET
Radio Show: Morning Answer with Chris Stigall
Host: Chris Stigall
Media Market: Philadelphia
Call-in number: **(b)(6)**
Backup: **(b)(6)**

Topics: DAs work to support drugs and vaccines to fight coronavirus, chloroquine, the hydroxychloroquine and ZPACK cocktail that some are claiming have saved their lives.

From: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Sent: Sunday, April 12, 2020 9:51 PM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan

<Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

Hi Molly,

Here is where the holds for these media requests have landed:

Monday or Tuesday: 20 minutes (whenever) for an **interview with David Lim from Politico**

- Tuesday, 4/14, 1:10-1:30 PM

30 minute holds on **Tuesday and Thursday AM**: preferably before 10:00 AM if possible for **Radio**

- Tuesday, 4/14, 8:00-8:30 AM
- Thursday, 4/16, 8:30-9:00 AM

45 minutes on Friday for a **Pen & Pad with FDA beat reporters** (Stephanie and Michael are running point on this one)

- Friday, 4/17, 8:00-8:45 AM

Frank

From: Olivarria, Frank
Sent: Friday, April 10, 2020 6:58 PM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

Thank you! Will get these hold on the calendar.

Frank

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Friday, April 10, 2020 6:57 PM
To: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

Yes on Keagan.

From: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Sent: Friday, April 10, 2020 6:56 PM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

Thank you Molly, appreciate this. Have these calendar additions been cleared with the Commissioner or COS?

Frank

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Friday, April 10, 2020 6:54 PM
To: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: Media Holds for next week

Can I get the follow holds on Dr. Hahn's calendar for media next week:

Monday or Tuesday: 20 minutes (whenever) for an interview with David Lim from Politico

30 minute holds on Tuesday and Thursday AM: preferably before 10:00 AM if possible for Radio

45 minutes on Friday for a Pen & Pad with FDA beat reporters (Stephanie and Michael are running point on this one)

From: Copeland, Jakea [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D7FE05ED233C42B68BE990B12AE2C8C8-JAKEA.COPEL]
Sent: 4/15/2020 4:28:16 PM
To: Block, Molly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e32ca68078848889751e7ec26910142-Molly.Block]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]
CC: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]
Subject: RE: Confirming Need: Media Holds for next week

Okay. Thanks for the heads up!

Jakea

From: Block, Molly <Molly.Block@fda.hhs.gov>
Date: April 15, 2020 at 4:27:36 PM EDT
To: Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>, Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>, Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>
Subject: RE: Confirming Need: Media Holds for next week

We're going to miss the 5:00 PM deadline, but we will get you something.

From: Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Sent: Wednesday, April 15, 2020 3:45 PM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>
Subject: RE: Confirming Need: Media Holds for next week

Hi Molly,

Please send all materials/TPs, by 5pm today.

Thank you,
Jakea

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Wednesday, April 15, 2020 3:40 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: Confirming Need: Media Holds for next week

Frank, Janice and Jakea –

We are confirmed for Washington Post Live: Confronting COVID-19

Details:
11:10 – 11:30
Moderated Q&A with Bob Costa
Be in chair by 11:00 AM (in HHS TV Studio)

Let me know if you need any additional info!
Molly

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, April 15, 2020 1:07 PM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: Confirming Need: Media Holds for next week

Ok, but we need to have an internal discussion first.

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Wednesday, April 15, 2020 12:53 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: Confirming Need: Media Holds for next week

Checking in on this. I've gotten two calls from the Post in the last 45 minutes

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From: Block, Molly
Sent: Wednesday, April 15, 2020 11:21 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: Confirming Need: Media Holds for next week

Thanks!

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, April 15, 2020 11:18 AM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: Confirming Need: Media Holds for next week

Need to speak with him about it. Should see him very shortly.

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Wednesday, April 15, 2020 11:12 AM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: Confirming Need: Media Holds for next week

Can I confirm this with Washington Post?

From: Block, Molly
Sent: Wednesday, April 15, 2020 10:26 AM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: Confirming Need: Media Holds for next week

And we have a murder board session today so we can tune up some answers.

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Sent: Wednesday, April 15, 2020 10:25 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Block, Molly <Molly.Block@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: Confirming Need: Media Holds for next week

Testing was the ask

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, April 15, 2020 10:25 AM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Block, Molly <Molly.Block@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea

<Jakea.Copeland@fda.hhs.gov>
Subject: RE: Confirming Need: Media Holds for next week

I am in favor. Will call him about it. Can we make sure Steve can talk about testing?

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Sent: Wednesday, April 15, 2020 10:23 AM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: Confirming Need: Media Holds for next week

Ok for WaPO – 11:10-11:30 I know he has a likely hard stop at 11:30 and this cuts into a reoccurring mtg but recommend this strongly. This is moderated q & a w Bob Costa, opp to talk to American public on broad topics focusing on testing, therapies. **Can we confirm this?**

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Wednesday, April 15, 2020 9:51 AM
To: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: Confirming Need: Media Holds for next week

lsh – they won't give us more details until their 2:00 PM rundown meeting.

I've been told his interview would be in the first half of the show. Would be in the range of 5 – 9 minutes. Will have a remote studio.

From: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Sent: Wednesday, April 15, 2020 9:50 AM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: Confirming Need: Media Holds for next week

Has Hannity for tonight been confirmed? if so, please provide the finalized details.

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Tuesday, April 14, 2020 4:12 PM
To: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: Confirming Need: Media Holds for next week

9:00 – 9:30 pm. I should be getting better sense of timing soon.

There will be a remote van sent to his house for the taping.

From: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Sent: Tuesday, April 14, 2020 4:09 PM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: Confirming Need: Media Holds for next week

What time should the hold for Hannity be? Laura informed it is cleared by COS for addition to the calendar, but if we could have the time at least for now – or time range to get this on the calendar as a hold. We will move the murder board to tomorrow, as soon as some other WH Leg affairs items land.

Thank you,
Frank

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Tuesday, April 14, 2020 1:15 PM
To: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: Confirming Need: Media Holds for next week

We really should have one before Hannity tomorrow night (in the process of getting that scheduled).

From: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Sent: Tuesday, April 14, 2020 1:12 PM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Block, Molly <Molly.Block@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: Confirming Need: Media Holds for next week

The Commissioner cannot participate in the murder board at 1:30p today.

I've been asked to reach out to evaluate the need for this additional time. Does Dr. Hahn need to do an additional murder board for TV media, or is this only if he feels he needs additional prep? Please advise.

Thank you,
Frank

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Monday, April 13, 2020 11:59 AM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

Sounds good.

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Monday, April 13, 2020 11:52 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <La ur a.Caliguiri@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

This wouldn't be for those radio hits. WH would like another murderboard before more TV this week.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Monday, April 13, 2020 11:47 AM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <La ur a.Caliguiri@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

Yes, when he agrees to media he agrees for the prep for them. Thanks. Does he really need them for radio though?

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Monday, April 13, 2020 11:46 AM
To: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

I believe so. Stephanie and Keagan have had discussions about regular comms prep for Dr. Hahn.

Stephanie - can you confirm?

From: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Sent: Monday, April 13, 2020 11:41 AM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

Has this additional calendar item (*murderboard prep tomorrow*) been approved by the Commissioner or COS?

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Monday, April 13, 2020 11:36 AM
To: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan

<Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

And one more to add to the calendar.

30 minute murderboard prep tomorrow (whenever works for Dr. Hahn)
Invitees: Laura, Stephanie, Michael, Molly, Devin O'Malley

From: Block, Molly
Sent: Monday, April 13, 2020 10:41 AM
To: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

Second confirmed interview:

Tuesday, April 13
Time: 8:17 – 8:30 AM ET
Radio Show: Paul W. Smith
Host: Paul Smith
Media Market: Detroit, MI
Call-in number: (b)(6)
Back-up: (b)(6)

Topics: FDA's work supporting drugs and vaccines to fight coronavirus, including chloroquine and the use of blood products to help treat infected individuals. In the last week or so, FDA issued an emergency use authorization for the first serology (antibody) test for COVID-19 to date and expanded national access to blood-related therapies for COVID-19 (aka convalescent plasma and hyperimmune globulin).

From: Block, Molly
Sent: Monday, April 13, 2020 10:29 AM
To: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

First confirmed interview:

Tuesday, April 13
Time: 8:02 – 8:15 AM ET
Radio Show: Morning Answer with Chris Stigall
Host: Chris Stigall
Media Market: Philadelphia
Call-in number: (b)(6)
Backup: (b)(6)

Topics: DAs work to support drugs and vaccines to fight coronavirus, chloroquine, the hydroxychloroquine and ZPACK cocktail that some are claiming have saved their lives.

From: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Sent: Sunday, April 12, 2020 9:51 PM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

Hi Molly,

Here is where the holds for these media requests have landed:

Monday or Tuesday: 20 minutes (whenever) for an **interview with David Lim from Politico**

- Tuesday, 4/14, 1:10-1:30 PM

30 minute holds on **Tuesday and Thursday AM**: preferably before 10:00 AM if possible for **Radio**

- Tuesday, 4/14, 8:00-8:30 AM
- Thursday, 4/16, 8:30-9:00 AM

45 minutes on Friday for a **Pen & Pad with FDA beat reporters** (Stephanie and Michael are running point on this one)

- Friday, 4/17, 8:00-8:45 AM

Frank

From: Olivarria, Frank
Sent: Friday, April 10, 2020 6:58 PM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

Thank you! Will get these hold on the calendar.

Frank

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Friday, April 10, 2020 6:57 PM
To: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

Yes on Keagan.

From: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Sent: Friday, April 10, 2020 6:56 PM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Media Holds for next week

Thank you Molly, appreciate this. Have these calendar additions been cleared with the Commissioner or COS?

Frank

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Friday, April 10, 2020 6:54 PM
To: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: Media Holds for next week

Can I get the follow holds on Dr. Hahn's calendar for media next week:

Monday or Tuesday: 20 minutes (whenever) for an interview with David Lim from Politico

30 minute holds on Tuesday and Thursday AM: preferably before 10:00 AM if possible for Radio

45 minutes on Friday for a Pen & Pad with FDA beat reporters (Stephanie and Michael are running point on this one)

Sent: 4/17/2020 4:16:29 PM
To: Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]; Chasan-Sloan, Deborah (FDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a41a2fb6525244da8f538047288b6763-Deborah.Cha]; Corrigan-Curay, Jacqueline [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cff7c455d5d24bc69c1239a23041a596-Jacqu.Corri]; Edmonds, Amanda [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=232186a24a53474298d2760c060a4cc7-Amanda.Edmo]
Subject: RE: Q&A

I def want

From: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Sent: Friday, April 17, 2020 4:14 PM
To: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Chasan-Sloan, Deborah (FDA) <Deborah.Chasan-Sloan@fda.hhs.gov>; Corrigan-Curay, Jacqueline <Jacqueline.Corrigan-Curay@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: Q&A

I am saying that this sentence is too hard to read:

(b)(5)

(b)(5)

From: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Sent: Friday, April 17, 2020 4:13 PM
To: Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Chasan-Sloan, Deborah (FDA) <Deborah.Chasan-Sloan@fda.hhs.gov>; Corrigan-Curay, Jacqueline <Jacqueline.Corrigan-Curay@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: Q&A

I thought we were landing on this?

(b)(5)

From: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Sent: Friday, April 17, 2020 4:11 PM
To: Chasan-Sloan, Deborah (FDA) <Deborah.Chasan-Sloan@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Corrigan-Curay, Jacqueline <Jacqueline.Corrigan-Curay@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: Q&A

I personally think that run on sentence is pretty hard to read. Below is the pre-cleared language that we use whenever we get a media or Hill inquiry about off-label use. **(b)(5)**

(b)(5)

Q: May health care providers prescribe chloroquine phosphate or hydroxychloroquine sulfate off-label to treat patients with COVID-19?

(b)(5)

From: Chasan-Sloan, Deborah (FDA) <Deborah.Chasan-Sloan@fda.hhs.gov>
Sent: Friday, April 17, 2020 4:08 PM
To: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Corrigan-Curay, Jacqueline <Jacqueline.Corrigan-Curay@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: RE: Q&A

Amanda and I conferred-- we think that's fine from a legal perspective.

From: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Sent: Friday, April 17, 2020 4:06 PM
To: Corrigan-Curay, Jacqueline <Jacqueline.Corrigan-Curay@fda.hhs.gov>; Chasan-Sloan, Deborah (FDA) <Deborah.Chasan-Sloan@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: RE: Q&A

OCC?

From: Corrigan-Curay, Jacqueline <Jacqueline.Corrigan-Curay@fda.hhs.gov>
Sent: Friday, April 17, 2020 4:05 PM
To: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Chasan-Sloan, Deborah (FDA) <Deborah.Chasan-Sloan@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: RE: Q&A

I like that better

From: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Sent: Friday, April 17, 2020 4:05 PM
To: Chasan-Sloan, Deborah (FDA) <Deborah.Chasan-Sloan@fda.hhs.gov>; Corrigan-Curay, Jacqueline <Jacqueline.Corrigan-Curay@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Lenihan, Keagan

<Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: RE: Q&A

Could this be a reasonable middle ground?

(b)(5)

Patrizia

From: Chasan-Sloan, Deborah (FDA) <Deborah.Chasan-Sloan@fda.hhs.gov>
Sent: Friday, April 17, 2020 4:01 PM
To: Corrigan-Curay, Jacqueline <Jacqueline.C orrigan-Curay@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Subject: RE: Q&A

(b)(5)

From: Corrigan-Curay, Jacqueline <Jacqueline.Corrigan-Curay@fda.hhs.gov>
Sent: Friday, April 17, 2020 3:59 PM
To: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Chasan-Sloan, Deborah (FDA) <Deborah.Chasan-Sloan@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Subject: RE: Q&A

(b)(5)

From: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>
Sent: Friday, April 17, 2020 3:55 PM
To: Chasan-Sloan, Deborah (FDA) <Deborah.Chasan-Sloan@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Corrigan-Curay, Jacqueline <Jacqueline.Corrigan-Curay@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Subject: RE: Q&A

My reaction is the same as Deborah's.

From: Chasan-Sloan, Deborah (FDA) <Deborah.Chasan-Sloan@fda.hhs.gov>
Sent: Friday, April 17, 2020 3:53 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Corrigan-Curay, Jacqueline <Jacqueline.Corrigan-Curay@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Cc: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>
Subject: RE: Q&A

I def erto CDER **(b)(5)**

(b)(5)

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Friday, April 17, 2020 3:51 PM
To: Corrigan-Curay, Jacqueline <Jacqueline.Corrigan-Curay@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Cc: Chasan-Sloan, Deborah (FDA) <Deborah.Chasan-Sloan@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>
Subject: RE: Q&A

(b)(5)

From: Corrigan-Curay, Jacqueline <Jacqueline.Corrigan-Curay@fda.hhs.gov>
Sent: Friday, April 17, 2020 3:49 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Cc: Chasan-Sloan, Deborah (FDA) <Deborah.Chasan-Sloan@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>
Subject: RE: Q&A

(b)(5)

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Friday, April 17, 2020 3:47 PM
To: Corrigan-Curay, Jacqueline <Jacqueline.Corrigan-Curay@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Cc: Chasan-Sloan, Deborah (FDA) <Deborah.Chasan-Sloan@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>
Subject: RE: Q&A

(b)(5)

From: Corrigan-Curay, Jacqueline <Jacqueline.Corrigan-Curay@fda.hhs.gov>
Sent: Friday, April 17, 2020 3:46 PM
To: Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Cc: Chasan-Sloan, Deborah (FDA) <Deborah.Chasan-Sloan@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>
Subject: RE: Q&A

I see
thanks

From: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Sent: Friday, April 17, 2020 3:45 PM
To: Corrigan-Curay, Jacqueline <Jacqueline.Corrigan-Curay@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Cc: Chasan-Sloan, Deborah (FDA) <Deborah.Chasan-Sloan@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>
Subject: RE: Q&A

+ Deborah and Amanda **(b)(5)**

(b)(5)

From: Corrigan-Curay, Jacqueline <Jacqueline.Corrigan-Curay@fda.hhs.gov>
Sent: Friday, April 17, 2020 3:43 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Subject: RE: Q&A

(b)(5)

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Friday, April 17, 2020 3:38 PM
To: Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Corrigan-Curay, Jacqueline <Jacqueline.Corrigan-Curay@fda.hhs.gov>
Subject: RE: Q&A

Ladies – OCC had some legal edits to your edits. Are you ok with the below?

Stacy: (b)(5)

(b)(5)

From: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Sent: Friday, April 17, 2020 3:34 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: Q&A

These are our edits to CDER's language. If you want to put us all on the same email chain perhaps that would be most efficient?

(b)(5)

Sent: 4/17/2020 4:26:38 PM
To: Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Corrigan-Curay, Jacqueline [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cff7c455d5d24bc69c1239a23041a596-Jacqu.Corri]; Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]; Chasan-Sloan, Deborah (FDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a41a2fb6525244da8f538047288b6763-Deborah.Cha]; Edmonds, Amanda [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=232186a24a53474298d2760c060a4cc7-Amanda.Edmo]
Subject: RE: Q&A

(b)(5)

Q: May health care providers prescribe chloroquine phosphate or hydroxychloroquine sulfate off-label to treat patients with COVID-19?

(b)(5)

From: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Sent: Friday, April 17, 2020 4:20 PM
To: Corrigan-Curay, Jacqueline <Jacqueline.Corrigan-Curay@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Chasan-Sloan, Deborah (FDA) <Deborah.Chasan-Sloan@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: Q&A

This option by Jacqueline looks ok to me to pass on. (b)(5)

(b)(5)

From: Corrigan-Curay, Jacqueline <Jacqueline.Corrigan-Curay@fda.hhs.gov>
Sent: Friday, April 17, 2020 4:15 PM
To: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Chasan-Sloan, Deborah (FDA) <Deborah.Chasan-Sloan@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: Q&A

What about this

From: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Sent: Friday, April 17, 2020 4:13 PM
To: Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Chasan-Sloan, Deborah (FDA) <Deborah.Chasan-Sloan@fda.hhs.gov>; Corrigan-Curay, Jacqueline <Jacqueline.Corrigan-Curay@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: Q&A

I thought we were landing on this?

(b)(5)

From: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Sent: Friday, April 17, 2020 4:11 PM
To: Chasan-Sloan, Deborah (FDA) <Deborah.Chasan-Sloan@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Corrigan-Curay, Jacqueline <Jacqueline.Corrigan-Curay@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: Q&A

I personally think that run on sentence is pretty hard to read. Below is the pre-cleared language that we use whenever we get a media or Hill inquiry about off-label use. **(b)(5)**

(b)(5)

Q: May health care providers prescribe chloroquine phosphate or hydroxychloroquine sulfate off-label to treat patients with COVID-19?

(b)(5)

From: Chasan-Sloan, Deborah (FDA) <Deborah.Chasan-Sloan@fda.hhs.gov>
Sent: Friday, April 17, 2020 4:08 PM
To: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Corrigan-Curay, Jacqueline <Jacqueline.Corrigan-Curay@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: RE: Q&A

Amanda and I conferred-- we think that's fine from a legal perspective.

From: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Sent: Friday, April 17, 2020 4:06 PM

To: Corrigan-Curay, Jacqueline <Jacqueline.Corrigan-Curay@fda.hhs.gov>; Chasan-Sloan, Deborah (FDA) <Deborah.Chasan-Sloan@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: RE: Q&A

OCC?

From: Corrigan-Curay, Jacqueline <Jacqueline.Corrigan-Curay@fda.hhs.gov>
Sent: Friday, April 17, 2020 4:05 PM
To: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Chasan-Sloan, Deborah (FDA) <Deborah.Chasan-Sloan@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: RE: Q&A

I like that better

From: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Sent: Friday, April 17, 2020 4:05 PM
To: Chasan-Sloan, Deborah (FDA) <Deborah.Chasan-Sloan@fda.hhs.gov>; Corrigan-Curay, Jacqueline <Jacqueline.Corrigan-Curay@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: RE: Q&A

Could this be a reasonable middle ground?

(b)(5)

Patrizia

From: Chasan-Sloan, Deborah (FDA) <Deborah.Chasan-Sloan@fda.hhs.gov>
Sent: Friday, April 17, 2020 4:01 PM
To: Corrigan-Curay, Jacqueline <Jacqueline.Corrigan-Curay@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Subject: RE: Q&A

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From: Corrigan-Curay, Jacqueline <Jacqueline.Corrigan-Curay@fda.hhs.gov>
Sent: Friday, April 17, 2020 3:59 PM
To: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Chasan-Sloan, Deborah (FDA) <Deborah.Chasan-Sloan@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Subject: RE: Q&A

(b)(5)

From: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>
Sent: Friday, April 17, 2020 3:55 PM
To: Chasan-Sloan, Deborah (FDA) <Deborah.Chasan-Sloan@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Corrigan-Curay, Jacqueline <Jacqueline.Corrigan-Curay@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Subject: RE: Q&A

My reaction is the same as Deborah's.

From: Chasan-Sloan, Deborah (FDA) <Deborah.Chasan-Sloan@fda.hhs.gov>
Sent: Friday, April 17, 2020 3:53 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Corrigan-Curay, Jacqueline <Jacqueline.Corrigan-Curay@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Cc: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>
Subject: RE: Q&A

I defer to CDER (b)(5)

(b)(5)

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Friday, April 17, 2020 3:51 PM
To: Corrigan-Curay, Jacqueline <Jacqueline.Corrigan-Curay@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Cc: Chasan-Sloan, Deborah (FDA) <Deborah.Chasan-Sloan@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>
Subject: RE: Q&A

(b)(5)

From: Corrigan-Curay, Jacqueline <Jacqueline.Corrigan-Curay@fda.hhs.gov>
Sent: Friday, April 17, 2020 3:49 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Cc: Chasan-Sloan, Deborah (FDA) <Deborah.Chasan-Sloan@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>
Subject: RE: Q&A

(b)(5)

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Friday, April 17, 2020 3:47 PM
To: Corrigan-Curay, Jacqueline <Jacqueline.Corrigan-Curay@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Cc: Chasan-Sloan, Deborah (FDA) <Deborah.Chasan-Sloan@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>
Subject: RE: Q&A

(b)(5)

From: Corrigan-Curay, Jacqueline <Jacqueline.Corrigan-Curay@fda.hhs.gov>
Sent: Friday, April 17, 2020 3:46 PM

To: Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Cc: Chasan-Sloan, Deborah (FDA) <Deborah.Chasan-Sloan@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>
Subject: RE: Q&A

I see
thanks

From: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Sent: Friday, April 17, 2020 3:45 PM
To: Corrigan-Curay, Jacqueline <Jacqueline.Corrigan-Curay@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Cc: Chasan-Sloan, Deborah (FDA) <Deborah.Chasan-Sloan@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>
Subject: RE: Q&A

+ Deborah and Amanda. **(b)(5)**

(b)(5)

From: Corrigan-Curay, Jacqueline <Jacqueline.Corrigan-Curay@fda.hhs.gov>
Sent: Friday, April 17, 2020 3:43 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Subject: RE: Q&A

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Sent: Friday, April 17, 2020 3:38 PM
To: Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Corrigan-Curay, Jacqueline <Jacqueline.Corrigan-Curay@fda.hhs.gov>
Subject: RE: Q&A

Ladies – OCC had some legal edits to your edits. Are you ok with the below?

Stacy, **(b)(5)**

(b)(5)

From: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Sent: Friday, April 17, 2020 3:34 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: Q&A

These are our edits to CDER's language. If you want to put us all on the same email chain perhaps that would be most efficient?

(b)(5)

(b)(5)

From: Caccomo, Stephanie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=950C32CEBC4B4F80B302C50CF31C8524-STEPHANIE.C]
Sent: 4/19/2020 4:00:02 PM
To: Block, Molly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e32ca68078848889751e7ec26910142-Molly.Block]; Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]
Subject: RE: Monday media time

We need to reschedule Sheila Kaplan NYT. Not happening tomorrow AM. Thx!

Stephanie Caccomo
Press Officer

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

From: Block, Molly <Molly.Block@fda.hhs.gov>
Date: April 19, 2020 at 3:35:46 PM EDT
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>, Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>
Subject: RE: Monday media time

Confirmed 8:20-8:30 am. Let me know if you need more info

Show: The Justice and Drew Show

Topics: We'd love to talk about the expanded access program for convalescent plasma FDA launched recently. Mayo Clinic is the lead institution for this and now more than 875 sites and 755 physician investigators nationwide have signed on to participate.

What is convalescent plasma? Convalescent plasma is an antibody-rich product made from blood donated by people who have recovered from the disease caused by the virus. Prior experience with respiratory viruses and limited data that have emerged from China suggest that convalescent plasma has the potential to lessen the severity or shorten the length of illness caused by COVID-19.

Those individuals who have recovered from COVID-19 could have an immediate impact in helping others who are severely ill. In fact, one donation has the potential to help up to four patients. We encourage individuals to consider donating. FDA just launched new webpage to provide resources for those who have recovered to find their local blood or plasma collection center to potentially donate. The American Red Cross has also set up a website for interested donors.

We're also happy to talk about FDA's work supporting drugs and vaccines to fight coronavirus, including chloroquine and the use of blood products to help treat infected individuals. This week, FDA issued 3 emergency use authorizations for the serology (antibody) tests, which will play an important role for reopening the economy.

(b)(6) (hotline)
(backup)

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Date: April 17, 2020 at 4:34:49 PM EDT
To: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Block, Molly <Molly.Block@fda.hhs.gov>, Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>
Subject: RE: Monday media time

I'll call Dr. Hahn and then add in Sheila.

(b)(6)

Stephanie Caccomo
Press Officer

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

From: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Sent: Friday, April 17, 2020 4:34 PM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Block, Molly <Molly.Block@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>
Subject: RE: Monday media time

Thank you, what will the dial-in/connection for Dr. Hahn be?

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Friday, April 17, 2020 4:32 PM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Block, Molly <Molly.Block@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>
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We're still lining up radio interviews, but we can confirm 8-8:10am with Sheila Kaplan/NYT

Stephanie Caccomo
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: 301-348-1956
Cell: (b)(6)
stephanie.caccomo@fda.hhs.gov

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Sent: Friday, April 17, 2020 1:54 PM
To: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Block, Molly <Molly.Block@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>
Cc: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: RE: Monday media time

TY

From: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Sent: Friday, April 17, 2020 1:48 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Block, Molly <Molly.Block@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>
Cc: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: RE: Monday media time

Hold placed on Dr. Hahn's calendar for Monday, 4/20, 8:00-8:30 AM.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Friday, April 17, 2020 1:40 PM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Block, Molly <Molly.Block@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>
Cc: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
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ok

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Sent: Friday, April 17, 2020 1:38 PM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>
Cc: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: RE: Monday media time

I recommend we offer this time or another if preferred to lock in now.

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Friday, April 17, 2020 1:37 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>
Cc: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: RE: Monday media time

They just want to know when Dr. Hahn is available for media on Monday.

Then they'll send radio/tv in that timeslot.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Friday, April 17, 2020 1:35 PM
To: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>
Cc: Block, Molly <Molly.Block@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: RE: Monday media time

What is WH asking for? We do need to do media for them.

From: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Sent: Friday, April 17, 2020 12:56 PM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Block, Molly <Molly.Block@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: RE: Monday media time

With COS or Commissioner approval, we are happy to do so. Have either one cleared this yet?

Frank

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Sent: Friday, April 17, 2020 12:53 PM
To: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Block, Molly <Molly.Block@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: Monday media time

We have been asked by WH for his availability. May we say 8-8:30am and put a hold on the calendar.

Laura Caliguiri
Associate Commissioner for External Affairs

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

Tel: 301 796-8546
Laura.Caliguiri@fda.hhs.gov

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