From: Amin, Stacy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CB3764B7438648838C22881A06FC6AFB-STACY.AMIN]
Sent: 3/20/2020 11:11:23 AM
To: Schiller, Lowell [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77949b06919e4f91aa788e9a616c50c7-Lowell.Schi]; 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]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]
CC: 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]
Subject: RE: COVID-19 request for assistance re: human convalescent plasma (HCP) therapy -- on behalf of Baylor College of Medicine and Johns Hopkins University

Commissioner has asked us to route these requests to Anand. He has a team tracking them and prioritizing them. I like to copy Jeet as well b/c Anand is in meetings all day.

From: Schiller, Lowell <Lowell.Schiller@fda.hhs.gov>
Sent: Friday, March 20, 2020 11:05 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: FW: COVID-19 request for assistance re: human convalescent plasma (HCP) therapy -- on behalf of Baylor College of Medicine and Johns Hopkins University

Thoughts on this request?

From: Stephen Northrup <snorthrup@rampynorthrup.com>
Sent: Friday, March 20, 2020 10:59 AM
To: Anna Abram <anna_abram@help.senate.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Schiller, Lowell <Lowell.Schiller@fda.hhs.gov>
Cc: Cybele Bjorklund <cbjorklund@jhu.edu>; Herb Butrum <butrum@bcm.edu>; Christopher Austin <chris.austin@jhu.edu>
Subject: COVID-19 request for assistance re: human convalescent plasma (HCP) therapy -- on behalf of Baylor College of Medicine and Johns Hopkins University

Anna, Keagan, Lowell -- I'm writing on behalf of Dr. Peter Hotez at Baylor College of Medicine and Dr. Arturo Casadevall at Johns Hopkins University about their efforts to advance human convalescent plasma (HCP) as a therapeutic option for the COVID-19 pandemic. I've copied Cybele Bjorklund and Chris Austin at JHU and also Herb Butrum at BCM.

You're familiar with this option, I'm sure, considering Commissioner Hahn's comments yesterday.

You may also know that JHU submitted an IND that arrived this morning at FDA, and there are close to 20 leading institutions now involved in the discussions about HCP therapy across the USA. These are all institutions of national significance, including Johns Hopkins University, Baylor College of Medicine, Duke University, Einstein Medical Center, Mayo Clinic, Michigan State University, University of Maryland, Loyola University Chicago, University of California,

University of Washington, Massachusetts General Hospital, Children's Hospital of Philadelphia, University of Pittsburgh, Cedars-Sinai Medical Center, and Stanford University

Drs. Hotez and Casadevall have asked us to contact people in the senior agency leadership to make you aware of this effort, to ensure that Commissioner Hahn is aware of this effort, and to identify someone at a senior level who might be willing to be a stand-by source of assistance and guidance for them.

I thought one of you might be able to identify the right person or people who could be that go-to resource.

Please advise as to how you would recommend proceeding, and thanks for your attention to this request and for everything you are doing right now to fight this pandemic.

A detailed article on this effort is pasted below, from the Milwaukee Journal-Sentinel.

Best regards,
Steve

Stephen Northrup
Rampy Northrup LLC
mobile: (b)(6)

https://www.jsonline.com/story/news/2020/03/18/coronavirus-treatment-emergency-clinical-trials-plasma-requested/2865766001/

Possible coronavirus treatment could be in clinical trials within weeks, using plasma from recovered patients, if doctors get FDA approval

Mark JohnsonUpdated 6:55 p.m. CT March 18, 2020

The Johns Hopkins University doctor coordinating a nationwide effort to launch emergency clinical trials of plasma from patients who've recovered from coronavirus said he expects to forward a plan to the U.S. Food & Drug Administration Wednesday and to start treating the first patients in about four weeks.

"We are in an emergency and this is the only thing we have," said Arturo Casadevall, chairman of Molecular Microbiology and Immunology at Johns Hopkins Bloomberg School of Public Health in Baltimore.

"This won't help patients who are sick today, but it will help the patients who become sick in the next two to five weeks," he said.

The time frame he described would still allow hospitals to begin testing the possible treatment before the new coronavirus peaks in the U.S., possibly a few months from now. Transfusions of plasma from

recovered patients carry potential side effects, including fever, allergic reaction and a very small risk of infectious disease transmission.

Casadevall said the centers that take part in the clinical trial will need approval from both the FDA and their own institutional review boards, groups established to protect the rights of human research subjects.

Treating people with plasma from a recovered patient was first used more than a century ago to save a child with diphtheria and has since been used to stifle numerous outbreaks of disease. The process would involve taking plasma, rich in virus-fighting antibodies, from patients who have recovered from COVID-19. That plasma would then be transfused into patients who are still sick with the disease.

Casadevall and Liise-anne Pirofski, of the Albert Einstein College of Medicine in New York, triggered the push for clinical trials when they co-authored a paper published Friday in The Journal of Clinical Investigation. The two urged "that institutions consider the emergency use (of plasma from recovered patients) and begin preparations as soon as possible. Time is of the essence."

On Tuesday, Pirofski told the Milwaukee Journal Sentinel: "The need for this is dire. One day for those involved (in caring for the sick) is like a year."

Pirofski, chief of the division of infectious diseases at Montefiore Medical Center — the teaching hospital associated with Einstein College — which consists of 11 hospitals, described the situation where she works:

"Monday we had (a total of) 18 patients in our center, all very sick. Today we have 10 new patients."

She described doctors coping with shortages of basic supplies and feeling overwhelmed, experiences echoed by other medical staff working in viral hot spots around the world.

"There is no personal protective equipment anywhere," she said. "We are running out. We took all of our medical students off the ward to avoid using up PPEs... It's just demoralizing and there is no end in sight."

She said doctors have two possible paths they can follow in using plasma from recovered patients. They can test it in clinical trials. They can also use it as an experimental "compassionate use" treatment for some of the sickest patients, as was done during the 2009 swine flu, the 2013 West African Ebola epidemic, and the early stages of the COVID-19 outbreak in China.

"It's been used in China but there is just one small press release on it," Pirofski said. "We have not seen that data. We're all very anxious to see the results."

100 to 150 patients, divided in half

Experimental use would require that doctors find recovered COVID-19 patients with high antibody levels who are willing to serve as donors. Antibodies are blood proteins that are made by the body's immune system in response to bacteria, viruses and other foreign invaders.

Casadevall said he favors starting clinical trials of plasma from recovered patients, rather than using it experimentally.

Although plasma from recovered patients has been used to quell outbreaks of poliomyelitis, measles, mumps and influenza, the plasma of a COVID-19 survivor is something new. FDA would consider

that plasma an investigational drug, meaning that it has been tested in the lab and is ready to be tested in people.

Survivor plasma, Pirofski said, "has not been (extensively tested) for this disease before, and the compound we'd be getting is new."

The basic setup for a clinical trial could involve 100 to 150 COVID-19 patients with half receiving serum from recovered patients, and the other half serving as a control group and receiving serum from patients who have never had COVID-19.

Casadevall said the trials could be used to test different groups who have been infected with the virus. One trial would test the use of survivor plasma on people who have been exposed to virus — likely doctors, nurses, emergency room staff and other first-responders. This group would include family members who have been at home caring for a loved one with COVID-19.

A second test of survivor plasma would involve patients who have been hospitalized with COVID-19, and are continuing to grow sicker.

A third test would involve severely ill COVID-19 patients.

Each of these tests has the potential to answer a different question:

- Can the plasma from recovered patients be used to prevent someone who has been exposed from coming down with the illness?
- Does the plasma have the ability to reverse the course of a patient whose health is declining?
- Can the plasma rescue a patient who has reached a very late stage of the illness?

"This is a good story in the midst of terrible news," said Casadevall, explaining how the paper he wrote with Pirofski led to the impromptu formation of a network of more than 100 doctors across the country.

The doctors have been discussing ways of collaborating to launch clinical trials of what appears to be the most immediate hope for treating COVID-19 patients. Various centers are being discussed as possible sites for the trials. The New York Blood Center is also partnering on the project, said Casadevall.

"If Johns Hopkins is ready to go, we'd very interested to see what they find," said Jeff Pothof, chief quality officer at UW Health in Madison. "I think we should do it quickly."

Casadevall agreed.

With a growing number of health care workers contracting the disease, "they're beginning to see the collapse of the healthcare system," he said.

"The problem in the U.S. is that something like this has never happened. In 1918 (during the Spanish flu) there was no FDA. There was no Centers of Disease Control and Prevention."

Casadevall urged the federal government to designate a point person for COVID-19 who would be knowledgeable enough to help hospitals and cities overcome logistical and other hurdles.

For example, he said, "Say Milwaukee needs serum and New York has it."

The "point person" could arrange coordination between different parts of the country that are in different stages of the pandemic.

***Mark Johnson** has written in-depth stories about health, science and research for the Journal Sentinel since 2000. He is a three-time Pulitzer Prize finalist and, in addition, was part of a team that won the 2011 Pulitzer Prize in Explanatory Reporting for a series of reports on the groundbreaking use of genetic technology to save a 4-year-old boy.*

***Email him at** mark.johnson@jrn.com; **follow him on Twitter**: @majohnso.*

From: Amin, Stacy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CB3764B7438648838C22881A06FC6AFB-STACY.AMIN]
Sent: 3/18/2020 11:51:13 PM
To: Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; 2019-nCoV FDA IMG JIC [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=289715a1146847558b07a33ccab6bccf-2019-nCoV F]; OCCRequests-COVID19 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcb756008a41407282a58324a7b5144a-OCCRequests]; 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]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; 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]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]
CC: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
Subject: RE: QUICK TURN-AROUND: updated POTUS TPs, due by 6:30AM to HHS

Stephanie – **(b)(5)**

(b)(5)

From: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Sent: Wednesday, March 18, 2020 11:22 PM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>; OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: RE: QUICK TURN-AROUND: updated POTUS TPs, due by 6:30AM to HHS

I have substantive edits , see attached

Patrizia

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Wednesday, March 18, 2020 11:03 PM
To: 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>; OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Cavazzoni, Patrizia

<Patrizia.Cavazzoni@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: QUICK TURN-AROUND: updated POTUS TPs, due by 6:30AM to HHS

Updated TPs for POTUS press briefing tomorrow on therapeutics. CDER/CBER—can you look at quickly? I've added edits and a note on attached version. This is due to HHS by 6:30am. Thanks!

Press Conference on FDA Developments

(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: Amin, Stacy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CB3764B7438648838C22881A06FC6AFB-STACY.AMIN]
Sent: 3/20/2020 8:36:51 AM
To: Cohen, Kenneth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44f565b739ea4879bdc516caf2e136bc-Kenneth.Coh]; 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]; Roth, Lauren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52bfd08572694f269a20c508f3c04a03-Lauren.Roth]; 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]; 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]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; 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]; Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]
Subject: RE: COVID19 FDA Guidance Tracker for March 20 2020

Sensitivity: Company Confidential

(b)(5)

From: Cohen, Kenneth <Kenneth.Cohen@fda.hhs.gov>
Sent: Friday, March 20, 2020 8:33 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Schiller, Lowell <Lowell.Schiller@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Steele, Danielle (OS) <Danielle.Steele@hhs.gov>; Malliou, Ekaterini (OS) <Ekaterini.Malliou@hhs.gov>
Cc: Hawkins, Jamar (OS) <jamar.hawkins@hhs.gov>; Horska, Katerina (OS) <Katerina.Horska@hhs.gov>; OC OPPB OP RPMS <OCOPPBOPRPMS@fda.hhs.gov>
Subject: COVID19 FDA Guidance Tracker for March 20 2020
Sensitivity: Confidential

At HHS or OMB

(1) CDER, FRDTS# 2020-230, SPS# 432860, Policy for Fulfilling Certain REMS Requirements During the COVID-19 Public Health Emergency

- Communicates Agency's temporary policy for certain risk evaluation and mitigation strategies requirements for the duration of the public health emergency.

Under Development in FDA

(b)(5)

Cleared for Posting Yesterday

(3) CDRH, 2020-228, 432842, Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring During the Coronavirus Disease

- Provides a policy for expanding the availability and capability of non-invasive remote monitoring devices to facilitate patient monitoring while reducing patient and healthcare provider contact and exposure to COVID-19 during the COVID-19 public health emergency.

(4) CDER, 2020-236, 432839, Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency

- Responds to a number of queries from entities that are not currently licensed or registered drug manufacturers that would like to prepare alcohol-based hand sanitizers, either for public distribution or for their own internal use.

DELIBERATIVE, INTERNAL, PRE-DECISIONAL

Kenneth R. Cohen, MHSA, MPP
Director, Regulations Policy and Management Staff
Office of Policy
301-796-7001
(b)(6) (mobile)

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From: Amin, Stacy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CB3764B7438648838C22881A06FC6AFB-STACY.AMIN]
Sent: 3/18/2020 12:06:44 PM
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]; 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]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; 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: POTUS tweet
Attachments: PM_FDAFlexibility 3.18.docx (b)(5) docx

I've seen it, it's fine. **(b)(5)**

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, March 18, 2020 10:51 AM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Shah, Anand <Anand.Shah@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: POTUS tweet

Will call you

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Wednesday, March 18, 2020 10:45 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Shah, Anand <Anand.Shah@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: POTUS tweet

Is it possible that there may be some announcement about an EO directing FDA to push the process for patients getting access to drugs? WSJ was asking.

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 9:33 AM
To: Hahn, Stephen <SH1@fda.hhs.gov>

Cc: Shah, Anand <Anand.Shah@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@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: POTUS tweet

Folks- about potus tweet this am, this is what the rest of WH thinks it is about. (b)(5) (b)(5) Feel like we are doing that with all the guidances we have been doing.

I heard it was:

(b)(5)

Sent from my iPhone

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/15/2020 4:34:13 PM
To: Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]
Subject: RE: Review Requested by 1620: Talking Points on COVID Therapeutics/Vaccines

Thanks David

From: Cho, David S (CBER) <David.Cho@fda.hhs.gov>
Sent: Sunday, March 15, 2020 4:33 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: RE: Review Requested by 1620: Talking Points on COVID Therapeutics/Vaccines

Hi Denise,
I did not have any further comments especially on the vaccines or immunotherapy statements.
Thanks,
David

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Sunday, March 15, 2020 3:55 PM
To: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>
Subject: Review Requested by 1620: Talking Points on COVID Therapeutics/Vaccines

Dear Colleagues,

Michael Felderbaum drafted the following and wanting to make sure you've laid eyes on it and have the opportunity to provide comments before it goes to Dr. Hahn if you haven't already.

Thanks,

Denise

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/15/2020 6:36:42 PM
To: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; 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]; Clarke, Mary Beth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b0124a15b9344d8483929470fefa403a-CLARKEM]
Subject: RE: Quick response requested: Talking Points on COVID Therapeutics/Vaccines - by 1630

Many thanks to all of you.

Best,

Denise

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Sunday, March 15, 2020 5:18 PM
To: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Farley, John <John.Farley@fda.hhs.gov>; Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>
Subject: RE: Quick response requested: Talking Points on COVID Therapeutics/Vaccines - by 1630

Dear Patrizia,

Thanks for copying us. Nothing to add.

Best Regards,
Peter

From: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Sent: Sunday, March 15, 2020 4:39 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>
Subject: Fwd: Quick response requested: Talking Points on COVID Therapeutics/Vaccines - by 1630

Denise
+ Peter Marks
In the two paragraphs on IL-7 inhibitors and convalescent plasma, respectively , I recommend replacing the section about Reducing/heeding off need for ventilator with :

"could potentially slow the progression of severe respiratory symptoms "

Patrizia

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Date: March 15, 2020 at 4:16:42 PM EDT

To: Farley, John <John.Farley@fda.hhs.gov>, Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>, Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>
Subject: Quick response requested: Talking Points on COVID Therapeutics/Vaccines - by 1630

Hi – sorry for short notice – any input before Michael Felderbaum sends to Dr. Hahn?

Thanks,

D

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/16/2020 7:01:58 AM
To: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]
CC: Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]
Subject: FW: Quick response requested: Talking Points on COVID Therapeutics/Vaccines - by 1630
Attachments: Therapeutics TPs 03152020 324pm.docx

Good morning Peter,

Did you have any comments in addition to Patrizia's?

Thank you,

Denise

From: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Sent: Sunday, March 15, 2020 4:39 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>
Subject: Fwd: Quick response requested: Talking Points on COVID Therapeutics/Vaccines - by 1630

Denise
+ Peter Marks
In the two paragraphs on IL-7 inhibitors and convalescent plasma, respectively , I recommend replacing the section about Reducing/heeding off need for ventilator with :

(b)(5)

Patrizia

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Date: March 15, 2020 at 4:16:42 PM EDT
To: Farley, John <John.Farley@fda.hhs.gov>, Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>, Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>
Subject: Quick response requested: Talking Points on COVID Therapeutics/Vaccines - by 1630

Hi – sorry for short notice – any input before Michael Felberbaum sends to Dr. Hahn?

Thanks,

D

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/16/2020 5:45:00 PM
To: McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Zeller, Mitchell [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=de7d2fda971e418ba33cb211a4013976-Mitchell.Ze]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Solomon, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e49ac6a056dc4f299ea269945e962e82-SSOLOMON]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]
CC: 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]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Hebert, Angelique A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aa08f3428a045f88eb3bd92c68a27cf-Angelique.H]; 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]; Hussey, Deirdre [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41a51a9bf937431c8470b69fb055fe81-Husseyd]; Barth, Janelle [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=18d28baf2bfa435abc9cdfa076774dc0-Janelle.Bar]; Stone, Eric [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5799d336f4c142aca71a655e4184d6bd-Eric.Stone]; Huttenlocker, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=65254282fa6a4e138f506f96cfe9049c-Denise.Hutt]; Domanski, Jeffrey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ed00c0aa83794cbebfc0a50f6cd4d7f9-Jeffrey.Dom]; Schweitzer, Roxanne K [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=292135d254924252958e25cc5a63b079-RSCHWEIT]; Branch, Tiffany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b45f1b97b5d648f68cdff5ce4f75a154-Tiffany.Bra]; Barfell, Glenda F [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33b220e98ac9456eb32888261156f400-GBARFELL]; Lynch, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d24ee4a4fc6241f48110d6b35e6704ed-Sarah.Lynch]
Subject: RE: Flagging for PDC/CD/ACRA: Commissioner all hands update to go out asap today

No suggested edits – thank you.

Denise

From: McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>
Sent: Monday, March 16, 2020 5:43 PM
To: Zeller, Mitchell <Mitchell.Zeller@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Solomon, Steven M <Steven.Solomon@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hebert, Angelique A. <Angelique.Hebert@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hussey, Deirdre <Deirdre.Hussey@fda.hhs.gov>; Barth, Janelle <Janelle.Barth@fda.hhs.gov>; Stone, Eric <Eric.Stone@fda.hhs.gov>; Huttenlocker, Denise <Denise.Huttenlocker@fda.hhs.gov>; Domanski, Jeffrey <Jeffrey.Domanski@fda.hhs.gov>; Schweitzer, Roxanne K <Roxanne.Schweitzer@fda.hhs.gov>; Branch, Tiffany <Tiffany.Branch@fda.hhs.gov>; Barfell, Glenda F <Glenda.Barfell@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>
Subject: RE: Flagging for PDC/CD/ACRA: Commissioner all hands update to go out asap today

No suggested edits from me, thanks!

From: Zeller, Mitchell <Mitchell.Zeller@fda.hhs.gov>
Sent: Monday, March 16, 2020 5:43 PM
To: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Solomon, Steven M <Steven.Solomon@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hebert, Angelique A. <Angelique.Hebert@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hussey, Deirdre <Deirdre.Hussey@fda.hhs.gov>; Barth, Janelle <Janelle.Barth@fda.hhs.gov>; Stone, Eric <Eric.Stone@fda.hhs.gov>; Huttenlocker, Denise <Denise.Huttenlocker@fda.hhs.gov>; Domanski, Jeffrey <Jeffrey.Domanski@fda.hhs.gov>; Schweitzer, Roxanne K <Roxanne.Schweitzer@fda.hhs.gov>; Branch, Tiffany <Tiffany.Branch@fda.hhs.gov>; Barfell, Glenda F <Glenda.Barfell@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>
Subject: RE: Flagging for PDC/CD/ACRA: Commissioner all hands update to go out asap today

Agreed.

Is there now an expedited clearance process for these types of messages?

Mitch

From: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
Sent: Monday, March 16, 2020 5:41 PM
To: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Solomon, Steven M <Steven.Solomon@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Zeller, Mitchell <Mitchell.Zeller@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>

Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hebert, Angelique A. <Angelique.Hebert@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hussey, Deirdre <Deirdre.Hussey@fda.hhs.gov>; Barth, Janelle <Janelle.Barth@fda.hhs.gov>; Stone, Eric <Eric.Stone@fda.hhs.gov>; Huttenlocker, Denise <Denise.Huttenlocker@fda.hhs.gov>; Domanski, Jeffrey <Jeffrey.Domanski@fda.hhs.gov>; Schweitzer, Roxanne K <Roxanne.Schweitzer@fda.hhs.gov>; Branch, Tiffany <Tiffany.Branch@fda.hhs.gov>; Barfell, Glenda F <Glenda.Barfell@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>
Subject: Re: Flagging for PDC/CD/ACRA: Commissioner all hands update to go out asap today

Reviewed. This looks good from my perspective.

From: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Sent: Monday, March 16, 2020 5:23 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Solomon, Steven M <Steven.Solomon@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Zeller, Mitchell <Mitchell.Zeller@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hebert, Angelique A. <Angelique.Hebert@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hussey, Deirdre <Deirdre.Hussey@fda.hhs.gov>; Barth, Janelle <Janelle.Barth@fda.hhs.gov>; Stone, Eric <Eric.Stone@fda.hhs.gov>; Huttenlocker, Denise <Denise.Huttenlocker@fda.hhs.gov>; Domanski, Jeffrey <Jeffrey.Domanski@fda.hhs.gov>; Schweitzer, Roxanne K <Roxanne.Schweitzer@fda.hhs.gov>; Branch, Tiffany <Tiffany.Branch@fda.hhs.gov>; Barfell, Glenda F <Glenda.Barfell@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>
Subject: Flagging for PDC/CD/ACRA: Commissioner all hands update to go out asap today

(b)(5)

(b)(5)

Sincerely,

Stephen M. Hahn, M.D.
FDA Commissioner

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 3/26/2020 8:56:25 AM
To: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]
Subject: RE: CDRH response update

Thank you.

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Thursday, March 26, 2020 8:55 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: RE: CDRH response update

Sure. We will get something together. jw

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Thursday, March 26, 2020 7:49 AM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: Fwd: CDRH response update

In an effort to keep SH fully up to speed on what's happening at CDRH, they have started putting these morning reports together. He has a check in with Grogan every morning at 7:45. It would be really helpful to get something similar from CDER and CBER so it was all in one place. There are so many moving pieces, summaries would help catalog the work. Do you think Mary Beth and Julie could put something together like this daily?

Pls.

Sent from my iPhone

Begin forwarded message:

From: "Hillebrenner, Elizabeth J" <Elizabeth.Hillebrenner@fda.hhs.gov>
Date: March 26, 2020 at 6:55:12 AM EDT
To: "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>
Cc: "Shuren, Jeff" <Jeff.Shuren@fda.hhs.gov>
Subject: FW: CDRH response update

Keagan,
Please let me know if I should make any adjustments to the daily emails, such as to the level of detail or otherwise. We want to make sure the Commissioner has what he needs.
Elizabeth

From: Hillebrenner, Elizabeth J
Sent: Thursday, March 26, 2020 6:52 AM
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,

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

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: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 2/1/2020 8:14:46 AM
To: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; 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]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
CC: Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]
Subject: RE: CDC Coronavirus Talking Points - 1/31/20

Thx Anna and Peter

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Date: February 1, 2020 at 7:54:58 AM EST
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>, Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Cc: Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Subject: RE: CDC Coronavirus Talking Points - 1/31/20

From: Mair, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F4511BDAD7564D7FAC7EADC7961467AB-MICHAEL.MAI]
Sent: 2/8/2020 10:07:08 AM
To: Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Solomon, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e49ac6a056dc4f299ea269945e962e82-SSOLOMON]; 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]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]; Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]
Subject: Clinical Characteristics of 138 Hospitalized Patients With 2019 Novel Coronavirus–Infected Pneumonia in Wuhan, China

JAMA: Clinical Characteristics of 138 Hospitalized Patients With 2019 Novel Coronavirus–Infected Pneumonia in Wuhan, China

Conclusions and Relevance In this single-center case series of 138 hospitalized patients with confirmed NCIP in Wuhan, China, presumed hospital-related transmission of 2019-nCoV was suspected in 41% of patients, 26% of patients received ICU care, and mortality was 4.3%.

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 2/9/2020 9:01:35 AM
To: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
CC: 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]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]
Subject: Re: Clinical Characteristics of 138 Hospitalized Patients With 2019 Novel Coronavirus–Infected Pneumonia in Wuhan, China

Thanks, Michael. Very interesting.

From: "Mair, Michael" <Michael.Mair@fda.hhs.gov>
Date: Saturday, February 8, 2020 at 10:07 AM
To: Anna Abram <Anna.Abram@fda.hhs.gov>, Stephen Hahn <SH1@fda.hhs.gov>, Steven Solomon <Steven.Solomon@fda.hhs.gov>, Keagan Lenihan <Keagan.Lenihan@fda.hhs.gov>, Stacy Amin <Stacy.Amin@fda.hhs.gov>, Erika Anderson <Erika.Anderson@fda.hhs.gov>, Denise Hinton <Denise.Hinton@fda.hhs.gov>, Peter Marks <Peter.Marks@fda.hhs.gov>, "Farley, John" <John.Farley@fda.hhs.gov>, "Schwartz, Suzanne" <Suzanne.Schwartz@fda.hhs.gov>
Subject: Clinical Characteristics of 138 Hospitalized Patients With 2019 Novel Coronavirus–Infected Pneumonia in Wuhan, China

JAMA: Clinical Characteristics of 138 Hospitalized Patients With 2019 Novel Coronavirus–Infected Pneumonia in Wuhan, China

Conclusions and Relevance In this single-center case series of 138 hospitalized patients with confirmed NCIP in Wuhan, China, presumed hospital-related transmission of 2019-nCoV was suspected in 41% of patients, 26% of patients received ICU care, and mortality was 4.3%.

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/22/2020 5:51:22 PM
To: 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]
CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: RE: COVID-19 Serologic Tests

Thanks, Jeff. Peter, I want us to remove any barriers to the development of convalescent plasma and hyperimmune globulin. Please let me know how we can engage industry or others to expedite.
Thanks

From: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Date: March 22, 2020 at 5:42:18 PM EDT
To: Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: COVID-19 Serologic Tests

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/27/2020 9:28:15 AM
To: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: Fwd: CDRH response update

Please print for me
thanks

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,

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

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: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 3/27/2020 12:11:27 PM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
Subject: FW: PETER PLEASE SEE ASAP: Comms for Today
Attachments: WH Presser TPs 03272020 1206pm.docx

It is Texas. Peter confirmed and he has small edits to the presser. Michael will send you clear copy.

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Friday, March 27, 2020 12:08 PM
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: PETER PLEASE SEE ASAP: Comms for Today

Dear Michael,

Very minor edits. Let's just stick with Texas for today. Thanks. (with attachment)

Best Regards,
Peter

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Sent: Friday, March 27, 2020 12:00 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: PETER PLEASE SEE ASAP: Comms for Today
Importance: High

Hi Peter –

From what I understand from the AEG call, **(b)(5)** have removed from Dr. Hahn's WH talking points – and we need to remove from the press release as well, correct?

Also he said you had mentioned that the **(b)(5)**

(b)(5)

Can you please weigh in ASAP so we make sure he has what he needs?

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: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/28/2020 1:49:10 PM
To: Katz, Mitchell [Mitchell.Katz@nychhc.org]
Subject: Re: is there a way to get other countries to produce convalescent serum?

Mitch
Are you all using convalescent plasma in NY? We set up/allowed/provided guidance about this starting earlier this week using a compassionate use process. Our plan is to move next week to an expanded access protocol?

We're working on identifying donors so I'll pass along your suggestion to the team. Mitch, you are doing great work. Please take care.
Steve

From: Katz, Mitchell <Mitchell.Katz@nychhc.org>
Date: March 28, 2020 at 12:41:07 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: is there a way to get other countries to produce convalescent serum?

Steve, hope you are hanging in. Things are pretty desperate here. We are using (b)(4) more ventilators today than yesterday for covid and we are only (b)(4) of hospital capacity.

The countries that are recovering abroad from this pandemic, especially china, seem like they would have capacity to produce convalescent serum and ship to US.

I don't know that this is a FDA issue. I know companies normally come to you to ask for licensing their product but could you give me any advice on how US could encourage this to happen.

Thank, Mitch

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From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/28/2020 2:22:18 PM
To: Katz, Mitchell [Mitchell.Katz@nychhc.org]
Subject: RE: is there a way to get other countries to produce convalescent serum?

Do you have time for a quick call?

From: Katz, Mitchell <Mitchell.Katz@nychhc.org>
Date: March 28, 2020 at 2:02:03 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: RE: is there a way to get other countries to produce convalescent serum?

Yes thanks to your guidance we are setting it up in NYC health and hospitals. Mt Sinai already doing it. I am thinking though that our ability to identify people who are immune and have antibodies and do the plasmapheresis will likely limit application. If a country that was over the bad part of the epidemic could be brought into service for money it might save lives.

Appreciate any suggestions your team has. Thanks for being so responsive. mitch

---

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Saturday, March 28, 2020 1:49 PM
To: Katz, Mitchell <Mitchell.Katz@nychhc.org>
Subject: Re: is there a way to get other countries to produce convalescent serum?

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe. Forward suspect email to spamadmin@nychhc.org as an attachment (Click the More button, then forward as attachment).

Mitch
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From: Katz, Mitchell <Mitchell.Katz@nychhc.org>
Date: March 28, 2020 at 12:41:07 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: is there a way to get other countries to produce convalescent serum?

Steve, hope you are hanging in. Things are pretty desperate here. We are using (b)(4) more ventilators today than yesterday for covid and we are only (b)(4) of hospital capacity.

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Thank, Mitch

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From: Mair, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F4511BDAD7564D7FAC7EADC7961467AB-MICHAEL.MAI]
Sent: 1/10/2020 1:30:38 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; 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]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]
CC: Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]
Subject: Update on Undiagnosed Pneumonia - China

Hi. I wanted to provide you with a quick update on the outbreak of pneumonia of unknown cause that is ongoing in Wuhan, China.

Overview:

- There are 59 cases of pneumonia listed as unknown etiology, 7 listed as severe.
- There is a limited clinical picture. Symptom onset of cases is from 12-29 December. Wuhan health officials have not announced any new cases since 05 Jan.
- All known cases are linked to live fish market in Wuhan (closed on 01 December) that also sells other animals.
- There have been no reported health care worker infections or human-to-human transmission.
- 153 known close contacts are being monitored.
- Chinese authorities have made a preliminary determination of a novel coronavirus as the etiologic agent, identified in a hospitalized person with pneumonia in Wuhan
- *Science* is reporting that the "*Two groups isolated the virus from samples from one patient*…[that]…*A total of 15* [of the 59 cases] *were positive for the novel virus, [based on] sequencing samples of [fluid injected into the lung and collected for examination]*…[and that]…*the virus is similar to some of the published* [corona]*viruses collected from bats. But it is not close to SARS and not close to MERS*."
- There has been no known international spread, but many countries in the region have activated protocols to monitor for pneumonia patients of unknown etiology who have recently traveled to China.

WHO Activities:

- WHO is closely monitoring the situation and is in close contact with national authorities in China.
- WHO has requested more information from China on the epidemiological situation and ongoing investigations
- WHO is not currently recommending any specific measures for travelers.
- WHO is developing guidance for member states.
- WHO R&D Blueprint Team held a teleconference on 10 Jan to update members of the Global Coordination Mechanism on the cluster of pneumonia cases and discuss next steps.

USG Activities:

- CDC issued a level 1 travel notice on 06 Jan.
- CDC issued a Health Alert Network notice on 08 Jan.

FDA Activities:

- The FDA Emerging Threats Task Force is monitoring the situation and working to advance and coordinate response activities as necessary.
- The Division of Microbiology (OHT7-OIR/CDRH) is proactively coordinating with CDC on diagnostic activities:
  - DMD had a telecon with CDC on 08 Jan:

- CDC briefed DMD on the current situation and noted that they expect the genetic sequence information to be released soon.
- In anticipation of testing specimens from returning travelers, CDC is developing a molecular test, likely based on the CDC Novel Coronavirus 2012 Real-time RT-PCR Assay (which FDA authorized for use under EUA in June 2014 for the presumptive detection of MERS-CoV), that they will CLIA validate for use in their labs.
- From a preparedness standpoint CDC is also planning on submitting a pre-EUA package in case distribution of the test within the Laboratory Response Network is necessary to meet testing demands. DMD is working on an EUA Review template outlining the data requirements for the Pre-EUA package based on previous experience with MERS-CoV.

From: McWilliams, Carly [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B68C7458214244D08424FD441FEA4FDA-CARLYLE.MCW]
Sent: 3/2/2020 5:54:44 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]; Lynch, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d24ee4a4fc6241f48110d6b35e6704ed-Sarah.Lynch]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
CC: Lutter, Randall [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=868b21db20e3456ab4e1b3109b56c23f-Randall.Lut]; 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]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Black, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aaf8a19f3672492293a7c1b2d1498059-Jennifer.Bl]; Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Rath, Prakash (FDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91bc5673db6c416e87a453f8b9527cc0-Prakash.Rat]
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.

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https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/laboratory-guidance

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Sent: Monday, March 2, 2020 6:16 PM
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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>
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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 Adviser

Center for Devices and Radiological Health
Office of Policy
U.S. Food and Drug Administration
Tel: 301-796-8924 - Cell: (b)(6)
jennifer.tomasello@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=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 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: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/15/2020 4:16:41 PM
To: Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]; Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]; Clarke, Mary Beth [Marybeth.Clarke@fda.hhs.gov]
Subject: Quick response requested: Talking Points on COVID Therapeutics/Vaccines - by 1630
Attachments: Therapeutics TPs 03152020 324pm.docx

Hi – sorry for short notice – any input before Michael Felderbaum sends to Dr. Hahn?

Thanks,

D

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/19/2020 6:45:11 PM
To: Nabakowski, Andrei [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c8bcecc310c4e45a5012d47d40886e1-NABAKOWSKIA]
Subject: FW: FOR YOUR REVIEW: today's all hands
Attachments: Day 4 all hands.rtf

From: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Sent: Thursday, March 19, 2020 4:59 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Hebert, Angelique A. <Angelique.Hebert@fda.hhs.gov>
Cc: Sigg, Jim <Jim.Sigg@fda.hhs.gov>; Tse, Tania <Tania.Tse@fda.hhs.gov>
Subject: FOR YOUR REVIEW: today's all hands

Please review today's draft all hands. OO secured clearance with center EOs on the 3rd paragraph detailing reporting requirements.

(b)(5)

Sincerely,

Stephen M. Hahn, M.D.
Commissioner of Food and Drugs

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: 1/31/2020 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: 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>
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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>
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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>
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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."

From: McWilliams, Carly [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B68C7458214244D08424FD441FEA4FDA-CARLYLE.MCW]
Sent: 3/2/2020 9:12:01 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: RE: Science Magazine Article + UPDATE + TOMORROW's Plan

Yes. Are you in clearance chain? Will make sure it goes to you after if you are not already in the chain.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Monday, March 2, 2020 9:11 PM
To: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
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>
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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>
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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>
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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>
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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

<image007.png>

<image009.jpg>

<image011.jpg>

<image013.jpg>

<image015.jpg>

<image017.jpg>

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https://www.research.net/s/cdrhcustomerservice?ID=5000&S=E

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(b)(5)
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By Jon CohenFeb. 28, 2020 , 5:45 PM

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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.

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Michael Mina, Brigham and Women's Hospital

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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

Thx

Sent from my iPhone

On Mar 2, 2020, at 9:12 PM, McWilliams, Carly <Carly.McWilliams@fda.hhs.gov> wrote:

Yes. Are you in clearance chain? Will make sure it goes to you after if you are not already in the chain.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Monday, March 2, 2020 9:11 PM
To: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
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 Adviser

Center for Devices and Radiological Health
Office of Policy
U.S. Food and Drug Administration
Tel: 301-796-8924 - Cell: **(b)(6)**
jennifer.tomasello@fda.hhs.gov

<image007.png>

<image009.jpg>

<image011.jpg>

<image013.jpg>

<image015.jpg>

<image017.jpg>

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=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 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: 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: 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

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: 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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Anticipated actions in the next 48 hours

(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

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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: Meister, Karen G [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7F2CDCD99E784C6CB3E8BF491FEE037F-KMEISTER]
Sent: 3/26/2020 9:06:32 PM
To: White, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6fa70699685245178c505c69d684872d-Erica.White]
Subject: FW: FOR JIC REVIEW: Press Release on Coronavirus Treatment Acceleration Program/Plasma

fyi

From: Zavagno, Denise <Denise.Zavagno@fda.hhs.gov>
Sent: Thursday, March 26, 2020 8:44 PM
To: OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>; 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>
Cc: Hunt, Christine <Christine.Hunt@fda.hhs.gov>; Madni, Rubina <Rubina.Madni@fda.hhs.gov>
Subject: RE: FOR JIC REVIEW: Press Release on Coronavirus Treatment Acceleration Program/Plasma

Good evening,
OCC clears the press release on coronavirus treatment acceleration program/plasma.
Kind regards,
Denise Zavagno

From: OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>
Sent: Thursday, March 26, 2020 5:56 PM
To: Zavagno, Denise <Denise.Zavagno@fda.hhs.gov>; Madni, Rubina <Rubina.Madni@fda.hhs.gov>
Cc: OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>
Subject: FW: FOR JIC REVIEW: Press Release on Coronavirus Treatment Acceleration Program/Plasma

For 8:30 PM review, on convalescent plasma and treatment acceleration program. If you'd like me to ask for more time or a drugs counselor, too, let me know.

Best,
Christine

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Sent: Thursday, March 26, 2020 5:43 PM
To: 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>
Cc: OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>
Subject: FOR JIC REVIEW: Press Release on Coronavirus Treatment Acceleration Program/Plasma

Hi all,

Attached for JIC review by **8:30 PM TODAY** is a draft press release regarding the Coronavirus Treatment Acceleration Program and our work on convalescent plasma/hyperimmune globulin. This press release is based on the previously cleared press release on convalescent plasma/hyperimmune globulin, CBER-cleared talkers on new developments on this topic and CDER/CBER-cleared talking points on the Coronavirus Treatment Acceleration Program.

Please make edits in SharePoint: http://sharepoint.fda.gov/orgs/OC-OCET/OCETdocs/nCoV/Shared%20Documents/JIC%20-%20FDA%20IMG/Press/For%20clearance/DRAFT PR CTAP%20+%20Plasma%2003262020.docx

Michael

Michael Felberbaum
Senior Advisor

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-3548 / Cell: (b)(6)
michael.felberbaum@fda.hhs.gov

U.S. FOOD & DRUG ADMINISTRATION

(b)(5)

(b)(5)

From: Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
Sent: 3/20/2020 1:00:48 PM
To: Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
CC: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
Subject: RE: Per our conversation ...

Happy to put eyes on it, too, as well as speak with media.

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Sent: Friday, March 20, 2020 12:55 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Per our conversation ...

Thank you Peter and Janet.

Janet - I appreciate the offer to speak with press on this topic (and we'll likely need that) but would also like to build out the responses to these questions so that we are all talking about this the same way across the agency – and in those instances where we can't schedule time to speak with media or others. It sounds like Peter will be freshening up previous responses and we can use that as a starting point (feel free to propose responses for the questions below).

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: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Friday, March 20, 2020 12:38 PM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Per our conversation ...

Dear Anand,

Thanks for the heads up on these. We have had to address very similar questions during previous outbreak. Granted, they were not on this scale, but the concepts are all there. We are prepared to respond and this weekend will freshen up the responses that we put together for previous outbreaks.

Best Regards,
Peter

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Friday, March 20, 2020 12:23 PM
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Per our conversation ...

Hi Michael –

Thanks for sharing these potential questions. I've included Janet, Peter, and Jeff here for their thoughts. I agree it would be helpful for us to carefully think through these questions and, whenever possible, have a coordinated approach to incoming questions from stakeholders including media.

Anand

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Sent: Friday, March 20, 2020 12:18 PM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: Per our conversation ...

Thanks for the chat. Here are the questions I think we need to be prepared to answer on this topic. Feel free to add to this list and let me know if you want to relay to Janet or others.

(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


FDA
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ADMINISTRATION

From: Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
Sent: 3/16/2020 5:49:10 PM
To: Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Solomon, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e49ac6a056dc4f299ea269945e962e82-SSOLOMON]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Zeller, Mitchell [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=de7d2fda971e418ba33cb211a4013976-Mitchell.Ze]; Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]
CC: 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]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Hebert, Angelique A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aa08f3428a045f88eb3bd92c68a27cf-Angelique.H]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; 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]; Hussey, Deirdre [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41a51a9bf937431c8470b69fb055fe81-Husseyd]; Barth, Janelle [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=18d28baf2bfa435abc9cdfa076774dc0-Janelle.Bar]; Stone, Eric [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5799d336f4c142aca71a655e4184d6bd-Eric.Stone]; Huttenlocker, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=65254282fa6a4e138f506f96cfe9049c-Denise.Hutt]; Domanski, Jeffrey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ed00c0aa83794cbebfc0a50f6cd4d7f9-Jeffrey.Dom]; Schweitzer, Roxanne K [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=292135d254924252958e25cc5a63b079-RSCHWEIT]; Branch, Tiffany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b45f1b97b5d648f68cdff5ce4f75a154-Tiffany.Bra]; Barfell, Glenda F [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33b220e98ac9456eb32888261156f400-GBARFELL]; Lynch, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d24ee4a4fc6241f48110d6b35e6704ed-Sarah.Lynch]
Subject: RE: Flagging for PDC/CD/ACRA: Commissioner all hands update to go out asap today

Looks good. Thank you.

Jeff

From: Mayne, Susan <Susan.Mayne@fda.hhs.gov>
Date: March 16, 2020 at 5:46:59 PM EDT
To: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>, Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>, Solomon, Steven M <Steven.Solomon@fda.hhs.gov>, Marks, Peter <Peter.Marks@fda.hhs.gov>, Zeller, Mitchell <Mitchell.Zeller@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>, McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>, Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>, Anderson, Erika <Erika.Anderson@fda.hhs.gov>, Hebert, Angelique A. <Angelique.Hebert@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Finnen, April <April.Finnen@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>, Hussey, Deirdre <Deirdre.Hussey@fda.hhs.gov>, Barth, Janelle <Janelle.Barth@fda.hhs.gov>, Stone, Eric <Eric.Stone@fda.hhs.gov>, Huttenlocker, Denise <Denise.Huttenlocker@fda.hhs.gov>, Domanski, Jeffrey <Jeffrey.Domanski@fda.hhs.gov>, Schweitzer, Roxanne K <Roxanne.Schweitzer@fda.hhs.gov>, Branch, Tiffany <Tiffany.Branch@fda.hhs.gov>, Barfell, Glenda F <Glenda.Barfell@fda.hhs.gov>, Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>
Subject: RE: Flagging for PDC/CD/ACRA: Commissioner all hands update to go out asap today

No edits. Thanks!
Susan

From: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Sent: Monday, March 16, 2020 5:24 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Solomon, Steven M <Steven.Solomon@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Zeller, Mitchell <Mitchell.Zeller@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hebert, Angelique A. <Angelique.Hebert@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hussey, Deirdre <Deirdre.Hussey@fda.hhs.gov>; Barth, Janelle <Janelle.Barth@fda.hhs.gov>; Stone, Eric <Eric.Stone@fda.hhs.gov>; Huttenlocker, Denise <Denise.Huttenlocker@fda.hhs.gov>; Domanski, Jeffrey <Jeffrey.Domanski@fda.hhs.gov>; Schweitzer, Roxanne K <Roxanne.Schweitzer@fda.hhs.gov>; Branch, Tiffany <Tiffany.Branch@fda.hhs.gov>; Barfell, Glenda F <Glenda.Barfell@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>
Subject: Flagging for PDC/CD/ACRA: Commissioner all hands update to go out asap today

(b)(5)

(b)(5)

Sincerely,

Stephen M. Hahn, M.D.
FDA Commissioner

From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 3/26/2020 7:45:41 PM
To: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]
Subject: RE: FOR JIC REVIEW: Press Release on Coronavirus Treatment Acceleration Program/Plasma

Hang in there. Jw

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Date: March 26, 2020 at 7:44:27 PM EDT
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>, Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>, Flanagan, Keith <Keith.Flanagan@fda.hhs.gov>, Rawlings, Kimberly <Kimberly.Rawlings@fda.hhs.gov>, Shreeve, Chris <Christine.Kuethe@fda.hhs.gov>, Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>
Cc: 2019-nCoV FDA IMG JIC CDER <2019-nCoVFDAIMGJICCDER@fda.hhs.gov>, CDER COVID-19 Response <CDERCOVID19Response@fda.hhs.gov>, McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>
Subject: RE: FOR JIC REVIEW: Press Release on Coronavirus Treatment Acceleration Program/Plasma

Dear Janet,

Thanks for your sage wisdom here (and groan).

Best Regards,
Peter

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Thursday, March 26, 2020 7:43 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Flanagan, Keith <Keith.Flanagan@fda.hhs.gov>; Rawlings, Kimberly <Kimberly.Rawlings@fda.hhs.gov>; Shreeve, Chris <Christine.Kuethe@fda.hhs.gov>; Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>
Cc: 2019-nCoV FDA IMG JIC CDER <2019-nCoVFDAIMGJICCDER@fda.hhs.gov>; CDER COVID-19 Response <CDERCOVID19Response@fda.hhs.gov>; McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>
Subject: RE: FOR JIC REVIEW: Press Release on Coronavirus Treatment Acceleration Program/Plasma

I think we can simply provide comments and see what they do. Our web page once we get it up, and tweets (groan) will communicate CTAP better. Jw

---

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Date: March 26, 2020 at 7:41:04 PM EDT
To: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>, Flanagan, Keith <Keith.Flanagan@fda.hhs.gov>, Rawlings, Kimberly <Kimberly.Rawlings@fda.hhs.gov>, Shreeve, Chris <Christine.Kuethe@fda.hhs.gov>, Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>, Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Cc: 2019-nCoV FDA IMG JIC CDER <2019-nCoVFDAIMGJICCDER@fda.hhs.gov>, CDER COVID-19 Response <CDERCOVID19Response@fda.hhs.gov>, McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>
Subject: RE: FOR JIC REVIEW: Press Release on Coronavirus Treatment Acceleration Program/Plasma

Dear All,

We originally had a separate release for these two products and the comms folks grafted it to the Accelerator.

Please feel absolutely free to remove these two products and replace them with CDER examples or start with CDER examples before these. We could also simply separate the releases again. Thanks.

Best Regards,
Peter

From: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Sent: Thursday, March 26, 2020 7:22 PM
To: Flanagan, Keith <Keith.Flanagan@fda.hhs.gov>; Rawlings, Kimberly <Kimberly.Rawlings@fda.hhs.gov>; Shreeve, Chris <Christine.Kuethe@fda.hhs.gov>; Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: 2019-nCoV FDA IMG JIC CDER <2019-nCoVFDAIMGJICCDER@fda.hhs.gov>; CDER COVID-19 Response <CDERCOVID19Response@fda.hhs.gov>
Subject: RE: FOR JIC REVIEW: Press Release on Coronavirus Treatment Acceleration Program/Plasma

I have the same comment as Keith's. CTAP originated in CDER (and specifically JW's brain) and doesn't showcase anything that CDER to andance new therapies. Antivirals? Immunomodulators? Expanded access programs?
+ Peter Marks, who also needs to clear this
Patrizia

From: Flanagan, Keith <Keith.Flanagan@fda.hhs.gov>
Sent: Thursday, March 26, 2020 7:13 PM
To: Rawlings, Kimberly <Kimberly.Rawlings@fda.hhs.gov>; Shreeve, Chris <Christine.Kuethe@fda.hhs.gov>; Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Cc: 2019-nCoV FDA IMG JIC CDER <2019-nCoVFDAIMGJICCDER@fda.hhs.gov>; CDER COVID-19 Response <CDERCOVID19Response@fda.hhs.gov>
Subject: RE: FOR JIC REVIEW: Press Release on Coronavirus Treatment Acceleration Program/Plasma

I made one technical edit in SharePoint per the instructions below.

Their draft has rhetorical overview, collapses the CDER-CBER content explaining CTAP, and showcases the CBER plasma products – and inter-Agency collaboration on it - in depth.

JW's original messaging (in the draft we sent them earlier today) is much crisper and would be well suited for inaugural JW Tweet(s).

From: Rawlings, Kimberly <Kimberly.Rawlings@fda.hhs.gov>
Sent: Thursday, March 26, 2020 6:10 PM
To: Flanagan, Keith <Keith.Flanagan@fda.hhs.gov>; Shreeve, Chris <Christine.Kuethe@fda.hhs.gov>; Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Cc: 2019-nCoV FDA IMG JIC CDER <2019-nCoVFDAIMGJICCDER@fda.hhs.gov>; CDER COVID-19 Response <CDERCOVID19Response@fda.hhs.gov>
Subject: FW: FOR JIC REVIEW: Press Release on Coronavirus Treatment Acceleration Program/Plasma

Keith,
Please review the PR to announce the Coronavirus Treatment Acceleration Program (CTAP).

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Sent: Thursday, March 26, 2020 5:43 PM
To: 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>
Cc: OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>
Subject: FOR JIC REVIEW: Press Release on Coronavirus Treatment Acceleration Program/Plasma

Hi all,

Attached for JIC review by **8:30 PM TODAY** is a draft press release regarding the Coronavirus Treatment Acceleration Program and our work on convalescent plasma/hyperimmune globulin. This press release is based on the previously cleared press release on convalescent plasma/hyperimmune globulin, CBER-cleared talkers on new developments on this topic and CDER/CBER-cleared talking points on the Coronavirus Treatment Acceleration Program.

Please make edits in SharePoint: http://sharepoint.fda.gov/orgs/OC-OCET/OCETdocs/nCoV/Shared%20Documents/JIC%20-%20FDA%20IMG/Press/For%20clearance/DRAFT PR CTAP%20+%20Plasma%2003262020.docx

Michael
Michael Felberbaum
Senior Advisor

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

U.S. FOOD & DRUG ADMINISTRATION

(b)(5)

(b)(5)

From: Cavazzoni, Patrizia [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C42ABD33834044ECBAA03D075CC0A5D2-PATRIZIA.CA]
Sent: 3/15/2020 4:38:46 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
CC: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]; Clarke, Mary Beth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b0124a15b9344d8483929470fefa403a-CLARKEM]
Subject: Fwd: Quick response requested: Talking Points on COVID Therapeutics/Vaccines - by 1630
Attachments: Therapeutics TPs 03152020 324pm.docx

Denise
+ Peter Marks
In the two paragraphs on IL-7 inhibitors and convalescent plasma, respectively , I recommend replacing the section about Reducing/heeding off need for ventilator with :

(b)(5)

Patrizia

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Date: March 15, 2020 at 4:16:42 PM EDT
To: Farley, John <John.Farley@fda.hhs.gov>, Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>, Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>
Subject: Quick response requested: Talking Points on COVID Therapeutics/Vaccines - by 1630

Hi – sorry for short notice – any input before Michael Felderbaum sends to Dr. Hahn?

Thanks,

D

From: Cavazzoni, Patrizia [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C42ABD33834044ECBAA03D075CC0A5D2-PATRIZIA.CA]
Sent: 3/16/2020 11:31:09 AM
To: Jungman, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5238a0caec064ba8b5d598115bc4f99f-Elizabeth.J]
CC: Kraus, Stefanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9d3959f3365b4fc39a7eb324539215bc-Stefanie.Kr]
Subject: RE: **(b)(5)**
Attachments: Therapeutics TPs 03152020 749pm.docx

From: Jungman, Elizabeth <Elizabeth.Jungman@fda.hhs.gov>
Sent: Monday, March 16, 2020 11:27 AM
To: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Cc: Kraus, Stefanie <Stefanie.Kraus@fda.hhs.gov>
Subject: RE: **(b)(5)**

Patrizia: The attachment did not come through. Can you please re-send?

Elizabeth Jungman
Director, Office of Regulatory Policy
Center for Drug Evaluation & Research, FDA
240-402-1563 (work)
(b)(6) (work cell)

From: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Sent: Monday, March 16, 2020 10:43 AM
To: Sipes, Grail <Grail.Sipes@fda.hhs.gov>
Cc: Jungman, Elizabeth <Elizabeth.Jungman@fda.hhs.gov>
Subject: RE: **(b)(5)**

EJ
These are TPs for SH that Peter Marks and I clear last night. I thought they could be helpful
Patrizia

From: Sipes, Grail <Grail.Sipes@fda.hhs.gov>
Sent: Monday, March 16, 2020 10:13 AM
To: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Cc: Jungman, Elizabeth <Elizabeth.Jungman@fda.hhs.gov>
Subject: RE: **(b)(5)**

Thank you Elizabeth and please keep me in the loop!

From: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Sent: Monday, March 16, 2020 9:54 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Birnkrant, Debra B <Debra.Birnkrant@fda.hhs.gov>; Sipes, Grail <Grail.Sipes@fda.hhs.gov>; Jungman, Elizabeth <Elizabeth.Jungman@fda.hhs.gov>
Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>; McLatchy, Johanna <Johanna.McLatchy@fda.hhs.gov>
Subject: RE: **(b)(5)**

Yes, and I will speak with EJ, who can work with Julia in CBER.
Patrizia

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Monday, March 16, 2020 9:53 AM
To: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Birnkrant, Debra B <Debra.Birnkrant@fda.hhs.gov>; Sipes, Grail <Grail.Sipes@fda.hhs.gov>; Jungman, Elizabeth <Elizabeth.Jungman@fda.hhs.gov>
Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>; McLatchy, Johanna <Johanna.McLatchy@fda.hhs.gov>
Subject: RE: **(b)(5)**

Then EJ/ORP is the lead for developing the response? jw

From: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Sent: Monday, March 16, 2020 9:52 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Birnkrant, Debra B <Debra.Birnkrant@fda.hhs.gov>; Sipes, Grail <Grail.Sipes@fda.hhs.gov>; Jungman, Elizabeth <Elizabeth.Jungman@fda.hhs.gov>
Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>; McLatchy, Johanna <Johanna.McLatchy@fda.hhs.gov>
Subject: RE: **(b)(5)**

We need to spare John and Debbie. I will review and clear, along with EJ
Patrizia

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Monday, March 16, 2020 9:50 AM
To: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Birnkrant, Debra B <Debra.Birnkrant@fda.hhs.gov>; Sipes, Grail <Grail.Sipes@fda.hhs.gov>; Jungman, Elizabeth <Elizabeth.Jungman@fda.hhs.gov>
Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>; McLatchy, Johanna <Johanna.McLatchy@fda.hhs.gov>
Subject: FW: **(b)(5)**

I don't see any need for this. Who should collect the comments? ORP? John and Debbie, you should not have to spend any time on this, I know you are busy with protocol review. Peter, we should coordinate. jw

---

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Monday, March 16, 2020 9:46 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Patel, Chaitali <Chaitali.Patel@fda.hhs.gov>; McLatchy, Johanna <Johanna.McLatchy@fda.hhs.gov>; Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>
Subject: FW: **(b)(5)**

PRE-DECISIONAL, CONFIDENTIAL

Dear Janet and Peter –

(b)(5) Stacy will also be sharing with the OCC team.

Thank you for prioritizing this review. I will need to provide HHS with comments by 5pm today.

Best,
Anand

From: Jungman, Elizabeth [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5238A0CAEC064BA8B5D598115BC4F99F-ELIZABETH.J]
Sent: 3/16/2020 4:27:04 PM
To: Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]
CC: Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Kraus, Stefanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9d3959f3365b4fc39a7eb324539215bc-Stefanie.Kr]; Maloney, Diane [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e59205500e944c9eacc4524ea18ed5bb-MaloneyD]; McLatchy, Johanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=895ad3bde51342d5817826ccc9bc1ba7-MCLATCHYJ]
Subject: FW: **(b)(5)**
Attachments: **(b)(5)**
Importance: High

Drs. Woodcock, Marks, and Cavazzoni:

Stefanie Kraus from CDER/ORP worked with Julie Tierney from CBER to draft the attached proposed response to the (b)(5) If you have edits, please cc Stefanie and she can help coordinate our response. We know **Anand was hoping to respond to HHS by 5pm today**, so apologies for the tight turnaround.

On the substance of the response:

(b)(5)

- Please note that if we end up needing a shorter summary response (e.g. for a cover email), we can just pull out the first paragraph.

Once we have a version you are all comfortable with, please let me know whether you'd rather we follow up with Anand or if you'd like to do so yourself.

Elizabeth Jungman
Director, Office of Regulatory Policy
Center for Drug Evaluation & Research, FDA
240-402-1563 (work)
(b)(6) (work cell)

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Monday, March 16, 2020 9:46 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Patel, Chaitali <Chaitali.Patel@fda.hhs.gov>; McLatchy, Johanna <Johanna.McLatchy@fda.hhs.gov>; Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>
Subject: FW: **(b)(5)**

PRE-DECISIONAL, CONFIDENTIAL

Dear Janet and Peter –

(b)(5) Stacy will also be sharing with the OCC team.

Thank you for prioritizing this review. I will need to provide HHS with comments by 5pm today.

Best,
Anand

From: Maloney, Diane [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E59205500E944C9EACC4524EA18ED5BB-MALONEYD]
Sent: 3/16/2020 4:38:13 PM
To: Jungman, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5238a0caec064ba8b5d598115bc4f99f-Elizabeth.J]; Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]
CC: Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Kraus, Stefanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9d3959f3365b4fc39a7eb324539215bc-Stefanie.Kr]; McLatchy, Johanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=895ad3bde51342d5817826ccc9bc1ba7-MCLATCHYJ]
Subject: RE: (b)(5)
Attachments: (b)(5)

Thanks, Elizabeth. I think this looks great. I added some comments for consideration.

From: Jungman, Elizabeth <Elizabeth.Jungman@fda.hhs.gov>
Sent: Monday, March 16, 2020 4:27 PM
To: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Kraus, Stefanie <Stefanie.Kraus@fda.hhs.gov>; Maloney, Diane <Diane.Maloney@fda.hhs.gov>; McLatchy, Johanna <Johanna.McLatchy@fda.hhs.gov>
Subject: FW: (b)(5)
Importance: High

Drs. Woodcock, Marks, and Cavazzoni:

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Elizabeth Jungman
Director, Office of Regulatory Policy
Center for Drug Evaluation & Research, FDA
240-402-1563 (work)
(b)(6) (work cell)

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Monday, March 16, 2020 9:46 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Patel, Chaitali <Chaitali.Patel@fda.hhs.gov>; McLatchy, Johanna <Johanna.McLatchy@fda.hhs.gov>; Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>
Subject: FW: (b)(5)

PRE-DECISIONAL, CONFIDENTIAL

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Best,
Anand

From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 3/16/2020 4:56:50 PM
To: Jungman, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5238a0caec064ba8b5d598115bc4f99f-Elizabeth.J]; Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]
CC: Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Kraus, Stefanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9d3959f3365b4fc39a7eb324539215bc-Stefanie.Kr]; Maloney, Diane [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e59205500e944c9eacc4524ea18ed5bb-MaloneyD]; McLatchy, Johanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=895ad3bde51342d5817826ccc9bc1ba7-MCLATCHYJ]
Subject: Re: **(b)(5)**

(b)(5)

Jw

From: Jungman, Elizabeth <Elizabeth.Jungman@fda.hhs.gov>
Date: March 16, 2020 at 4:27:05 PM EDT
To: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>, Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>, Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>, Kraus, Stefanie <Stefanie.Kraus@fda.hhs.gov>, Maloney, Diane <Diane.Maloney@fda.hhs.gov>, McLatchy, Johanna <Johanna.McLatchy@fda.hhs.gov>
Subject: FW **(b)(5)**
Importance: High

Drs. Woodcock, Marks, and Cavazzoni:

Stefanie Kraus from CDER/ORP worked with Julie Tierney from CBER to draft the attached proposed response to the (b)(5) If you have edits, please cc Stefanie and she can help coordinate our response. We know **Anand was hoping to respond to HHS by 5pm today**, so apologies for the tight turnaround.

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Elizabeth Jungman
Director, Office of Regulatory Policy
Center for Drug Evaluation & Research, FDA
240-402-1563 (work)
(b)(6) (work cell)

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Monday, March 16, 2020 9:46 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Patel, Chaitali <Chaitali.Patel@fda.hhs.gov>; McLatchy, Johanna <Johanna.McLatchy@fda.hhs.gov>; Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>
Subject: FW: **(b)(5)**

PRE-DECISIONAL, CONFIDENTIAL

Dear Janet and Peter –

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Anand

From: Jungman, Elizabeth [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5238A0CAEC064BA8B5D598115BC4F99F-ELIZABETH.J]
Sent: 3/16/2020 5:01:47 PM
To: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; 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]
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Subject: RE: **(b)(5)**

Thank you all. I know Patrizia was going to circulate comments in the same vein, so we'll punch it up and recirculate.

Elizabeth Jungman
Director, Office of Regulatory Policy
Center for Drug Evaluation & Research, FDA
240-402-1563 (work)
(b)(6) (work cell)

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Monday, March 16, 2020 4:59 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Jungman, Elizabeth <Elizabeth.Jungman@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Kraus, Stefanie <Stefanie.Kraus@fda.hhs.gov>; Maloney, Diane <Diane.Maloney@fda.hhs.gov>; McLatchy, Johanna <Johanna.McLatchy@fda.hhs.gov>
Subject: RE: **(b)(5)**

Dear Janet,

Thanks. I don't have anything more to add to Janet's comments, except to note the minor additional edit in the attached.

Best Regards,
Peter

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Monday, March 16, 2020 4:57 PM
To: Jungman, Elizabeth <Elizabeth.Jungman@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Kraus, Stefanie <Stefanie.Kraus@fda.hhs.gov>; Maloney, Diane <Diane.Maloney@fda.hhs.gov>; McLatchy, Johanna <Johanna.McLatchy@fda.hhs.gov>
Subject: Re: **(b)(5)**

(b)(5)

Jw

From: Jungman, Elizabeth <Elizabeth.Jungman@fda.hhs.gov>
Date: March 16, 2020 at 4:27:05 PM EDT
To: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>, Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>, Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>, Kraus, Stefanie <Stefanie.Kraus@fda.hhs.gov>, Maloney, Diane <Diane.Maloney@fda.hhs.gov>, McLatchy, Johanna <Johanna.McLatchy@fda.hhs.gov>
Subject: FW: **(b)(5)**
Importance: High

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On the substance of the response:

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Director, Office of Regulatory Policy
Center for Drug Evaluation & Research, FDA
240-402-1563 (work)
(b)(6) (work cell)

From: Shah, Anand <Anand.Shah@fda.hhs.g●v>
Sent: Monday, March 16, 2020 9:46 AM
To: Woodcock, Janet <Janet.W●●dc●ck@fda.hhs.g●v>; Marks, Peter <Peter.Marks@fda.hhs.g●v>
Cc: Amin, Stacy <Stacy.Amin@fda.hhs.g●v>; Guram, Jeet <Jeet.Guram@fda.hhs.g●v>; Patel, Chaitali <Chaitali.Patel@fda.hhs.g●v>; McLatchy, Johanna <J●hanna.McLatch▼@fda.hhs.g●v>; Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.g●v>
Subject: FW: (b)(5)

PRE-DECISIONAL, CONFIDENTIAL

Dear Janet and Peter –

(b)(5) Stacy will also be sharing with the OCC team.

Thank you for prioritizing this review. I will need to provide HHS with comments by 5pm today.

Best,
Anand

From: Cavazzoni, Patrizia [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C42ABD33834044ECBAA03D075CC0A5D2-PATRIZIA.CA]
Sent: 3/16/2020 5:09:42 PM
To: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Jungman, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5238a0caec064ba8b5d598115bc4f99f-Elizabeth.J]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]
CC: Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Kraus, Stefanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9d3959f3365b4fc39a7eb324539215bc-Stefanie.Kr]; Maloney, Diane [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e59205500e944c9eacc4524ea18ed5bb-MaloneyD]; McLatchy, Johanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=895ad3bde51342d5817826ccc9bc1ba7-MCLATCHYJ]
Subject: RE: (b)(5)
Attachments: (b)(5)

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Patrizia

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Monday, March 16, 2020 4:57 PM
To: Jungman, Elizabeth <Elizabeth.Jungman@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Kraus, Stefanie <Stefanie.Kraus@fda.hhs.gov>; Maloney, Diane <Diane.Maloney@fda.hhs.gov>; McLatchy, Johanna <Johanna.McLatchy@fda.hhs.gov>
Subject: Re: (b)(5)

(b)(5)

Jw

From: Jungman, Elizabeth <Elizabeth.Jungman@fda.hhs.gov>
Date: March 16, 2020 at 4:27:05 PM EDT
To: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>, Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>, Marks, Peter <Peter.Marks@fda.hhs.gov>
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Subject: FW: **(b)(5)**
Importance: High

Drs. Woodcock, Marks, and Cavazzoni:

Stefanie Kraus from CDER/ORP worked with Julie Tierney from CBER to draft the attached proposed response to the **(b)(5)** If you have edits, please cc Stefanie and she can help coordinate our response. We know **Anand was hoping to respond to HHS by 5pm today**, so apologies for the tight turnaround.

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(b)(5)

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Director, Office of Regulatory Policy
Center for Drug Evaluation & Research, FDA
240-402-1563 (work)
(b)(6) (work cell)

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PRE-DECISIONAL, CONFIDENTIAL

Dear Janet and Peter –

(b)(5) Stacy will also be sharing with the OCC team.

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Best,
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Sent: 3/16/2020 5:43:52 PM
To: Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Jungman, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5238a0caec064ba8b5d598115bc4f99f-Elizabeth.J]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]
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(b)(5)

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Importance: High

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Sent: 3/16/2020 5:49:25 PM
To: Kraus, Stefanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9d3959f3365b4fc39a7eb324539215bc-Stefanie.Kr]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Jungman, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5238a0caec064ba8b5d598115bc4f99f-Elizabeth.J]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]
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To: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Jungman, Elizabeth <Elizabeth.Jungman@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
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Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Kraus, Stefanie <Stefanie.Kraus@fda.hhs.gov>; Maloney, Diane <Diane.Maloney@fda.hhs.gov>; McLatchy, Johanna <Johanna.McLatchy@fda.hhs.gov>
Subject: Re: **(b)(5)**

(b)(5)

Jw

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Date: March 16, 2020 at 4:27:05 PM EDT
To: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>, Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>, Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>, Kraus, Stefanie <Stefanie.Kraus@fda.hhs.gov>, Maloney, Diane <Diane.Maloney@fda.hhs.gov>, McLatchy, Johanna <Johanna.McLatchy@fda.hhs.gov>
Subject: FW: **(b)(5)**
Importance: High

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Sent: 3/16/2020 5:49:59 PM
To: Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]
Subject: RE: Flagging for PDC/CD/ACRA: Commissioner all hands update to go out asap today

No comments
Patrizia

From: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Sent: Monday, March 16, 2020 5:24 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Solomon, Steven M <Steven.Solomon@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Zeller, Mitchell <Mitchell.Zeller@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hebert, Angelique A. <Angelique.Hebert@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hussey, Deirdre <Deirdre.Hussey@fda.hhs.gov>; Barth, Janelle <Janelle.Barth@fda.hhs.gov>; Stone, Eric <Eric.Stone@fda.hhs.gov>; Huttenlocker, Denise <Denise.Huttenlocker@fda.hhs.gov>; Domanski, Jeffrey <Jeffrey.Domanski@fda.hhs.gov>; Schweitzer, Roxanne K <Roxanne.Schweitzer@fda.hhs.gov>; Branch, Tiffany <Tiffany.Branch@fda.hhs.gov>; Barfell, Glenda F <Glenda.Barfell@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>
Subject: Flagging for PDC/CD/ACRA: Commissioner all hands update to go out asap today

(b)(5)

(b)(5)

Sincerely,

Stephen M. Hahn, M.D.
FDA Commissioner

From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 3/16/2020 6:00:20 PM
To: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]; Kraus, Stefanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9d3959f3365b4fc39a7eb324539215bc-Stefanie.Kr]; Jungman, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5238a0caec064ba8b5d598115bc4f99f-Elizabeth.J]
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Looks very good now. I think we can send forward. Jw

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Subject: RE: **(b)(5)**

Dear Stephanie,

This looks good to me. Patrizia's edit took care of my one edit, so I am set.

Best Regards,
Peter

From: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
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Center for Drug Evaluation & Research, FDA
240-402-1563 (work)
(b)(6) (work cell)

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Sent: Monday, March 16, 2020 9:46 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Patel, Chaitali <Chaitali.Patel@fda.hhs.gov>; McLatchy, Johanna <Johanna.McLatchy@fda.hhs.gov>; Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>
Subject: FW: **(b)(5)**

PRE-DECISIONAL, CONFIDENTIAL

Dear Janet and Peter –

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Sent: 3/16/2020 6:00:34 PM
To: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]; Kraus, Stefanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9d3959f3365b4fc39a7eb324539215bc-Stefanie.Kr]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
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(b)(5)

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How about you send to Ananda Shah, Stacy and Keagan, cc JW, Peter M, Julia, Grail and I?
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Cc: Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Patel, Chaitali <Chaitali.Patel@fda.hhs.gov>; McLatchy, Johanna <Johanna.McLatchy@fda.hhs.gov>; Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>
Subject: FW: **(b)(5)**

PRE-DECISIONAL, CONFIDENTIAL

Dear Janet and Peter –

(b)(5) Stacy will also be sharing with the OCC team.

Thank you for prioritizing this review. I will need to provide HHS with comments by 5pm today.

Best,
Anand

From: Jungman, Elizabeth [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5238A0CAEC064BA8B5D598115BC4F99F-ELIZABETH.J]
Sent: 3/16/2020 6:05:26 PM
To: Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]
Subject: RE: **(b)(5)**

On it. Thanks.

Elizabeth Jungman
Director, Office of Regulatory Policy
Center for Drug Evaluation & Research, FDA
240-402-1563 (work)
(b)(6) (work cell)

From: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Date: March 16, 2020 at 6:05:11 PM EDT
To: Jungman, Elizabeth <Elizabeth.Jungman@fda.hhs.gov>
Subject: RE: **(b)(5)**

How about you send to Ananda Shah, Stacy and Keagan, cc JW, Peter M, Julia, Grail and I?
Or if you prefer, I can send
Patrizia

From: Jungman, Elizabeth <Elizabeth.Jungman@fda.hhs.gov>
Sent: Monday, March 16, 2020 6:01 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Kraus, Stefanie <Stefanie.Kraus@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Maloney, Diane <Diane.Maloney@fda.hhs.gov>; McLatchy, Johanna <Johanna.McLatchy@fda.hhs.gov>
Subject: RE: **(b)(5)**

Super. Assuming Dr. Woodcock is also on board, should we respond to the Commissioner's office or would others prefer to carry that message? Either works.

Elizabeth Jungman
Director, Office of Regulatory Policy
Center for Drug Evaluation & Research, FDA
240-402-1563 (work)
(b)(6) (work cell)

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Monday, March 16, 2020 5:51 PM
To: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Kraus, Stefanie <Stefanie.Kraus@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Jungman, Elizabeth <Elizabeth.Jungman@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Maloney, Diane <Diane.Maloney@fda.hhs.gov>; McLatchy, Johanna <Johanna.McLatchy@fda.hhs.gov>
Subject: RE: **(b)(5)**

Dear Stephanie,

This looks good to me. Patrizia's edit took care of my one edit, so I am set.

Best Regards,
Peter

From: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Sent: Monday, March 16, 2020 5:49 PM
To: Kraus, Stefanie <Stefanie.Kraus@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Jungman, Elizabeth <Elizabeth.Jungman@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Maloney, Diane <Diane.Maloney@fda.hhs.gov>; McLatchy, Johanna <Johanna.McLatchy@fda.hhs.gov>
Subject: RE: **(b)(5)**

Stephanie
One edits, for internal consistency . Also, feel free to edit the text I added if you think it may be too forceful.

Patrizia

From: Kraus, Stefanie <Stefanie.Kraus@fda.hhs.gov>
Sent: Monday, March 16, 2020 5:44 PM
To: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Jungman, Elizabeth <Elizabeth.Jungman@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Maloney, Diane <Diane.Maloney@fda.hhs.gov>; McLatchy, Johanna <Johanna.McLatchy@fda.hhs.gov>
Subject: RE: **(b)(5)**

Hi all; I've discussed the comments with EJ and revised the draft to address them. I'm circulating the updated draft with redlines to reflect the bullets suggested and language on severely ill patients. We accepted Diane's and Peter's edits. Please let us know if we've addressed the comments adequately and are on the right track.

-Stefanie

From: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Sent: Monday, March 16, 2020 5:10 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Jungman, Elizabeth <Elizabeth.Jungman@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Kraus, Stefanie <Stefanie.Kraus@fda.hhs.gov>; Maloney, Diane <Diane.Maloney@fda.hhs.gov>; McLatchy, Johanna <Johanna.McLatchy@fda.hhs.gov>
Subject: RE: **(b)(5)**

Some added text , in the same vein as JW's comments. I think we need to be stronger and agree that the bulleted approach would convey the most important points clearly and upfront.
Patrizia

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Monday, March 16, 2020 4:57 PM
To: Jungman, Elizabeth <Elizabeth.Jungman@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Kraus, Stefanie <Stefanie.Kraus@fda.hhs.gov>; Maloney, Diane <Diane.Maloney@fda.hhs.gov>; McLatchy, Johanna <Johanna.McLatchy@fda.hhs.gov>
Subject: Re: **(b)(5)**

(b)(5)

Jw

From: Jungman, Elizabeth <Elizabeth.Jungman@fda.hhs.gov>
Date: March 16, 2020 at 4:27:05 PM EDT
To: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>, Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>, Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>, Kraus, Stefanie <Stefanie.Kraus@fda.hhs.gov>, Maloney, Diane <Diane.Maloney@fda.hhs.gov>, McLatchy, Johanna <Johanna.McLatchy@fda.hhs.gov>
Subject: FW: (b)(5)
Importance: High

Drs. Woodcock, Marks, and Cavazzoni:

Stefanie Kraus from CDER/ORP worked with Julie Tierney from CBER to draft the attached proposed response to the (b)(5) If you have edits, please cc Stefanie and she can help coordinate our response. We know **Anand was hoping to respond to HHS by 5pm today**, so apologies for the tight turnaround.

On the substance of the response:

(b)(5)

- Please note that if we end up needing a shorter summary response (e.g. for a cover email), we can just pull out the first paragraph.

Once we have a version you are all comfortable with, please let me know whether you'd rather we follow up with Anand or if you'd like to do so yourself.

Elizabeth Jungman
Director, Office of Regulatory Policy
Center for Drug Evaluation & Research, FDA
240-402-1563 (work)
(b)(6) (work cell)

From: Shah, Anand <Anand.Shah@fda.hhs.g●v>
Sent: Monday, March 16, 2020 9:46 AM
To: Woodcock, Janet <Janet.W●●dc●ck@fda.hhs.g●v>; Marks, Peter <Peter.Marks@fda.hhs.g●v>
Cc: Amin, Stacy <Stacy.Amin@fda.hhs.g●v>; Guram, Jeet <Jeet.Guram@fda.hhs.g●v>; Patel, Chaitali <Chaitali.Patel@fda.hhs.g●v>; McLatchy, Johanna <J●hanna.McLatchy@fda.hhs.g●v>; Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.g●v>
Subject: FW: (b)(5)

PRE-DECISIONAL, CONFIDENTIAL

Dear Janet and Peter –

(b)(5) Stacy will also be sharing with the OCC team.

Thank you for prioritizing this review. I will need to provide HHS with comments by 5pm today.

Best,
Anand

From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 3/17/2020 9:50:46 AM
To: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]
Subject: RE: **(b)(5)**

I will be at 796 3426 for an hour. w

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Tuesday, March 17, 2020 9:48 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Subject: RE: **(b)(5)**

Dear Janet and Patrizia,

Do you have a minute to discuss? I had a call with Anand, Geet, and OIRA yesterday on vaccines that provided some interesting insight.

Best Regards,
Peter

From: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Sent: Tuesday, March 17, 2020 9:45 AM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Jungman, Elizabeth <Elizabeth.Jungman@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Sipes, Grail <Grail.Sipes@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Kraus, Stefanie <Stefanie.Kraus@fda.hhs.gov>
Subject: RE: **(b)(5)**

Thank you all for the quick turnaround. As a next step, Dr. Hahn is interested in ideas **(b)(5)**

(b)(5)

(b)(5) Just let us know if you have any questions on this request.

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Date: March 17, 2020 at 9:06:09 AM EDT
To: Jungman, Elizabeth <Elizabeth.Jungman@fda.hhs.gov>, Amin, Stacy <Stacy.Amin@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Guram, Jeet <Jeet.Guram@fda.hhs.gov>
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Subject: RE: **(b)(5)**

Hi Elizabeth –

Steve reviewed the response to the (b)(5) and has some feedback. Jeet will follow up shortly

Thanks again

Anand

From: Shah, Anand
Sent: Tuesday, March 17, 2020 6:47 AM
To: Jungman, Elizabeth <Elizabeth.Jungman@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>
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Subject: RE: **(b)(5)**

Thank you, Elizabeth and team, for the detailed review that I have also shared with Steve.

Anand

From: Jungman, Elizabeth <Elizabeth.Jungman@fda.hhs.gov>
Sent: Monday, March 16, 2020 6:12 PM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>
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Subject: FW: **(b)(5)**

Please see attached a joint CDER-CBER proposed response to the **(b)(5)**

Elizabeth Jungman
Director, Office of Regulatory Policy
Center for Drug Evaluation & Research, FDA
240-402-1563 (work)
(b)(6) (work cell)

From: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Sent: Monday, March 16, 2020 9:52 AM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: RE: **(b)(5)**

Janet and Peter good to meet you – I recently joined OC from CMS.

Just let us know; also as fyi, initial/high-level comments would be most helpful on this. Thanks so much.

--

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: Monday, March 16, 2020 9:49 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Subject: RE: **(b)(5)**

Janet and Peter –

I've asked Jeet to reach out to you with some additional context

Please let us know the best #'s to reach you for a few min

Anand

PRE-DECISIONAL, CONFIDENTIAL

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PRE-DECISIONAL, CONFIDENTIAL

Dear Janet and Peter –

(b)(5) Stacy will also be sharing with the OCC team.

Thank you for prioritizing this review. I will need to provide HHS with comments by 5pm today.

Best,

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From: Cavazzoni, Patrizia [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C42ABD33834044ECBAA03D075CC0A5D2-PATRIZIA.CA]
Sent: 3/17/2020 9:59:56 AM
To: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]
Subject: RE: **(b)(5)**

We can use my dial-in number

Dial In Number Local/Toll Number 1-210-795-1100 Freephone/Toll Free Number 866-880-0098 Passcodes Leader: **(b)(6)** Participant: **(b)(6)**

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(b)(5)

(b)(5) Just let us know if you have any questions on this request.

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Date: March 17, 2020 at 9:06:09 AM EDT
To: Jungman, Elizabeth <Elizabeth.Jungman@fda.hhs.gov>, Amin, Stacy <Stacy.Amin@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Guram, Jeet <Jeet.Guram@fda.hhs.gov>
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Subject: FW: (b)(5)

Please see attached a joint CDER-CBER proposed response to the (b)(5)

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Director, Office of Regulatory Policy
Center for Drug Evaluation & Research, FDA
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Subject: RE: **(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

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PRE-DECISIONAL, CONFIDENTIAL

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Sent: 3/17/2020 10:01:50 AM
To: Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]
Subject: RE: **(b)(5)**

Peter just called me. I'm going to call Anand. **(b)(5)**
(b)(5)
(b)(5) If you call me, 63426 we can discuss additional developments. jw

---

From: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Sent: Tuesday, March 17, 2020 10:00 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: RE: **(b)(5)**

We can use my dial-in number

Dial In Number Local/Toll Number 1-210-795-1100 Freephone/Toll Free Number 866-880-0098 Passcodes Leader: **(b)(6)** Participant: **(b)(6)**

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Best Regards,
Peter

From: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Sent: Tuesday, March 17, 2020 9:45 AM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Jungman, Elizabeth <Elizabeth.Jungman@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Sipes, Grail <Grail.Sipes@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Kraus, Stefanie <Stefanie.Kraus@fda.hhs.gov>
Subject: RE: **(b)(5)**

Thank you all for the quick turnaround. As a next step, Dr. Hahn is interested in ideas **(b)(5)**
(b)(5)

(b)(5)

(b)(5) Just let us know if you have any questions on this request.

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Date: March 17, 2020 at 9:06:09 AM EDT
To: Jungman, Elizabeth <Elizabeth.Jungman@fda.hhs.gov>, Amin, Stacy <Stacy.Amin@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Cc: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>, Marks, Peter <Peter.Marks@fda.hhs.gov>, Tierney, Julia <Julia.Tierney@fda.hhs.gov>, Sipes, Grail <Grail.Sipes@fda.hhs.gov>, Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>, Kraus, Stefanie <Stefanie.Kraus@fda.hhs.gov>
Subject: RE: (b)(5)

Hi Elizabeth –

Steve reviewed the response to the (b)(5) and has some feedback. Jeet will follow up shortly

Thanks again

Anand

From: Shah, Anand
Sent: Tuesday, March 17, 2020 6:47 AM
To: Jungman, Elizabeth <Elizabeth.Jungman@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Cc: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Sipes, Grail <Grail.Sipes@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Kraus, Stefanie <Stefanie.Kraus@fda.hhs.gov>
Subject: RE: (b)(5)

Thank you, Elizabeth and team, for the detailed review that I have also shared with Steve.

Anand

From: Jungman, Elizabeth <Elizabeth.Jungman@fda.hhs.gov>
Sent: Monday, March 16, 2020 6:12 PM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Cc: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Sipes, Grail <Grail.Sipes@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Kraus, Stefanie <Stefanie.Kraus@fda.hhs.gov>
Subject: FW: (b)(5)

Please see attached a joint CDER-CBER proposed response to the (b)(5)

Elizabeth Jungman

Director, Office of Regulatory Policy
Center for Drug Evaluation & Research, FDA
240-402-1563 (work)
(b)(6) (work cell)

From: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Sent: Monday, March 16, 2020 9:52 AM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: RE: (b)(5)

Janet and Peter good to meet you – I recently joined OC from CMS.

Just let us know; also as fyi, initial/high-level comments would be most helpful on this. Thanks so much.

--

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: Monday, March 16, 2020 9:49 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Subject: RE: (b)(5)

Janet and Peter –

I've asked Jeet to reach out to you with some additional context

Please let us know the best #'s to reach you for a few min

Anand

PRE-DECISIONAL, CONFIDENTIAL

From: Shah, Anand
Sent: Monday, March 16, 2020 9:46 AM

To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Patel, Chaitali <Chaitali.Patel@fda.hhs.gov>; McLatchy, Johanna <Johanna.McLatchy@fda.hhs.gov>; Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>
Subject: FW: **(b)(5)**

PRE-DECISIONAL, CONFIDENTIAL

Dear Janet and Peter –

(b)(5) Stacy will also be sharing with the OCC team.

Thank you for prioritizing this review. I will need to provide HHS with comments by 5pm today.

Best,

Anand

From: Caccomo, Stephanie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=950C32CEBC4B4F80B302C50CF31C8524-STEPHANIE.C]
Sent: 3/18/2020 11:03:23 PM
To: 2019-nCoV FDA IMG JIC [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=289715a1146847558b07a33ccab6bccf-2019-nCoV F]; OCCRequests-COVID19 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcb756008a41407282a58324a7b5144a-OCCRequests]; 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]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]; 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]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]
Subject: QUICK TURN-AROUND: updated POTUS TPs, due by 6:30AM to HHS
Attachments: POTUS_TPS_11pm_FDA.docx

Updated TPs for POTUS press briefing tomorrow on therapeutics. CDER/CBER—can you look at quickly? I've added edits and a note on attached version. This is due to HHS by 6:30am. Thanks!

Press Conference on FDA Developments

(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: Cavazzoni, Patrizia [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C42ABD33834044ECBAA03D075CC0A5D2-PATRIZIA.CA]
Sent: 3/18/2020 11:22:26 PM
To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; 2019-nCoV FDA IMG JIC [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=289715a1146847558b07a33ccab6bccf-2019-nCoV F]; OCCRequests-COVID19 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcb756008a41407282a58324a7b5144a-OCCRequests]; 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]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; 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]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]
CC: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
Subject: RE: QUICK TURN-AROUND: updated POTUS TPs, due by 6:30AM to HHS
Attachments: POTUS_TPS_11pm_FDA_CDER.docx

I have substantive edits , see attached

Patrizia

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Wednesday, March 18, 2020 11:03 PM
To: 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>; OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: QUICK TURN-AROUND: updated POTUS TPs, due by 6:30AM to HHS

Updated TPs for POTUS press briefing tomorrow on therapeutics. CDER/CBER—can you look at quickly? I've added edits and a note on attached version. This is due to HHS by 6:30am. Thanks!

Press Conference on FDA Developments

(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: 3/19/2020 7:02:23 AM
To: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; 2019-nCoV FDA IMG JIC [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=289715a1146847558b07a33ccab6bccf-2019-nCoV F]; OCCRequests-COVID19 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcb756008a41407282a58324a7b5144a-OCCRequests]; 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]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]; 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]
Subject: RE: QUICK TURN-AROUND: updated POTUS TPs, due by 6:30AM to HHS

Got it 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: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Thursday, March 19, 2020 7:02 AM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>; OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>
Subject: RE: QUICK TURN-AROUND: updated POTUS TPs, due by 6:30AM to HHS

Dear Stephanie,

The situation for blood has changed somewhat, so updated that, including language that CDC and FDA agreed upon.

Best Regards,
Peter

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Wednesday, March 18, 2020 11:03 PM
To: 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>; OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: QUICK TURN-AROUND: updated POTUS TPs, due by 6:30AM to HHS

Updated TPs for POTUS press briefing tomorrow on therapeutics. CDER/CBER—can you look at quickly? I've added edits and a note on attached version. This is due to HHS by 6:30am. Thanks!

Press Conference on FDA Developments

(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: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 3/20/2020 12:34:10 PM
To: Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]
CC: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]
Subject: RE: Per our conversation ...

(b)(5)

(b)(5) Happy to help in talking to the press. jW

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Friday, March 20, 2020 12:23 PM
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Per our conversation ...

Hi Michael –

Thanks for sharing these potential questions. I've included Janet, Peter, and Jeff here for their thoughts. I agree it would be helpful for us to carefully think through these questions and, whenever possible, have a coordinated approach to incoming questions from stakeholders including media.

Anand

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Sent: Friday, March 20, 2020 12:18 PM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: Per our conversation ...

Thanks for the chat. Here are the questions I think we need to be prepared to answer on this topic. Feel free to add to this list and let me know if you want to relay to Janet or others.

(b)(5)

(b)(5)

Michael

Michael Felberbaum
Senior Advisor

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

From: Cavazzoni, Patrizia [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C42ABD33834044ECBAA03D075CC0A5D2-PATRIZIA.CA]
Sent: 3/21/2020 7:52:58 AM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; 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]; Edmonds, Amanda [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=232186a24a53474298d2760c060a4cc7-Amanda.Edmo]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
Subject: Re: Vaccine development idea

In case Sen.Daines' office insists to make contact directly, here is the contact information. Existence and description of the trials is publicly available as of this morning (we gave Roche-Genentech authorization to proceed yesterday).

Regeneron

phase 2/3 clinical program studying arthritis med Kevzara as a therapy for patients hospitalized with severe COVID-19, Sanofi said Monday.

Maya Bermingham
Vice President, Public Policy and Government Affairs
914-598-3031

Roche-Genentech

randomized, double-blind, placebo-controlled phase 3 clinical trial to study Actemra in hospitalized patients with severe COVID-19 pneumonia

Catherine Phillips
Director
919-308-1942

From: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Date: March 20, 2020 at 7:43:45 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>, Amin, Stacy <Stacy.Amin@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>, Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>, Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: Re: Vaccine development idea

This started when Peter suggested that we include monoclonals . They have a completely different purpose vs vaccines. We have already reached out to the Government Affairs contacts at Regeneron and Roche - Genentech to contact the Senator's office . The information on the IL-6 inhibitors is CCI, as opposed to vaccines which is apparently public .
Patrizia

From: Hahn, Stephen <SH1@fda.hhs.gov>
Date: March 20, 2020 at 7:07:53 PM EDT
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>, Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>, Amin, Stacy <Stacy.Amin@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>, Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>, Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: Re: Vaccine development idea

Very helpful. Thanks, Peter.
Patrizia, a similar list would be helpful for me to pass along to the Senator.
Steve

Sent from my iPad

On Mar 20, 2020, at 6:39 PM, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov> wrote:

Very helpful! Thank you Peter.

Patrizia, are you sending the same thing or just encouraging your firms to reach out to Daines?

Sent from my iPhone

On Mar 20, 2020, at 6:12 PM, Marks, Peter <Peter.Marks@fda.hhs.gov> wrote:

Dear Keagan,

Sorry – took a while to get permission from manufacturers. Just got the last one. Please see the attached and below. Just let me know if you need assistance talking to anyone over the weekend.

Best Regards,
Peter

ModernaTX, Inc.	mRNA-1273, a novel lipid-encapsulated mRNA-based prophylactic vaccine encoding the pre-fusion stabilized Spike (S) glycoprotein of the SARS-CoV-2 virus	Tal Zaks, MD Chief Medical Officer ModernaTX Inc Tal.zaks@modernatx.com | modernatx.com | mobile (b)(6)

(b)(4) (b)(5)

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Friday, March 20, 2020 5:47 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Cc: Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: RE: Vaccine development idea

Any update on vaccines?

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Friday, March 20, 2020 12:38 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Cc: Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: RE: Vaccine development idea

Dear Keagan,

Thanks. That sounds fine to me. I have a feeling that we will not have the vaccine information ready until late today, so we might need to have this call over the weekend.

Best Regards,
Peter

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Cc: Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
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Thank you all. Would like to make sure we are coordinated and understand what we are getting back to the Hill.

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Dear Keagan,

My vote is that we get more info, get it prepped for the hill and then touch bases if need be, or after it is reviewed on the hill to take care of questions.

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Peter and I spoke. We are going to take the same approach as CBER, ie reach out to Gov Affairs in the companies in question (monoclonals) and ask them that they reach out to Sen. Daines
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Subject: Re: Vaccine development idea

Should we hop on a call to discuss?

Sent from my iPhone

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We don't think this is a good idea.
Patrizia

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Subject: RE: Vaccine development idea

Dear Keagan,

Definitely would consider these! This is CDER's domain, so looping Patrizia in. (Patrizia – let me know when you have time and I can call you to loop you in.)

Best Regards,
Peter

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
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Subject: Re: Vaccine development idea

Peter- can you think through monoclonal antibodies as well, and if we should be exploring that avenue with the vaccines?

Sent from my iPhone

On Mar 20, 2020, at 9:08 AM, Marks, Peter <Peter.Marks@fda.hhs.gov> wrote:

Dear Commissioner and Amanda,

We are working on getting permission from the most promising 3-4 vaccine companies for permission to have the Senator or staffers to contact them. Expect this by the end of the day.

I remain available at any time if you need anything here.

Best Regards,
Peter

From: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Sent: Friday, March 20, 2020 9:06 AM
To: Hahn, Stephen <SH1@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>
Subject: Vaccine development idea

Commissioner – I have Amanda Edmonds working on this—Amanda is my best lawyer and will get this worked through with Peter. We agree it will require some creative leg writing.

Is the next step for us to connect with Sen Daines once we have an idea of how to do this?

Best,
Stacy

****

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

<SARS-CoV-2 vaccine manufacturers.docx>

From: Cavazzoni, Patrizia [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C42ABD33834044ECBAA03D075CC0A5D2-PATRIZIA.CA]
Sent: 3/21/2020 10:46:13 AM
To: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]
Subject: RE: Vaccine development idea

No problem .
Patrizia

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Date: March 21, 2020 at 10:20:34 AM EDT
To: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Subject: RE: Vaccine development idea

Dear Patrizia,

Sorry – did not mean to cause you headaches.

Best Regards,
Peter

From: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Sent: Friday, March 20, 2020 7:44 PM
To: Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: Re: Vaccine development idea

This started when Peter suggested that we include monoclonals . They have a completely different purpose vs vaccines. We have already reached out to the Government Affairs contacts at Regeneron and Roche - Genentech to contact the Senator's office . The information on the IL-6 inhibitors is CCI, as opposed to vaccines which is apparently public .
Patrizia

From: Hahn, Stephen <SH1@fda.hhs.gov>
Date: March 20, 2020 at 7:07:53 PM EDT
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>, Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>, Amin, Stacy <Stacy.Amin@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>, Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>, Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: Re: Vaccine development idea

Very helpful. Thanks, Peter.
Patrizia, a similar list would be helpful for me to pass along to the Senator.
Steve

Sent from my iPad

On Mar 20, 2020, at 6:39 PM, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov> wrote:

Very helpful! Thank you Peter.

Patrizia, are you sending the same thing or just encouraging your firms to reach out to Daines?

Sent from my iPhone

On Mar 20, 2020, at 6:12 PM, Marks, Peter <Peter.Marks@fda.hhs.gov> wrote:

Dear Keagan,

Sorry – took a while to get permission from manufacturers. Just got the last one. Please see the attached and below. Just let me know if you need assistance talking to anyone over the weekend.

Best Regards,
Peter

ModernaTX, Inc.	mRNA-1273, a novel lipid-encapsulated mRNA-based prophylactic vaccine encoding the pre-fusion stabilized Spike (S) glycoprotein of the SARS-CoV-2 virus	Tal Zaks, MD Chief Medical Officer ModernaTX Inc Tal.zaks@modernatx.com | modernatx.com | mobile **(b)(6)**

(b)(4) (b)(5)

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Friday, March 20, 2020 5:47 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Cc: Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: RE: Vaccine development idea

Any update on vaccines?

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Thanks. That sounds fine to me. I have a feeling that we will not have the vaccine information ready until late today, so we might need to have this call over the weekend.

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Commissioner – I have Amanda Edmonds working on this—Amanda is my best lawyer and will get this worked through with Peter. We agree it will require **(b)(5)**

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Best,
Stacy

****

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

<SARS-CoV-2 vaccine manufacturers.docx>

From: Gruber, Marion [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=019CD2669C7048F7A116D72B7682DE44-GRUBER]
Sent: 3/19/2020 9:08:46 AM
To: Hess, Maureen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=23ed9c01196f4765b89921c357f855f9-Hessma]
Subject: RE: COVID vaccines meeting -- request to post FDA statement

Ohh ☺

From: Hess, Maureen <Maureen.Hess@fda.hhs.gov>
Sent: Thursday, March 19, 2020 9:08 AM
To: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Subject: RE: COVID vaccines meeting -- request to post FDA statement

I guess that my sarcasm doesn't come across in email.

From: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Sent: Thursday, March 19, 2020 8:57 AM
To: Hess, Maureen <Maureen.Hess@fda.hhs.gov>
Subject: RE: COVID vaccines meeting -- request to post FDA statement

No, I do not think so.

From: Hess, Maureen <Maureen.Hess@fda.hhs.gov>
Sent: Thursday, March 19, 2020 8:30 AM
To: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Subject: RE: COVID vaccines meeting -- request to post FDA statement

Trump kept teasing in his press conference yesterday about something big/great that the FDA is doing, that he would announce today- maybe this is it!

From: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Sent: Thursday, March 19, 2020 8:02 AM
To: Hess, Maureen <Maureen.Hess@fda.hhs.gov>
Subject: FW: COVID vaccines meeting -- request to post FDA statement

FYI - There is a story to this that I can fill you in on by phone some time. **(b)(5)**
I will let you know if there is going to be an FDA statement. The Europe FDA office discussing right now.
Marion

From: Nalubola, Ritu <Ritu.Nalubola@fda.hhs.gov>
Sent: Thursday, March 19, 2020 7:32 AM
To: Riley, Karen <Karen.Riley@fda.hhs.gov>
Cc: Abdoo, Mark <Mark.Abdoo@fda.hhs.gov>; Ross, Bruce <Bruce.Ross@fda.hhs.gov>; Klein, Vashti * <Vashti.Klein@fda.hhs.gov>; Blair, Joan W. (CBER) <Joan.Blair@fda.hhs.gov>; Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Kweder, Sandra L <Sandra.Kweder@fda.hhs.gov>
Subject: COVID vaccines meeting -- request to post FDA statement

Hi Karen – Re: COVID vaccine global regulators meeting yesterday -- we'd like to do an FDA posting to piggy back on this EMA statement:

https://www.ema.europa.eu/en/news/first-regulatory-workshop-covid-19-facilitates-global-collaboration-vaccine-development

Peter Marks is fine with moving ahead with this as a joint EMA-FDA statement so I think best to use the same wording from EMA's statement.

I've copied CBER leads and they can help if any questions and also consider if you have other suggestions for PR. We'll definitely add a blurb in OGPS' next monthly distribution.

Thanks,
Ritu

From: Gruber, Marion [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=019CD2669C7048F7A116D72B7682DE44-GRUBER]
Sent: 3/19/2020 12:45:54 PM
To: Nalubola, Ritu [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3103228e5eba458f9c2aa1a846d25c7c-PNalubol]; 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]; Blair, Joan W. (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8cc3d088be164491a76b9ce048d71a02-BLAIR]
CC: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Abdoo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dca42e5f1795433c9df447f8f11bc80e-Mark.Abdoo]; Ross, Bruce [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4ae281dfd2164cb8959133dfe0026cee-Bruce.Ross]
Subject: RE: Vaccines meeting -- narrative for State Dept cable
Attachments: Vaccines meeting -Narrative for cable.docxclean.docx; Vaccines meeting -Narrative for cable.docx

Dear Ritu,
Please see attached document with track changes and a version of clean document. I have shortened taking out some of the details and tried to summarize (high level) main points discussed. This document needs probably to be tweaked a bit more by the communication experts. Happy to look at another version. Thank you for providing me with the opportunity to review.
Marion

From: Nalubola, Ritu <Ritu.Nalubola@fda.hhs.gov>
Sent: Thursday, March 19, 2020 10:38 AM
To: Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Louati, Claudia (FSN)* <Claudia.Louati@fda.hhs.gov>; Kweder, Sandra L <Sandra.Kweder@fda.hhs.gov>; Blair, Joan W. (CBER) <Joan.Blair@fda.hhs.gov>
Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>; Abdoo, Mark <Mark.Abdoo@fda.hhs.gov>; Ross, Bruce <Bruce.Ross@fda.hhs.gov>
Subject: Vaccines meeting -- narrative for State Dept cable

Hi all – Attached first stab at write up intended for use by front office in drafting the State Dept cable. Please review and send comments by COB today your time. Marion, I relied heavily on the summary notes that you are working on with Marco. Please feel free to edit/rewrite as you see fit. It is very technical and if you can make it less so, that would be great.

DCA wants to be able to send out cable tomorrow COB here. Just FYI, State Dept cables have a wide distribution but still internal USG.

(Peter – we can share a near final version if you want to hold off – or you can review this now. I defer to you and Marion.)

Thanks,
Ritu

Ritu Nalubola, Ph.D.
Director, Europe Office
U.S. Food and Drug Administration

U.S. Mission to the European Union
Boulevard du Regent 40
B-1000 Brussels, Belgium
Phone: +32-2-811-5733
Mobile: (b)(6)
Email: Ritu.Nalubola@fda.hhs.gov

U.S. FOOD & DRUG ADMINISTRATION

From: Gruber, Marion [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=019CD2669C7048F7A116D72B7682DE44-GRUBER]
Sent: 3/19/2020 12:55:14 PM
To: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; McNeill, Lorrie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77b0b352c9c24851bf0c7330f53e00d9-McNeill]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Maloney, Diane [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e59205500e944c9eacc4524ea18ed5bb-MaloneyD]; Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Rouse, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=185bae767862490d88eda44db74a75b3-RouseD]; Blair, Joan W. (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8cc3d088be164491a76b9ce048d71a02-BLAIR]
CC: Frantz-Bohn, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4c4a10821c774ffa9c5cf59bda6bcf75-frantz_bohn]; Bartell, Diane [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e9ea8198fc524f22a73af02438cba1c5-Bartell]; Richards, Paul [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=04b2b41d286c4c12b60b827b5fb0c96c-richards]; Hess, Maureen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=23ed9c01196f4765b89921c357f855f9-Hessma]; Nalubola, Ritu [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3103228e5eba458f9c2aa1a846d25c7c-PNalubol]
Subject: RE: Statement/Communication requested about COVID Vaccine meeting
Attachments: Vaccines meeting -Narrative for cable.docxclean.docx

All,
As discussed below, this is the draft for the State Dept. cable. I just sent my revisions back to Ritu and I am attaching a clean version for your considerations. If we want to do some sort of public statement the remaining technical aspects in this document could probably be taken out.
Marion

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Thursday, March 19, 2020 9:24 AM
To: Gruber, Marion <Marion.Gruber@fda.hhs.gov>; McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Maloney, Diane <Diane.Maloney@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Rouse, David <David.Rouse@fda.hhs.gov>; Blair, Joan W. (CBER) <Joan.Blair@fda.hhs.gov>
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Subject: RE: Statement/Communication requested about COVID Vaccine meeting

Dear All,

I support Marion's approach here.

Best Regards,
Peter

From: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Sent: Thursday, March 19, 2020 8:48 AM

To: McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Maloney, Diane <Diane.Maloney@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Rouse, David <David.Rouse@fda.hhs.gov>; Blair, Joan W. (CBER) <Joan.Blair@fda.hhs.gov>
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Subject: COVID vaccines meeting -- request to post FDA statement

Hi Karen – Re: COVID vaccine global regulators meeting yesterday -- we'd like to do an FDA posting to piggy back on this EMA statement:

https://www.ema.europa.eu/en/news/first-regulatory-workshop-covid-19-facilitates-global-collaboration-vaccine-development

Peter Marks is fine with moving ahead with this as a joint EMA-FDA statement so I think best to use the same wording from EMA's statement.

I've copied CBER leads and they can help if any questions and also consider if you have other suggestions for PR. We'll definitely add a blurb in OGPS' next monthly distribution.

Thanks,
Ritu

From: Gruber, Marion [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=019CD2669C7048F7A116D72B7682DE44-GRUBER]
Sent: 3/19/2020 4:34:36 PM
To: Nalubola, Ritu [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3103228e5eba458f9c2aa1a846d25c7c-PNalubol]; 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]; Blair, Joan W. (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8cc3d088be164491a76b9ce048d71a02-BLAIR]
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Subject: RE: Vaccines meeting -- narrative for State Dept cable
Attachments: Vaccines meeting -Narrative for cable-clean-EO.docxMFG 031920.docx

Dear all,
Here are my further revisions and comments.
Marion

From: Nalubola, Ritu <Ritu.Nalubola@fda.hhs.gov>
Sent: Thursday, March 19, 2020 2:38 PM
To: Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Louati, Claudia (FSN)* <Claudia.Louati@fda.hhs.gov>; Kweder, Sandra L <Sandra.Kweder@fda.hhs.gov>; Blair, Joan W. (CBER) <Joan.Blair@fda.hhs.gov>
Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>; Abdoo, Mark <Mark.Abdoo@fda.hhs.gov>; Ross, Bruce <Bruce.Ross@fda.hhs.gov>
Subject: RE: Vaccines meeting -- narrative for State Dept cable

Many thanks, Marion! Sandy, Claudia, and I made just a few more changes for context and plain-language. All of our input is tracked – please see attached and add any further changes.

Dear Peter – This version is ready for your review. Please send any input by end today, if at all possible. Or just let us know if you don't plan on reviewing. Thanks!

Best regards,
Ritu

From: Gruber, Marion
Sent: Thursday, March 19, 2020 5:46 PM
To: Nalubola, Ritu <Ritu.Nalubola@fda.hhs.gov>; Louati, Claudia (FSN)* <Claudia.Louati@fda.hhs.gov>; Kweder, Sandra L <Sandra.Kweder@fda.hhs.gov>; Blair, Joan W. (CBER) <Joan.Blair@fda.hhs.gov>
Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>; Abdoo, Mark <Mark.Abdoo@fda.hhs.gov>; Ross, Bruce <Bruce.Ross@fda.hhs.gov>
Subject: RE: Vaccines meeting -- narrative for State Dept cable

Dear Ritu,
Please see attached document with track changes and a version of clean document. I have shortened taking out some of the details and tried to summarize (high level) main points discussed. This document needs probably to

be tweaked a bit more by the communication experts. Happy to look at another version. Thank you for providing me with the opportunity to review.
Marion

From: Nalubola, Ritu <Ritu.Nalubola@fda.hhs.gov>
Sent: Thursday, March 19, 2020 10:38 AM
To: Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Louati, Claudia (FSN)* <Claudia.Louati@fda.hhs.gov>; Kweder, Sandra L <Sandra.Kweder@fda.hhs.gov>; Blair, Joan W. (CBER) <Joan.Blair@fda.hhs.gov>
Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>; Abdoo, Mark <Mark.Abdoo@fda.hhs.gov>; Ross, Bruce <Bruce.Ross@fda.hhs.gov>
Subject: Vaccines meeting -- narrative for State Dept cable

Hi all – Attached first stab at write up intended for use by front office in drafting the State Dept cable. Please review and send comments by COB today your time. Marion, I relied heavily on the summary notes that you are working on with Marco. Please feel free to edit/rewrite as you see fit. It is very technical and if you can make it less so, that would be great.

DCA wants to be able to send out cable tomorrow COB here. Just FYI, State Dept cables have a wide distribution but still internal USG.

(Peter – we can share a near final version if you want to hold off – or you can review this now. I defer to you and Marion.)

Thanks,
Ritu

Ritu Nalubola, Ph.D.
Director, Europe Office
U.S. Food and Drug Administration
U.S. Mission to the European Union
Boulevard du Regent 40
B-1000 Brussels, Belgium
Phone: +32-2-811-5733
Mobile: (b)(6)
Email: Ritu.Nalubola@fda.hhs.gov

From: Maloney, Diane [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E59205500E944C9EACC4524EA18ED5BB-MALONEYD]
Sent: 3/19/2020 4:49:37 PM
To: Gruber, Marion [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=019cd2669c7048f7a116d72b7682de44-gruber]; McNeill, Lorrie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77b0b352c9c24851bf0c7330f53e00d9-McNeill]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Rouse, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=185bae767862490d88eda44db74a75b3-RouseD]; Blair, Joan W. (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8cc3d088be164491a76b9ce048d71a02-BLAIR]
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Attachments: Vaccines meeting -Narrative for cable.docxredlineaccepteddm.docx; Vaccines meeting -Narrative for cable.docxcleandm.docx

Hi Marion,
Thanks so much for your work on this. my understanding is that this would be used as a summary of the meeting. Is that correct? That's what I considered as I reviewed it. Please see my suggested edits – given in the spirit of trying to help. the first document is somewhat clean (I revised some of the narrative and made additional changes but left my comments in the margin). The second one is the redline. I may have introduced inaccuracies inadvertently.

If I can help at all, just let me know.
Thanks,
Diane

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Sent: Thursday, March 19, 2020 8:48 AM
To: McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Maloney, Diane <Diane.Maloney@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Rouse, David <David.Rouse@fda.hhs.gov>; Blair, Joan W. (CBER) <Joan.Blair@fda.hhs.gov>
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Sent: 3/19/2020 4:58:15 PM
To: Hess, Maureen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=23ed9c01196f4765b89921c357f855f9-Hessma]
Subject: RE: Statement/Communication requested about COVID Vaccine meeting

Give me 20 min, I send something revised then.

From: Hess, Maureen <Maureen.Hess@fda.hhs.gov>
Sent: Thursday, March 19, 2020 4:53 PM
To: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Subject: RE: Statement/Communication requested about COVID Vaccine meeting

Do you want me to try to flesh this out more- the intro, stuff like that?

Maureen

From: Maloney, Diane <Diane.Maloney@fda.hhs.gov>
Sent: Thursday, March 19, 2020 4:50 PM
To: Gruber, Marion <Marion.Gruber@fda.hhs.gov>; McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Rouse, David <David.Rouse@fda.hhs.gov>; Blair, Joan W. (CBER) <Joan.Blair@fda.hhs.gov>
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Sent: Thursday, March 19, 2020 7:32 AM
To: Riley, Karen <Karen.Riley@fda.hhs.gov>
Cc: Abdoo, Mark <Mark.Abdoo@fda.hhs.gov>; Ross, Bruce <Bruce.Ross@fda.hhs.gov>; Klein, Vashti * <Vashti.Klein@fda.hhs.gov>; Blair, Joan W. (CBER) <Joan.Blair@fda.hhs.gov>; Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Kweder, Sandra L <Sandra.Kweder@fda.hhs.gov>
Subject: COVID vaccines meeting -- request to post FDA statement

Hi Karen – Re: COVID vaccine global regulators meeting yesterday -- we'd like to do an FDA posting to piggy back on this EMA statement:

https://www.ema.europa.eu/en/news/first-regulatory-workshop-covid-19-facilitates-global-collaboration-vaccine-development

Peter Marks is fine with moving ahead with this as a joint EMA-FDA statement so I think best to use the same wording from EMA's statement.

I've copied CBER leads and they can help if any questions and also consider if you have other suggestions for PR. We'll definitely add a blurb in OGPS' next monthly distribution.

Thanks,
Ritu

From: Louati, Claudia (FSN)* [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C682E89FFBB049C6BE95D65E2EEB04EB-CLAUDIA.LOU]
Sent: 3/20/2020 7:04:53 AM
To: Gruber, Marion [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=019cd2669c7048f7a116d72b7682de44-gruber]; Cavaleri Marco [Marco.Cavaleri@ema.europa.eu]
CC: Nalubola, Ritu [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3103228e5eba458f9c2aa1a846d25c7c-PNalubol]
Subject: RE: March 18 Global regulators meeting summary finaL
Attachments: March 18 Global regulators meeting summary_final.pdf

Yes, we have a final document and a final email ☺ I will send within the next 30 minutes. Thank you all for your help and the great communication!
Best,
Claudia

From: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Sent: Friday, March 20, 2020 12:01 PM
To: Louati, Claudia (FSN)* <Claudia.Louati@fda.hhs.gov>; Cavaleri Marco <Marco.Cavaleri@ema.europa.eu>
Cc: Nalubola, Ritu <Ritu.Nalubola@fda.hhs.gov>
Subject: RE: March 18 Global regulators meeting summary finaL

You saw my very latest email, right?

From: Louati, Claudia (FSN)* <Claudia.Louati@fda.hhs.gov>
Sent: Friday, March 20, 2020 6:49 AM
To: Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Cavaleri Marco <Marco.Cavaleri@ema.europa.eu>
Cc: Nalubola, Ritu <Ritu.Nalubola@fda.hhs.gov>
Subject: RE: March 18 Global regulators meeting summary finaL

I will pdf to discourage track changes. I guess I'm still waiting for Agnes' feedback before sending, right, Marco?

From: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Sent: Friday, March 20, 2020 11:47 AM
To: Cavaleri Marco <Marco.Cavaleri@ema.europa.eu>
Cc: Louati, Claudia (FSN)* <Claudia.Louati@fda.hhs.gov>; Nalubola, Ritu <Ritu.Nalubola@fda.hhs.gov>
Subject: RE: March 18 Global regulators meeting summary finaL

Changes accepted.

From: Cavaleri Marco <Marco.Cavaleri@ema.europa.eu>
Sent: Friday, March 20, 2020 3:47 AM
To: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Cc: Louati, Claudia (FSN)* <Claudia.Louati@fda.hhs.gov>; Nalubola, Ritu <Ritu.Nalubola@fda.hhs.gov>
Subject: March 18 Global regulators meeting summary finaL

Thanks Marion, excellent

A couple of very minor suggestions
Marco

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This e-mail has been scanned for all known viruses by European Medicines Agency.

From: Nalubola, Ritu [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3103228E5EBA458F9C2AA1A846D25C7C-PNALUBOL]
Sent: 3/20/2020 8:00:01 AM
To: Gruber, Marion [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=019cd2669c7048f7a116d72b7682de44-gruber]; 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]; Blair, Joan W. (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8cc3d088be164491a76b9ce048d71a02-BLAIR]
CC: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Abdoo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dca42e5f1795433c9df447f8f11bc80e-Mark.Abdoo]; Ross, Bruce [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4ae281dfd2164cb8959133dfe0026cee-Bruce.Ross]
Subject: RE: Vaccines meeting -- narrative for State Dept cable
Attachments: Vaccines meeting-Draft cable-3.20.20- (Baker Henry N (USEU)).docx

Thanks, Marion. I edited out the sections **(b)(5)**
Others here review/add from broader USEU lens and make it into a cable form without harming our technical input – standard cable drafting and clearance process.
Attached is the near-final form. I'll send the final when it's issued.
Best regards,
Ritu

From: Gruber, Marion
Sent: Thursday, March 19, 2020 9:35 PM
To: Nalubola, Ritu <Ritu.Nalubola@fda.hhs.gov>; Louati, Claudia (FSN)* <Claudia.Louati@fda.hhs.gov>; Kweder, Sandra L <Sandra.Kweder@fda.hhs.gov>; Blair, Joan W. (CBER) <Joan.Blair@fda.hhs.gov>
Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>; Abdoo, Mark <Mark.Abdoo@fda.hhs.gov>; Ross, Bruce <Bruce.Ross@fda.hhs.gov>
Subject: RE: Vaccines meeting -- narrative for State Dept cable

Dear all,
Here are my further revisions and comments.
Marion

From: Nalubola, Ritu <Ritu.Nalubola@fda.hhs.gov>
Sent: Thursday, March 19, 2020 2:38 PM
To: Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Louati, Claudia (FSN)* <Claudia.Louati@fda.hhs.gov>; Kweder, Sandra L <Sandra.Kweder@fda.hhs.gov>; Blair, Joan W. (CBER) <Joan.Blair@fda.hhs.gov>
Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>; Abdoo, Mark <Mark.Abdoo@fda.hhs.gov>; Ross, Bruce <Bruce.Ross@fda.hhs.gov>
Subject: RE: Vaccines meeting -- narrative for State Dept cable

Many thanks, Marion! Sandy, Claudia, and I made just a few more changes for context and plain-language. All of our input is tracked – please see attached and add any further changes.

Dear Peter – This version is ready for your review. Please send any input by end today, if at all possible. Or just let us know if you don't plan on reviewing. Thanks!

Best regards,
Ritu

From: Gruber, Marion
Sent: Thursday, March 19, 2020 5:46 PM
To: Nalubola, Ritu <Ritu.Nalubola@fda.hhs.gov>; Louati, Claudia (FSN)* <Claudia.Louati@fda.hhs.gov>; Kweder, Sandra L <Sandra.Kweder@fda.hhs.gov>; Blair, Joan W. (CBER) <Joan.Blair@fda.hhs.gov>
Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>; Abdoo, Mark <Mark.Abdoo@fda.hhs.gov>; Ross, Bruce <Bruce.Ross@fda.hhs.gov>
Subject: RE: Vaccines meeting -- narrative for State Dept cable

Dear Ritu,
Please see attached document with track changes and a version of clean document. I have shortened taking out some of the details and tried to summarize (high level) main points discussed. This document needs probably to be tweaked a bit more by the communication experts. Happy to look at another version. Thank you for providing me with the opportunity to review.
Marion

From: Nalubola, Ritu <Ritu.Nalubola@fda.hhs.gov>
Sent: Thursday, March 19, 2020 10:38 AM
To: Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Louati, Claudia (FSN)* <Claudia.Louati@fda.hhs.gov>; Kweder, Sandra L <Sandra.Kweder@fda.hhs.gov>; Blair, Joan W. (CBER) <Joan.Blair@fda.hhs.gov>
Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>; Abdoo, Mark <Mark.Abdoo@fda.hhs.gov>; Ross, Bruce <Bruce.Ross@fda.hhs.gov>
Subject: Vaccines meeting -- narrative for State Dept cable

Hi all – Attached first stab at write up intended for use by front office in drafting the State Dept cable. Please review and send comments by COB today your time. Marion, I relied heavily on the summary notes that you are working on with Marco. Please feel free to edit/rewrite as you see fit. It is very technical and if you can make it less so, that would be great.

DCA wants to be able to send out cable tomorrow COB here. Just FYI, State Dept cables have a wide distribution but still internal USG.

(Peter – we can share a near final version if you want to hold off – or you can review this now. I defer to you and Marion.)

Thanks,
Ritu

Ritu Nalubola, Ph.D.
Director, Europe Office
U.S. Food and Drug Administration
U.S. Mission to the European Union
Boulevard du Regent 40
B-1000 Brussels, Belgium
Phone: +32-2-811-5733
Mobile: (b)(6)
Email: Ritu.Nalubola@fda.hhs.gov

From: Gruber, Marion [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=019CD2669C7048F7A116D72B7682DE44-GRUBER]
Sent: 3/20/2020 11:46:41 AM
To: McNeill, Lorrie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77b0b352c9c24851bf0c7330f53e00d9-McNeill]
CC: Maloney, Diane [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e59205500e944c9eacc4524ea18ed5bb-MaloneyD]; Hess, Maureen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=23ed9c01196f4765b89921c357f855f9-Hessma]
Subject: RE: Vaccines mtg -- comms heads-up
Attachments: March 18 Global regulators meeting summary finaL.docx; FDA communication regarding March 18 Global regulators meeting.docx; Vaccines meeting-Draft cable-3.20.20- (Baker Henry N (USEU)).docx

Dear Lorrie,
As per our discussions, please see attached the March 18 Global regulators meeting summary that is to be posted by ICMRA, EMA and FDA (EMA wants to post early next week and there is some urgency as regulators want to have that document). The "FDA communications regarding.. "document I wrote yesterday to be used as a potential FDA PR or to serve as communication to be postet together with key bullets. I am also attaching the State Dept. cable.
Marion

From: McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>
Sent: Friday, March 20, 2020 11:16 AM
To: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Subject: RE: Vaccines mtg -- comms heads-up

Hi Marion – I have about 5 minutes before I have to jump on a call – 301-412-0976

From: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Sent: Friday, March 20, 2020 11:15 AM
To: McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>
Subject: RE: Vaccines mtg -- comms heads-up

Lorrie, can I briefly call you?? What number?

From: McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>
Sent: Friday, March 20, 2020 10:38 AM
To: Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Riley, Karen <Karen.Riley@fda.hhs.gov>; Nalubola, Ritu <Ritu.Nalubola@fda.hhs.gov>; Blair, Joan W. (CBER) <Joan.Blair@fda.hhs.gov>
Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>; Louati, Claudia (FSN)* <Claudia.Louati@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Maloney, Diane <Diane.Maloney@fda.hhs.gov>
Subject: RE: Vaccines mtg -- comms heads-up

There are so many different email strings, I think we need to pull this back together and get everyone on the same page. I believe we were thinking about taking the document Marion drafted and turn that into some type of agency statement? If that's not the case, please let me know. We will need to clear it in both of our organizations, then it will have to go through agency clearance per the current process. I'm happy to coordinate that, but we really need to make sure we're all on board and not working at cross purposes.

Lorrie

From: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Sent: Friday, March 20, 2020 10:33 AM
To: Riley, Karen <Karen.Riley@fda.hhs.gov>; Nalubola, Ritu <Ritu.Nalubola@fda.hhs.gov>; Blair, Joan W. (CBER) <Joan.Blair@fda.hhs.gov>; McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>
Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>; Louati, Claudia (FSN)* <Claudia.Louati@fda.hhs.gov>
Subject: RE: Vaccines mtg -- comms heads-up

Why are we not taking the text I wrote and do our own posting?
Marion

From: Riley, Karen <Karen.Riley@fda.hhs.gov>
Sent: Friday, March 20, 2020 10:32 AM
To: Nalubola, Ritu <Ritu.Nalubola@fda.hhs.gov>; Blair, Joan W. (CBER) <Joan.Blair@fda.hhs.gov>; McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>
Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>; Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Louati, Claudia (FSN)* <Claudia.Louati@fda.hhs.gov>
Subject: RE: Vaccines mtg -- comms heads-up

+ McNeill
Looks like the EMA will be writing a press release to reference this summary document. If so, we can readily point to that on Twitter and can also post the release on our website. Lorrie, other ideas?

From: Nalubola, Ritu <Ritu.Nalubola@fda.hhs.gov>
Sent: Friday, March 20, 2020 10:23 AM
To: Blair, Joan W. (CBER) <Joan.Blair@fda.hhs.gov>; Riley, Karen <Karen.Riley@fda.hhs.gov>
Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>; Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Louati, Claudia (FSN)* <Claudia.Louati@fda.hhs.gov>
Subject: Vaccines mtg -- comms heads-up

Internal FDA only.

Hi Joan – I'm sharing below as a heads-up with Karen Riley from OGPS side.

Mission wants to do their own public sharing after the next round of FDA posting so we'll just stay tuned for when that occurs.

Thanks,
Ritu

From: Saint Raymond Agnes <Agnes.Saint-Raymond@ema.europa.eu>
Sent: Friday, March 20, 2020 2:08 PM
To: Blair, Joan W. (CBER) <Joan.Blair@fda.hhs.gov>; Heine Marie-Agnes <Marie-Agnes.Heine@ema.europa.eu>; Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Cavaleri Marco <Marco.Cavaleri@ema.europa.eu>
Cc: Louati, Claudia (FSN)* <Claudia.Louati@fda.hhs.gov>; Nalubola, Ritu <Ritu.Nalubola@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: RE: March 18 Global regulators meeting summary finaL (002)

Dear Joan
Our Communication Department intends to accompany the summary with a 'press release', which I think fits with what you have in mind and what Marion had produced yesterday. We will share when it's ready (thanks to my colleagues!)
Kind regards

Dr Agnès Saint-Raymond
Head of Division
+31 (0)88781 7017
Office 17-S-27

International Affairs | European Medicines Agency
Agnès Saint-Raymond | Riccardo Luigetti | Elena Mezquita González | Magdalena Pajewska | Tânia Teixeira
Sandra Gogo | Christoph Hasslböck | Clément Lagalice

Domenico Scarlattilaan 6 | 1083 HS Amsterdam | The Netherlands

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From: Blair, Joan W. (CBER) <Joan.Blair@fda.hhs.gov>
Sent: 20 March 2020 13:58
To: Heine Marie-Agnes <Marie-Agnes.Heine@ema.europa.eu>; Saint Raymond Agnes <Agnes.Saint-Raymond@ema.europa.eu>; Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Cavaleri Marco <Marco.Cavaleri@ema.europa.eu>
Cc: Louati, Claudia (FSN)* <Claudia.Louati@fda.hhs.gov>; Nalubola, Ritu <Ritu.Nalubola@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: RE: March 18 Global regulators meeting summary finaL (002)

I may have been unclear, and my assumption may be wrong. What I am referencing in terms of narrative is perhaps any opening, contextual narrative that leads into the summary. If no one plans to have any, that's fine.

From: Blair, Joan W. (CBER)
Sent: Friday, March 20, 2020 8:38 AM
To: Heine Marie-Agnes <Marie-Agnes.Heine@ema.europa.eu>; Saint Raymond Agnes <Agnes.Saint-Raymond@ema.europa.eu>; Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Cavaleri Marco <Marco.Cavaleri@ema.europa.eu>
Cc: Louati, Claudia (FSN)* <Claudia.Louati@fda.hhs.gov>; Nalubola, Ritu <Ritu.Nalubola@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: RE: March 18 Global regulators meeting summary finaL (002)

Will EMA write the first draft of the narrative around the meeting summary that would be posted on the ICMRA site and the EMA site? FDA would like to align as possible so would appreciate learning of any proposed language. Thank you! - Joan

---

From: Heine Marie-Agnes <Marie-Agnes.Heine@ema.europa.eu>
Sent: Friday, March 20, 2020 7:30 AM
To: Saint Raymond Agnes <Agnes.Saint-Raymond@ema.europa.eu>; Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Cavaleri Marco <Marco.Cavaleri@ema.europa.eu>
Cc: Louati, Claudia (FSN)* <Claudia.Louati@fda.hhs.gov>; Nalubola, Ritu <Ritu.Nalubola@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Blair, Joan W. (CBER) <Joan.Blair@fda.hhs.gov>
Subject: RE: March 18 Global regulators meeting summary finaL (002)

Thanks to all of you.
Monday, would be the better option to get more visibility.

Best wishes

Marie-Agnes

Marie-Agnes Heine
Head
Communication Department
Stakeholders & Communication Division

Office 16-N-24 | Ext. 7805 | Mobile +31650089390

From: Saint Raymond Agnes <Agnes.Saint-Raymond@ema.europa.eu>
Sent: 20 March 2020 12:28
To: Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Cavaleri Marco <Marco.Cavaleri@ema.europa.eu>; Heine Marie-Agnes <Marie-Agnes.Heine@ema.europa.eu>
Cc: Louati, Claudia (FSN)* <Claudia.Louati@fda.hhs.gov>; Nalubola, Ritu <Ritu.Nalubola@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Blair, Joan W. (CBER) <Joan.Blair@fda.hhs.gov>
Subject: RE: March 18 Global regulators meeting summary finaL (002)

Perfect! What timeframe for the publication would you consider? Next Monday to get more attention? Or as early as possible (Marie-Agnes?)

Dr Agnès Saint-Raymond
Head of Division
+31 (0)88781 7017
Office 17-S-27

International Affairs | European Medicines Agency
Agnès Saint-Raymond | Riccardo Luigetti | Elena Mezquita González | Magdalena Pajewska | Tânia Teixeira
Sandra Gogo | Christoph Hasslböck | Clément Lagalice

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From: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Sent: 20 March 2020 12:26
To: Saint Raymond Agnes <Agnes.Saint-Raymond@ema.europa.eu>; Cavaleri Marco <Marco.Cavaleri@ema.europa.eu>; Heine Marie-Agnes <Marie-Agnes.Heine@ema.europa.eu>
Cc: Louati, Claudia (FSN)* <Claudia.Louati@fda.hhs.gov>; Nalubola, Ritu <Ritu.Nalubola@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Blair, Joan W. (CBER) <Joan.Blair@fda.hhs.gov>
Subject: RE: March 18 Global regulators meeting summary finaL (002)

Dear Agnes,
I have discussed this with Marco and others and we were not expecting comments. We tried to word the summary carefully as to not imply a consensus agreement but we feel rather strongly that there was broad agreement on the key points documented. That being said, if particular NRAs have questions we would be happy to engage in discussions. A simultaneous publication on ICMRA, FDA and EMA website would be ideal from my perspective. I have copied Peter and Joan on this email.
Marion

From: Saint Raymond Agnes <Agnes.Saint-Raymond@ema.europa.eu>
Sent: Friday, March 20, 2020 7:12 AM
To: Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Cavaleri Marco <Marco.Cavaleri@ema.europa.eu>; Heine Marie-Agnes <Marie-Agnes.Heine@ema.europa.eu>
Cc: Louati, Claudia (FSN)* <Claudia.Louati@fda.hhs.gov>; Nalubola, Ritu <Ritu.Nalubola@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Blair, Joan W. (CBER) <Joan.Blair@fda.hhs.gov>
Subject: RE: March 18 Global regulators meeting summary finaL (002)

Thank you Marion
I am copying Marie-Agnes as Head of our communication team. They will prepare a text 'from ICMRA' for the website and let us know. Then when the participants have seen the summary, do you expect them to agree? Do we need a deadline for them or do we not expect any comment?
I would suggest then a simultaneous publication on ICMRA, FDA and EMA websites? Is this possible for FDA and do you agree?
Kind regards

Dr Agnès Saint-Raymond
Head of Division
+31 (0)88781 7017
Office 17-S-27

EMA 25 years
International Affairs | **European Medicines Agency**
Agnès Saint-Raymond | Riccardo Luigetti | Elena Mezquita González | Magdalena Pajewska | Tânia Teixeira
Sandra Gogo | Christoph Hasslböck | Clément Lagalice

Domenico Scarlattilaan 6 | 1083 HS Amsterdam | The Netherlands

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From: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Sent: 20 March 2020 12:00
To: Cavaleri Marco <Marco.Cavaleri@ema.europa.eu>; Saint Raymond Agnes <Agnes.Saint-Raymond@ema.europa.eu>
Cc: Louati, Claudia (FSN)* <Claudia.Louati@fda.hhs.gov>; Nalubola, Ritu <Ritu.Nalubola@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Blair, Joan W. (CBER) <Joan.Blair@fda.hhs.gov>
Subject: RE: March 18 Global regulators meeting summary finaL (002)

Dear all,
Thank you for your helpful comments and revisions to this document. I have updated and considered all revisions but had to reject some, in particular in the introduction. Please see attached the FINAL version of this document.
Thank you for your input.
Sincerely,
Marion

From: Cavaleri Marco <Marco.Cavaleri@ema.europa.eu>
Sent: Friday, March 20, 2020 5:33 AM
To: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Subject: March 18 Global regulators meeting summary finaL (002)

Hi Marion, here are comments from Agnes.

Marco

Classified as internal/staff & contractors by the European Medicines Agency

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Sent: 3/20/2020 5:33:48 PM
To: Riley, Karen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9941d592a1354b74be835c6288542ed5-Karen.Riley]; McNeill, Lorrie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77b0b352c9c24851bf0c7330f53e00d9-McNeill]; Nalubola, Ritu [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3103228e5eba458f9c2aa1a846d25c7c-PNalubol]; Louati, Claudia (FSN)* [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c682e89ffbb049c6be95d65e2eeb04eb-Claudia.Lou]
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Subject: RE: Draft FDA Voices - ICMRA Meeting
Attachments: 20200320_FDA Voices - March 18 Global regulators meetingkr.docx

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If you have any questions, please let me know. Thank you in advance!

Best –

Lorrie

Lorrie H. McNeill
Director

Office of Communication, Outreach and Development
Center for Biologics Evaluation and Research
U.S. Food and Drug Administration
Tel: 240-402-8119
lorrie.mcneill@fda.hhs.gov

From: McNeill, Lorrie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=77B0B352C9C24851BF0C7330F53E00D9-MCNEILL]
Sent: 3/20/2020 5:44:21 PM
To: Gruber, Marion [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=019cd2669c7048f7a116d72b7682de44-gruber]; Riley, Karen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9941d592a1354b74be835c6288542ed5-Karen.Riley]; Nalubola, Ritu [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3103228e5eba458f9c2aa1a846d25c7c-PNalubol]; Louati, Claudia (FSN)* [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c682e89ffbb049c6be95d65e2eeb04eb-Claudia.Lou]
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Sent: 3/20/2020 6:03:42 PM
To: McNeill, Lorrie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77b0b352c9c24851bf0c7330f53e00d9-McNeill]; Riley, Karen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9941d592a1354b74be835c6288542ed5-Karen.Riley]; Gruber, Marion [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=019cd2669c7048f7a116d72b7682de44-gruber]; Nalubola, Ritu [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3103228e5eba458f9c2aa1a846d25c7c-PNalubol]; Louati, Claudia (FSN)* [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c682e89ffbb049c6be95d65e2eeb04eb-Claudia.Lou]
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Subject: RE: Draft FDA Voices - ICMRA Meeting
Attachments: 20200320_FDA Voices - March 18 Global regulators meeting (1).docx

Dear All,

I tried to address some of Karen's concerns in the attached. Hopefully, we can quickly settle on something.

We need to stop wasting too much time on this in the middle of our response to the most challenging global public health crisis of our lifetimes.

From: McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>
Sent: Friday, March 20, 2020 5:58 PM
To: Riley, Karen <Karen.Riley@fda.hhs.gov>; Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Nalubola, Ritu <Ritu.Nalubola@fda.hhs.gov>; Louati, Claudia (FSN)* <Claudia.Louati@fda.hhs.gov>
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Subject: RE: Draft FDA Voices - ICMRA Meeting

Understood. But so you're aware, the instructions I received (in order to speed clearance) were to keep short and sweet.

From: Riley, Karen <Karen.Riley@fda.hhs.gov>
Sent: Friday, March 20, 2020 5:52 PM
To: McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>; Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Nalubola, Ritu <Ritu.Nalubola@fda.hhs.gov>; Louati, Claudia (FSN)* <Claudia.Louati@fda.hhs.gov>
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This article will be read by nonscientists. Readers can't be expected to be familiar with the vaccine development process. That should be explained so they can understand the significance of this first meeting. An FDA Voice is not a press release, it is the opportunity to use a news peg to explain something. Also, the first mention of the Phase 1 trial is confusing. Has this happened?

From: McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>
Sent: Friday, March 20, 2020 5:44 PM
To: Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Riley, Karen <Karen.Riley@fda.hhs.gov>; Nalubola, Ritu <Ritu.Nalubola@fda.hhs.gov>; Louati, Claudia (FSN)* <Claudia.Louati@fda.hhs.gov>
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Lorrie

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Sent: 3/23/2020 8:09:44 AM
To: Nalubola, Ritu [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3103228e5eba458f9c2aa1a846d25c7c-PNalubol]; Gruber, Marion [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=019cd2669c7048f7a116d72b7682de44-gruber]
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Subject: RE: Vaccines mtg PR
Attachments: 20200320_FDA Voices - March 18 Global regulators meeting FINAL.docx

Good morning, Ritu and Marion –

Attached is the OCC-cleared version of the FDA Voices draft. Unless there are any show-stoppers, I will work with the JIC and OEA on next steps for posting. The target for posting the piece is today.

Thanks very much in advance –

Lorrie

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Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>; Blair, Joan W. (CBER) <Joan.Blair@fda.hhs.gov>; Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Louati, Claudia (FSN)* <Claudia.Louati@fda.hhs.gov>
Subject: Vaccines mtg PR

Hi Lorrie, Karen – Wondering if we're still on for today release of the additional details about the workshop, plus FDA Voices statement.
Please send me the weblinks when done. Don't need to see anything else. Happy to defer on coordination with EMA, as well, to you.
Thanks so much!
Ritu

Ritu Nalubola, Ph.D.
Director, Europe Office
U.S. Food and Drug Administration
U.S. Mission to the European Union
Boulevard du Regent 40
B-1000 Brussels, Belgium
Phone: +32-2-811-5733
Mobile: (b)(6)
Email: Ritu.Nalubola@fda.hhs.gov

U.S. FOOD & DRUG ADMINISTRATION

From: McNeill, Lorrie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=77B0B352C9C24851BF0C7330F53E00D9-MCNEILL]
Sent: 3/23/2020 3:58:06 PM
To: Gruber, Marion [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=019cd2669c7048f7a116d72b7682de44-gruber]
Subject: RE: Vaccines mtg PR
Attachments: March 18 Global regulators meeting summary finaL.docx

Forgive me, Marion – I completely missed that we were going to post the bullets, too. I will chat with Kristin about where we should post on our site, and we can ask OEA to add a link to the FDA Voices document once it's up.

My sincere apologies. I'm not doing terribly well at keeping the plates spinning.

Lorrie

From: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Sent: Monday, March 23, 2020 3:53 PM
To: McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>
Subject: RE: Vaccines mtg PR

Lorie,
The bullet summary document, when will that post and where?
Marion

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To: Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Nalubola, Ritu <Ritu.Nalubola@fda.hhs.gov>
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Subject: RE: Vaccines mtg PR

Hi all – the FDA Voices piece has posted on the web: https://www.fda.gov/news-events/fda-voices-perspectives-fda-leadership-and-experts/fda-and-ema-collaborate-facilitate-sars-cov-2-vaccine-development.

OEA is working on clearing tweets to send with a link to the piece.

Any questions, please let me know.

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Subject: RE: Vaccines mtg PR

No show stoppers from my side.
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Sent: Monday, March 23, 2020 8:10 AM
To: Nalubola, Ritu <Ritu.Nalubola@fda.hhs.gov>; Gruber, Marion <Marion.Gruber@fda.hhs.gov>
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Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>; Blair, Joan W. (CBER) <Joan.Blair@fda.hhs.gov>; Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Louati, Claudia (FSN)* <Claudia.Louati@fda.hhs.gov>
Subject: Vaccines mtg PR

Hi Lorrie, Karen – Wondering if we're still on for today release of the additional details about the workshop, plus FDA Voices statement.
Please send me the weblinks when done. Don't need to see anything else. Happy to defer on coordination with EMA, as well, to you.
Thanks so much!
Ritu

Ritu Nalubola, Ph.D.
Director, Europe Office
U.S. Food and Drug Administration
U.S. Mission to the European Union
Boulevard du Regent 40
B-1000 Brussels, Belgium
Phone: +32-2-811-5733
Mobile: (b)(6)
Email: Ritu.Nalubola@fda.hhs.gov

U.S. FOOD & DRUG ADMINISTRATION

From: Gruber, Marion [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=019CD2669C7048F7A116D72B7682DE44-GRUBER]
Sent: 3/31/2020 6:59:33 AM
To: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]
Subject: FW: Exchange of Information under our Confidentiality Arrangements: Press release on treatments and vaccines in the context of pandemic
Attachments: Press release - Update on treatments and vaccines against COVID-19 under development.docx

I wonder whether FFA should consider doing something like this?

From: Kweder, Sandra L <Sandra.Kweder@fda.hhs.gov>
Sent: Tuesday, March 31, 2020 6:26 AM
To: Farley, John <John.Farley@fda.hhs.gov>; Nambiar, Sumathi <Sumathi.Nambiar@fda.hhs.gov>; Birnkrant, Debra B <Debra.Birnkrant@fda.hhs.gov>; Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Cc: Blair, Joan W. (CBER) <Joan.Blair@fda.hhs.gov>; Mullin, Theresa <Theresa.Mullin@fda.hhs.gov>; Limoli, Michelle <Michelle.Limoli@fda.hhs.gov>; Badoo, Judith <Judith.Badoo@fda.hhs.gov>; Nalubola, Ritu <Ritu.Nalubola@fda.hhs.gov>; Louati, Claudia (FSN)* <Claudia.Louati@fda.hhs.gov>; Thor, Shannon <Shannon.Thor@fda.hhs.gov>
Subject: FW: Exchange of Information under our Confidentiality Arrangements: Press release on treatments and vaccines in the context of pandemic

All,
Sending this along, a statement to publish at 4 PM today in Europe (10 AM EDT). No surprises.
Sandy

From: Synodinou Aliki [mailto:Aliki.Synodinou@ema.europa.eu] **On Behalf Of** Garcia Juan
Sent: Tuesday, March 31, 2020 12:19 PM
To: Garcia Juan <Juan.Garcia@ema.europa.eu>
Cc: De Verdiere Morgane <Morgane.DeVerdiere@ema.europa.eu>; Lupescu Diana <Diana.Lupescu@ema.europa.eu>; Malaguti Linda <linda.malaguti@ema.europa.eu>; Synodinou Aliki <Aliki.Synodinou@ema.europa.eu>
Subject: Exchange of Information under our Confidentiality Arrangements: Press release on treatments and vaccines in the context of pandemic

Dear Colleagues,

Please find attached the planned EMA press release which provides **a brief overview of treatments and vaccines candidates in the context of COVID-19 and currently under development**.

The attached document will be published on EMA website **today, Tuesday, 31 March 2020, 16:00hrs, CEST**. Please note that there is an embargo until such time.

Please forward this message to relevant colleagues within your organisation.

If you need further information, please do not hesitate to contact me.

Best regards,

Juan García Burgos
Head of Public and Stakeholders Engagement
Stakeholders and Communication Division
European Medicines Agency

Telephone +31 (0)88 781 7120
Juan.Garcia@ema.europa.eu | www.ema.europa.eu

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Classified as confidential by the European Medicines Agency

This e-mail has been scanned for all known viruses by European Medicines Agency.

Sent: 5/19/2020 10:55:47 AM
To: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]
CC: Krause, Philip [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00c6330fea0042fdb5571c3fdef792ed-krause]
Subject: FW: COVID-19 Update

Dear Peter,

I came across the message from the Commissioner that he sent last Sunday. Please see highlighted text below. **(b)(5)**

(b)(5)

Marion

From: A Message from the Commissioner <message@fda.hhs.gov>
Sent: Sunday, May 17, 2020 10:22 AM
To: FDA-Wide <FDA-Wide@fda.hhs.gov>
Subject: COVID-19 Update

From the Desk of
the Commissioner

U.S. FOOD & DRUG ADMINISTRATION

Dear Colleagues,

In a White House press conference Friday, it was announced that our own Drs. Janet Woodcock and Peter Marks will be bringing their diverse experience to cross-government efforts to expedite the development and availability of therapeutics and vaccines to combat COVID-19 under the Operation Warp Speed Project. The fact that Drs. Woodcock and Marks are playing such pivotal leadership roles in this effort speaks volumes to their abilities and the confidence the nation has in our agency. Drs. Woodcock and Marks will continue as directors of their respective centers while working closely with other center and agency leadership to ensure continuity of day-to-day operations. They will also recuse themselves from the supervisory chain of command in matters related to product review decisions for applications related to the areas that they are advancing that have a nexus to COVID-19.

The President's Coronavirus Task Force continues to analyze and monitor the prevalence of the virus in the U.S. using the best available science to track, predict and mitigate the curve of the pathogen. While there are metropolitan areas that are now moving to a stable or declining state in COVID-19 positive cases, such as New York City, Providence, Boston, Chicago and Houston, some cities are seeing persistence in COVID-19 positive cases, including the Washington, DC and Baltimore areas, Minneapolis, Dallas and Portland.

With those data in mind, Chief Operating Officer Jim Sigg provided important direction Friday that ***all FDA telework-eligible employees should continue teleworking until further notice***. This direction is in alignment with the National Guidelines for Opening Up America Again, guidance from the Office of Management and Budget (OMB) and the Office of Personnel Management (OPM), and the FDA Leadership Team's commitment to putting our employees and their families first.

As we continue to develop plans for an eventual phased return to FDA facilities, we will also continue to take a measured and deliberate approach that ensures your health and safety remain uppermost in our approach. We will be closely assessing local health and operational conditions in states across our nation, particularly in the Washington, DC, Maryland, and Virginia area since the data indicate that this geographic area is continuing to experience COVID-19 cases.

Remember you have my commitment that employees will be afforded maximum flexibility for continuing to take care of children and other family members while carrying out FDA work. As we continue to go through this together, I really commend everyone for doing their very best in meeting your work responsibilities while being mindful of what we are all going through as individuals. I know it hasn't been easy, and everyone's circumstance is unique, which is also why I want employees to feel supported during this prolonged period of time. So, when the FDA decides the time is right to initiate a phased approach for employees to return to FDA facilities, the agency will continue to offer workplace flexibilities to employees, including those who the CDC identifies as being at high risk for severe illness from COVID-19, and employees managing dependent care while continuing to work.

I want to end by saying thank you for all of the warm thoughts sent my way after sharing with you my potential exposure to COVID-19. I continue to feel healthy as well as truly blessed to be a part of the FDA family.

To all employees, please be extra careful to keep yourself and your loved ones safe, using the power you have as individuals to #SlowTheSpread. Be good to yourselves and please take the time you need to protect and promote YOUR public health. Stay safe, well and #FDAStrong.

Sincerely,

Stephen M. Hahn, M.D.
Commissioner of Food and Drugs

FDA U.S. FOOD & DRUG ADMINISTRATION

From: Tierney, Julia [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1160D300BC4248B790DED292A082E9A8-JULIA.TIERN]
Sent: 1/24/2020 11:16:52 AM
To: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]
Subject: FW: information on coronavirus
Attachments: Wuhan Coronavirus Briefer_1.22.2020_.docx

From: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>
Sent: Friday, January 24, 2020 10:45 AM
To: McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>
Cc: Jordan, Lillian T <Lillian.Jordan@fda.hhs.gov>; OC OCOD Contacts <OCOCODContacts@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Maloney, Diane <Diane.Maloney@fda.hhs.gov>
Subject: RE: information on coronavirus

Thanks, Lorrie. We also reached out to other folks to get a little more clarification on the request, and it turns out the Commissioner received the attached briefer a few days ago. OCET is coordinating the coronavirus effort and we'll work with them to get updates going forward.

Thank you,
Prakash

From: McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>
Sent: Friday, January 24, 2020 10:33 AM
To: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>
Cc: Jordan, Lillian T <Lillian.Jordan@fda.hhs.gov>; OC OCOD Contacts <OCOCODContacts@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Maloney, Diane <Diane.Maloney@fda.hhs.gov>
Subject: RE: information on coronavirus

HI Prakash –

Thank you for the additional time. Below high-level talking points:

- FDA/CBER will take all effective measures to ensure the safety of the nation's blood supply and tissue supply.
- There are no immediate concerns about blood and tissue safety. FDA remains in close communication with our sister agencies within HHS and international regulatory partners, and will continue to actively monitor the situation going forward.
- CBER is collaborating with FDA's other medical product centers to assist with the development of reagents for diagnostic products.
- CBER is also collaborating with other government agencies and regulated industry to facilitate the development of medical countermeasures, including vaccines, for the prevention and treatment of coronavirus.

As the situation develops, we're happy to provide updates as needed. If you have any questions, please let us know.

Best –

Lorrie

From: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>
Sent: Thursday, January 23, 2020 11:17 AM
To: McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>; OC OCOD Contacts <OCOCODContacts@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Maloney, Diane <Diane.Maloney@fda.hhs.gov>
Cc: Jordan, Lillian T <Lillian.Jordan@fda.hhs.gov>
Subject: RE: information on coronavirus

Thank you. In that case, if you are able to send something by tomorrow around noon, that would be really helpful.

Prakash

From: McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>
Sent: Thursday, January 23, 2020 11:15 AM
To: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; OC OCOD Contacts <OCOCODContacts@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Maloney, Diane <Diane.Maloney@fda.hhs.gov>
Cc: Jordan, Lillian T <Lillian.Jordan@fda.hhs.gov>
Subject: RE: information on coronavirus

Hi Prakash –

We don't have any TPs that have been provided in response to media inquiries (I don't believe OMA has contacted us on any media questions). We can discuss and get something to you soonest.

Lorrie

From: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>
Sent: Thursday, January 23, 2020 11:11 AM
To: OC OCOD Contacts <OCOCODContacts@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Maloney, Diane <Diane.Maloney@fda.hhs.gov>
Cc: Jordan, Lillian T <Lillian.Jordan@fda.hhs.gov>
Subject: information on coronavirus

Hello,

The commissioner is starting his rounds meeting with various Congressman. As we update background memos for him we are being asked to include information on the coronavirus outbreak. Do you all have TP's that you are providing for media inquires that you could share with us? If you already have something cleared, could you please send information by COB today?

Thanks,
Prakash

From: Marks, Peter [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DFBB2B5BD38445CB9C9ADCA3F72DF53A-MARKSP]
Sent: 1/28/2020 12:48:29 PM
To: Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]
CC: Jenkins, Charlene [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e722b6438b04d2e9029c72543639a67-Charlene.Je]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Anna Abram (Anna.Abram@fda.hhs.gov) [/o=FDA/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Anna.Abram3ba]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Celia Witten (celia.witten@fda.hhs.gov) [celia.witten@fda.hhs.gov]; Tierney, Julia (Julia.Tierney@fda.hhs.gov) [/o=FDA/ou=First Administrative Group/cn=Recipients/cn=Julia.Tierney]
Subject: RE: TELECON: Weekly CBER Meeting with the Commissioner and Chief of Staff
Attachments: CBER Agenda for January 29.docx

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: Cho, David S (CBER) [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D47AF9D991AF4C1FBF7CB4C1D287F83E-CHOD]
Sent: 1/30/2020 8:08:01 AM
To: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]
Subject: RE: daily nCoV PCC

HI Peter,
Should I cover the PCC this morning and ask David Rouse to sit in on the convalescent serum call with you and OBRR? I am flexible and we can cover both meetings this way. Just let me know.
Thanks,
David

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Wednesday, January 29, 2020 11:29 PM
To: Cho, David S (CBER) <David.Cho@fda.hhs.gov>
Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: RE: daily nCoV PCC

I am going to try to attend

From: Cho, David S (CBER) <David.Cho@fda.hhs.gov>
Sent: Wednesday, January 29, 2020 10:28 PM
To: Mair, Michael <Michael.Mair@fda.hhs.gov>
Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: RE: daily nCoV PCC

Thanks Michael,
I'm glad we can join by SVTC. Given where we still are in the response and with some potential competing CoV meetings in the mornings the next couple of days, is OCET able to cover these calls? If not or if you think we need to be there also, we can look to readjust.
Thanks,
David

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Wednesday, January 29, 2020 9:01 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Fisher, Robert <Robert.Fisher@fda.hhs.gov>; Yates, Thomas <Thomas.Yates@fda.hhs.gov>
Subject: daily nCoV PCC

Hi. The daily nCoV PCC has been rescheduled for 9 – 10:30 AM daily for the foreseeable future. CDC Atlanta, NIAD, and FDA are the only entities that are authorized for SVTC.

Thomas – hi. Please advise if we can get the SCIF. Thx - m

From: McSeveney, Megan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0D4B7FC0CFED46C7B1BFCDDD41F240D7-MEGAN.MCSEV]
Sent: 2/3/2020 6:32:43 AM
To: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; McNeill, Lorrie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77b0b352c9c24851bf0c7330f53e00d9-McNeill]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; 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]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]
CC: Finnen, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]; 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]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Meyer, Lyndsay [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00176f0991c84d34b3927bfb410d5483-Lyndsay.Mey]
Subject: For review - NIH Media Inquiry for FDA review
Attachments: NIH Media inquiry.docx

Good morning! During this coronavirus response, as with the Ebola response, we are working to coordinate messaging across the department. NIH has shared through HHS a media inquiry they received from the Times of London about their efforts to work on a coronavirus vaccines. Attached is that inquiry which has some initial edits in track changes for your review. The deadline is COB today for NIH, so I am requesting this back by 3pm today. 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: McNeill, Lorrie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=77B0B352C9C24851BF0C7330F53E00D9-MCNEILL]
Sent: 2/3/2020 8:46:09 AM
To: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]
Subject: FW: For review - NIH Media Inquiry for FDA review
Attachments: NIH Media inquiry.docx

Good morning –

Please see the email below and attached responses NIH plans to use for response to a press inquiry. I'm okay with Megan's revisions, although I did move one phrase towards the end from where she inserted.

Please let me know if you have any comments or edits. The response is due back to Megan at 3:00pm today.

Thanks!

Lorrie

From: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
Sent: Monday, February 3, 2020 6:33 AM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Cc: Finnen, April <April.Finnen@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Stark, Angela <Angela.Stark@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Meyer, Lyndsay <Lyndsay.Meyer@fda.hhs.gov>
Subject: For review - NIH Media Inquiry for FDA review

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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: Marks, Peter [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DFBB2B5BD38445CB9C9ADCA3F72DF53A-MARKSP]
Sent: 2/3/2020 8:51:14 AM
To: McNeill, Lorrie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77b0b352c9c24851bf0c7330f53e00d9-McNeill]; Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]
Subject: RE: For review - NIH Media Inquiry for FDA review
Attachments: NIH Media inquiry (1).docx

Dear Lorrie,

Sorry that the suggested edits in the attached are not in your version. Thanks.

Best Regards,
Peter

From: McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>
Sent: Monday, February 3, 2020 8:46 AM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>
Subject: FW: For review - NIH Media Inquiry for FDA review

Good morning –

Please see the email below and attached responses NIH plans to use for response to a press inquiry. I'm okay with Megan's revisions, although I did move one phrase towards the end from where she inserted.

Please let me know if you have any comments or edits. The response is due back to Megan at 3:00pm today.

Thanks!

Lorrie

From: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
Sent: Monday, February 3, 2020 6:33 AM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Cc: Finnen, April <April.Finnen@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Stark, Angela <Angela.Stark@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Meyer, Lyndsay <Lyndsay.Meyer@fda.hhs.gov>
Subject: For review - NIH Media Inquiry for FDA review

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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: McNeill, Lorrie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=77B0B352C9C24851BF0C7330F53E00D9-MCNEILL]
Sent: 2/3/2020 8:54:05 AM
To: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]
Subject: RE: For review - NIH Media Inquiry for FDA review
Attachments: NIH Media inquiry.docx

Hi Peter –

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Lorrie

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Sent: Monday, February 3, 2020 8:51 AM
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Sent: 2/3/2020 8:55:21 AM
To: McNeill, Lorrie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77b0b352c9c24851bf0c7330f53e00d9-McNeill]; Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]
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FDA U.S. FOOD & DRUG ADMINISTRATION

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Sent: 2/3/2020 9:01:17 AM
To: Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]
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Sent: 2/3/2020 9:37:05 AM
To: McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; 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]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]
CC: Finnen, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]; 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]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Meyer, Lyndsay [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00176f0991c84d34b3927bfb410d5483-Lyndsay.Mey]
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Sent: 2/7/2020 4:18:11 PM
To: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; McNeill, Lorrie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77b0b352c9c24851bf0c7330f53e00d9-McNeill]
Subject: FW: 5pm review request - tweets for Commissioner Hahn on nCoV

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Thanks,
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From: Leggin, Brooke <Brooke.Leggin@fda.hhs.gov>
Sent: Friday, February 7, 2020 4:14 PM
To: 2019-nCoV FDA IMG <2019-nCoVFDAIMG@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>
Cc: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
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Below are draft tweets for your review and clearance. Please send any edits or questions by 5pm today. Thank you.

@SteveFDA

- Today, the President's #Coronavirus Task Force provided an update to the public on current outbreak efforts. Here at FDA, we continue to coordinate closely with our @HHSgov & USG partners and are ready to respond around the clock to the outbreak. #2019nCoV [IMAGE or QRT]

- At today's press briefing on the 2019 novel #coronavirus, I shared that FDA has received no reports of disruptions to the supply chain from medical supply manufacturers. We continue to monitor this closely & communicate w/ manufacturers. #2019nCoV [HAHN VIDEO]

- A key focus of FDA is providing regulatory advice, guidance, and technical assistance to help expedite the development & availability of critical medical products to diagnose, treat, mitigate and prevent #2019nCoV.

(b)(5)

- **(b)(5)** at FDA, we are fully engaged with our experts participating in USG response efforts to develop vaccines & therapeutics for novel #coronavirus and are working closely with our government and international partners.

(b)(5)

Brooke Leggin, MPH
Writer Editor

Office of Editorial and Creative Services
Office of External Affairs
U.S. Food and Drug Administration

Mon, Thurs, Fri 301-796-8466
Tues, Wed 301-864-2607
brooke.leggin@fda.hhs.gov

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Sent: 2/7/2020 4:21:00 PM
To: Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]
Subject: RE: 5pm review request - tweets for Commissioner Hahn on nCoV

Hi David –

Thanks for sharing these. No comments from me.

Lorrie

From: Cho, David S (CBER) <David.Cho@fda.hhs.gov>
Sent: Friday, February 7, 2020 4:18 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>
Subject: FW: 5pm review request - tweets for Commissioner Hahn on nCoV

Hi Lorrie,
Just sending your way for awareness and in case you had any comments on these tweets. A couple near end on vaccines.
Thanks,
David

From: Leggin, Brooke <Brooke.Leggin@fda.hhs.gov>
Sent: Friday, February 7, 2020 4:14 PM
To: 2019-nCoV FDA IMG <2019-nCoVFDAIMG@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>
Cc: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: 5pm review request - tweets for Commissioner Hahn on nCoV

Below are draft tweets for your review and clearance. Please send any edits or questions by 5pm today. Thank you.

@SteveFDA

- Today, the President's #Coronavirus Task Force provided an update to the public on current outbreak efforts. Here at FDA, we continue to coordinate closely with our @HHSgov & USG partners and are ready to respond around the clock to the outbreak. #2019nCoV [IMAGE or QRT]

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(b)(5)

- (b)(5) at FDA, we are fully engaged with our experts participating in USG response efforts to develop vaccines & therapeutics for novel #coronavirus and are working closely with our government and international partners.

(b)(5)

Brooke Leggin, MPH
Writer Editor

Office of Editorial and Creative Services
Office of External Affairs
U.S. Food and Drug Administration

Mon, Thurs, Fri **301-796-8466**
Tues, Wed **301-864-2607**
brooke.leggin@fda.hhs.gov

From: Cho, David S (CBER) [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D47AF9D991AF4C1FBF7CB4C1D287F83E-CHOD]
Sent: 2/7/2020 4:22:37 PM
To: McNeill, Lorrie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77b0b352c9c24851bf0c7330f53e00d9-McNeill]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]
Subject: RE: 5pm review request - tweets for Commissioner Hahn on nCoV

Thanks Lorrie.
David

From: McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>
Sent: Friday, February 7, 2020 4:21 PM
To: Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: RE: 5pm review request - tweets for Commissioner Hahn on nCoV

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Thanks for sharing these. No comments from me.

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From: Cho, David S (CBER) <David.Cho@fda.hhs.gov>
Sent: Friday, February 7, 2020 4:18 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>
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Sent: Friday, February 7, 2020 4:14 PM
To: 2019-nCoV FDA IMG <2019-nCoVFDAIMG@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>
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(b)(5)

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(b)(5)

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brooke.leggin@fda.hhs.gov

From: Marks, Peter [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DFBB2B5BD38445CB9C9ADCA3F72DF53A-MARKSP]
Sent: 2/7/2020 4:32:47 PM
To: Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; McNeill, Lorrie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77b0b352c9c24851bf0c7330f53e00d9-McNeill]
Subject: RE: 5pm review request - tweets for Commissioner Hahn on nCoV

Dear David,

These look fine to me.

Best Regards,
Peter

From: Cho, David S (CBER) <David.Cho@fda.hhs.gov>
Sent: Friday, February 7, 2020 4:19 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>
Subject: RE: 5pm review request - tweets for Commissioner Hahn on nCoV

Peter, please comment if you see anything to note. Overall looked ok.
Thanks,
David

From: Cho, David S (CBER)
Sent: Friday, February 7, 2020 4:18 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>
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brooke.leggin@fda.hhs.gov

FDA U.S. FOOD & DRUG ADMINISTRATION

From: Cho, David S (CBER) [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D47AF9D991AF4C1FBF7CB4C1D287F83E-CHOD]
Sent: 2/7/2020 4:34:25 PM
To: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; McNeill, Lorrie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77b0b352c9c24851bf0c7330f53e00d9-McNeill]
Subject: RE: 5pm review request - tweets for Commissioner Hahn on nCoV

Thanks Peter,
David

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Friday, February 7, 2020 4:33 PM
To: Cho, David S (CBER) <David.Cho@fda.hhs.gov>; McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>
Subject: RE: 5pm review request - tweets for Commissioner Hahn on nCoV

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Tues, Wed 301-864-2607
brooke.leggin@fda.hhs.gov

From: Marks, Peter [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DFBB2B5BD38445CB9C9ADCA3F72DF53A-MARKSP]
Sent: 3/8/2020 8:46:14 PM
To: Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; McNeill, Lorrie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77b0b352c9c24851bf0c7330f53e00d9-McNeill]; Hussey, Deirdre [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41a51a9bf937431c8470b69fb055fe81-Husseyd]
Subject: RE: COVID19 CONPLAN review
Attachments: 20200305_FDA_COVID19 CONPLAN_March_2020 V1.2.3.4_updatedjctpwm.docx

Dear All,

Please see my additional suggested edits added to those previously made in the attached.

Best Regards,
Peter

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Sunday, March 8, 2020 1:49 PM
To: Cho, David S (CBER) <David.Cho@fda.hhs.gov>; McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>; Hussey, Deirdre <Deirdre.Hussey@fda.hhs.gov>
Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: RE: COVID19 CONPLAN review

(b)(5)

Thanks,
Julie

From: Cho, David S (CBER) <David.Cho@fda.hhs.gov>
Sent: Saturday, March 7, 2020 10:58 AM
To: McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>; Hussey, Deirdre <Deirdre.Hussey@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: RE: COVID19 CONPLAN review

Thanks Lorrie,

(b)(5)

Thanks,
David

From: McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>
Date: March 7, 2020 at 10:29:24 AM EST
To: Cho, David S (CBER) <David.Cho@fda.hhs.gov>, Hussey, Deirdre <Deirdre.Hussey@fda.hhs.gov>, Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: RE: COVID19 CONPLAN review

Hi David –

(b)(5)

Lorrie

From: Cho, David S (CBER) <David.Cho@fda.hhs.gov>
Sent: Saturday, March 7, 2020 10:01 AM
To: Hussey, Deirdre <Deirdre.Hussey@fda.hhs.gov>; McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: RE: COVID19 CONPLAN review

Hi Deirdre,
I added my comments onto Lorrie's version.
Thanks,
David

From: Hussey, Deirdre <Deirdre.Hussey@fda.hhs.gov>
Sent: Friday, March 6, 2020 6:08 PM
To: McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: RE: COVID19 CONPLAN review

Thank you.

From: McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>
Date: March 6, 2020 at 4:40:11 PM EST
To: Hussey, Deirdre <Deirdre.Hussey@fda.hhs.gov>, Cho, David S (CBER) <David.Cho@fda.hhs.gov>, Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: RE: COVID19 CONPLAN review

Hi Deirdre –

A comment on page 6 and two minor edits and a comment on page 30.

Thanks –

Lorrie

From: Hussey, Deirdre <Deirdre.Hussey@fda.hhs.gov>
Sent: Friday, March 6, 2020 12:26 PM
To: Cho, David S (CBER) <David.Cho@fda.hhs.gov>; McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: FW: COVID19 CONPLAN review

All,

We've been asked to not share this widely, but to review and provide comments by Monday at noon. Could you let me know if you have any comments? Thanks.

Deirdre

From: Branch, Tiffany <Tiffany.Branch@fda.hhs.gov>
Date: March 6, 2020 at 11:09:25 AM EST
To: Stone, Eric <Eric.Stone@fda.hhs.gov>, Barfell, Glenda F <Glenda.Barfell@fda.hhs.gov>, Barth, Janelle <Janelle.Barth@fda.hhs.gov>, Huttenlocker, Denise <Denise.Huttenlocker@fda.hhs.gov>, Hussey, Deirdre <Deirdre.Hussey@fda.hhs.gov>, Cason, Winona <Winona.Cason@fda.hhs.gov>, Domanski, Jeffrey <Jeffrey.Domanski@fda.hhs.gov>, Schweitzer, Roxanne K <Roxanne.Schweitzer@fda.hhs.gov>
Subject: FW: COVID19 CONPLAN review

Good morning,

Below please find the link to the COVID-2019 ConOps plan. I will share more on the call.

Best,
Tiffany

From: Carter, Lionel <Lionel.Carter@fda.hhs.gov>
Sent: Friday, March 6, 2020 12:11 AM
To: Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Hebert, Angelique A. <Angelique.Hebert@fda.hhs.gov>; Sigg, Jim <Jim.Sigg@fda.hhs.gov>; Branch, Tiffany <Tiffany.Branch@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Solomon, Steven M <Steven.Solomon@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Abdoo, Mark <Mark.Abdoo@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Tootle, William <William.Tootle@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Tse, Tania <Tania.Tse@fda.hhs.gov>; Rogers, Michael <Michael.Rogers@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Solberg, Tim <Tim.Solberg@fda.hhs.gov>; Musser, Steven M <Steven.Musser@fda.hhs.gov>; Tyler, James <James.Tyler@fda.hhs.gov>; Throckmorton, Douglas C <Douglas.Throckmorton@fda.hhs.gov>; Mignone, Alfred <Alfred.Mignone@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Keller, Melanie <Melanie.Keller@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Zeller, Mitchell <Mitchell.Zeller@fda.hhs.gov>; Ross, Bruce <Bruce.Ross@fda.hhs.gov>; Musser, Steven M <Steven.Musser@fda.hhs.gov>
Subject: COVID19 CONPLAN review

To All

Here is the updated CONPLAN in SharePoint for AEG review. Comments are due by 12:00 noon on Monday, March 9, 2020.

V/r,

Lionel Carter Acting Director
Office of Security and Emergency Management
10903 New Hampshire Avenue, WO32 RM1353
Silver Spring, MD 20993
PH: 301-796-2796 | Mobile: (b)(6)
Lionel.Carter@fda.hhs.gov

From: Cho, David S (CBER) [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D47AF9D991AF4C1FBF7CB4C1D287F83E-CHOD]
Sent: 3/15/2020 4:32:43 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]
Subject: RE: Review Requested by 1620: Talking Points on COVID Therapeutics/Vaccines

Hi Denise,
I did not have any further comments especially on the vaccines or immunotherapy statements.
Thanks,
David

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Sunday, March 15, 2020 3:55 PM
To: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>
Subject: Review Requested by 1620: Talking Points on COVID Therapeutics/Vaccines

Dear Colleagues,

Michael Felderbaum drafted the following and wanting to make sure you've laid eyes on it and have the opportunity to provide comments before it goes to Dr. Hahn if you haven't already.

Thanks,

Denise

From: Marks, Peter [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DFBB2B5BD38445CB9C9ADCA3F72DF53A-MARKSP]
Sent: 3/15/2020 5:17:53 PM
To: Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
CC: Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]; Clarke, Mary Beth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b0124a15b9344d8483929470fefa403a-CLARKEM]
Subject: RE: Quick response requested: Talking Points on COVID Therapeutics/Vaccines - by 1630

Dear Patrizia,

Thanks for copying us. Nothing to add.

Best Regards,
Peter

From: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Sent: Sunday, March 15, 2020 4:39 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>
Subject: Fwd: Quick response requested: Talking Points on COVID Therapeutics/Vaccines - by 1630

Denise
+ Peter Marks
In the two paragraphs on IL-7 inhibitors and convalescent plasma, respectively , I recommend replacing the section about Reducing/heeding off need for ventilator with :

(b)(5)

Patrizia

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Date: March 15, 2020 at 4:16:42 PM EDT
To: Farley, John <John.Farley@fda.hhs.gov>, Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>, Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>
Subject: Quick response requested: Talking Points on COVID Therapeutics/Vaccines - by 1630

Hi – sorry for short notice – any input before Michael Felderbaum sends to Dr. Hahn?

Thanks,

D

From: Marks, Peter [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DFBB2B5BD38445CB9C9ADCA3F72DF53A-MARKSP]
Sent: 3/16/2020 7:22:41 AM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
CC: Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]
Subject: RE: Quick response requested: Talking Points on COVID Therapeutics/Vaccines - by 1630
Attachments: Therapeutics TPs 03152020 324pm (1).docx

Dear Denise,

Please see the attached with one comment.

Best Regards,
Peter

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Monday, March 16, 2020 7:02 AM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: FW: Quick response requested: Talking Points on COVID Therapeutics/Vaccines - by 1630

Good morning Peter,

Did you have any comments in addition to Patrizia's?

Thank you,

Denise

From: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Sent: Sunday, March 15, 2020 4:39 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>
Subject: Fwd: Quick response requested: Talking Points on COVID Therapeutics/Vaccines - by 1630

Denise
+ Peter Marks
In the two paragraphs on IL-7 inhibitors and convalescent plasma, respectively , I recommend replacing the section about Reducing/heeding off need for ventilator with :

(b)(5)

Patrizia

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Date: March 15, 2020 at 4:16:42 PM EDT
To: Farley, John <John.Farley@fda.hhs.gov>, Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>, Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>
Subject: Quick response requested: Talking Points on COVID Therapeutics/Vaccines - by 1630

Hi – sorry for short notice – any input before Michael Felberbaum sends to Dr. Hahn?

Thanks,

D

From: Felberbaum, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4819A643CA2945CDB1A2631B83E69673-MICHAEL.FEL]
Sent: 3/16/2020 8:19:14 AM
To: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
Subject: RE: Quick response requested: Talking Points on COVID Therapeutics/Vaccines - by 1630

Thank you, Peter. I will revise the bullet based on your comment to the following:

(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: 202-906-0229
michael.felberbaum@fda.hhs.gov

FDA U.S. FOOD & DRUG ADMINISTRATION

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Monday, March 16, 2020 7:23 AM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: RE: Quick response requested: Talking Points on COVID Therapeutics/Vaccines - by 1630

Dear Denise,

Please see the attached with one comment.

Best Regards,
Peter

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Monday, March 16, 2020 7:02 AM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: FW: Quick response requested: Talking Points on COVID Therapeutics/Vaccines - by 1630

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Thank you,

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Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>
Subject: Fwd: Quick response requested: Talking Points on COVID Therapeutics/Vaccines - by 1630

Denise
+ Peter Marks
In the two paragraphs on IL-7 inhibitors and convalescent plasma, respectively , I recommend replacing the section about Reducing/heeding off need for ventilator with :

"could potentially slow the progression of severe respiratory symptoms "

Patrizia

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Date: March 15, 2020 at 4:16:42 PM EDT
To: Farley, John <John.Farley@fda.hhs.gov>, Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>, Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>
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Thanks,

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From: Marks, Peter [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DFBB2B5BD38445CB9C9ADCA3F72DF53A-MARKSP]
Sent: 3/16/2020 8:22:24 AM
To: Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
Subject: RE: Quick response requested: Talking Points on COVID Therapeutics/Vaccines - by 1630

Dear Michael,

Thanks – this looks great. It addresses the issue nicely.

Best Regards,
Peter

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Sent: Monday, March 16, 2020 8:19 AM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: Quick response requested: Talking Points on COVID Therapeutics/Vaccines - by 1630

Thank you, Peter. I will revise the bullet based on your comment to the following:

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Michael

Michael Felberbaum
Senior Adviser

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

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Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>
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Denise
+ Peter Marks
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Patrizia

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Date: March 15, 2020 at 4:16:42 PM EDT
To: Farley, John <John.Farley@fda.hhs.gov>, Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>, Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>
Subject: Quick response requested: Talking Points on COVID Therapeutics/Vaccines - by 1630

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Thanks,

D

From: Marks, Peter [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DFBB2B5BD38445CB9C9ADCA3F72DF53A-MARKSP]
Sent: 3/16/2020 11:45:17 AM
To: Jenkins, Charlene [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e722b6438b04d2e9029c72543639a67-Charlene.Je]; Copeland, Jakea [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7fe05ed233c42b68be990b12ae2c8c8-Jakea.Copel]
Subject: RE: Materials Inquiry: Weekly CBER Meeting with the Commissioner

Dear Jakea,

Here is the agenda for Wednesday:

1) Coronavirus response updates
a. Blood supply
b. Convalescent plasma and hyperimmune globulin
c. Vaccines
2) Center continuity of operations
a. Regulatory review
b. Laboratory research
c. Policy development

Best Regards,
Peter

From: Jenkins, Charlene <Charlene.Jenkins@fda.hhs.gov>
Sent: Monday, March 16, 2020 11:15 AM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: FW: Materials Inquiry: Weekly CBER Meeting with the Commissioner

FYI

From: Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Sent: Monday, March 16, 2020 11:14 AM
To: Jenkins, Charlene <Charlene.Jenkins@fda.hhs.gov>
Cc: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Subject: Materials Inquiry: Weekly CBER Meeting with the Commissioner

Good Morning Charlene,

Does Dr. Marks have any materials/agenda for the weekly CBER meeting with the Commissioner, scheduled for Wed, 3/18? If so, please send by 12pm Tues, 3/17.

Thank you,
Jakea

-----Original Appointment-----
From: Sheehy, Janice **On Behalf Of** Hahn, Stephen
Sent: Monday, December 30, 2019 11:56 AM
To: Hahn, Stephen; Lenihan, Keagan; Marks, Peter; Witten, Celia (CBER); Abram, Anna; Shah, Anand; Rom, Colin
Cc: Tierney, Julia; Tierney, Julia (Julia.Tierney@fda.hhs.gov)
Subject: Weekly CBER Meeting with the Commissioner

When: Wednesday, March 18, 2020 11:00 AM-11:30 AM (UTC-05:00) Eastern Time (US & Canada).
Where: Commissioner's Office (WO1/2217)

From: Copeland, Jakea [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D7FE05ED233C42B68BE990B12AE2C8C8-JAKEA.COPEL]
Sent: 3/16/2020 11:50:27 AM
To: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Jenkins, Charlene [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e722b6438b04d2e9029c72543639a67-Charlene.Je]
CC: Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]
Subject: RE: Materials Inquiry: Weekly CBER Meeting with the Commissioner

Thank you, Dr. Marks.

Jakea

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Monday, March 16, 2020 11:45 AM
To: Jenkins, Charlene <Charlene.Jenkins@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: Materials Inquiry: Weekly CBER Meeting with the Commissioner

Dear Jakea,

Here is the agenda for Wednesday:

1) Coronavirus response updates
a. Blood supply
b. Convalescent plasma and hyperimmune globulin
c. Vaccines
2) Center continuity of operations
a. Regulatory review
b. Laboratory research
c. Policy development

Best Regards,
Peter

From: Jenkins, Charlene <Charlene.Jenkins@fda.hhs.gov>
Sent: Monday, March 16, 2020 11:15 AM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: FW: Materials Inquiry: Weekly CBER Meeting with the Commissioner

FYI

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Sent: Monday, March 16, 2020 11:14 AM
To: Jenkins, Charlene <Charlene.Jenkins@fda.hhs.gov>
Cc: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Subject: Materials Inquiry: Weekly CBER Meeting with the Commissioner

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Does Dr. Marks have any materials/agenda for the weekly CBER meeting with the Commissioner, scheduled for Wed, 3/18? If so, please send by 12pm Tues, 3/17.

Thank you,
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From: Sheehy, Janice **On Behalf Of** Hahn, Stephen
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To: Hahn, Stephen; Lenihan, Keagan; Marks, Peter; Witten, Celia (CBER); Abram, Anna; Shah, Anand; Rom, Colin
Cc: Tierney, Julia; Tierney, Julia (Julia.Tierney@fda.hhs.gov)
Subject: Weekly CBER Meeting with the Commissioner
When: Wednesday, March 18, 2020 11:00 AM-11:30 AM (UTC-05:00) Eastern Time (US & Canada).
Where: Commissioner's Office (WO1/2217)

From: McNeill, Lorrie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=77B0B352C9C24851BF0C7330F53E00D9-MCNEILL]
Sent: 3/16/2020 12:32:00 PM
To: Guram, Jeet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ef73bea97e2b477b847ea302c4730ccf-Gurjeet.Gur]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
CC: Patel, Chaitali [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=815d91f3d5e143b387acd82539f7e149-Chaitali.Pa]
Subject: RE: Comms today - reminder
Attachments: NIAID press release mRNA Phase 1 FINAL with numbers.docx

Attached is the latest draft press release from NIAID – they plan to issue imminently, once they confirm the patient has received the vaccine.

My recommendation would be to draft one or two tweets from the main FDA account, retweeting NIH's messaging and link to the press release. If you all are in agreement, I will work with the JIC and OMA to draft and clear.

Lorrie

From: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Sent: Monday, March 16, 2020 12:01 PM
To: McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Patel, Chaitali <Chaitali.Patel@fda.hhs.gov>
Subject: RE: Comms today - reminder

That all sounds good – thanks Lorrie

--
Jeet Guram, M.D.
Senior Advisor, Office of the Commissioner
Food and Drug Administration
+1 (202) 230-0451 | jeet.guram@fda.hhs.gov

From: McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>
Sent: Monday, March 16, 2020 12:00 PM
To: Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Patel, Chaitali <Chaitali.Patel@fda.hhs.gov>
Subject: RE: Comms today - reminder

Hi Jeet –

I will work on that. As Peter notes, our regulations don't allow us to disclose any information about an IND, so I think amplifying their comms is the way to go. We would refer specific questions to NIAID for response.

I'll circle back ASAP on the draft release.

Lorrie

From: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Sent: Monday, March 16, 2020 11:58 AM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Patel, Chaitali <Chaitali.Patel@fda.hhs.gov>; McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>
Subject: RE: Comms today - reminder

Thank you Peter, and Lorrie it's nice to meet you. Lorrie do you know if we will get a copy of NIAID's announcement before it goes out, so we can be prepared to amplify and augment it?

--
Jeet Guram, M.D.
Senior Advisor, Office of the Commissioner
Food and Drug Administration
+1 (202) 230-0451 | jeet.guram@fda.hhs.gov

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Monday, March 16, 2020 11:56 AM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Patel, Chaitali <Chaitali.Patel@fda.hhs.gov>; McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>
Subject: RE: Comms today - reminder

Dear Anand,

Since this is under IND, we have to wait until NIAID makes an announcement before we can say anything, and even then, we will largely defer to them. Copying Lorrie McNeill, who leads our comms shop.

Best Regards,
Peter

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Monday, March 16, 2020 10:15 AM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Patel, Chaitali <Chaitali.Patel@fda.hhs.gov>
Subject: FW: Comms today - reminder

Hi Peter –
Please see below.
Can you connect me with folks on your team who may have more info on the vaccine patient?
We will work with you on the comms
Thanks,
Anand

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Sent: Monday, March 16, 2020 7:15 AM

To: Hahn, Stephen <SH1@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Comms today - reminder

Copy sir. Re: blood we connected Peter to ARC through an EOP stakeholder inquiry. He contacted them yesterday. They plan to have a larger push on Wed. and he offered them a support video. Anand, can you run the vaccine patient to ground? TY.

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Monday, March 16, 2020 7:12 AM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: Comms today - reminder

Need comms today about first vaccine patient and our role. Also blood donation and diagnostics

From: Guram, Jeet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EF73BEA97E2B477B847EA302C4730CCF-GURJEET.GUR]
Sent: 3/16/2020 3:23:32 PM
To: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
CC: Patel, Chaitali [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=815d91f3d5e143b387acd82539f7e149-Chaitali.Pa]; Zeta, Lowell [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c0fc7eb68244f4cb4260898d5dacadb-Lowell.Zeta]
Subject: RE: FDA leg requests

Perfect – Chaitali just sent an invite for 4-4:30pm today

--
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: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Monday, March 16, 2020 1:35 PM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Patel, Chaitali <Chaitali.Patel@fda.hhs.gov>; Zeta, Lowell <Lowell.Zeta@fda.hhs.gov>
Subject: RE: FDA leg requests

Dear Anand,

Sure. between 4 and 5 would be best, but will do what I need to free up before if need be.

Best Regards,
Peter

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Monday, March 16, 2020 1:21 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Patel, Chaitali <Chaitali.Patel@fda.hhs.gov>; Zeta, Lowell <Lowell.Zeta@fda.hhs.gov>
Subject: FW: FDA leg requests
Importance: High

Hi Peter –

Can you join a call with the White House (to be scheduled as early as later today) on COVID-19 vaccines and **(b)(5)** **(b)(5)** We'll need your team's expertise. Please see the note below and two attachments.

It might be helpful to connect for 10 minutes beforehand so that we are coordinated from FDA.

Thanks very much

Anand

PRE-DECISIONAL, CONFIDENTIAL

From: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Sent: Monday, March 16, 2020 12:20 PM
To: Paul Ray - OMB (b)(6) Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: FDA leg requests
Importance: High

Anand – (b)(5)

(b)(5)

Paul -- attached are FDA's leg requests (b)(5)

(b)(5)

****

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

From: Marks, Peter [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DFBB2B5BD38445CB9C9ADCA3F72DF53A-MARKSP]
Sent: 3/19/2020 9:29:18 AM
To: McNeill, Lorrie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77b0b352c9c24851bf0c7330f53e00d9-McNeill]
Subject: RE: Statement/Communication requested about COVID Vaccine meeting

Dear Lorrie,

Marion is apparently working on this with Ritu. Just let me know what you need.

Best Regards,
Peter

From: McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>
Sent: Thursday, March 19, 2020 8:39 AM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Maloney, Diane <Diane.Maloney@fda.hhs.gov>; Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Rouse, David <David.Rouse@fda.hhs.gov>; Blair, Joan W. (CBER) <Joan.Blair@fda.hhs.gov>
Cc: Frantz-Bohn, Susan <Susan.Frantzbohn@fda.hhs.gov>; Bartell, Diane <Diane.Bartell@fda.hhs.gov>; Richards, Paul <Paul.Richards@fda.hhs.gov>
Subject: FW: Statement/Communication requested about COVID Vaccine meeting

Good morning – please see the emails below regarding the ICMRA meeting yesterday. Would welcome thoughts on best approach on this. I think we could develop tweets and retweet EMA's statement, which doesn't say much.

Thanks –

Lorrie

From: Riley, Karen <Karen.Riley@fda.hhs.gov>
Sent: Thursday, March 19, 2020 8:33 AM
To: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>
Subject: Statement/Communication requested about COVID Vaccine meeting

Yesterday the International Coalition of Medicines Regulatory Authorities held a virtual international workshop, co-chaired by the EMA and FDA, on the development of vaccines against COVID-19. The EMA subsequently put out a brief statement about the meeting, which you can see in the link below. My folks would like us to put out something as well. We could mirror the EMA statement, or even post it, as we have done in the past, although I think more information could be added. Could we do something like this today? At the very least, I will look for the statement on Twitter and will retweet it.

From: Nalubola, Ritu <Ritu.Nalubola@fda.hhs.gov>
Sent: Thursday, March 19, 2020 7:32 AM
To: Riley, Karen <Karen.Riley@fda.hhs.gov>
Cc: Abdoo, Mark <Mark.Abdoo@fda.hhs.gov>; Ross, Bruce <Bruce.Ross@fda.hhs.gov>; Klein, Vashti * <Vashti.Klein@fda.hhs.gov>; Blair, Joan W. (CBER) <Joan.Blair@fda.hhs.gov>; Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Kweder, Sandra L <Sandra.Kweder@fda.hhs.gov>
Subject: COVID vaccines meeting -- request to post FDA statement

Hi Karen – Re: COVID vaccine global regulators meeting yesterday -- we'd like to do an FDA posting to piggy back on this EMA statement:

https://www.ema.europa.eu/en/news/first-regulatory-workshop-covid-19-facilitates-global-collaboration-vaccine-development

Peter Marks is fine with moving ahead with this as a joint EMA-FDA statement so I think best to use the same wording from EMA's statement.

I've copied CBER leads and they can help if any questions and also consider if you have other suggestions for PR. We'll definitely add a blurb in OGPS' next monthly distribution.

Thanks,
Ritu

From: Marks, Peter [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DFBB2B5BD38445CB9C9ADCA3F72DF53A-MARKSP]
Sent: 3/19/2020 12:29:33 PM
To: Nalubola, Ritu [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3103228e5eba458f9c2aa1a846d25c7c-PNalubol]
Subject: RE: Statement/Communication requested about COVID Vaccine meeting

Dear Ritu,

Sorry – this was not your issue at all, but one on my end. Thanks for all of your help with this.

Best Regards,
Peter

From: Nalubola, Ritu <Ritu.Nalubola@fda.hhs.gov>
Sent: Thursday, March 19, 2020 9:32 AM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: RE: Statement/Communication requested about COVID Vaccine meeting

Sure, Peter, will do. Apologies!
I thought I got the direction from you and so moved ahead per your concurrence – with Marion on drafting cable and within OGPS on FDA statement with cc to your staff – just didn't want to inundate you with further staff-level back-forth. I'll continue to keep you in cc.
Best regards,
Ritu

From: Marks, Peter
Sent: Thursday, March 19, 2020 2:25 PM
To: Nalubola, Ritu <Ritu.Nalubola@fda.hhs.gov>
Subject: FW: Statement/Communication requested about COVID Vaccine meeting

Dear Ritu,

I am fine with having you proceed as you are planning,
but the future please do not remove me from a communication stream when you contact my content experts.

Best Regards,
Peter

From: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Sent: Thursday, March 19, 2020 8:48 AM
To: McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Maloney, Diane <Diane.Maloney@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Rouse, David <David.Rouse@fda.hhs.gov>; Blair, Joan W. (CBER) <Joan.Blair@fda.hhs.gov>
Cc: Frantz-Bohn, Susan <Susan.Frantzbohn@fda.hhs.gov>; Bartell, Diane <Diane.Bartell@fda.hhs.gov>; Richards, Paul <Paul.Richards@fda.hhs.gov>; Hess, Maureen <Maureen.Hess@fda.hhs.gov>
Subject: RE: Statement/Communication requested about COVID Vaccine meeting

I just got off the phone with Ritu and they are doing a State dept cable. I will work with her on language so that we get at least that one right. We could use similar language if we are to

communicate as I think we should. I am not in favor of retweeting EMA's statement as we can do better than that.
Marion

From: McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>
Sent: Thursday, March 19, 2020 8:39 AM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Maloney, Diane <Diane.Maloney@fda.hhs.gov>; Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Rouse, David <David.Rouse@fda.hhs.gov>; Blair, Joan W. (CBER) <Joan.Blair@fda.hhs.gov>
Cc: Frantz-Bohn, Susan <Susan.Frantzbohn@fda.hhs.gov>; Bartell, Diane <Diane.Bartell@fda.hhs.gov>; Richards, Paul <Paul.Richards@fda.hhs.gov>
Subject: FW: Statement/Communication requested about COVID Vaccine meeting

Good morning – please see the emails below regarding the ICMRA meeting yesterday. Would welcome thoughts on best approach on this. I think we could develop tweets and retweet EMA's statement, which doesn't say much.

Thanks –

Lorrie

From: Riley, Karen <Karen.Riley@fda.hhs.gov>
Sent: Thursday, March 19, 2020 8:33 AM
To: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>
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To: Riley, Karen <Karen.Riley@fda.hhs.gov>
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Subject: COVID vaccines meeting -- request to post FDA statement

Hi Karen – Re: COVID vaccine global regulators meeting yesterday -- we'd like to do an FDA posting to piggy back on this EMA statement:

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Peter Marks is fine with moving ahead with this as a joint EMA-FDA statement so I think best to use the same wording from EMA's statement.

I've copied CBER leads and they can help if any questions and also consider if you have other suggestions for PR. We'll definitely add a blurb in OGPS' next monthly distribution.

Thanks,
Ritu

From: Schiller, Lowell [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=77949B06919E4F91AA788E9A616C50C7-LOWELL.SCHI]
Sent: 3/20/2020 11:19:58 AM
To: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; 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]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]
Subject: RE: COVID-19 request for assistance re: human convalescent plasma (HCP) therapy -- on behalf of Baylor College of Medicine and Johns Hopkins University

Will loop you and Anand into the original thread now

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Friday, March 20, 2020 11:16 AM
To: Schiller, Lowell <Lowell.Schiller@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: RE: COVID-19 request for assistance re: human convalescent plasma (HCP) therapy -- on behalf of Baylor College of Medicine and Johns Hopkins University

Dear
Anand and Lowell,

Can you please connect the lead person people who want to have a discussion with me? We recognize some of the investigators listed here and I am very concerned that there is not a full understanding of what the USG effort is and about how they should best proceed here, but we can help guide them. We should avoid cross purposes here. Thanks.

Best Regards,
Peter

From: Schiller, Lowell <Lowell.Schiller@fda.hhs.gov>
Sent: Friday, March 20, 2020 11:05 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: FW: COVID-19 request for assistance re: human convalescent plasma (HCP) therapy -- on behalf of Baylor College of Medicine and Johns Hopkins University

Thoughts on this request?

From: Stephen Northrup <snorthrup@rampynorthrup.com>
Sent: Friday, March 20, 2020 10:59 AM
To: Anna Abram <anna abram@help.senate.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Schiller, Lowell <Lowell.Schiller@fda.hhs.gov>

Cc: Cybele Bjorklund <cbjorklund@jhu.edu>; Herb Butrum <butrum@bcm.edu>; Christopher Austin <chris.austin@jhu.edu>
Subject: COVID-19 request for assistance re: human convalescent plasma (HCP) therapy -- on behalf of Baylor College of Medicine and Johns Hopkins University

Anna, Keagan, Lowell -- I'm writing on behalf of Dr. Peter Hotez at Baylor College of Medicine and Dr. Arturo Casadevall at Johns Hopkins University about their efforts to advance human convalescent plasma (HCP) as a therapeutic option for the COVID-19 pandemic. I've copied Cybele Bjorklund and Chris Austin at JHU and also Herb Butrum at BCM.

You're familiar with this option, I'm sure, considering Commissioner Hahn's comments yesterday.

You may also know that JHU submitted an IND that arrived this morning at FDA, and there are close to 20 leading institutions now involved in the discussions about HCP therapy across the USA. These are all institutions of national significance, including Johns Hopkins University, Baylor College of Medicine, Duke University, Einstein Medical Center, Mayo Clinic, Michigan State University, University of Maryland, Loyola University Chicago, University of California, University of Washington, Massachusetts General Hospital, Children's Hospital of Philadelphia, University of Pittsburgh, Cedars-Sinai Medical Center, and Stanford University

Drs. Hotez and Casadevall have asked us to contact people in the senior agency leadership to make you aware of this effort, to ensure that Commissioner Hahn is aware of this effort, and to identify someone at a senior level who might be willing to be a stand-by source of assistance and guidance for them.

I thought one of you might be able to identify the right person or people who could be that go-to resource.

Please advise as to how you would recommend proceeding, and thanks for your attention to this request and for everything you are doing right now to fight this pandemic.

A detailed article on this effort is pasted below, from the Milwaukee Journal-Sentinel.

Best regards,
Steve

Stephen Northrup
Rampy Northrup LLC
mobile (b)(6)

https://www.jsonline.com/story/news/2020/03/18/coronavirus-treatment-emergency-clinical-trials-plasma-requested/2865766001/

Possible coronavirus treatment could be in clinical trials within weeks, using plasma from recovered patients, if doctors get FDA approval

Mark JohnsonUpdated 6:55 p.m. CT March 18, 2020

The Johns Hopkins University doctor coordinating a nationwide effort to launch emergency clinical trials of plasma from patients who've recovered from coronavirus said he expects to forward a plan to the U.S. Food & Drug Administration Wednesday and to start treating the first patients in about four weeks.

"We are in an emergency and this is the only thing we have," said Arturo Casadevall, chairman of Molecular Microbiology and Immunology at Johns Hopkins Bloomberg School of Public Health in Baltimore.

"This won't help patients who are sick today, but it will help the patients who become sick in the next two to five weeks," he said.

The time frame he described would still allow hospitals to begin testing the possible treatment before the new coronavirus peaks in the U.S., possibly a few months from now. Transfusions of plasma from recovered patients carry potential side effects, including fever, allergic reaction and a very small risk of infectious disease transmission.

Casadevall said the centers that take part in the clinical trial will need approval from both the FDA and their own institutional review boards, groups established to protect the rights of human research subjects.

Treating people with plasma from a recovered patient was first used more than a century ago to save a child with diphtheria and has since been used to stifle numerous outbreaks of disease. The process would involve taking plasma, rich in virus-fighting antibodies, from patients who have recovered from COVID-19. That plasma would then be transfused into patients who are still sick with the disease.

Casadevall and Liise-anne Pirofski, of the Albert Einstein College of Medicine in New York, triggered the push for clinical trials when they co-authored a paper published Friday in The Journal of Clinical Investigation. The two urged "that institutions consider the emergency use (of plasma from recovered patients) and begin preparations as soon as possible. Time is of the essence."

On Tuesday, Pirofski told the Milwaukee Journal Sentinel: "The need for this is dire. One day for those involved (in caring for the sick) is like a year."

Pirofski, chief of the division of infectious diseases at Montefiore Medical Center — the teaching hospital associated with Einstein College — which consists of 11 hospitals, described the situation where she works:

"Monday we had (a total of) 18 patients in our center, all very sick. Today we have 10 new patients."

She described doctors coping with shortages of basic supplies and feeling overwhelmed, experiences echoed by other medical staff working in viral hot spots around the world.

"There is no personal protective equipment anywhere," she said. "We are running out. We took all of our medical students off the ward to avoid using up PPEs... It's just demoralizing and there is no end in sight."

She said doctors have two possible paths they can follow in using plasma from recovered patients. They can test it in clinical trials. They can also use it as an experimental "compassionate use" treatment for some of the sickest patients, as was done during the 2009 swine flu, the 2013 West African Ebola epidemic, and the early stages of the COVID-19 outbreak in China.

"It's been used in China but there is just one small press release on it," Pirofski said. "We have not seen that data. We're all very anxious to see the results."

100 to 150 patients, divided in half

Experimental use would require that doctors find recovered COVID-19 patients with high antibody levels who are willing to serve as donors. Antibodies are blood proteins that are made by the body's immune system in response to bacteria, viruses and other foreign invaders.

Casadevall said he favors starting clinical trials of plasma from recovered patients, rather than using it experimentally.

Although plasma from recovered patients has been used to quell outbreaks of poliomyelitis, measles, mumps and influenza, the plasma of a COVID-19 survivor is something new. FDA would consider that plasma an investigational drug, meaning that it has been tested in the lab and is ready to be tested in people.

Survivor plasma, Pirofski said, "has not been (extensively tested) for this disease before, and the compound we'd be getting is new."

The basic setup for a clinical trial could involve 100 to 150 COVID-19 patients with half receiving serum from recovered patients, and the other half serving as a control group and receiving serum from patients who have never had COVID-19.

Casadevall said the trials could be used to test different groups who have been infected with the virus. One trial would test the use of survivor plasma on people who have been exposed to virus — likely doctors, nurses, emergency room staff and other first-responders. This group would include family members who have been at home caring for a loved one with COVID-19.

A second test of survivor plasma would involve patients who have been hospitalized with COVID-19, and are continuing to grow sicker.

A third test would involve severely ill COVID-19 patients.

Each of these tests has the potential to answer a different question:

- Can the plasma from recovered patients be used to prevent someone who has been exposed from coming down with the illness?
- Does the plasma have the ability to reverse the course of a patient whose health is declining?
- Can the plasma rescue a patient who has reached a very late stage of the illness?

"This is a good story in the midst of terrible news," said Casadevall, explaining how the paper he wrote with Pirofski led to the impromptu formation of a network of more than 100 doctors across the country.

The doctors have been discussing ways of collaborating to launch clinical trials of what appears to be the most immediate hope for treating COVID-19 patients. Various centers are being discussed as possible sites for the trials. The New York Blood Center is also partnering on the project, said Casadevall.

"If Johns Hopkins is ready to go, we'd very interested to see what they find," said Jeff Pothof, chief quality officer at UW Health in Madison. "I think we should do it quickly."

Casadevall agreed.

With a growing number of health care workers contracting the disease, "they're beginning to see the collapse of the healthcare system," he said.

"The problem in the U.S. is that something like this has never happened. In 1918 (during the Spanish flu) there was no FDA. There was no Centers of Disease Control and Prevention."

Casadevall urged the federal government to designate a point person for COVID-19 who would be knowledgeable enough to help hospitals and cities overcome logistical and other hurdles.

For example, he said, "Say Milwaukee needs serum and New York has it."

The "point person" could arrange coordination between different parts of the country that are in different stages of the pandemic.

Mark Johnson *has written in-depth stories about health, science and research for the Journal Sentinel since 2000. He is a three-time Pulitzer Prize finalist and, in addition, was part of a team that won the 2011 Pulitzer Prize in Explanatory Reporting for a series of reports on the groundbreaking use of genetic technology to save a 4-year-old boy.*

Email him at mark.johnson@jrn.com; ***follow him on Twitter:*** *@majohnso.*

From: McNeill, Lorrie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=77B0B352C9C24851BF0C7330F53E00D9-MCNEILL]
Sent: 3/20/2020 12:40:52 PM
To: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]
Subject: RE: Per our conversation ...

Hi Peter –

Will pull something together soonest for your review.

Thanks!

Lorrie

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Friday, March 20, 2020 12:39 PM
To: McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>
Subject: FW: Per our conversation ...

Dear Lorrie,

Can we dust off some of the Ebola/Zika/PanFlu TPs to address some of the questions below? Would aim for early next week to have something together.

Best Regards,
Peter

From: Marks, Peter
Sent: Friday, March 20, 2020 12:38 PM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Per our conversation ...

Dear Anand,

Thanks for the heads up on these. We have had to address very similar questions during previous outbreak. Granted, they were not on this scale, but the concepts are all there. We are prepared to respond and this weekend will freshen up the responses that we put together for previous outbreaks.

Best Regards,
Peter

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Friday, March 20, 2020 12:23 PM
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Per our conversation ...

Hi Michael –

Thanks for sharing these potential questions. I've included Janet, Peter, and Jeff here for their thoughts. I agree it would be helpful for us to carefully think through these questions and, whenever possible, have a coordinated approach to incoming questions from stakeholders including media.

Anand

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Sent: Friday, March 20, 2020 12:18 PM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: Per our conversation ...

Thanks for the chat. Here are the questions I think we need to be prepared to answer on this topic. Feel free to add to this list and let me know if you want to relay to Janet or others.

(b)(5)

Michael

Michael Felberbaum
Senior Advisor

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

From: McNeill, Lorrie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=77B0B352C9C24851BF0C7330F53E00D9-MCNEILL]
Sent: 3/22/2020 9:01:58 PM
To: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Rouse, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=185bae767862490d88eda44db74a75b3-RouseD]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]
CC: Frantz-Bohn, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4c4a10821c774ffa9c5cf59bda6bcf75-frantz_bohn]; Maloney, Diane [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e59205500e944c9eacc4524ea18ed5bb-MaloneyD]
Subject: RE: COVID-19 MCM Accelerator Webpage Content

Thanks Peter! I have the daily JIC call at 9:30, and then am free from 10:30 to 1:30pm. Also free before 9:30 (anytime after 7:30am).

Lorrie

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Date: March 22, 2020 at 7:36:20 PM EDT
To: McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>, Cho, David S (CBER) <David.Cho@fda.hhs.gov>, Rouse, David <David.Rouse@fda.hhs.gov>, Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Cc: Frantz-Bohn, Susan <Susan.Frantzbohn@fda.hhs.gov>, Maloney, Diane <Diane.Maloney@fda.hhs.gov>
Subject: RE: COVID-19 MCM Accelerator Webpage Content

Dear Lorrie,

Will give you a call, but see at least:

1. Vaccines
2. Convalescent plasma
3. Hyperimmune globulin

As things that we might be able to discuss. Will be good to touch bases live.

Best Regards,
Peter

From: McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>
Sent: Sunday, March 22, 2020 4:50 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Rouse, David <David.Rouse@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>

Cc: Frantz-Bohn, Susan <Susan.Frantzbohn@fda.hhs.gov>; Maloney, Diane <Diane.Maloney@fda.hhs.gov>
Subject: FW: COVID-19 MCM Accelerator Webpage Content

Hi all – please see the email below. I'm not sure what was discussed, so wanted to check to see what thoughts folks have on what could be included. I think we could include the efforts on convalescent plasma (to develop a master protocol?), and expediting discussions with sponsors of potential SARS-CoV-2 vaccines.

Welcome thoughts on content CBER could provide. Thanks much!

Lorrie

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Sent: Sunday, March 22, 2020 2:40 PM
To: Choe, Lena <Lena.Choe@fda.hhs.gov>; Rawlings, Kimberly <Kimberly.Rawlings@fda.hhs.gov>; McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>; MacLennan, Lori <Lori.MacLennan@fda.hhs.gov>; Pagan Motta, Monica <Monica.PaganMotta@fda.hhs.gov>; Schulken, Susan <Susan.Schulken@fda.hhs.gov>
Cc: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Elicker, Janet <Janet.Elicker@fda.hhs.gov>; Mulieri, Chris <Charles.Mulieri@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>
Subject: COVID-19 MCM Accelerator Webpage Content

Hi all –

Stemming from a conversation with CDER, CBER and CDRH leadership – they want to create a webpage that contains a rundown of all the work we're doing to accelerate medical countermeasures – therapeutics, etc. It sounded like at least some of the center leadership had already tasked their comms shops with pulling this web content together. I just wanted to check in to see who had already begun work and, if not, if you could please check in with center leadership on this request?

Can the centers please provide an update on their efforts and anticipated timelines? I think they were looking to have something posted mid-week or sooner.

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: Marks, Peter [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DFBB2B5BD38445CB9C9ADCA3F72DF53A-MARKSP]
Sent: 3/23/2020 7:14:03 AM
To: lorrie.mcneill@fda.hhs.gov
Subject: FW: Per our conversation …

Dear Lorrie,

Can you/OCOD help here with a draft that could help add to/edit? I think that the JIC is not going to be able to handle this effectively. Thanks.

Best Regards,
Peter

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Sunday, March 22, 2020 10:15 PM
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Per our conversation ...

Hi Peter –
We may now have a reporter (or two) asking some of these questions. Whenever you're able to share the responses from previous outbreaks, Michael and I will get these into Share Point for the Centers to review together. Thanks very much.
Anand

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Sent: Friday, March 20, 2020 2:45 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Per our conversation ...

We may have answered similar questions in the past, but I think we should consider these responses in context of this pandemic and the political sensitivities. Appreciate working with this group on responses. I'm happy to build out based on anything Peter shares but will certainly need your collective expertise on the specific scientific considerations. Thanks all.

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Friday, March 20, 2020 2:16 PM
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Per our conversation ...

Well I would think that OEA would have responses to many of these from before. As I said, most of these issues are recurring. jw

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Sent: Friday, March 20, 2020 12:55 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Per our conversation ...

Thank you Peter and Janet.

Janet - I appreciate the offer to speak with press on this topic (and we'll likely need that) but would also like to build out the responses to these questions so that we are all talking about this the same way across the agency – and in those instances where we can't schedule time to speak with media or others. It sounds like Peter will be freshening up previous responses and we can use that as a starting point (feel free to propose responses for the questions below).

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: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Friday, March 20, 2020 12:38 PM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Per our conversation ...

Dear Anand,

Thanks for the heads up on these. We have had to address very similar questions during previous outbreak. Granted, they were not on this scale, but the concepts are all there. We are prepared to respond and this weekend will freshen up the responses that we put together for previous outbreaks.

Best Regards,
Peter

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Friday, March 20, 2020 12:23 PM
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Per our conversation ...

Hi Michael –

Thanks for sharing these potential questions. I've included Janet, Peter, and Jeff here for their thoughts. I agree it would be helpful for us to carefully think through these questions and, whenever possible, have a coordinated approach to incoming questions from stakeholders including media.

Anand

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Sent: Friday, March 20, 2020 12:18 PM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: Per our conversation ...

Thanks for the chat. Here are the questions I think we need to be prepared to answer on this topic. Feel free to add to this list and let me know if you want to relay to Janet or others.

(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: Marks, Peter [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DFBB2B5BD38445CB9C9ADCA3F72DF53A-MARKSP]
Sent: 3/24/2020 1:30:36 PM
To: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Kimbrell, Maarika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6ae656d4e81e44249270b416f1e2e203-Maarika.Kim]; Flanagan, Keith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15dcaab5c1ea4007adbc43e9acd413a6-Keith.Flana]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]
Subject: RE: Time Sensitive: WH + CTAP

Dear Maarika,

Completely agree with Janet – #'s 3, 4, 5 look best.

Best Regards,
Peter

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Tuesday, March 24, 2020 1:23 PM
To: Kimbrell, Maarika <Maarika.Kimbrell@fda.hhs.gov>; Flanagan, Keith <Keith.Flanagan@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: RE: Time Sensitive: WH + CTAP

Ok these are pretty bland. I'm OK with them, #3, 4 and 5 might be best. I had sent suggestions yesterday. jw

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From: Kimbrell, Maarika <Maarika.Kimbrell@fda.hhs.gov>
Sent: Tuesday, March 24, 2020 1:12 PM
To: Flanagan, Keith <Keith.Flanagan@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: RE: Time Sensitive: WH + CTAP

Janet, Peter, Keith:
Let us know if these work for you all or if you have comments:

Draft Tweets:

(b)(5)

(b)(5)

From: Flanagan, Keith <Keith.Flanagan@fda.hhs.gov>
Sent: Tuesday, March 24, 2020 1:02 PM
To: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Kimbrell, Maarika <Maarika.Kimbrell@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: RE: Time Sensitive: WH + CTAP

Julie, send a short blurb to Maarika and she can plug it in to a CDER-CBER comm

---

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Date: March 24, 2020 at 12:47:00 PM EDT
To: Flanagan, Keith <Keith.Flanagan@fda.hhs.gov>, Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>, Kimbrell, Maarika <Maarika.Kimbrell@fda.hhs.gov>, Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: RE: Time Sensitive: WH + CTAP

Yes, I think we would want to. Maarika/Keith, please feel free to give me a call to work through. Do you want me to take a stab at a tweet specific to CBER therapeutics?

From: Flanagan, Keith <Keith.Flanagan@fda.hhs.gov>
Sent: Tuesday, March 24, 2020 12:41 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Kimbrell, Maarika <Maarika.Kimbrell@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: Time Sensitive: WH + CTAP

Keagan needs something to feed the beast today. Maarika, please send JW the draft top line message, 2-3 Tweets worth: Announcement of CTAP plus ~3 top line, short bullets re what CTAP does.
Flagging for Julie in case CBER wants in.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Date: March 24, 2020 at 12:27:54 PM EDT
To: Flanagan, Keith <Keith.Flanagan@fda.hhs.gov>
Cc: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Subject: RE: Accelerator Program

(b)(6)

From: Flanagan, Keith <Keith.Flanagan@fda.hhs.gov>
Sent: Tuesday, March 24, 2020 12:20 PM

To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Subject: RE: Accelerator Program

Adding Jeet, who I briefed re this.

From: Flanagan, Keith <Keith.Flanagan@fda.hhs.gov>
Date: March 24, 2020 at 12:18:24 PM EDT
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: Accelerator Program

Keagan, what's your phone #?

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Date: March 24, 2020 at 12:17:03 PM EDT
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Marks, Peter <Peter.Marks@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Flanagan, Keith <Keith.Flanagan@fda.hhs.gov>
Cc: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: RE: Accelerator Program

Please direct inquiries to Keith Flanagan. He is CDER's lead on this part. He told me we will have something before the end of the week. jw

---

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Sent: Tuesday, March 24, 2020 11:36 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Cc: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: RE: Accelerator Program

We are happy to support, but need content to from the centers to build from.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Tuesday, March 24, 2020 11:30 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Cc: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: Accelerator Program

Hi All –

WH is really looking for us to get this out soon. I know everyone has a ton on their plates, but is there anything we could message up and show we are already doing this and just call it the work?

From: Flanagan, Keith [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=15DCAAB5C1EA4007ADBC43E9ACD413A6-KEITH.FLANA]
Sent: 3/24/2020 2:58:13 PM
To: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Kimbrell, Maarika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6ae656d4e81e44249270b416f1e2e203-Maarika.Kim]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]
Subject: Fwd: PER YOUR REQUEST - CTAP Blurb

FYI

From: Flanagan, Keith <Keith.Flanagan@fda.hhs.gov>
Date: March 24, 2020 at 2:57:31 PM EDT
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: PER YOUR REQUEST - CTAP Blurb

Sorry I don't know when website launches. Working on that.
I bet we could issue a more polished, aggressive description of the CTAP by end of this week or first thing next week. Why the delay? Because it's a real program, not a cosmetic gesture. We are working at full tilt to make sure we can do what we promise. This blurb was sort of a placeholder.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Date: March 24, 2020 at 2:46:08 PM EDT
To: Flanagan, Keith <Keith.Flanagan@fda.hhs.gov>
Subject: RE: PER YOUR REQUEST - CTAP Blurb

When is the website launching and what else do you expect to put out this week?

From: Flanagan, Keith <Keith.Flanagan@fda.hhs.gov>
Sent: Tuesday, March 24, 2020 2:23 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Kimbrell, Maarika <Maarika.Kimbrell@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: PER YOUR REQUEST - CTAP Blurb

Hi Keagan –

Attached please find announcement of CTAP and gist of what it does.

I'm your point of contact for any questions, etc.

Kind regards,
Keith

From: Kimbrell, Maarika <Maarika.Kimbrell@fda.hhs.gov>
Sent: Tuesday, March 24, 2020 1:52 PM
To: Flanagan, Keith <Keith.Flanagan@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: Draft CTAP Tweets

(b)(5)

Maarika Kimbrell, J.D., M.S.
Deputy Director, Office of New Drug Policy

Center for Drug Evaluation and Research
Office of New Drugs
U.S. Food and Drug Administration
Tel: 240-402-5924
maarika.kimbrell@fda.hhs.gov

U.S. FOOD & DRUG
ADMINISTRATION

From: Marks, Peter [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DFBB2B5BD38445CB9C9ADCA3F72DF53A-MARKSP]
Sent: 3/25/2020 8:00:12 AM
To: Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]
Subject: RE: Expanded Mesenchymal Stem Cells May Offer Hope for COVID-19 Patients

Dear Julie,

Let's sequence our comms and energy:

Thursday: Convalescent Plasma and Hyperimmune Globulins

Friday or Monday: Deferral changes

Tuesday or Wednesday: Stem cell treatments

Best Regards,
Peter

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Tuesday, March 24, 2020 10:42 AM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: FW: Expanded Mesenchymal Stem Cells May Offer Hope for COVID-19 Patients

FYI and I think we need to get something on the web post haste and we can leverage that language.

From: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>
Sent: Tuesday, March 24, 2020 10:29 AM
To: OC OCOD Contacts <OCOCODContacts@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Maloney, Diane <Diane.Maloney@fda.hhs.gov>
Cc: OC OL CBER/CDRH Team <OCOLCBERCDRHTeam@fda.hhs.gov>
Subject: FW: Expanded Mesenchymal Stem Cells May Offer Hope for COVID-19 Patients

Hi all,

Please see the message and attachment from Sen. Paul's office. This looks like an fyi, but I would like to respond to the office with some messaging, perhaps sending the treatment outreach from last week. https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-continues-facilitate-development-treatments

Is there anything more specific I can or should say regarding the stem cell aspect? Please let me know by this afternoon.

Thanks,
Prakash

From: Bennett, Zach (Paul) <Zach_Bennett@paul.senate.gov>
Sent: Tuesday, March 24, 2020 9:50 AM
To: Schwarcz, Cristi L. (CDC/OD/CDCWO) <zcj1@cdc.gov>
Cc: Arbes, Sarah (HHS/ASL) <Sarah.Arbes@hhs.gov>; Gross, Karas (FDA/OC) <Karas.Gross@fda.hhs.gov>
Subject: FW: Expanded Mesenchymal Stem Cells May Offer Hope for COVID-19 Patients

Good morning,

Please see the attached press release, which contains links to a journal article (and related materials) published in the *Pain Physician* about the use of umbilical cord mesenchymal stem cells in critical COVID-19 cases to reduce morbidity and mortality. If this is an avenue the agency wishes to explore, please reach out directly to the article's author, Dr. Laxmaiah Manchikanti, M.D. His contact information is in the e-mail forwarded below.

Thanks for all the work you're doing,

--

Zach Bennett
Legislative Counsel
U.S. Senator Rand Paul, M.D.
167 Russell Senate Office Building
Washington, D.C. 20510

From: "Henderson, William (Paul)" <William_Henderson@paul.senate.gov>
Date: Monday, March 23, 2020 at 5:00 PM
To: "Laxmaiah Manchikanti, MD" <drcm@asipp.org>
Cc: "Bennett, Zach (Paul)" <Zach_Bennett@paul.senate.gov>
Subject: Re: Expanded Mesenchymal Stem Cells May Offer Hope for COVID-19 Patients

Good afternoon. Thank you for sending this. Zach can work with you to get this to the right people in the administration.

> On Mar 23, 2020, at 4:28 PM, Laxmaiah Manchikanti, MD <drcm@asipp.org> wrote:
>
>
> American Society of Interventional Pain Physicians®
> "The Voice of Interventional Pain Management"
> 81 Lakeview Drive, Paducah, KY 42001
> Phone: (270) 554-9412 - Fax: (270) 554-5394
> https://protect2.fireeye.com/url?k=74f27034-28a779e4-74f2410b-0cc47a6a52de-9f8abe90a8b042dc&u=http://www.asipp.org/
>
> March 23, 2020
>
> Senator Rand Paul
> 167 Russell Senate Office Building
> Washington DC, 20510
> william_henderson@paul.senate.gov
>
> RE: Expanded Mesenchymal Stem Cell Infusions in COVID-19 Patients
>
> Honorable Senator Rand Paul:
>
> Thank you for all the help the Senate is providing and supporting the Administration in these hard times. We appreciate your dedication to the Commonwealth of Kentucky and the United States of America. As you know, small practices like ours are hit the most. We were hoping that the Senate bill introduced by Senator Barrasso would pass and be signed into law. However, it appears like it is now a longshot.
>
> Apart from that, we have accumulated evidence in reference to expanded mesenchymal stem cell infusions in COVID-19 patients. I am enclosing a manuscript describing the same.
>

> Please look over the attached press release and see if there is any way we can reach the President or Coronavirus Task Force to provide them with this information. The links for the Fact Sheet, Abstract, and Manuscript can be found in the attached Press Release.
>
> Thank you again for all your help.
>
>
> Laxmaiah Manchikanti, MD
> Chairman of the Board and Chief Executive Officer, ASIPP and SIPMS
> Co-Director, Pain Management Centers of America
> Medical Director, Pain Management Centers of Paducah and Marion
> Ambulatory Surgery Center and Pain Care Surgery Center
> Clinical Professor
> Anesthesiology and Perioperative Medicine
> University of Louisville, Kentucky
> Professor of Anesthesiology-Research
> Department of Anesthesiology, School of Medicine
> LSU Health Sciences Center
>
> 2831 Lone Oak Road
> Paducah, KY 42003
>
> Phone: 270-554-8373 ext. 4101
> Fax: 270-554-8987
> E-mail: drm@asipp.org
>
> LM/den
> To view some of Dr. Manchikanti's publications go to:
> http://www.ncbi.nlm.nih.gov/sites/entrez?cmd=search&db=pubmed&term=manchikanti
> “The most entrenched conflict of interest in medicine is a disinclination to reverse a previous opinion.” Yudkin JS et al. Lancet 2011
> “There is no limit to what a man can do or where he can go if he doesn’t mind who gets the credit.” Ronald Reagan
>
>

From: Maloney, Diane [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E59205500E944C9EACC4524EA18ED5BB-MALONEYD]
Sent: 3/25/2020 11:51:02 AM
To: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Witten, Celia (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fc08ebb3ac61486da9f1b4046757c5cf-Witten]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Verdun, Nicole [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a3aa59faf502446fa6c7a9b2bbe5a946-VERDUNN]; Eder, Anne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a00272f83bac449199cbd1e5d918bf28-Anne.Eder]; Scharpf, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=073b4a34a1094aab911e9662c2a43402-Scharpf]; Zavagno, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=18ed60daba0346b5b8f6277ecdb5bcb4-DZavagno]; Madni, Rubina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6173079ca1d4ebe9e41a770df07016e-Rubina.Madn]
CC: Ripley, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad3fa0068da444cc855fccd951355957-ripley]; Walker Udechukwu, Jessica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1f84acbad5c448459cea6b29a9ec33f5-Jessica.Wal]
Subject: FW: COVID-19 guidance
Attachments: Blood alternative procedures guidance 032520-JDrev ljs.docx

Dear all,
OP reviewed. See minor edits – look okay to me. if any concerns, just let me know.

Dear Denise and Rubina,
Please use this version.

Thanks,
Diane

From: Schiller, Lowell <Lowell.Schiller@fda.hhs.gov>
Sent: Wednesday, March 25, 2020 11:45 AM
To: Maloney, Diane <Diane.Maloney@fda.hhs.gov>; Roth, Lauren <Lauren.Roth@fda.hhs.gov>
Cc: OC OPPB OP RPMS <OCOPPBOPRPMS@fda.hhs.gov>; Ripley, Stephen <Stephen.Ripley@fda.hhs.gov>; Walker Udechukwu, Jessica <Jessica.WalkerUdechukwu@fda.hhs.gov>; Dupont, Jarilyn <Jarilyn.Dupont@fda.hhs.gov>
Subject: RE: COVID-19 guidance

OP edits attached. Would you please send us a clean and a redline that incorporates OCC's edits when available? Thanks!

Lowell

From: Maloney, Diane <Diane.Maloney@fda.hhs.gov>
Sent: Wednesday, March 25, 2020 7:06 AM
To: Schiller, Lowell <Lowell.Schiller@fda.hhs.gov>; Roth, Lauren <Lauren.Roth@fda.hhs.gov>
Cc: OC OPPB OP RPMS <OCOPPBOPRPMS@fda.hhs.gov>; Ripley, Stephen <Stephen.Ripley@fda.hhs.gov>; Walker Udechukwu, Jessica <Jessica.WalkerUdechukwu@fda.hhs.gov>
Subject: COVID-19 guidance

Dear Lowell and Lauren,
Please see attached COVID-19 guidance on blood alternative procedures to address blood shortages. We would like to issue this guidance this week. Should you have any questions, please let us know.
Thank you,
Diane

From: Tierney, Julia [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1160D300BC4248B790DED292A082E9A8-JULIA.TIERN]
Sent: 4/3/2020 4:14:35 PM
To: Edmonds, Amanda [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=232186a24a53474298d2760c060a4cc7-Amanda.Edmo]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Witten, Celia (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fc08ebb3ac61486da9f1b4046757c5cf-Witten]; Maloney, Diane [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e59205500e944c9eacc4524ea18ed5bb-MaloneyD]; Verdun, Nicole [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a3aa59faf502446fa6c7a9b2bbe5a946-VERDUNN]; Eder, Anne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a00272f83bac449199cbd1e5d918bf28-Anne.Eder]; Scharpf, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=073b4a34a1094aab911e9662c2a43402-Scharpf]; McNeill, Lorrie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77b0b352c9c24851bf0c7330f53e00d9-McNeill]
CC: Zavagno, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=18ed60daba0346b5b8f6277ecdb5bcb4-DZavagno]; Madni, Rubina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6173079ca1d4ebe9e41a770df07016e-Rubina.Madn]
Subject: RE: redline from current webpage
Attachments: comparison to existing cp eind webpage.docx

Try this. I have not validated all of the changes yet.

From: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>
Sent: Friday, April 3, 2020 4:09 PM
To: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Witten, Celia (CBER) <Celia.Witten@fda.hhs.gov>; Maloney, Diane <Diane.Maloney@fda.hhs.gov>; Verdun, Nicole <Nicole.Verdun@fda.hhs.gov>; Eder, Anne <Anne.Eder@fda.hhs.gov>; Scharpf, Jennifer <Jennifer.Scharpf@fda.hhs.gov>; McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>
Cc: Zavagno, Denise <Denise.Zavagno@fda.hhs.gov>; Madni, Rubina <Rubina.Madni@fda.hhs.gov>
Subject: RE: redline from current webpage

Thanks, I didn't realize this was an update to material that was already on the web. What is the best way to view this to see how the current website would be different with the new updates? (There is redlining from several authors, so hard to tell what would be new as compared to original here).

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Friday, April 3, 2020 4:06 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Witten, Celia (CBER) <Celia.Witten@fda.hhs.gov>; Maloney, Diane <Diane.Maloney@fda.hhs.gov>; Verdun, Nicole <Nicole.Verdun@fda.hhs.gov>; Eder, Anne <Anne.Eder@fda.hhs.gov>; Scharpf, Jennifer <Jennifer.Scharpf@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>
Subject: redline from current webpage

Current webpage for reference:https://www.fda.gov/vaccines-blood-biologics/investigational-new-drug-ind-or-device-exemption-ide-process-cber/investigational-covid-19-convalescent-plasma-emergency-inds

From: Marks, Peter [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DFBB2B5BD38445CB9C9ADCA3F72DF53A-MARKSP]
Sent: 3/16/2020 4:59:25 PM
To: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Jungman, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5238a0caec064ba8b5d598115bc4f99f-Elizabeth.J]; Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]
CC: Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Kraus, Stefanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9d3959f3365b4fc39a7eb324539215bc-Stefanie.Kr]; Maloney, Diane [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e59205500e944c9eacc4524ea18ed5bb-MaloneyD]; McLatchy, Johanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=895ad3bde51342d5817826ccc9bc1ba7-MCLATCHYJ]
Subject: RE: **(b)(5)**
Attachments: **(b)(5)**

Dear Janet,

Thanks. I don't have anything more to add to Janet's comments, except to note the minor additional edit in the attached.

Best Regards,
Peter

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Monday, March 16, 2020 4:57 PM
To: Jungman, Elizabeth <Elizabeth.Jungman@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Kraus, Stefanie <Stefanie.Kraus@fda.hhs.gov>; Maloney, Diane <Diane.Maloney@fda.hhs.gov>; McLatchy, Johanna <Johanna.McLatchy@fda.hhs.gov>
Subject: Re: **(b)(5)**

(b)(5)

Jw

From: Jungman, Elizabeth <Elizabeth.Jungman@fda.hhs.gov>
Date: March 16, 2020 at 4:27:05 PM EDT
To: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>, Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>, Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>, Kraus, Stefanie <Stefanie.Kraus@fda.hhs.gov>, Maloney, Diane <Diane.Maloney@fda.hhs.gov>, McLatchy, Johanna <Johanna.McLatchy@fda.hhs.gov>
Subject: FW: **(b)(5)**
Importance: High

Drs. Woodcock, Marks, and Cavazzoni:

Stefanie Kraus from CDER/ORP worked with Julie Tierney from CBER to draft the attached proposed response to the **(b)(5)** If you have edits, please cc Stefanie and she can help coordinate our response. We know **Anand was hoping to respond to HHS by 5pm today**, so apologies for the tight turnaround.

On the substance of the response:

(b)(5)

- Please note that if we end up needing a shorter summary response (e.g. for a cover email), we can just pull out the first paragraph.

Once we have a version you are all comfortable with, please let me know whether you'd rather we follow up with Anand or if you'd like to do so yourself.

Elizabeth Jungman
Director, Office of Regulatory Policy
Center for Drug Evaluation & Research, FDA
240-402-1563 (work)
(b)(6) (work cell)

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Monday, March 16, 2020 9:46 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Patel, Chaitali <Chaitali.Patel@fda.hhs.gov>; McLatchy, Johanna <Johanna.McLatchy@fda.hhs.gov>; Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>
Subject: FW: **(b)(5)**

PRE-DECISIONAL, CONFIDENTIAL

Dear Janet and Peter –

(b)(5) Stacy will also be sharing with the OCC team.

Thank you for prioritizing this review. I will need to provide HHS with comments by 5pm today.

Best,
Anand

From: Marks, Peter [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DFBB2B5BD38445CB9C9ADCA3F72DF53A-MARKSP]
Sent: 3/16/2020 5:45:44 PM
To: McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Zeller, Mitchell [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=de7d2fda971e418ba33cb211a4013976-Mitchell.Ze]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Solomon, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e49ac6a056dc4f299ea269945e962e82-SSOLOMON]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]
CC: 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]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Hebert, Angelique A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aa08f3428a045f88eb3bd92c68a27cf-Angelique.H]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; 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]; Hussey, Deirdre [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41a51a9bf937431c8470b69fb055fe81-Husseyd]; Barth, Janelle [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=18d28baf2bfa435abc9cdfa076774dc0-Janelle.Bar]; Stone, Eric [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5799d336f4c142aca71a655e4184d6bd-Eric.Stone]; Huttenlocker, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=65254282fa6a4e138f506f96cfe9049c-Denise.Hutt]; Domanski, Jeffrey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ed00c0aa83794cbebfc0a50f6cd4d7f9-Jeffrey.Dom]; Schweitzer, Roxanne K [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=292135d254924252958e25cc5a63b079-RSCHWEIT]; Branch, Tiffany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b45f1b97b5d648f68cdff5ce4f75a154-Tiffany.Bra]; Barfell, Glenda F [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33b220e98ac9456eb32888261156f400-GBARFELL]; Lynch, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d24ee4a4fc6241f48110d6b35e6704ed-Sarah.Lynch]
Subject: RE: Flagging for PDC/CD/ACRA: Commissioner all hands update to go out asap today

Nor from me. Thanks so much!

Peter

From: McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>
Sent: Monday, March 16, 2020 5:43 PM
To: Zeller, Mitchell <Mitchell.Zeller@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Solomon, Steven M <Steven.Solomon@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hebert, Angelique A. <Angelique.Hebert@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hussey, Deirdre <Deirdre.Hussey@fda.hhs.gov>; Barth, Janelle <Janelle.Barth@fda.hhs.gov>; Stone, Eric <Eric.Stone@fda.hhs.gov>; Huttenlocker, Denise <Denise.Huttenlocker@fda.hhs.gov>; Domanski, Jeffrey <Jeffrey.Domanski@fda.hhs.gov>; Schweitzer, Roxanne K <Roxanne.Schweitzer@fda.hhs.gov>; Branch, Tiffany <Tiffany.Branch@fda.hhs.gov>; Barfell, Glenda F <Glenda.Barfell@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>
Subject: RE: Flagging for PDC/CD/ACRA: Commissioner all hands update to go out asap today

No suggested edits from me, thanks!

From: Zeller, Mitchell <Mitchell.Zeller@fda.hhs.gov>
Sent: Monday, March 16, 2020 5:43 PM
To: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Solomon, Steven M <Steven.Solomon@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hebert, Angelique A. <Angelique.Hebert@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hussey, Deirdre <Deirdre.Hussey@fda.hhs.gov>; Barth, Janelle <Janelle.Barth@fda.hhs.gov>; Stone, Eric <Eric.Stone@fda.hhs.gov>; Huttenlocker, Denise <Denise.Huttenlocker@fda.hhs.gov>; Domanski, Jeffrey <Jeffrey.Domanski@fda.hhs.gov>; Schweitzer, Roxanne K <Roxanne.Schweitzer@fda.hhs.gov>; Branch, Tiffany <Tiffany.Branch@fda.hhs.gov>; Barfell, Glenda F <Glenda.Barfell@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>
Subject: RE: Flagging for PDC/CD/ACRA: Commissioner all hands update to go out asap today

Agreed.

Is there now an expedited clearance process for these types of messages?

Mitch

From: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
Sent: Monday, March 16, 2020 5:41 PM
To: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Solomon, Steven M <Steven.Solomon@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Zeller, Mitchell <Mitchell.Zeller@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>

Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hebert, Angelique A. <Angelique.Hebert@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hussey, Deirdre <Deirdre.Hussey@fda.hhs.gov>; Barth, Janelle <Janelle.Barth@fda.hhs.gov>; Stone, Eric <Eric.Stone@fda.hhs.gov>; Huttenlocker, Denise <Denise.Huttenlocker@fda.hhs.gov>; Domanski, Jeffrey <Jeffrey.Domanski@fda.hhs.gov>; Schweitzer, Roxanne K <Roxanne.Schweitzer@fda.hhs.gov>; Branch, Tiffany <Tiffany.Branch@fda.hhs.gov>; Barfell, Glenda F <Glenda.Barfell@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>
Subject: Re: Flagging for PDC/CD/ACRA: Commissioner all hands update to go out asap today

Reviewed. This looks good from my perspective.

From: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Sent: Monday, March 16, 2020 5:23 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Solomon, Steven M <Steven.Solomon@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Zeller, Mitchell <Mitchell.Zeller@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hebert, Angelique A. <Angelique.Hebert@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hussey, Deirdre <Deirdre.Hussey@fda.hhs.gov>; Barth, Janelle <Janelle.Barth@fda.hhs.gov>; Stone, Eric <Eric.Stone@fda.hhs.gov>; Huttenlocker, Denise <Denise.Huttenlocker@fda.hhs.gov>; Domanski, Jeffrey <Jeffrey.Domanski@fda.hhs.gov>; Schweitzer, Roxanne K <Roxanne.Schweitzer@fda.hhs.gov>; Branch, Tiffany <Tiffany.Branch@fda.hhs.gov>; Barfell, Glenda F <Glenda.Barfell@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>
Subject: Flagging for PDC/CD/ACRA: Commissioner all hands update to go out asap today

(b)(5)

(b)(5)

Stephen M. Hahn, M.D.
FDA Commissioner

From: Marks, Peter [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DFBB2B5BD38445CB9C9ADCA3F72DF53A-MARKSP]
Sent: 3/16/2020 5:50:53 PM
To: Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]; Kraus, Stefanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9d3959f3365b4fc39a7eb324539215bc-Stefanie.Kr]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Jungman, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5238a0caec064ba8b5d598115bc4f99f-Elizabeth.J]
CC: Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Maloney, Diane [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e59205500e944c9eacc4524ea18ed5bb-MaloneyD]; McLatchy, Johanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=895ad3bde51342d5817826ccc9bc1ba7-MCLATCHYJ]
Subject: RE: **(b)(5)**

Dear Stephanie,

This looks good to me. Patrizia's edit took care of my one edit, so I am set.

Best Regards,
Peter

From: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Sent: Monday, March 16, 2020 5:49 PM
To: Kraus, Stefanie <Stefanie.Kraus@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Jungman, Elizabeth <Elizabeth.Jungman@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Maloney, Diane <Diane.Maloney@fda.hhs.gov>; McLatchy, Johanna <Johanna.McLatchy@fda.hhs.gov>
Subject: RE: **(b)(5)**

Stephanie
One edits, for internal consistency . Also, feel free to edit the text I added if you think it may be too forceful.

Patrizia

From: Kraus, Stefanie <Stefanie.Kraus@fda.hhs.gov>
Sent: Monday, March 16, 2020 5:44 PM
To: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Jungman, Elizabeth <Elizabeth.Jungman@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Maloney, Diane <Diane.Maloney@fda.hhs.gov>; McLatchy, Johanna <Johanna.McLatchy@fda.hhs.gov>
Subject: RE: **(b)(5)**

Hi all; I've discussed the comments with EJ and revised the draft to address them. I'm circulating the updated draft with redlines to reflect the bullets suggested and language on severely ill patients. We accepted Diane's and Peter's edits. Please let us know if we've addressed the comments adequately and are on the right track.

-Stefanie

From: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Sent: Monday, March 16, 2020 5:10 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Jungman, Elizabeth <Elizabeth.Jungman@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Kraus, Stefanie <Stefanie.Kraus@fda.hhs.gov>; Maloney, Diane <Diane.Maloney@fda.hhs.gov>; McLatchy, Johanna <Johanna.McLatchy@fda.hhs.gov>
Subject: RE: **(b)(5)**

Some added text , in the same vein as JW's comments. I think we need to be stronger and agree that the bulleted approach would convey the most important points clearly and upfront.
Patrizia

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Monday, March 16, 2020 4:57 PM
To: Jungman, Elizabeth <Elizabeth.Jungman@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Kraus, Stefanie <Stefanie.Kraus@fda.hhs.gov>; Maloney, Diane <Diane.Maloney@fda.hhs.gov>; McLatchy, Johanna <Johanna.McLatchy@fda.hhs.gov>
Subject: Re: **(b)(5)**

(b)(5)

Jw

From: Jungman, Elizabeth <Elizabeth.Jungman@fda.hhs.gov>
Date: March 16, 2020 at 4:27:05 PM EDT
To: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>, Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>, Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>, Kraus, Stefanie <Stefanie.Kraus@fda.hhs.gov>, Maloney, Diane <Diane.Maloney@fda.hhs.gov>, McLatchy, Johanna <Johanna.McLatchy@fda.hhs.gov>
Subject: FW: **(b)(5)**
Importance: High

Drs. Woodcock, Marks, and Cavazzoni:

Stefanie Kraus from CDER/ORP worked with Julie Tierney from CBER to draft the attached proposed response to the (b)(5) If you have edits, please cc Stefanie and she can help coordinate our response. We know **Anand was hoping to respond to HHS by 5pm today**, so apologies for the tight turnaround.

On the substance of the response:

(b)(5)

- Please note that if we end up needing a shorter summary response (e.g. for a cover email), we can just pull out the first paragraph.

Once we have a version you are all comfortable with, please let me know whether you'd rather we follow up with Anand or if you'd like to do so yourself.

Elizabeth Jungman
Director, Office of Regulatory Policy
Center for Drug Evaluation & Research, FDA
240-402-1563 (work)
(b)(6) (work cell)

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Monday, March 16, 2020 9:46 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Patel, Chaitali <Chaitali.Patel@fda.hhs.gov>; McLatchy, Johanna <Johanna.McLatchy@fda.hhs.gov>; Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>
Subject: FW: **(b)(5)**

PRE-DECISIONAL, CONFIDENTIAL

Dear Janet and Peter –

(b)(5) Stacy will also be sharing with the OCC team.

Thank you for prioritizing this review. I will need to provide HHS with comments by 5pm today.

Best,
Anand

From: Marks, Peter [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DFBB2B5BD38445CB9C9ADCA3F72DF53A-MARKSP]
Sent: 3/17/2020 9:48:22 AM
To: 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]
Subject: RE: **(b)(5)**

Dear Janet and Patrizia,

Do you have a minute to discuss? I had a call with Anand, Geet, and OIRA yesterday on vaccines that provided some interesting insight.

Best Regards,
Peter

From: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Sent: Tuesday, March 17, 2020 9:45 AM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Jungman, Elizabeth <Elizabeth.Jungman@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Sipes, Grail <Grail.Sipes@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Kraus, Stefanie <Stefanie.Kraus@fda.hhs.gov>
Subject: RE: **(b)(5)**

Thank you all for the quick turnaround. As a next step, Dr. Hahn is interested in ideas **(b)(5)**

(b)(5)

(b)(5) Just let us know if you have any questions on this request.

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Date: March 17, 2020 at 9:06:09 AM EDT
To: Jungman, Elizabeth <Elizabeth.Jungman@fda.hhs.gov>, Amin, Stacy <Stacy.Amin@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Cc: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>, Marks, Peter <Peter.Marks@fda.hhs.gov>, Tierney, Julia <Julia.Tierney@fda.hhs.gov>, Sipes, Grail <Grail.Sipes@fda.hhs.gov>, Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>, Kraus, Stefanie <Stefanie.Kraus@fda.hhs.gov>
Subject: RE: **(b)(5)**

Hi Elizabeth –

Steve reviewed the response to the (b)(5) and has some feedback. Jeet will follow up shortly

Thanks again

Anand

From: Shah, Anand
Sent: Tuesday, March 17, 2020 6:47 AM
To: Jungman, Elizabeth <Elizabeth.Jungman@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>
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Thank you, Elizabeth and team, for the detailed review that I have also shared with Steve.

Anand

From: Jungman, Elizabeth <Elizabeth.Jungman@fda.hhs.gov>
Sent: Monday, March 16, 2020 6:12 PM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>
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Subject: FW: **(b)(5)**

Please see attached a joint CDER-CBER proposed response to the **(b)(5)**

Elizabeth Jungman
Director, Office of Regulatory Policy
Center for Drug Evaluation & Research, FDA
240-402-1563 (work)
(b)(6) (work cell)

From: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Sent: Monday, March 16, 2020 9:52 AM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: RE: **(b)(5)**

Janet and Peter good to meet you – I recently joined OC from CMS.

Just let us know; also as fyi, initial/high-level comments would be most helpful on this. Thanks so much.

--

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: Monday, March 16, 2020 9:49 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Subject: RE: **(b)(5)**

Janet and Peter –

I've asked Jeet to reach out to you with some additional context

Please let us know the best #'s to reach you for a few min

Anand

PRE-DECISIONAL, CONFIDENTIAL

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PRE-DECISIONAL, CONFIDENTIAL

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(b)(5) Stacy will also be sharing with the OCC team.

Thank you for prioritizing this review. I will need to provide HHS with comments by 5pm today.

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Sent: 3/17/2020 10:01:38 AM
To: Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
Subject: RE: **(b)(5)**

Dear Patrizia,

Just had a quick touch base with Janet. I am sure that we are all on the same page. We can catch up later to synch on anything.

Best Regards,
Peter

From: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Sent: Tuesday, March 17, 2020 10:00 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: RE: **(b)(5)**

We can use my dial-in number

Dial In Number Local/Toll Number 1-210-795-1100 Freephone/Toll Free Number 866-880-0098 Passcodes Leader: **(b)(6)** Participant: **(b)(6)**

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Tuesday, March 17, 2020 9:51 AM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Subject: RE: **(b)(5)**

I will be at 796 3426 for an hour. w

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Tuesday, March 17, 2020 9:48 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Subject: RE: **(b)(5)**

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Cc: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Sipes, Grail <Grail.Sipes@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Kraus, Stefanie <Stefanie.Kraus@fda.hhs.gov>
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<Patrizia.Cavazzoni@fda.hhs.gov>; Kraus, Stefanie <Stefanie.Kraus@fda.hhs.gov>
Subject: FW: **(b)(5)**

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Elizabeth Jungman
Director, Office of Regulatory Policy
Center for Drug Evaluation & Research, FDA
240-402-1563 (work)
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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: **(b)(5)**

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PRE-DECISIONAL, CONFIDENTIAL

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Best,

Anand

From: Marks, Peter [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DFBB2B5BD38445CB9C9ADCA3F72DF53A-MARKSP]
Sent: 3/19/2020 7:01:40 AM
To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; 2019-nCoV FDA IMG JIC [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=289715a1146847558b07a33ccab6bccf-2019-nCoV F]; OCCRequests-COVID19 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcb756008a41407282a58324a7b5144a-OCCRequests]; 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]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]; 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]
Subject: RE: QUICK TURN-AROUND: updated POTUS TPs, due by 6:30AM to HHS
Attachments: POTUS_TPS_11pm_FDA (1).docx

Dear Stephanie,

The situation for blood has changed somewhat, so updated that, including language that CDC and FDA agreed upon.

Best Regards,
Peter

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Wednesday, March 18, 2020 11:03 PM
To: 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>; OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: QUICK TURN-AROUND: updated POTUS TPs, due by 6:30AM to HHS

Updated TPs for POTUS press briefing tomorrow on therapeutics. CDER/CBER—can you look at quickly? I've added edits and a note on attached version. This is due to HHS by 6:30am. Thanks!

Press Conference on FDA Developments

(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: Marks, Peter [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DFBB2B5BD38445CB9C9ADCA3F72DF53A-MARKSP]
Sent: 3/20/2020 6:12:21 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]
CC: Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Edmonds, Amanda [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=232186a24a53474298d2760c060a4cc7-Amanda.Edmo]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
Subject: RE: Vaccine development idea
Attachments: SARS-CoV-2 vaccine manufacturers.docx

Dear Keagan,

Sorry – took a while to get permission from manufacturers. Just got the last one. Please see the attached and below. Just let me know if you need assistance talking to anyone over the weekend.

Best Regards,
Peter

ModernaTX, Inc.	mRNA-1273, a novel lipid-encapsulated mRNA-based prophylactic vaccine encoding the pre-fusion stabilized Spike (S) glycoprotein of the SARS-CoV-2 virus	Tal Zaks, MD Chief Medical Officer ModernaTX Inc Tal.zaks@modernatx.com | modernatx.com | mobile **(b)(6)**

(b)(4) (b)(5)

(b)(4) (b)(5)

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Friday, March 20, 2020 5:47 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Cc: Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: RE: Vaccine development idea

Any update on vaccines?

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Friday, March 20, 2020 12:38 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Cc: Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: RE: Vaccine development idea

Dear Keagan,

Thanks. That sounds fine to me. I have a feeling that we will not have the vaccine information ready until late today, so we might need to have this call over the weekend.

Best Regards,
Peter

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Friday, March 20, 2020 12:36 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Cc: Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: RE: Vaccine development idea

Thank you all. Would like to make sure we are coordinated and understand what we are getting back to the Hill.

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Friday, March 20, 2020 11:09 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Cc: Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: RE: Vaccine development idea

Dear Keagan,

My vote is that we get more info, get it prepped for the hill and then touch bases if need be, or after it is reviewed on the hill to take care of questions.

Best Regards,
Peter

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Friday, March 20, 2020 11:05 AM
To: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: RE: Vaccine development idea

Do we need a call? Or more info first?

From: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Sent: Friday, March 20, 2020 10:49 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: RE: Vaccine development idea

Peter and I spoke. We are going to take the same approach as CBER, ie reach out to Gov Affairs in the companies in question (monoclonals) and ask them that they reach out to Sen. Daines
Patrizia

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Friday, March 20, 2020 9:58 AM
To: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: Re: Vaccine development idea

Should we hop on a call to discuss?

Sent from my iPhone

On Mar 20, 2020, at 9:53 AM, Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov> wrote:

We don't think this is a good idea.
Patrizia

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Friday, March 20, 2020 9:26 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Subject: RE: Vaccine development idea

Dear Keagan,

Definitely would consider these! This is CDER's domain, so looping Patrizia in. (Patrizia – let me know when you have time and I can call you to loop you in.)

Best Regards,
Peter

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Friday, March 20, 2020 9:19 AM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>
Subject: Re: Vaccine development idea

Peter- can you think through monoclonal antibodies as well, and if we should be exploring that avenue with the vaccines?

Sent from my iPhone

On Mar 20, 2020, at 9:08 AM, Marks, Peter <Peter.Marks@fda.hhs.gov> wrote:

Dear Commissioner and Amanda,

We are working on getting permission from the most promising 3-4 vaccine companies for permission to have the Senator or staffers to contact them. Expect this by the end of the day.

I remain available at any time if you need anything here.

Best Regards,
Peter

From: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Sent: Friday, March 20, 2020 9:06 AM
To: Hahn, Stephen <SH1@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>
Subject: Vaccine development idea

Commissioner – I have Amanda Edmonds working on this—Amanda is my best lawyer and will get this worked through with Peter. We agree it will require some creative leg writing.

Is the next step for us to connect with Sen Daines once we have an idea of how to do this?

Best,
Stacy

****

Stacy Cline Amin
Chief Counsel
Food and Drug Administration

Deputy General Counsel
Department of Health and Human Services

From: Marks, Peter [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DFBB2B5BD38445CB9C9ADCA3F72DF53A-MARKSP]
Sent: 2/8/2020 10:34:20 AM
To: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Solomon, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e49ac6a056dc4f299ea269945e962e82-SSOLOMON]; 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]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]; Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]
Subject: RE: Clinical Characteristics of 138 Hospitalized Patients With 2019 Novel Coronavirus–Infected Pneumonia in Wuhan, China

Dear Michael,

Thanks very much for forwarding this along.

Best Regards,
Peter

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Saturday, February 8, 2020 10:07 AM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; 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>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
Subject: Clinical Characteristics of 138 Hospitalized Patients With 2019 Novel Coronavirus–Infected Pneumonia in Wuhan, China

JAMA: Clinical Characteristics of 138 Hospitalized Patients With 2019 Novel Coronavirus–Infected Pneumonia in Wuhan, China

Conclusions and Relevance In this single-center case series of 138 hospitalized patients with confirmed NCIP in Wuhan, China, presumed hospital-related transmission of 2019-nCoV was suspected in 41% of patients, 26% of patients received ICU care, and mortality was 4.3%.

From: Marks, Peter [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DFBB2B5BD38445CB9C9ADCA3F72DF53A-MARKSP]
Sent: 1/10/2020 2:35:31 PM
To: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; 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: Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]
Subject: RE: Update on Undiagnosed Pneumonia - China

Dear Michael,

Thanks so much for this update.

Best Regards,
Peter

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Friday, January 10, 2020 1:31 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Subject: Update on Undiagnosed Pneumonia - China

Hi. I wanted to provide you with a quick update on the outbreak of pneumonia of unknown cause that is ongoing in Wuhan, China.

Overview:

- There are 59 cases of pneumonia listed as unknown etiology, 7 listed as severe.
- There is a limited clinical picture. Symptom onset of cases is from 12-29 December. Wuhan health officials have not announced any new cases since 05 Jan.
- All known cases are linked to live fish market in Wuhan (closed on 01 December) that also sells other animals.
- There have been no reported health care worker infections or human-to-human transmission.
- 153 known close contacts are being monitored.
- Chinese authorities have made a preliminary determination of a novel coronavirus as the etiologic agent, identified in a hospitalized person with pneumonia in Wuhan
- *Science* is reporting that the "*Two groups isolated the virus from samples from one patient*…[that]…*A total of 15* [of the 59 cases] *were positive for the novel virus, [based on] sequencing samples of [fluid injected into the lung and collected for examination]*…[and that]…*the virus is similar to some of the published* [corona]*viruses collected from bats. But it is not close to SARS and not close to MERS*."
- There has been no known international spread, but many countries in the region have activated protocols to monitor for pneumonia patients of unknown etiology who have recently traveled to China.

WHO Activities:

- WHO is closely monitoring the situation and is in close contact with national authorities in China.
- WHO has requested more information from China on the epidemiological situation and ongoing investigations
- WHO is not currently recommending any specific measures for travelers.
- WHO is developing guidance for member states.

- WHO R&D Blueprint Team held a teleconference on 10 Jan to update members of the Global Coordination Mechanism on the cluster of pneumonia cases and discuss next steps.

USG Activities:

- CDC issued a level 1 travel notice on 06 Jan.
- CDC issued a Health Alert Network notice on 08 Jan.

FDA Activities:

- The FDA Emerging Threats Task Force is monitoring the situation and working to advance and coordinate response activities as necessary.
- The Division of Microbiology (OHT7-OIR/CDRH) is proactively coordinating with CDC on diagnostic activities:
  - DMD had a telecon with CDC on 08 Jan:
    - CDC briefed DMD on the current situation and noted that they expect the genetic sequence information to be released soon.
    - In anticipation of testing specimens from returning travelers, CDC is developing a molecular test, likely based on the CDC Novel Coronavirus 2012 Real-time RT-PCR Assay (which FDA authorized for use under EUA in June 2014 for the presumptive detection of MERS-CoV), that they will CLIA validate for use in their labs.
    - From a preparedness standpoint CDC is also planning on submitting a pre-EUA package in case distribution of the test within the Laboratory Response Network is necessary to meet testing demands. DMD is working on an EUA Review template outlining the data requirements for the Pre-EUA package based on previous experience with MERS-CoV.

From: Marks, Peter [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DFBB2B5BD38445CB9C9ADCA3F72DF53A-MARKSP]
Sent: 1/31/2020 8:04:03 AM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; 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]; Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]
Subject: Vaccine TPs
Attachments: Considerations in coronavirus vaccine development 013120.docx

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: Marks, Peter [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DFBB2B5BD38445CB9C9ADCA3F72DF53A-MARKSP]
Sent: 1/31/2020 4:55:46 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; 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]; Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]
Subject: RE: Vaccine TPs
Attachments: Considerations in coronavirus vaccine development 013120.docx

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: Marks, Peter [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DFBB2B5BD38445CB9C9ADCA3F72DF53A-MARKSP]
Sent: 3/16/2020 2:03:11 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: RE: blood supply
Attachments: AABB-COVID-19-Outbreak-Checklist.docx

Dear Keagan,

The blood centers have the attached extensive checklist, but the long and the short of it is the following:

- Blood centers either have or are working on developing appointment calendars for individuals to donate, so that people don't have to wait in long lines
- Blood centers screen donors before they enter the donor room to make sure that they are healthy
- Staff are skilled at dealing with infection control practices from prior experience and will be taking all appropriate precautions to facilitate donor safety.

Just let me know if you need anything else. Happy to brief anyone on this as need be.

Best Regards,
Peter

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Monday, March 16, 2020 1:47 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: blood supply

Hi Peter – Kelly Anne Conway is going to help get the message out on blood supply. Can you get me the AAV guidance on social distancing, but still giving blood?