From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 8/19/2020 8:59:26 AM
To: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]
CC: FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]; 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]; 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]; 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]; Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; Jenkins, Charlene [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e722b6438b04d2e9029c72543639a67-Charlene.Je]
Subject: Re: Telecon: Weekly CBER Meeting with the Commissioner

Looks good Peter

Sent from my iPad

On Aug 19, 2020, at 4:54 AM, Marks, Peter <Peter.Marks@fda.hhs.gov> wrote:

Dear All,

My apologies for the late agenda. Please let me know if there are topics that you would like to add:

1. Update on (b) (4)
2. Progress on convalescent plasma EUA
3. (b) (4)
4. Potential logistics of an EUA and VRBPAC AC meeting planning

a. Committee composition
b. Meeting dates
c. Webcasting

We have an addition 15 minutes on the calendar on August 20 in the event that we do not get through the AC agenda.

Best Regards,
Peter

-----Original Appointment-----
From: FDA Commissioner <Stephen.Hahn@fda.hhs.gov>
Sent: Friday, April 17, 2020 11:18 PM

To: FDA Commissioner; Hahn, Stephen; Lenihan, Keagan; Abram, Anna; Marks, Peter; Witten, Celia (CBER); Tierney, Julia; Shah, Anand
Cc: Rom, Colin
Subject: Telecon: Weekly CBER Meeting with the Commissioner
When: Wednesday, August 19, 2020 11:00 AM-11:30 AM (UTC-05:00) Eastern Time (US & Canada).
Where: 1-877-465-7975,,(b) (6)

From: Sheehy, Janice [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F45A6C96F5274724A1BE5970EB648FF7-JSHEEHY]
Sent: 8/23/2020 10:30:07 AM
To: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]

Subject: Rose Garden Press Event

Start: 8/23/2020 6:00:00 PM
End: 8/23/2020 6:30:00 PM
Show Time As: Busy

From: Caccomo, Stephanie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=950C32CEBC4B4F80B302C50CF31C8524-STEPHANIE.C]
Sent: 8/23/2020 8:12:28 AM
To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Lenihan, Keagan [Keagan.Lenihan@fda.hhs.gov]; Shah, Anand [Anand.Shah@fda.hhs.gov]; Wagner, John [John.Wolf.Wagner@fda.hhs.gov]; Miller, Emily [Emily.Miller@fda.hhs.gov]; Pratt, Michael (OS) [Michael.Pratt@hhs.gov]; Marks, Peter [Peter.Marks@fda.hhs.gov]; Murphy, Ryan (OS) [Ryan.Murphy1@hhs.gov]; Caputo, Michael R (OS) [Michael.Caputo@hhs.gov]; Felberbaum, Michael [Michael.Felberbaum@fda.hhs.gov]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]

Subject: CP rollout prep for SH

Start: 8/23/2020 2:00:00 PM
End: 8/23/2020 2:30:00 PM
Show Time As: Tentative

Required Attendees: Lenihan, Keagan; Shah, Anand; Wagner, John; Miller, Emily; Pratt, Michael (OS); Marks, Peter; Murphy, Ryan (OS); Caputo, Michael R (OS); Felberbaum, Michael; Hahn, Stephen

Join by phone
210-795-0506 US Toll
877-465-7975 US Toll Free
Access code: (b) (6)

From: Caccomo, Stephanie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=950C32CEBC4B4F80B302C50CF31C8524-STEPHANIE.C]
Sent: 8/22/2020 3:50:51 PM
To: 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]; Lenihan, Keagan [Keagan.Lenihan@fda.hhs.gov]; Shah, Anand [Anand.Shah@fda.hhs.gov]; Wagner, John [John.Wolf.Wagner@fda.hhs.gov]; Miller, Emily [Emily.Miller@fda.hhs.gov]; Pratt, Michael (OS) [Michael.Pratt@hhs.gov]; Marks, Peter [Peter.Marks@fda.hhs.gov]; McNeill, Lorrie [Lorrie.McNeill@fda.hhs.gov]; Frantz-Bohn, Susan [Susan.Frantzbohn@fda.hhs.gov]; Murphy, Ryan (OS) [Ryan.Murphy1@hhs.gov]; Felberbaum, Michael [Michael.Felberbaum@fda.hhs.gov]; Guevara, Bessy [Bessy.Guevara@fda.hhs.gov]; Caputo, Michael R (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dac6080dfebe436da01db07986b63377-HHS-Michael]
CC: Tierney, Julia [Julia.Tierney@fda.hhs.gov]; Emily Miller [emilymiller.miller@gmail.com]

Subject: PREP FOR CP

Start: 8/23/2020 11:00:00 AM
End: 8/23/2020 11:30:00 AM
Show Time As: Tentative

Required Attendees: Caccomo, Stephanie; Hahn, Stephen; Lenihan, Keagan; Shah, Anand; Wagner, John; Miller, Emily; Pratt, Michael (OS); Marks, Peter; McNeill, Lorrie; Frantz-Bohn, Susan; Murphy, Ryan (OS); Caputo, Michael R (OS); Felberbaum, Michael; Guevara, Bessy

Join by phone
210-795-0506 US Toll
877-465-7975 US Toll Free
Access code: (b) (6)

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 8/19/2020 11:15:44 AM
To: Secretary Scheduler (OS/IOS) [Secretary.Scheduler@hhs.gov]

Subject: Accepted: AMA update on Convalescent Plasma
Location: 615-F / 202-619-7800

Start: 8/21/2020 3:00:00 PM
End: 8/21/2020 3:30:00 PM

Recurrence: (none)

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 8/19/2020 10:08:16 AM
To: 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]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]
Subject: Re: Flag, NYT Qs on CP EUA

Please

Sent from my iPad

On Aug 19, 2020, at 10:07 AM, Marks, Peter <Peter.Marks@fda.hhs.gov> wrote:

Dear Commissioner and Keagan,

I would like to at least touch upon this at our meeting today. Thanks.

Best Regards,
Peter

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Wednesday, August 19, 2020 9:38 AM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Wagner, John <John.Wolf.Wagner@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Miller, Emily <Emily.Miller@fda.hhs.gov>
Subject: RE: Flag, NYT Qs on CP EUA

Peter—the source was Dr. Lane from NIAID. On the record.

Story from NYT posted:

WASHINGTON — Last week, just as the Food and Drug Administration was preparing to issue an emergency authorization for blood plasma as a Covid-19 treatment, a group of top federal health officials including Dr. Francis S. Collins and Dr. Anthony S. Fauci intervened, arguing that emerging data on the treatment was too weak, according to two senior administration officials.

The authorization is on hold for now as more data is reviewed, according to H. Clifford Lane, the clinical director at the National Institute of Allergy and Infectious Diseases. An emergency approval could still be issued in the near future, he said.

Donated by people who have survived the disease, antibody-rich plasma is considered safe. President Trump has hailed it as a "beautiful ingredient" in the veins of people who have survived Covid-19.

But clinical trials have not proved whether plasma can help people fighting the coronavirus.

Several top health officials — led by Dr. Collins, the director of the National Institutes of Health; Dr. Fauci, the government's top infectious disease expert; and Dr. Lane — urged their colleagues last week to hold off, citing recent

data from the country's largest plasma study, run by the Mayo Clinic. They thought the study's data to date was not strong enough to warrant an emergency approval.

"The three of us are pretty aligned on the importance of robust data through randomized control trials, and that a pandemic does not change that," Dr. Lane said in an interview on Tuesday.

The drafted emergency authorization leaned on the history of plasma's use in other disease outbreaks and on animal research and a spate of plasma studies, including the Mayo Clinic's program, which has given infusions to more than 66,000 Covid-19 patients thanks to financing from the federal government.

An F.D.A. spokeswoman declined to comment.

Plasma, the pale yellow liquid leftover after blood is stripped of its red and white cells, has been the subject of months of intense enthusiasm from scientists, celebrities and Mr. Trump, part of the administration's push for coronavirus treatments as a stopgap while pharmaceutical companies race to complete dozens of clinical trials for coronavirus vaccines.

Emergency authorizations, which do not require the same level of evidence as a full F.D.A. approval would, have been a fraught subject for the government during the pandemic. The agency gave one to the malaria drugs hydroxychloroquine and chloroquine only to rescind it months later after the drugs were found to be ineffective against the coronavirus, and potentially harmful. An emergency authorization for blood plasma would most likely ease the clerical burdens on hospitals in conducting infusions.

Senior health officials have privately expressed concern about the rapid growth of the Mayo program and the perceived rush to declare plasma effective without the affirmation of results from randomized trials, which scientists have long relied on as the gold standard of evidence. Skyrocketing enrollment in the program has prompted a debate among researchers about what kind of empirical certainty is needed in treating patients in a public health emergency.

An emergency approval now would "change the way people view trials," said Dr. Mila B. Ortigoza, an infectious disease specialist at N.Y.U. Langone Health who started a trial with colleagues at Montefiore Medical Center.

"We want to make sure that when we say it works, we are confident, with indisputable evidence," she said. "We're dealing with patients' lives here."

Unlike the malaria drugs, plasma, which has been used since the 1890s to treat infectious diseases, has earned the attention of a highly credentialed community of microbiologists and immunologists eager to prove its usefulness. The Mayo Clinic has already published analysis on tens of thousands of patients in its expanded access program showing that plasma is safe.

The most recent batch of data from the program included more than 35,000 Covid-19 patients, many of them in intensive care and on ventilators, and suggested that plasma administered within three days of a diagnosis reduced mortality rates. When calculated a month after the infusions, the death rate of patients who received plasma within three days of diagnosis was lower (21.6 percent) than it was for those who received plasma later (26.7 percent).

Coronavirus Schools Briefing: The pandemic is upending education. Get the latest news and tips as students go back to school.

But the study did not have a control group of patients given a placebo to compare with those given plasma, making it difficult for scientists to assess whether the treatment really worked. And given the limited supply of plasma, it is not clear how realistic treating patients within three days of diagnosis would be.

The program's enrollment has surged to more than 30 times as high as initially expected, complicating the ability of scientists to recruit sick patients to randomized trials.

It "ballooned to a degree that, you know, is becoming unmanageable," Dr. Lane said.

Statisticians at the F.D.A. are now examining the Mayo data to better understand what factors other than the treatment might have influenced patient responses, such as higher-quality care in the hospital, Dr. Lane said.

A research team from Houston Methodist hospitals also published preliminary results from a plasma trial last week. Their study of hospitalized Covid-19 patients in the American Journal of Pathology reported that a group of 136 patients who received the treatment were more likely to be alive four weeks later compared with 251 patients who did not

receive it. That study found a statistically significant benefit only when patients were treated within three days of admission and when the plasma contained a high concentration of antibodies.

The Houston study was not randomized, meaning that all of the patients enrolled received the treatment and none received a placebo. (The researchers later compared their outcomes to records from other Covid-19 patients who were not in the study but were matched to be similar to them.)

A surge in cases in Texas this summer quickly brought the hospital system to its enrollment cap, and doctors there have not been able to provide the experimental treatment since mid-July. If the F.D.A. gave an emergency authorization, doctors at the hospital could possibly begin administering it again, said Dr. Eric Salazar, the study's principal investigator.

But an emergency authorization could have the unintended effect of making it harder for rigorous clinical trials to definitively show whether plasma works. Scientists have struggled to recruit patients for randomized trials, as many patients and their doctors — knowing they could get the treatment under the Mayo program — have been unwilling to risk receiving a placebo.

Last month, one such trial in the Netherlands was stopped when researchers realized that patients given plasma showed no difference in mortality, length of hospital stay or disease severity compared with those given a placebo. Most of the patients had already developed their own antibodies by the time they entered the study, the researchers noted.

At least 10 randomized trials in the United States have collectively enrolled only a few hundred people. They have also been stymied by the waning of the virus outbreak in many cities, complicating the ability of researchers to recruit sick people. Dr. Collins has encouraged a strategy of pooling the results from randomized trials, an idea that has met resistance from some researchers.

Dr. R. Scott Wright, who is helping oversee the Mayo Clinic's plasma program, was an early proponent of conducting randomized trials. But he said in a recent interview that the mechanics of setting up large studies were complicated by early shortages of plasma, coordination via videoconference calls and the difficulty of predicting where the virus would spread next.

If the F.D.A. does grant the emergency authorization, it could make it even harder to get answers, said Dr. Ortigoza of N.Y.U.

"We will keep going, because we're in desperate need of a randomized placebo-controlled trial for convalescent plasma," she said. "This is something our country and the world really needs right now."

Stephanie Caccomo
Media Relations Director

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: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Tuesday, August 18, 2020 5:06 PM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Wagner, John <John.Wolf.Wagner@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: RE: Flag, NYT Qs on CP EUA

Dear Stephanie,

What you propose to get back to the reporter with is absolutely fine with me.

There is a much more disturbing aspect to me about this, aside from the fact that it is FDA and not NIH that determines whether or not something meets the standard for EUA: this was yet another leak of information from a meeting that should have been a confidential one, and could undermine the type of open dialogue that would optimally take place.

Best Regards,
Peter

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Tuesday, August 18, 2020 4:55 PM
To: Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Wagner, John <John.Wolf.Wagner@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: Flag, NYT Qs on CP EUA

Noah Weiland at NYT reached out about the CP EUA.

From reporter:
I'm working on a story with a few colleagues today about the convalescent plasma EUA. We've heard from senior officials that the EUA was ready to go late last week, but that several health officials, including Francis Collins and Tony Fauci, intervened, worried that the data from the Mayo Clinic expanded access program was too weak to use as a foundation of the EUA. The FDA decided to put the EUA on hold for now as it reevaluates data from that program and other studies. We report that the EUA could still come in the near future. A draft of it, we report, included references to the history of success plasma has had in other disease outbreaks, plasma in animal models and a group of plasma studies conducted during the coronavirus pandemic.

(b) (5) [redacted]

[redacted]

Stephanie Caccomo
Media Relations Director

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: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 8/21/2020 8:10:40 AM
To: Pence, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3f21407a02d44cd4901bcce26f9b3074-HHS-Laura.P]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Steele, Danielle (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=634b96dc13cf48f3971ce676b65e952f-HHS-Daniell]
Subject: Re: FYI--NIH trials on CP

Thx Laura. As you know FDA strongly supports the performance of well-designed RCTs for COVID-19 therapeutics.
Best
Steve

From: Pence, Laura (HHS/IOS) <Laura.Pence@hhs.gov>
Date: August 20, 2020 at 6:09:25 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Steele, Danielle (OS) <Danielle.Steele@hhs.gov>
Subject: FYI--NIH trials on CP

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 8/19/2020 8:59:16 AM
To: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]
CC: FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]; 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]; 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]; 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]; Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; Jenkins, Charlene [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e722b6438b04d2e9029c72543639a67-Charlene.Je]
Subject: Re: Telecon: Weekly CBER Meeting with the Commissioner

Looks good Peter

Sent from my iPad

On Aug 19, 2020, at 4:54 AM, Marks, Peter <Peter.Marks@fda.hhs.gov> wrote:

Dear All,

My apologies for the late agenda. Please let me know if there are topics that you would like to add:

1. Update on (b) (4)
2. Progress on convalescent plasma EUA
3. (b) (4)
4. Potential logistics of an EUA and VRBPAC AC meeting planning

a. Committee composition
b. Meeting dates
c. Webcasting

We have an addition 15 minutes on the calendar on August 20 in the event that we do not get through the AC agenda.

Best Regards,
Peter

-----Original Appointment-----
From: FDA Commissioner <Stephen.Hahn@fda.hhs.gov>
Sent: Friday, April 17, 2020 11:18 PM
To: FDA Commissioner; Hahn, Stephen; Lenihan, Keagan; Abram, Anna; Marks, Peter; Witten, Celia (CBER); Tierney, Julia; Shah, Anand
Cc: Rom, Colin

Subject: Telecon: Weekly CBER Meeting with the Commissioner
When: Wednesday, August 19, 2020 11:00 AM-11:30 AM (UTC-05:00) Eastern Time (US & Canada).
Where: 1-877-465-7975,,(b) (6)

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 8/19/2020 8:47:39 AM
To: 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]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Witten, Celia (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fc08ebb3ac61486da9f1b4046757c5cf-Witten]
Subject: Re: early EHR data

Thanks, Peter. Really helpful.

Steve

Sent from my iPad

On Aug 19, 2020, at 8:07 AM, Marks, Peter <Peter.Marks@fda.hhs.gov> wrote:

Dear Commissioner,

Though it is only supportive, please see the figure by Mayo collaborators developed below from EHR data on the optimal patient population that we described (n=124 convalescent plasma, 1040 matched controls).

Best Regards,
Peter

From: Joyner, Michael J., M.D. <joyner.michael@mayo.edu>
Sent: Tuesday, August 18, 2020 5:58 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Carter, Rickey E., Ph.D. <Carter.Rickey@mayo.edu>; Nigel Paneth (paneth@epi.msu.edu) <paneth@epi.msu.edu>; Arturo Casadevall (acasade1@jhu.edu) <acasade1@jhu.edu>; Wright, R. Scott, M.D. <wright.scott@mayo.edu>
Subject: early EHR data
Importance: High

Peter, this is a first look at some EHR data mining mostly early in the pandemic from the NYC area. This is less than 3 days no vent, matched etc. It is pretty consistent….. Long way to go on this, but consistent with other signals.

Mike

<image003.png>

From: Caccomo, Stephanie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=950C32CEBC4B4F80B302C50CF31C8524-STEPHANIE.C]
Sent: 8/22/2020 3:50:51 PM
To: 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]; 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]; Wagner, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a481c74326041d0b268d42f2d70d9f5-John.Wagner]; Miller, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=349ea636fe504b488adf664e48ce87e6-Emily.Mille]; Pratt, Michael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=facc5c0e27c74fd4964699547a71849d-HHS-Michael]; 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]; Frantz-Bohn, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4c4a10821c774ffa9c5cf59bda6bcf75-frantz_bohn]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Caputo, Michael R (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dac6080dfebe436da01db07986b63377-HHS-Michael]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Guevara, Bessy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58097ba8edea47afb3338e671a43dc04-Bessy.Gueva]
CC: Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Emily Miller [emilymiller.miller@gmail.com]

Subject: Canceled: PREP FOR CP

Start: 8/23/2020 11:00:00 AM
End: 8/23/2020 11:30:00 AM
Show Time As: Free

Importance: High

Join by phone
210-795-0506 US Toll
877-465-7975 US Toll Free
Access code: (b) (6)

From: Miller, Emily [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]
Sent: 8/23/2020 12:33:03 PM
To: Wagner, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a481c74326041d0b268d42f2d70d9f5-John.Wagner]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
Subject: RE: Outline of schedule for the CP rollout

This is very good so reporters will have base of knowledge to get stories up and going accurately before live presser.

Emily Miller
FDA Assistant Commissioner for Media Affairs
Text/call: (240) 805-3909

From: Wagner, John <John.Wolf.Wagner@fda.hhs.gov>
Date: August 23, 2020 at 12:09:15 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Miller, Emily <Emily.Miller@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: RE: Outline of schedule for the CP rollout

Steve-
WH sends this updated timeline request:

3:00pm – HHS/FDA embargoed SME call to answer technical/medical questions & frame the new data for media
4:30pm – EUA package posted publicly to FDA site and embargo lifted
4:45pm – FDA press release issued
6:00pm – POTUS briefing from Rose Garden to spotlight announcement (30 min; w/ Azar and Hahn)

John 'Wolf' Wagner
Associate Commissioner

From: Wagner, John
Sent: Sunday, August 23, 2020 11:32 AM
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Miller, Emily <Emily.Miller@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: Outline of schedule for the CP rollout
Importance: High

Steve-

Here's what we have based on 11:27 am including WH input:

1400: prep call for Dr Hahn / FDA/ASPA team (or whenever you are available prior to 3pm)
1500: Media roundtable call for Dr Marks/Dr Hahn ON THE RECORD
1600: Dr Hahn movement to WH/Testing/Security
1700: Prep time at WH
1745: EUA package posts on FDA site (already is signed by Adm Hinton)
1800: FDA press release posts (WH Comms wants this out just prior to POTUS beginning. We want package posting time prior to the release in order to ensure no improper overlap)
1800: GO time for Rose Garden event

John 'Wolf' Wagner
Associate Commissioner

Office of External Affairs
U.S. Food and Drug Administration
john.wolf.wagner@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: 8/19/2020 10:07:14 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: Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]
Subject: Recall: Flag, NYT Qs on CP EUA

Marks, Peter would like to recall the message, "Flag, NYT Qs on CP EUA".

From: Miller, Emily [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]
Sent: 8/22/2020 12:38:21 PM
To: Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Wagner, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a481c74326041d0b268d42f2d70d9f5-John.Wagner]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
Subject: Re: CP strategic communications plan

(b) (5)

Emily Miller
FDA Assistant Commissioner for Media Affairs
Text/call: (240) 805-3909

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Date: August 22, 2020 at 12:21:52 PM EDT
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Miller, Emily <Emily.Miller@fda.hhs.gov>, Wagner, John <John.Wolf.Wagner@fda.hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Re: CP strategic communications plan

(b) (5)

On Aug 22, 2020, at 11:30, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov> wrote:

Others weigh in (b) (5)

From: Miller, Emily <Emily.Miller@fda.hhs.gov>
Date: August 22, 2020 at 11:21:41 AM EDT
To: Wagner, John <John.Wolf.Wagner@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: RE: CP strategic communications plan

We are running out of time. I have Stephanie coordinating getting the messaging for each audience cleared and redo existing collateral materials for consistency. She will send those back to everyone for clearance.

(b) (5) [redacted].

From: Wagner, John <John.Wolf.Wagner@fda.hhs.gov>
Date: August 22, 2020 at 11:18:05 AM EDT
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Miller, Emily <Emily.Miller@fda.hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>
Subject: RE: CP strategic communications plan

Ok. We are pulling an OMA/OEA call this afternoon and we'll cover then.

John 'Wolf' Wagner
Associate Commissioner

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Saturday, August 22, 2020 10:54 AM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Wagner, John <John.Wolf.Wagner@fda.hhs.gov>
Cc: Miller, Emily <Emily.Miller@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Re: CP strategic communications plan

Wolf- can you pull the team together an build out the details on when and how we are achieving the goals with each audience that Emily has outlined?

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Date: August 22, 2020 at 8:04:06 AM EDT
To: Wagner, John <John.Wolf.Wagner@fda.hhs.gov>
Cc: Miller, Emily <Emily.Miller@fda.hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: Re: CP strategic communications plan

Agree. Great work Emily. Can you have CBER review the top line messaging ?

On Aug 22, 2020, at 07:41, Wagner, John <John.Wolf.Wagner@fda.hhs.gov> wrote:

I think this is spot on. Combine it with the roll-out timeline and the other materials and I think we've got a solid base.

John 'Wolf' Wagner
Associate Commissioner

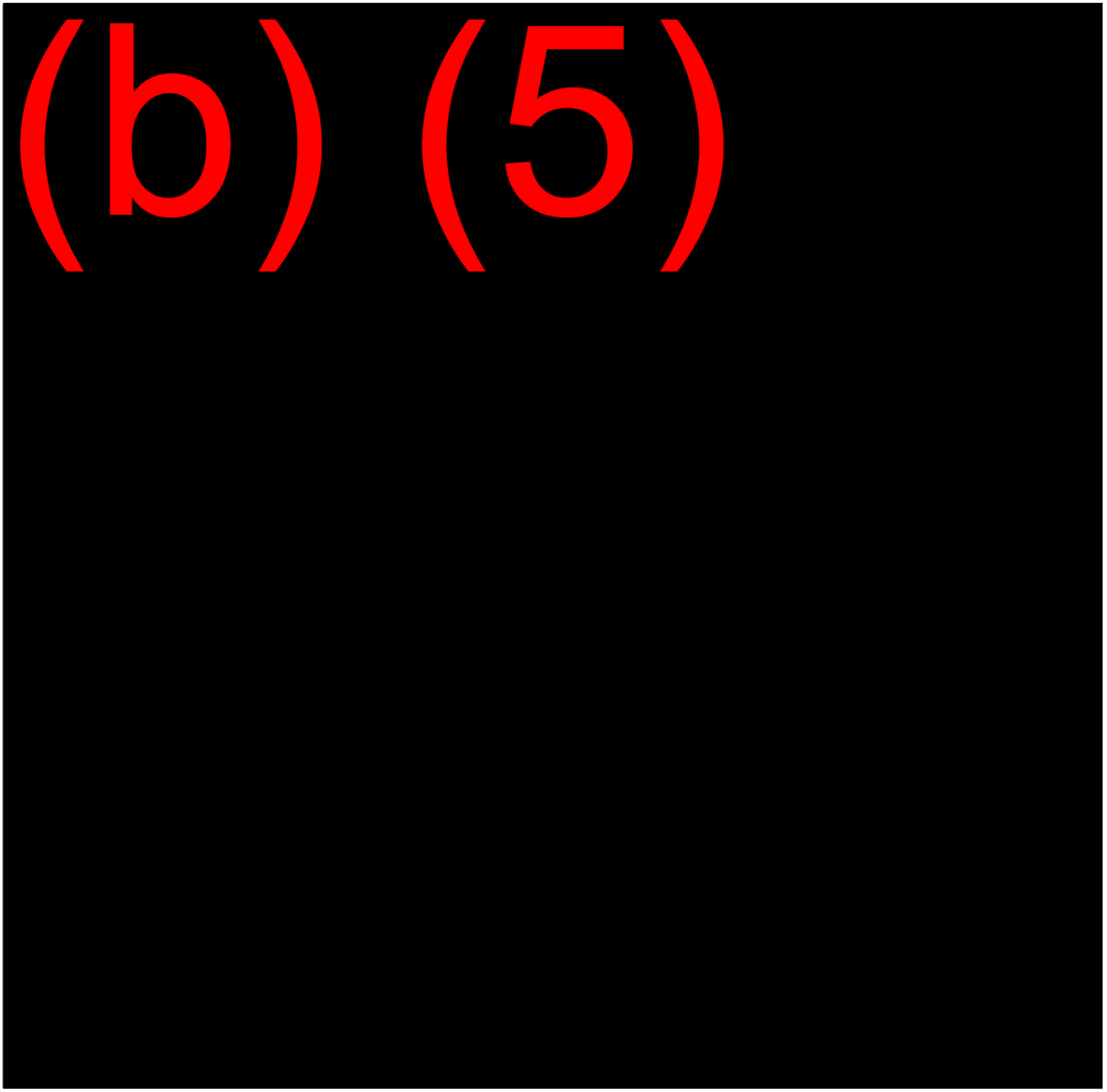
From: Miller, Emily <Emily.Miller@fda.hhs.gov>
Sent: Friday, August 21, 2020 8:50 PM

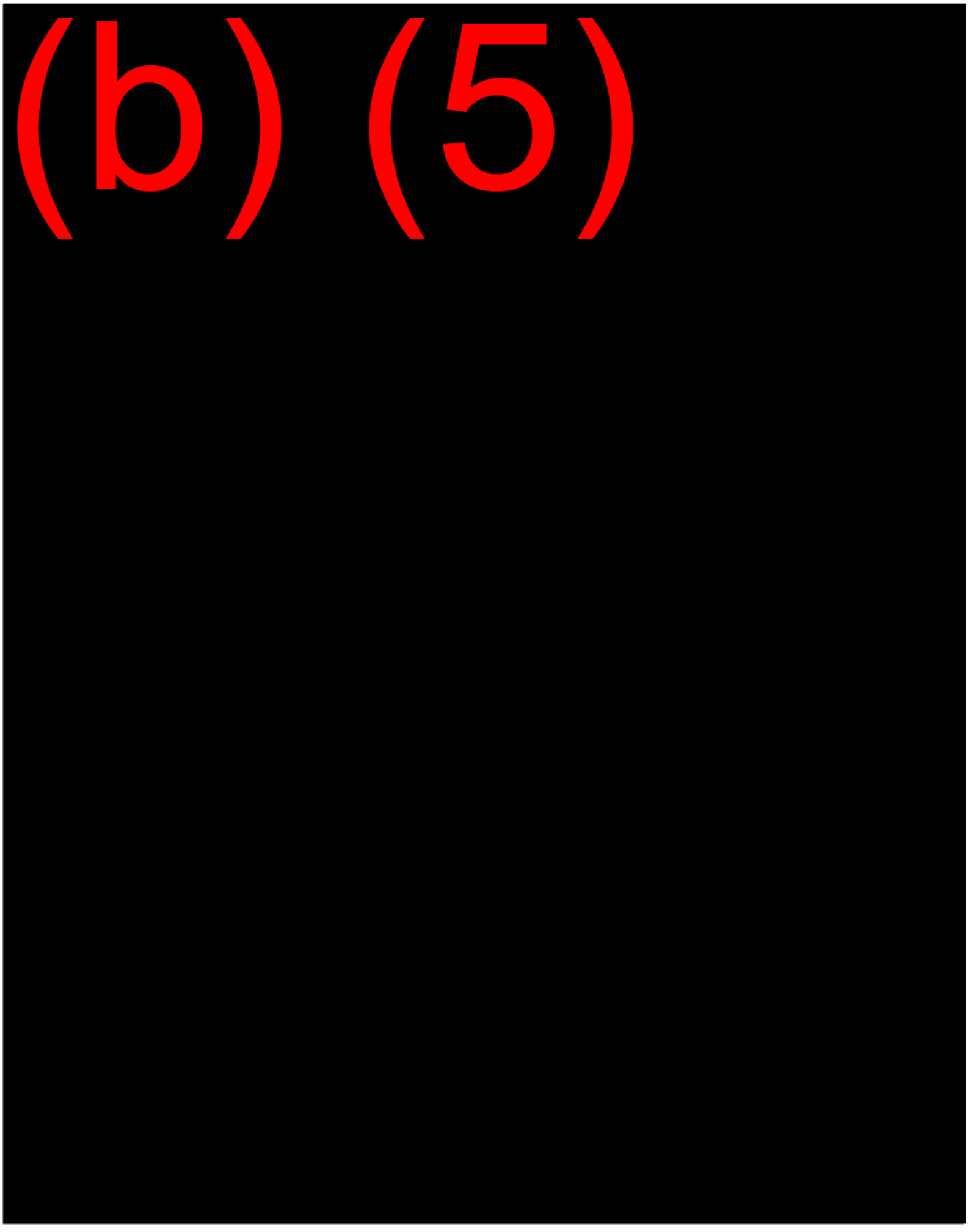
To: Hahn, Stephen <SH1@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Wagner, John <John.Wolf.Wagner@fda.hhs.gov>
Subject: CP strategic communications plan

I wrote a strategic communications plan for convalescent plasma news– attached and pasted below. Please edit for message and accuracy.

Once we're on the same page with our goals to achieve, we can start assigning tasks from it and line up the messaging to be consistent. The existing collateral materials can be just plugged into the overall plan.

Thanks, Emily




(b) (5)

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 8/22/2020 11:29:38 AM
To: Wagner, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a481c74326041d0b268d42f2d70d9f5-John.Wagner]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
CC: Miller, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=349ea636fe504b488adf664e48ce87e6-Emily.Mille]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
Subject: RE: CP strategic communications plan

Thx.

From: Wagner, John <John.Wolf.Wagner@fda.hhs.gov>
Date: August 22, 2020 at 11:18:05 AM EDT
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Miller, Emily <Emily.Miller@fda.hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>
Subject: RE: CP strategic communications plan

Ok. We are pulling an OMA/OEA call this afternoon and we'll cover then.

John 'Wolf' Wagner
Associate Commissioner

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Saturday, August 22, 2020 10:54 AM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Wagner, John <John.Wolf.Wagner@fda.hhs.gov>
Cc: Miller, Emily <Emily.Miller@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Re: CP strategic communications plan

Wolf- can you pull the team together an build out the details on when and how we are achieving the goals with each audience that Emily has outlined?

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Date: August 22, 2020 at 8:04:06 AM EDT
To: Wagner, John <John.Wolf.Wagner@fda.hhs.gov>
Cc: Miller, Emily <Emily.Miller@fda.hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: Re: CP strategic communications plan

Agree. Great work Emily. Can you have CBER review the top line messaging ?

On Aug 22, 2020, at 07:41, Wagner, John <John.Wolf.Wagner@fda.hhs.gov> wrote:

I think this is spot on. Combine it with the roll-out timeline and the other materials and I think we've got a solid base.

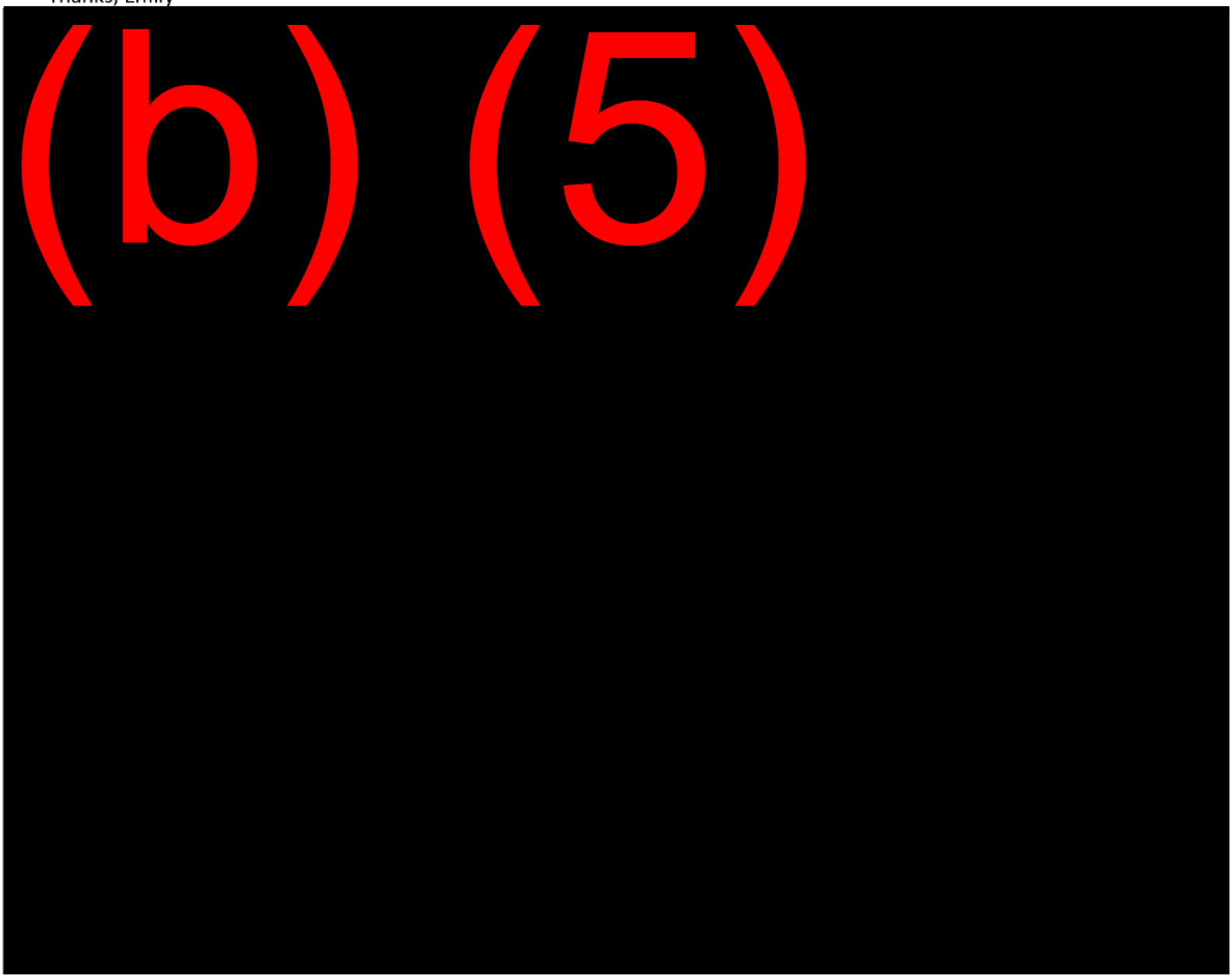
John 'Wolf' Wagner
Associate Commissioner

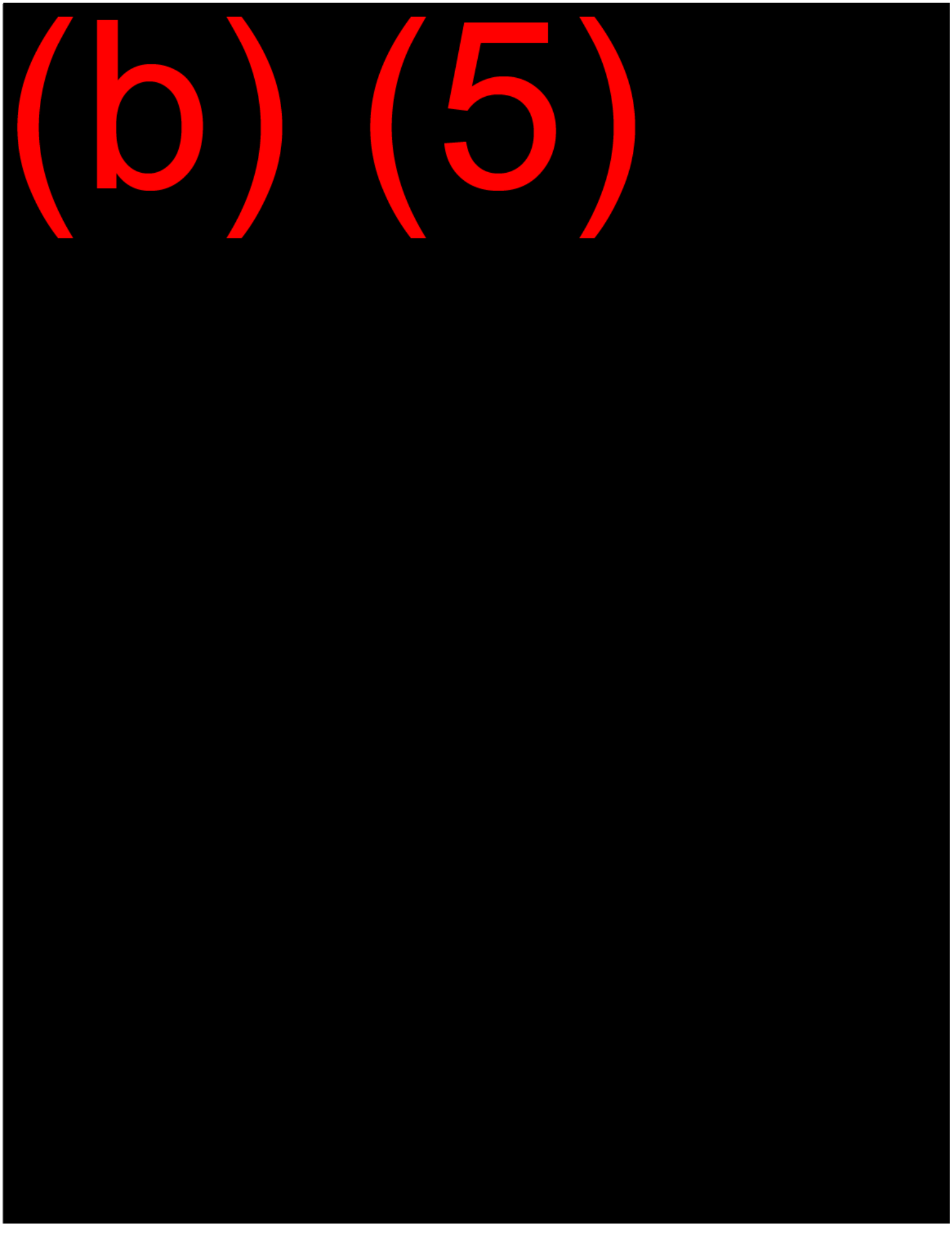
From: Miller, Emily <Emily.Miller@fda.hhs.gov>
Sent: Friday, August 21, 2020 8:50 PM
To: Hahn, Stephen <SH1@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Wagner, John <John.Wolf.Wagner@fda.hhs.gov>
Subject: CP strategic communications plan

I wrote a strategic communications plan for convalescent plasma news– attached and pasted below. Please edit for message and accuracy.

Once we're on the same page with our goals to achieve, we can start assigning tasks from it and line up the messaging to be consistent. The existing collateral materials can be just plugged into the overall plan.

Thanks, Emily




(b) (5)


(b) (5)

From: Wagner, John [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8A481C74326041D0B268D42F2D70D9F5-JOHN.WAGNER]
Sent: 8/23/2020 9:49:53 AM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
CC: Miller, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=349ea636fe504b488adf664e48ce87e6-Emily.Mille]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Guevara, Bessy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58097ba8edea47afb3338e671a43dc04-Bessy.Gueva]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]
Subject: RE: tentative timeline for CP rollout based on info 0800am

I have no knowledge of anyone being asked to accompany.

John 'Wolf' Wagner
Associate Commissioner

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Sunday, August 23, 2020 9:48 AM
To: Wagner, John <John.Wolf.Wagner@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Miller, Emily <Emily.Miller@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Guevara, Bessy <Bessy.Guevara@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>
Subject: Re: tentative timeline for CP rollout based on info 0800am

Is anyone staffing him at the WH?

From: Wagner, John <John.Wolf.Wagner@fda.hhs.gov>
Date: August 23, 2020 at 8:32:31 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Miller, Emily <Emily.Miller@fda.hhs.gov>, Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>, Guevara, Bessy <Bessy.Guevara@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>, Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>, Sheehy, Janice

<Janice.Sheehy@fda.hhs.gov>
Subject: tentative timeline for CP rollout based on info 0800am

BLUF: WH Rose Garden event on Convalescent Plasma, 6pm Sunday 23 August 2020
ALL subject to WH/CoS approval. ASPA working with WH comms to confirm.

0815: Sec Azar prep call
0930: Rollout Team / FDA planning call
1100: Prep call for Dr Marks / FDA, ASPA, WH Comms
1400: prep call for Dr Hahn / FDA/ASPA team
1500: Media roundtable call for Dr Marks/Dr Hahn

1600: Dr Hahn movement to WH/Testing/Security
1700: Prep time at WH
1800: GO time for Rose Garden event
1800: package posts on FDA site
1815: FDA press release posts

John 'Wolf' Wagner
Associate Commissioner

Office of External Affairs
U.S. Food and Drug Administration
john.wolf.wagner@fda.hhs.gov

FDA U.S. FOOD & DRUG ADMINISTRATION

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 8/22/2020 8:31:07 AM
To: Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Wagner, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a481c74326041d0b268d42f2d70d9f5-John.Wagner]
CC: Miller, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=349ea636fe504b488adf664e48ce87e6-Emily.Mille]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
Subject: Re: CP strategic communications plan

Thanks, Emily. Looks good. Agree with checking in with CBER and I would love to see Peter Marks play a big role in Sunday/Monday rollout.

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Date: August 22, 2020 at 8:04:06 AM EDT
To: Wagner, John <John.Wolf.Wagner@fda.hhs.gov>
Cc: Miller, Emily <Emily.Miller@fda.hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: Re: CP strategic communications plan

Agree. Great work Emily. Can you have CBER review the top line messaging ?

On Aug 22, 2020, at 07:41, Wagner, John <John.Wolf.Wagner@fda.hhs.gov> wrote:

I think this is spot on. Combine it with the roll-out timeline and the other materials and I think we've got a solid base.

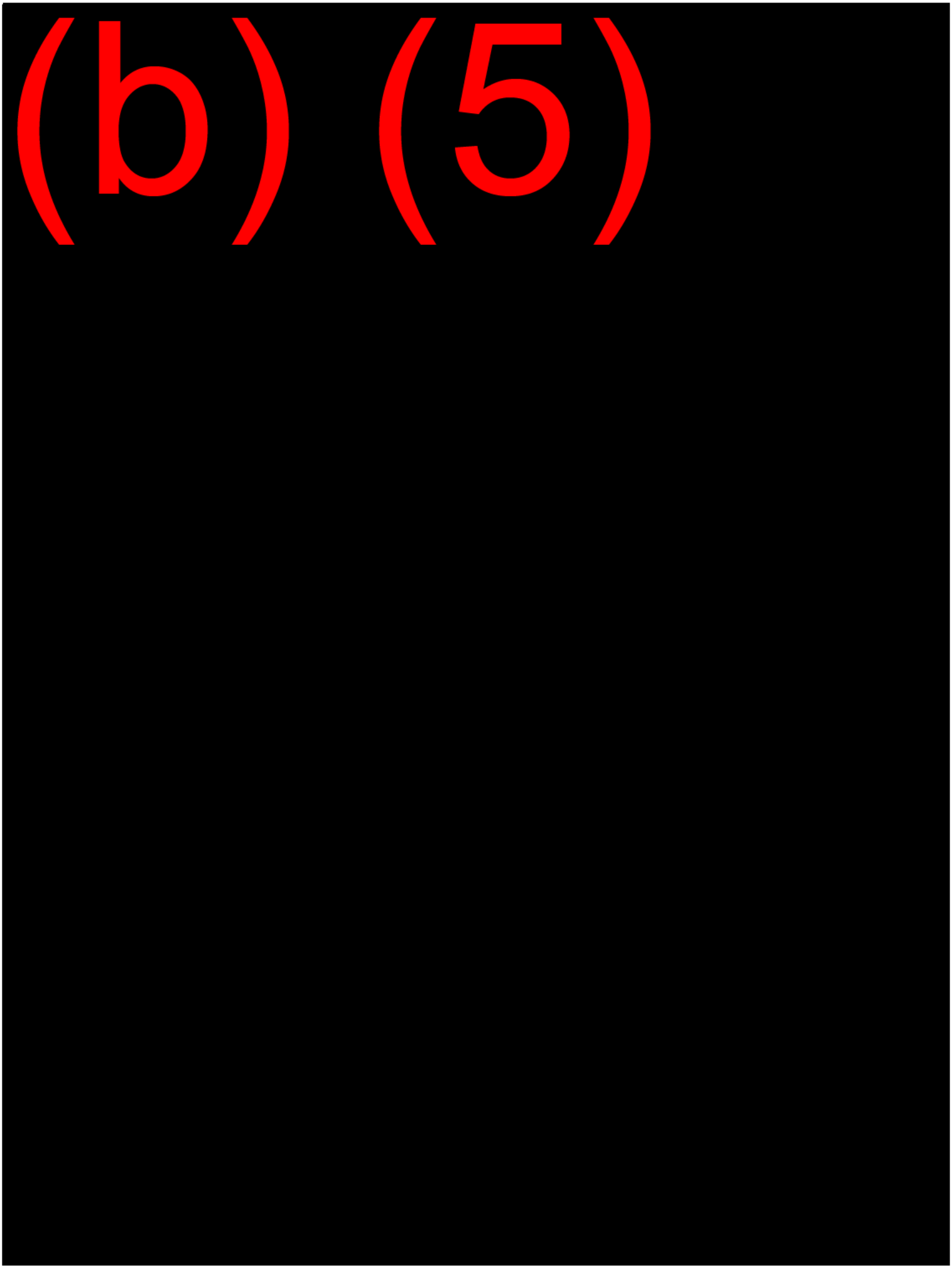
John 'Wolf' Wagner
Associate Commissioner

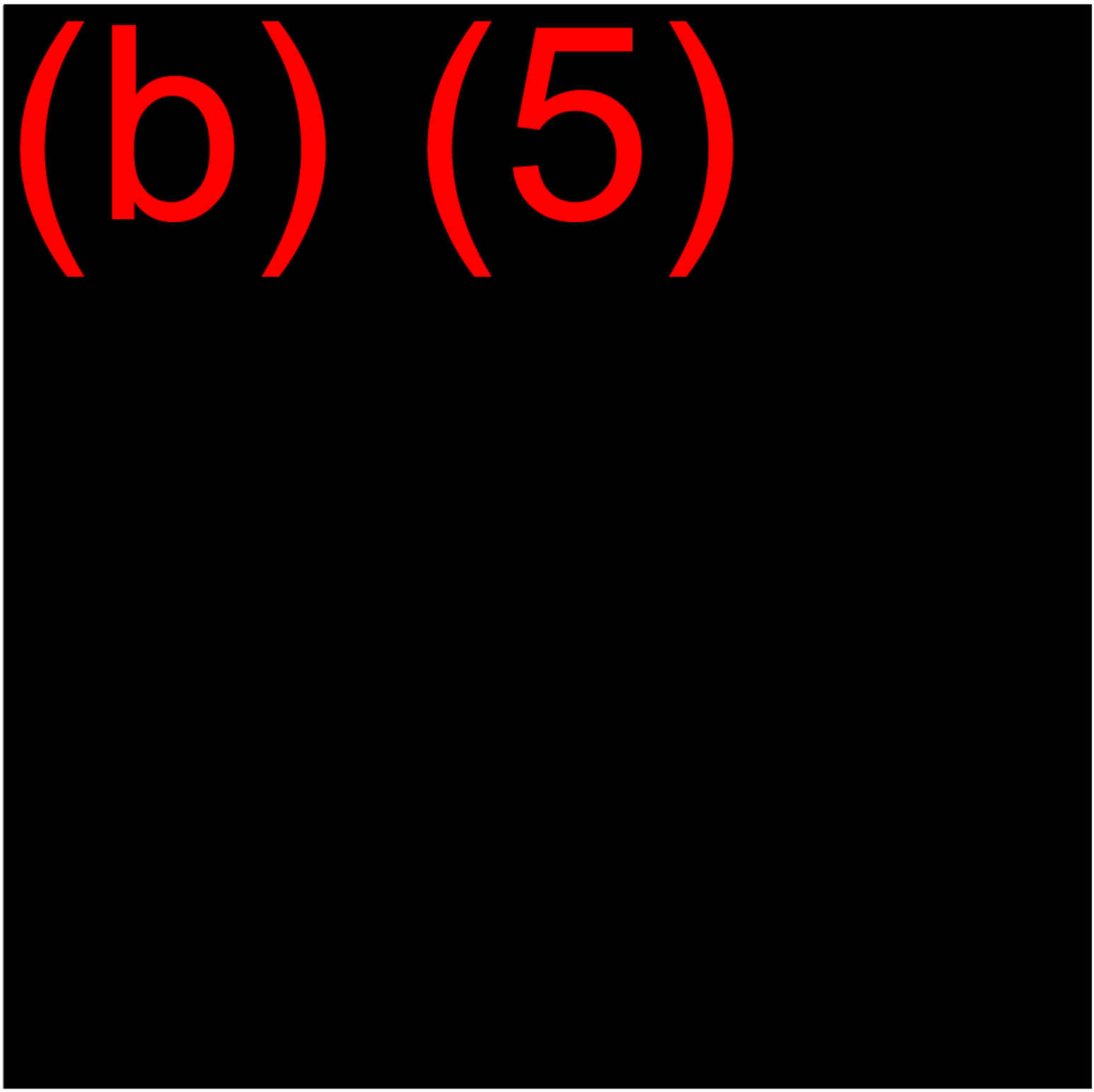
From: Miller, Emily <Emily.Miller@fda.hhs.gov>
Sent: Friday, August 21, 2020 8:50 PM
To: Hahn, Stephen <SH1@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Wagner, John <John.Wolf.Wagner@fda.hhs.gov>
Subject: CP strategic communications plan

I wrote a strategic communications plan for convalescent plasma news– attached and pasted below. Please edit for message and accuracy.

Once we're on the same page with our goals to achieve, we can start assigning tasks from it and line up the messaging to be consistent. The existing collateral materials can be just plugged into the overall plan.

Thanks, Emily


(b) (5)


(b) (5)

From: Keagan Lenihan <Keagan.Lenihan@fda.hhs.gov>
Date: Monday, August 17, 2020 at 6:53 AM
To: Alex Azar <(b) (6) HHS.GOV>
Cc: Stephen Hahn <SH1@fda.hhs.gov>, Brian Harrison <Brian.Harrison@hhs.gov>, Paul Mango <Paul.Mango@hhs.gov>
Subject: EUA

Sir,

To clarify, we had multiple conversations with NIH, Dr. Birx and Paul about moving forward with an EUA(b) (5) [redacted] It is my understanding the Commissioner spoke with both the VPs office and Meadows office to read them in on the plan. I tried to find time on your calendar Friday for you and the Commissioner to discuss, but haven't had any luck.

Apologize if there was any confusion.

Commissioner, anything else to add?

Thanks,
Keagan

From: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
Sent: 8/23/2020 6:04:19 AM
To: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]
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]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]
Subject: Re: EUA Update - confidential and predecisional

Thanks, Peter. I completely support your conclusion. Please give my thanks to your incredible team.
Steve

From: Peter Marks <Peter.Marks@fda.hhs.gov>
Date: Saturday, August 22, 2020 at 8:16 PM
To: Stephen Hahn <SH1@fda.hhs.gov>
Cc: Anand Shah <Anand.Shah@fda.hhs.gov>, Keagan Lenihan <Keagan.Lenihan@fda.hhs.gov>, "Tierney, Julia" <Julia.Tierney@fda.hhs.gov>
Subject: EUA Update - confidential and predecisional

Dear Commissioner,

The EUA should be signed off by Denise by about 10 AM tomorrow. The ASPR is doing a final review of their revised submission based on OCC review, and then Denise can sign.

Though the dataset that came in from the Mayo is smaller than we would have liked due to the clinical follow up that they had in their database, the analysis of the new samples does reach statistical significance. In the overall data set, though there may be benefit for all non-intubated patients, as previously, the strongest data are in non-intubated patients less that 80 years of age treated within 3 days of diagnosis with high titer convalescent plasma – at 7 days there is a 35% improvement in survival, and it doesn't fall off too badly – at 100 days there is a 25% improvement in survival. This is not too far off from other interventions for specific populations such as dexamethasone and remdesivir. Looking at the totality of the evidence, the various titering methods, and various sample sets used to get to essentially the same results, our statisticians feel very confident in the robust nature of this analysis.

From my perspective it is a definite go. Look forward to discussing further tomorrow.

Safe travels!

Best Regards,
Peter

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 8/19/2020 10:08:20 AM
To: 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]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]
Subject: Re: Flag, NYT Qs on CP EUA

Please

Sent from my iPad

On Aug 19, 2020, at 10:07 AM, Marks, Peter <Peter.Marks@fda.hhs.gov> wrote:

Dear Commissioner and Keagan,

I would like to at least touch upon this at our meeting today. Thanks.

Best Regards,
Peter

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Wednesday, August 19, 2020 9:38 AM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Wagner, John <John.Wolf.Wagner@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Miller, Emily <Emily.Miller@fda.hhs.gov>
Subject: RE: Flag, NYT Qs on CP EUA

Peter—the source was Dr. Lane from NIAID. On the record.

Story from NYT posted:

WASHINGTON — Last week, just as the Food and Drug Administration was preparing to issue an emergency authorization for blood plasma as a Covid-19 treatment, a group of top federal health officials including Dr. Francis S. Collins and Dr. Anthony S. Fauci intervened, arguing that emerging data on the treatment was too weak, according to two senior administration officials.

The authorization is on hold for now as more data is reviewed, according to H. Clifford Lane, the clinical director at the National Institute of Allergy and Infectious Diseases. An emergency approval could still be issued in the near future, he said.

Donated by people who have survived the disease, antibody-rich plasma is considered safe. President Trump has hailed it as a “beautiful ingredient” in the veins of people who have survived Covid-19.

But clinical trials have not proved whether plasma can help people fighting the coronavirus.

Several top health officials — led by Dr. Collins, the director of the National Institutes of Health; Dr. Fauci, the government's top infectious disease expert; and Dr. Lane — urged their colleagues last week to hold off, citing recent data from the country's largest plasma study, run by the Mayo Clinic. They thought the study's data to date was not strong enough to warrant an emergency approval.

"The three of us are pretty aligned on the importance of robust data through randomized control trials, and that a pandemic does not change that," Dr. Lane said in an interview on Tuesday.

The drafted emergency authorization leaned on the history of plasma's use in other disease outbreaks and on animal research and a spate of plasma studies, including the Mayo Clinic's program, which has given infusions to more than 66,000 Covid-19 patients thanks to financing from the federal government.

An F.D.A. spokeswoman declined to comment.

Plasma, the pale yellow liquid leftover after blood is stripped of its red and white cells, has been the subject of months of intense enthusiasm from scientists, celebrities and Mr. Trump, part of the administration's push for coronavirus treatments as a stopgap while pharmaceutical companies race to complete dozens of clinical trials for coronavirus vaccines.

Emergency authorizations, which do not require the same level of evidence as a full F.D.A. approval would, have been a fraught subject for the government during the pandemic. The agency gave one to the malaria drugs hydroxychloroquine and chloroquine only to rescind it months later after the drugs were found to be ineffective against the coronavirus, and potentially harmful. An emergency authorization for blood plasma would most likely ease the clerical burdens on hospitals in conducting infusions.

Senior health officials have privately expressed concern about the rapid growth of the Mayo program and the perceived rush to declare plasma effective without the affirmation of results from randomized trials, which scientists have long relied on as the gold standard of evidence. Skyrocketing enrollment in the program has prompted a debate among researchers about what kind of empirical certainty is needed in treating patients in a public health emergency.

An emergency approval now would "change the way people view trials," said Dr. Mila B. Ortigoza, an infectious disease specialist at N.Y.U. Langone Health who started a trial with colleagues at Montefiore Medical Center.

"We want to make sure that when we say it works, we are confident, with indisputable evidence," she said. "We're dealing with patients' lives here."

Unlike the malaria drugs, plasma, which has been used since the 1890s to treat infectious diseases, has earned the attention of a highly credentialed community of microbiologists and immunologists eager to prove its usefulness. The Mayo Clinic has already published analysis on tens of thousands of patients in its expanded access program showing that plasma is safe.

The most recent batch of data from the program included more than 35,000 Covid-19 patients, many of them in intensive care and on ventilators, and suggested that plasma administered within three days of a diagnosis reduced mortality rates. When calculated a month after the infusions, the death rate of patients who received plasma within three days of diagnosis was lower (21.6 percent) than it was for those who received plasma later (26.7 percent).

Coronavirus Schools Briefing: The pandemic is upending education. Get the latest news and tips as students go back to school.

But the study did not have a control group of patients given a placebo to compare with those given plasma, making it difficult for scientists to assess whether the treatment really worked. And given the limited supply of plasma, it is not clear how realistic treating patients within three days of diagnosis would be.

The program's enrollment has surged to more than 30 times as high as initially expected, complicating the ability of scientists to recruit sick patients to randomized trials.

It "ballooned to a degree that, you know, is becoming unmanageable," Dr. Lane said.

Statisticians at the F.D.A. are now examining the Mayo data to better understand what factors other than the treatment might have influenced patient responses, such as higher-quality care in the hospital, Dr. Lane said.

A research team from Houston Methodist hospitals also published preliminary results from a plasma trial last week. Their study of hospitalized Covid-19 patients in the American Journal of Pathology reported that a group of 136 patients who received the treatment were more likely to be alive four weeks later compared with 251 patients who did not receive it. That study found a statistically significant benefit only when patients were treated within three days of admission and when the plasma contained a high concentration of antibodies.

The Houston study was not randomized, meaning that all of the patients enrolled received the treatment and none received a placebo. (The researchers later compared their outcomes to records from other Covid-19 patients who were not in the study but were matched to be similar to them.)

A surge in cases in Texas this summer quickly brought the hospital system to its enrollment cap, and doctors there have not been able to provide the experimental treatment since mid-July. If the F.D.A. gave an emergency authorization, doctors at the hospital could possibly begin administering it again, said Dr. Eric Salazar, the study's principal investigator.

But an emergency authorization could have the unintended effect of making it harder for rigorous clinical trials to definitively show whether plasma works. Scientists have struggled to recruit patients for randomized trials, as many patients and their doctors — knowing they could get the treatment under the Mayo program — have been unwilling to risk receiving a placebo.

Last month, one such trial in the Netherlands was stopped when researchers realized that patients given plasma showed no difference in mortality, length of hospital stay or disease severity compared with those given a placebo. Most of the patients had already developed their own antibodies by the time they entered the study, the researchers noted.

At least 10 randomized trials in the United States have collectively enrolled only a few hundred people. They have also been stymied by the waning of the virus outbreak in many cities, complicating the ability of researchers to recruit sick people. Dr. Collins has encouraged a strategy of pooling the results from randomized trials, an idea that has met resistance from some researchers.

Dr. R. Scott Wright, who is helping oversee the Mayo Clinic's plasma program, was an early proponent of conducting randomized trials. But he said in a recent interview that the mechanics of setting up large studies were complicated by early shortages of plasma, coordination via videoconference calls and the difficulty of predicting where the virus would spread next.

If the F.D.A. does grant the emergency authorization, it could make it even harder to get answers, said Dr. Ortigoza of N.Y.U.

"We will keep going, because we're in desperate need of a randomized placebo-controlled trial for convalescent plasma," she said. "This is something our country and the world really needs right now."

Stephanie Caccomo
Media Relations Director

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: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Tuesday, August 18, 2020 5:06 PM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Wagner, John <John.Wolf.Wagner@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: RE: Flag, NYT Qs on CP EUA

Dear Stephanie,

What you propose to get back to the reporter with is absolutely fine with me.

There is a much more disturbing aspect to me about this, aside from the fact that it is FDA and not NIH that determines whether or not something meets the standard for EUA: this was yet another leak of information from a meeting that should have been a confidential one, and could undermine the type of open dialogue that would optimally take place.

Best Regards,
Peter

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Tuesday, August 18, 2020 4:55 PM
To: Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Wagner, John <John.Wolf.Wagner@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: Flag, NYT Qs on CP EUA

Noah Weiland at NYT reached out about the CP EUA.

From reporter:
I'm working on a story with a few colleagues today about the convalescent plasma EUA. We've heard from senior officials that the EUA was ready to go late last week, but that several health officials, including Francis Collins and Tony Fauci, intervened, worried that the data from the Mayo Clinic expanded access program was too weak to use as a foundation of the EUA. The FDA decided to put the EUA on hold for now as it reevaluates data from that program and other studies. We report that the EUA could still come in the near future. A draft of it, we report, included references to the history of success plasma has had in other disease outbreaks, plasma in animal models and a group of plasma studies conducted during the coronavirus pandemic.

(b) (5) [redacted]

[redacted]

Stephanie Caccomo
Media Relations Director

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: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
Sent: 8/20/2020 9:16:08 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]
CC: Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]
Subject: Re: CBER Update - 8/20/2020

Thanks, Peter

From: Peter Marks <Peter.Marks@fda.hhs.gov>
Date: Thursday, August 20, 2020 at 5:02 AM
To: Stephen Hahn <SH1@fda.hhs.gov>, Keagan Lenihan <Keagan.Lenihan@fda.hhs.gov>
Cc: Anna Abram <Anna.Abram@fda.hhs.gov>, Colin Rom <Colin.Rom@fda.hhs.gov>, "Tierney, Julia" <Julia.Tierney@fda.hhs.gov>
Subject: CBER Update - 8/20/2020

Dear Commissioner,

Here is today's CBER update.

Convalescent plasma and hyperimmune globulin
Data

- EAP numbers for 8/18/2020: Pending
- (b) (4) eINDs for convalescent plasma issued
- (b) (4)
- Plan is to have EUA signature ready by COB Friday
- (b) (4)

Actions/Decisions Needed

(b) (4)

- **Will need to discuss strategy for Friday PM AMA CP meeting that includes our HHS partners**

Vaccine Development
Data

(b) (4)

Actions/Decisions Needed

- Continuing work on advisory committee meeting planning
- Continuing to monitor status of trials.

Best Regards,
Peter

From: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
Sent: 8/20/2020 11:08:29 AM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
Subject: FW: FOR URGENT REVIEW: Response on NYT/ Plasma EUA Statement

---

From: Stephen Hahn <SH1@fda.hhs.gov>
Date: Thursday, August 20, 2020 at 9:36 AM
To: John Wagner <John.Wolf.Wagner@fda.hhs.gov>
Subject: Re: FOR URGENT REVIEW: Response on NYT/ Plasma EUA Statement

Well, she needs to be in charge of OMA starting today. That is her job and we need her to move things forward. Please, Wolf, make sure that happens today and please make sure she sees the CP statement before it goes out.
Thanks
Steve

From: John Wagner <John.Wolf.Wagner@fda.hhs.gov>
Date: Thursday, August 20, 2020 at 9:34 AM
To: Stephen Hahn <SH1@fda.hhs.gov>
Subject: RE: FOR URGENT REVIEW: Response on NYT/ Plasma EUA Statement

No laptop or FDA phone. Wasn't able to procure yesterday. She's at WO retrieving it I understand, today.

John 'Wolf' Wagner
Associate Commissioner

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Thursday, August 20, 2020 9:33 AM
To: Wagner, John <John.Wolf.Wagner@fda.hhs.gov>
Subject: Re: FOR URGENT REVIEW: Response on NYT/ Plasma EUA Statement

What does that mean? She runs the OMA office.
Steve

From: John Wagner <John.Wolf.Wagner@fda.hhs.gov>
Date: Thursday, August 20, 2020 at 9:32 AM
To: Stephen Hahn <SH1@fda.hhs.gov>
Subject: RE: FOR URGENT REVIEW: Response on NYT/ Plasma EUA Statement

I don't think she's up on comms yet- picking up today.

John 'Wolf' Wagner
Associate Commissioner

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Thursday, August 20, 2020 9:32 AM
To: Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Wagner, John <John.Wolf.Wagner@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Miller, Emily <Emily.Miller@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Zeta, Lowell <Lowell.Zeta@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>
Subject: Re: FOR URGENT REVIEW: Response on NYT/ Plasma EUA Statement

Emily, have you reviewed? Do you have any concerns?
Thanks
Steve

From: Stacy Amin <Stacy.Amin@fda.hhs.gov>
Date: Wednesday, August 19, 2020 at 3:38 PM
To: John Wagner <John.Wolf.Wagner@fda.hhs.gov>, Anand Shah <Anand.Shah@fda.hhs.gov>, Stephanie Caccomo <Stephanie.Caccomo@fda.hhs.gov>, Stephen Hahn <SH1@fda.hhs.gov>, Keagan Lenihan <Keagan.Lenihan@fda.hhs.gov>, Peter Marks <Peter.Marks@fda.hhs.gov>
Cc: "Miller, Emily" <Emily.Miller@fda.hhs.gov>, "Felberbaum, Michael" <Michael.Felberbaum@fda.hhs.gov>, "Zeta, Lowell" <Lowell.Zeta@fda.hhs.gov>, "Edmonds, Amanda" <Amanda.Edmonds@fda.hhs.gov>
Subject: RE: FOR URGENT REVIEW: Response on NYT/ Plasma EUA Statement

Looks fine to me.

From: Wagner, John <John.Wolf.Wagner@fda.hhs.gov>
Sent: Wednesday, August 19, 2020 3:24 PM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Miller, Emily <Emily.Miller@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Zeta, Lowell <Lowell.Zeta@fda.hhs.gov>
Subject: RE: FOR URGENT REVIEW: Response on NYT/ Plasma EUA Statement

FINAL REVIEW VERSION:

(b) (5)

(b) (5)

John 'Wolf' Wagner
Associate Commissioner

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Wednesday, August 19, 2020 3:19 PM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Wagner, John <John.Wolf.Wagner@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Miller, Emily <Emily.Miller@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Zeta, Lowell <Lowell.Zeta@fda.hhs.gov>
Subject: RE: FOR URGENT REVIEW: Response on NYT/ Plasma EUA Statement

Last sentence…

(b) (5)

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Wednesday, August 19, 2020 3:11 PM
To: Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Wagner, John <John.Wolf.Wagner@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Miller, Emily <Emily.Miller@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Zeta, Lowell <Lowell.Zeta@fda.hhs.gov>
Subject: RE: FOR URGENT REVIEW: Response on NYT/ Plasma EUA Statement

How about below, (b) (5)

(b) (5)

Stephanie Caccomo
Media Relations Director

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: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Sent: Wednesday, August 19, 2020 2:15 PM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Wagner, John <John.Wolf.Wagner@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Miller, Emily <Emily.Miller@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Zeta, Lowell <Lowell.Zeta@fda.hhs.gov>
Subject: RE: FOR URGENT REVIEW: Response on NYT/ Plasma EUA Statement

(b) (5)

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Wednesday, August 19, 2020 1:51 PM
To: Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Wagner, John <John.Wolf.Wagner@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Miller, Emily <Emily.Miller@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Zeta, Lowell <Lowell.Zeta@fda.hhs.gov>
Subject: RE: FOR URGENT REVIEW: Response on NYT/ Plasma EUA Statement

Yes, there was additional data.

Heard feedback from Amanda to just make one edit, good from OCC?

Stephanie Caccomo
Media Relations Director

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: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Sent: Wednesday, August 19, 2020 1:30 PM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Wagner, John <John.Wolf.Wagner@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Miller, Emily <Emily.Miller@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Zeta, Lowell <Lowell.Zeta@fda.hhs.gov>
Subject: RE: FOR URGENT REVIEW: Response on NYT/ Plasma EUA Statement

(b) (5)

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Wednesday, August 19, 2020 12:33 PM
To: Wagner, John <John.Wolf.Wagner@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Cc: Miller, Emily <Emily.Miller@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Zeta, Lowell <Lowell.Zeta@fda.hhs.gov>
Subject: RE: FOR URGENT REVIEW: Response on NYT/ Plasma EUA Statement

My edits attached – thank you

From: Shah, Anand
Sent: Wednesday, August 19, 2020 12:23 PM
To: Wagner, John <John.Wolf.Wagner@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Cc: Miller, Emily <Emily.Miller@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: RE: FOR URGENT REVIEW: Response on NYT/ Plasma EUA Statement

I'll have a few proposed edits in Word momentarily…

From: Wagner, John <John.Wolf.Wagner@fda.hhs.gov>
Sent: Wednesday, August 19, 2020 12:22 PM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Cc: Miller, Emily <Emily.Miller@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: Re: FOR URGENT REVIEW: Response on NYT/ Plasma EUA Statement

Doc is good. We're good. Get this to occ and ASPA ASPA for super expedited clearance please

John 'Wolf' Wagner

Associate Commissioner

Office of External Affairs
U.S. Food and Drug Administration
john.wolf.wagner@fda.hhs.gov

Sent from my mobile device

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Date: August 19, 2020 at 12:15:59 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Marks, Peter <Peter.Marks@fda.hhs.gov>, Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Cc: Wagner, John <John.Wolf.Wagner@fda.hhs.gov>, Miller, Emily <Emily.Miller@fda.hhs.gov>, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: FOR URGENT REVIEW: Response on NYT/ Plasma EUA Statement
Importance: High

Hi—

Updated language below to use responsively on CP EUA. We propose to share with WaPo first, but will share with other outlets. Many reporters are pinging about story, so would appreciate ok asap!

Statement attributable to Anand Shah, M.D., FDA's Deputy Commissioner for Medical and Scientific Affairs:

From: Felberbaum, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4819A643CA2945CDB1A2631B83E69673-MICHAEL.FEL]
Sent: 8/23/2020 2:06:31 PM
To: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; 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]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
CC: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Wagner, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a481c74326041d0b268d42f2d70d9f5-John.Wagner]; Miller, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=349ea636fe504b488adf664e48ce87e6-Emily.Mille]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
Subject: RE: FOR REVIEW: Media Briefing Script
Attachments: SCRIPT_CP EUA Briefing 08232020 204pm.docx; PM Remarks for Media Briefing 08232020.docx

Thank you Peter. Attaching two documents:

1) Main script that includes call flow and Dr. Hahn's main bullets
2) Peter's talkers

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Sunday, August 23, 2020 1:05 PM
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Wagner, John <John.Wolf.Wagner@fda.hhs.gov>; Miller, Emily <Emily.Miller@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: RE: FOR REVIEW: Media Briefing Script

Dear Michael,

Please see the attached. Thanks.

Best Regards,
Peter

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Sent: Sunday, August 23, 2020 11:46 AM
To: Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Wagner, John <John.Wolf.Wagner@fda.hhs.gov>; Miller, Emily <Emily.Miller@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: FOR REVIEW: Media Briefing Script

PRE-DECISIONAL, DELIBERATIVE, CONFIDENTIAL

Hi all –

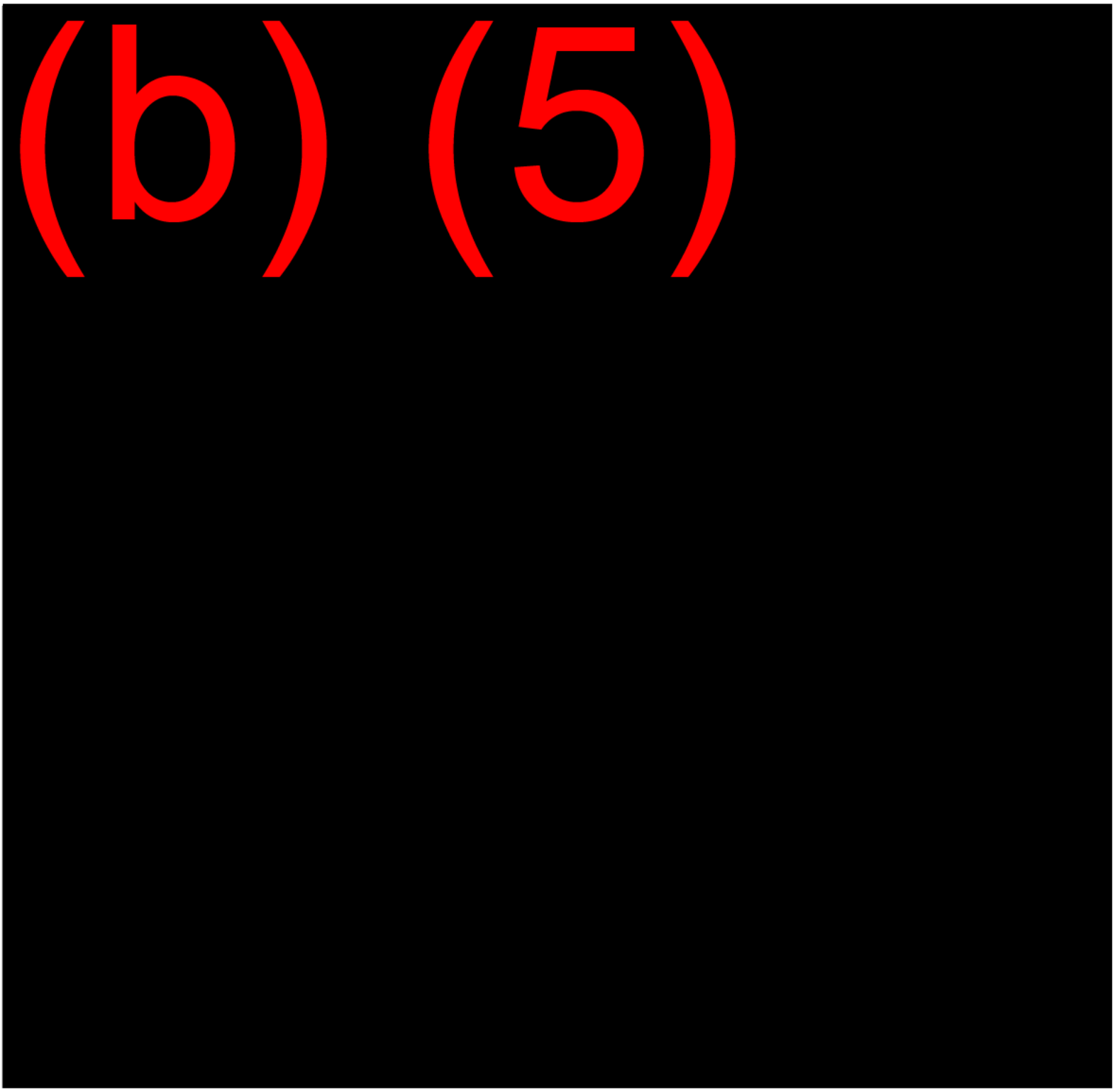
Attached and pasted below is the draft script for the embargoed media briefing anticipated for 3 p.m.

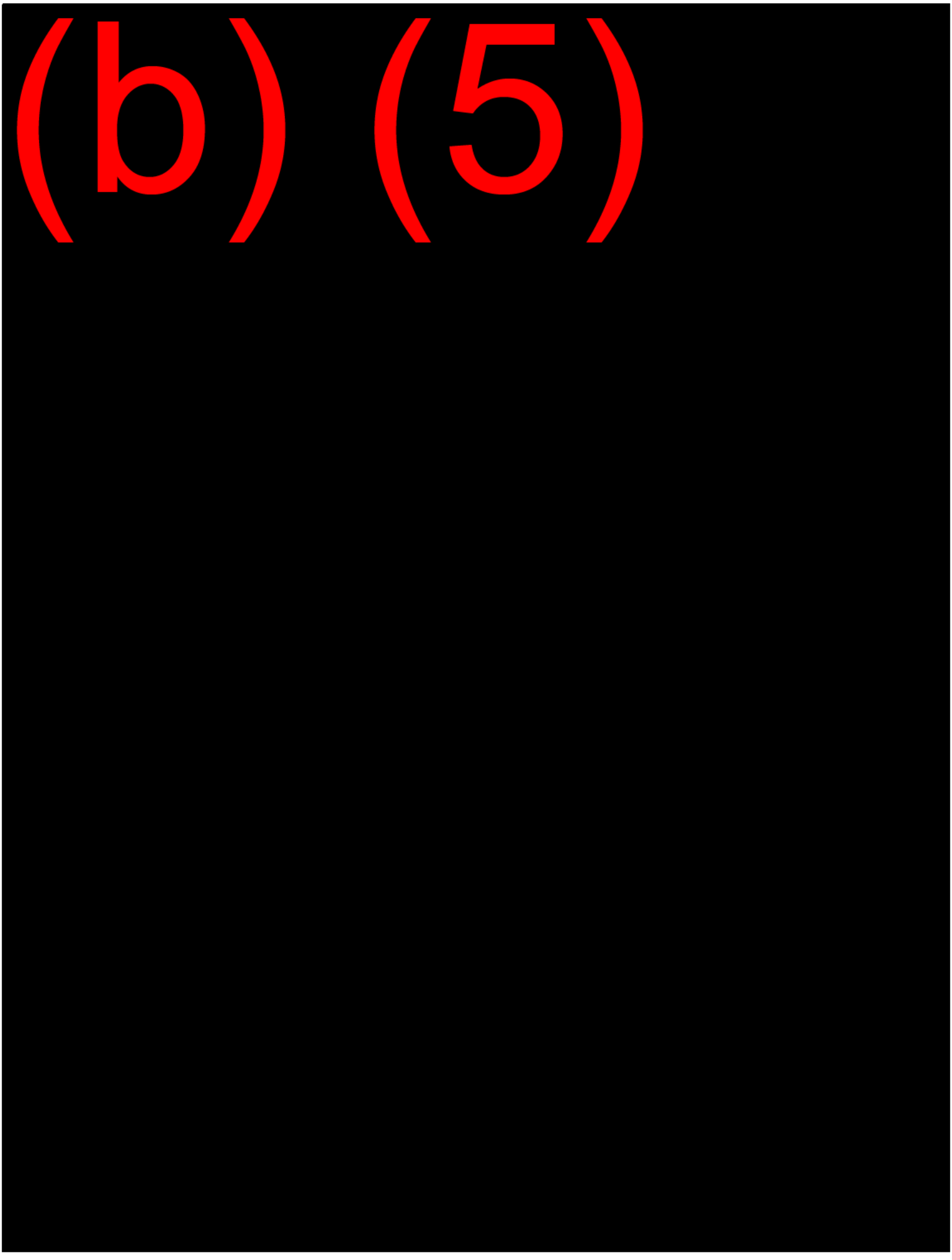
Emily has provided suggested topline bullets for Dr. Hahn and Dr. Marks to guide their remarks.

Please share any edits, additions, comments at your earliest convenience.

Thanks,

Michael




(b) (5)

If you have follow-up questions, please don't hesitate to the FDA Office of Media Affairs.

Thank you.

From: Wagner, John [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8A481C74326041D0B268D42F2D70D9F5-JOHN.WAGNER]
Sent: 8/19/2020 11:01:13 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]
Subject: Proposed statement for CP response

Importance: High

From MF and SC:

Statement attributable to Anand Shah, M.D., FDA's Deputy Commissioner for Medical and Scientific Affairs:

(b) (5)

John 'Wolf' Wagner
Associate Commissioner

Office of External Affairs
U.S. Food and Drug Administration
john.wolf.wagner@fda.hhs.gov

FDA U.S. FOOD & DRUG ADMINISTRATION

From: Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]
Sent: 8/19/2020 3:26:24 PM
To: Wagner, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a481c74326041d0b268d42f2d70d9f5-John.Wagner]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; 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]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]
CC: Miller, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=349ea636fe504b488adf664e48ce87e6-Emily.Mille]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Zeta, Lowell [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c0fc7eb68244f4cb4260898d5dacadb-Lowell.Zeta]
Subject: RE: FOR URGENT REVIEW: Response on NYT/ Plasma EUA Statement

OK with me – thanks Wolf

From: Wagner, John <John.Wolf.Wagner@fda.hhs.gov>
Sent: Wednesday, August 19, 2020 3:24 PM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Miller, Emily <Emily.Miller@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Zeta, Lowell <Lowell.Zeta@fda.hhs.gov>
Subject: RE: FOR URGENT REVIEW: Response on NYT/ Plasma EUA Statement

FINAL REVIEW VERSION:

John 'Wolf' Wagner
Associate Commissioner

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Wednesday, August 19, 2020 3:19 PM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Wagner, John <John.Wolf.Wagner@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Miller, Emily <Emily.Miller@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Zeta, Lowell <Lowell.Zeta@fda.hhs.gov>
Subject: RE: FOR URGENT REVIEW: Response on NYT/ Plasma EUA Statement

Last sentence…

(b) (5) [redacted]

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Wednesday, August 19, 2020 3:11 PM
To: Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Wagner, John <John.Wolf.Wagner@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Miller, Emily <Emily.Miller@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Zeta, Lowell <Lowell.Zeta@fda.hhs.gov>
Subject: RE: FOR URGENT REVIEW: Response on NYT/ Plasma EUA Statement

How about below, please note (b) (5) [redacted]

(b) (5) [redacted]

Stephanie Caccomo
Media Relations Director

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: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Sent: Wednesday, August 19, 2020 2:15 PM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Wagner, John

<John.Wolf.Wagner@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Miller, Emily <Emily.Miller@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Zeta, Lowell <Lowell.Zeta@fda.hhs.gov>
Subject: RE: FOR URGENT REVIEW: Response on NYT/ Plasma EUA Statement

(b) (5)

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Wednesday, August 19, 2020 1:51 PM
To: Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Wagner, John <John.Wolf.Wagner@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Miller, Emily <Emily.Miller@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Zeta, Lowell <Lowell.Zeta@fda.hhs.gov>
Subject: RE: FOR URGENT REVIEW: Response on NYT/ Plasma EUA Statement

Yes, there was additional data.

Heard feedback from Amanda to just make one edit, good from OCC?

Stephanie Caccomo
Media Relations Director

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: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Sent: Wednesday, August 19, 2020 1:30 PM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Wagner, John <John.Wolf.Wagner@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Miller, Emily <Emily.Miller@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Zeta, Lowell <Lowell.Zeta@fda.hhs.gov>
Subject: RE: FOR URGENT REVIEW: Response on NYT/ Plasma EUA Statement

(b) (5)

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Wednesday, August 19, 2020 12:33 PM
To: Wagner, John <John.Wolf.Wagner@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Cc: Miller, Emily <Emily.Miller@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Zeta, Lowell <Lowell.Zeta@fda.hhs.gov>
Subject: RE: FOR URGENT REVIEW: Response on NYT/ Plasma EUA Statement

My edits attached – thank you

From: Shah, Anand
Sent: Wednesday, August 19, 2020 12:23 PM
To: Wagner, John <John.Wolf.Wagner@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Cc: Miller, Emily <Emily.Miller@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: RE: FOR URGENT REVIEW: Response on NYT/ Plasma EUA Statement

I'll have a few proposed edits in Word momentarily…

From: Wagner, John <John.Wolf.Wagner@fda.hhs.gov>
Sent: Wednesday, August 19, 2020 12:22 PM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Cc: Miller, Emily <Emily.Miller@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: Re: FOR URGENT REVIEW: Response on NYT/ Plasma EUA Statement

Doc is good. We're good. Get this to occ and ASPA ASPA for super expedited clearance please

John 'Wolf' Wagner

Associate Commissioner

Office of External Affairs
U.S. Food and Drug Administration
john.wolf.wagner@fda.hhs.gov

Sent from my mobile device

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Date: August 19, 2020 at 12:15:59 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Marks, Peter <Peter.Marks@fda.hhs.gov>, Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Cc: Wagner, John <John.Wolf.Wagner@fda.hhs.gov>, Miller, Emily <Emily.Miller@fda.hhs.gov>, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: FOR URGENT REVIEW: Response on NYT/ Plasma EUA Statement
Importance: High

Hi—

Updated language below to use responsively on CP EUA. We propose to share with WaPo first, but will share with other outlets. Many reporters are pinging about story, so would appreciate ok asap!

Statement attributable to Anand Shah, M.D., FDA's Deputy Commissioner for Medical and Scientific Affairs:


(b) (5)

From: Caccomo, Stephanie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=950C32CEBC4B4F80B302C50CF31C8524-STEPHANIE.C]
Sent: 8/21/2020 1:32:04 PM
To: Miller, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=349ea636fe504b488adf664e48ce87e6-Emily.Mille]; 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]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]
CC: Wagner, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a481c74326041d0b268d42f2d70d9f5-John.Wagner]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]
Subject: RE: CP EUA press release
Attachments: 082020 FDA Press Release CP EUA_SC.docx

Thanks Emily and Anna—I've incorporated edits here. We will move this version to HHS.

Stephanie Caccomo
Media Relations Director

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: Miller, Emily <Emily.Miller@fda.hhs.gov>
Sent: Friday, August 21, 2020 12:32 PM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>
Cc: Wagner, John <John.Wolf.Wagner@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: RE: CP EUA press release

For press releases, I'd like us to identify exactly what we want the press to pick up in the quotes. We can do that by shortening them and writing in a way that can be inserted into print/online stories. I propose Hahn quote look like this—feel free to edit for accuracy too. I highlighted what I would hope gets pickup in stories.

(b) (5) [redacted]

," said FDA Commissioner Stephen M. Hahn, M.D.

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Friday, August 21, 2020 11:01 AM
To: Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>
Cc: Wagner, John <John.Wolf.Wagner@fda.hhs.gov>; Miller, Emily <Emily.Miller@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: CP EUA press release

Good morning!

Attaching for your review is the convalescent plasma EUA press release. CBER and OCC cleared.

We plan to move this to HHS later today so PR can be ready to go by Monday. Of note--Azar quote is proposed by FDA, so we'll flag any changes his staff make to his quote. If you have any concerns or edits, please let us know today.

Thank you so much!

Stephanie Caccomo
Media Relations Director

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 [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 8/19/2020 3:13:31 PM
To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Wagner, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a481c74326041d0b268d42f2d70d9f5-John.Wagner]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]
CC: Miller, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=349ea636fe504b488adf664e48ce87e6-Emily.Mille]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Zeta, Lowell [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c0fc7eb68244f4cb4260898d5dacadb-Lowell.Zeta]
Subject: RE: FOR URGENT REVIEW: Response on NYT/ Plasma EUA Statement

Looks good to me.

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Date: August 19, 2020 at 3:10:31 PM EDT
To: Amin, Stacy <Stacy.Amin@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Wagner, John <John.Wolf.Wagner@fda.hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Miller, Emily <Emily.Miller@fda.hhs.gov>, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>, Zeta, Lowell <Lowell.Zeta@fda.hhs.gov>
Subject: RE: FOR URGENT REVIEW: Response on NYT/ Plasma EUA Statement

How about below, please note (b) (5)

(b) (5)

Stephanie Caccomo
Media Relations Director

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: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Sent: Wednesday, August 19, 2020 2:15 PM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Wagner, John <John.Wolf.Wagner@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Miller, Emily <Emily.Miller@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Zeta, Lowell <Lowell.Zeta@fda.hhs.gov>
Subject: RE: FOR URGENT REVIEW: Response on NYT/ Plasma EUA Statement

(b) (5)

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Wednesday, August 19, 2020 1:51 PM
To: Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Wagner, John <John.Wolf.Wagner@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Miller, Emily <Emily.Miller@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Zeta, Lowell <Lowell.Zeta@fda.hhs.gov>
Subject: RE: FOR URGENT REVIEW: Response on NYT/ Plasma EUA Statement

Yes, there was additional data.

Heard feedback from Amanda to just make one edit, good from OCC?

Stephanie Caccomo
Media Relations Director

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: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Sent: Wednesday, August 19, 2020 1:30 PM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Wagner, John <John.Wolf.Wagner@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Miller, Emily <Emily.Miller@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Zeta, Lowell <Lowell.Zeta@fda.hhs.gov>
Subject: RE: FOR URGENT REVIEW: Response on NYT/ Plasma EUA Statement

(b) (5)

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Wednesday, August 19, 2020 12:33 PM
To: Wagner, John <John.Wolf.Wagner@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Cc: Miller, Emily <Emily.Miller@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Zeta, Lowell <Lowell.Zeta@fda.hhs.gov>
Subject: RE: FOR URGENT REVIEW: Response on NYT/ Plasma EUA Statement

My edits attached – thank you

From: Shah, Anand
Sent: Wednesday, August 19, 2020 12:23 PM
To: Wagner, John <John.Wolf.Wagner@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Cc: Miller, Emily <Emily.Miller@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: RE: FOR URGENT REVIEW: Response on NYT/ Plasma EUA Statement

I'll have a few proposed edits in Word momentarily…

From: Wagner, John <John.Wolf.Wagner@fda.hhs.gov>
Sent: Wednesday, August 19, 2020 12:22 PM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Cc: Miller, Emily <Emily.Miller@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: Re: FOR URGENT REVIEW: Response on NYT/ Plasma EUA Statement

Doc is good. We're good. Get this to occ and ASPA ASPA for super expedited clearance please

John 'Wolf' Wagner

Associate Commissioner

Office of External Affairs
U.S. Food and Drug Administration
john.wolf.wagner@fda.hhs.gov

FDA U.S. FOOD & DRUG ADMINISTRATION

Sent from my mobile device

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Date: August 19, 2020 at 12:15:59 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Marks, Peter <Peter.Marks@fda.hhs.gov>, Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Cc: Wagner, John <John.Wolf.Wagner@fda.hhs.gov>, Miller, Emily <Emily.Miller@fda.hhs.gov>, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: FOR URGENT REVIEW: Response on NYT/ Plasma EUA Statement
Importance: High

Hi—
Updated language below to use responsively on CP EUA. We propose to share with WaPo first, but will share with other outlets. Many reporters are pinging about story, so would appreciate ok asap!

Statement attributable to Anand Shah, M.D., FDA's Deputy Commissioner for Medical and Scientific Affairs:

From: Rom, Colin [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F59636221F4340D697DBD43EE27255FB-COLIN.ROM]
Sent: 8/23/2020 4:30:06 PM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
Subject: Fwd: FINAL - Hahn remarks at White House today
Attachments: SCRIPT VERSION -- SH remarks at WH on CP.docx

Emily pulled this version together for focusing emphasis on podium for you to take a look at. Let me know if this is helpful

---

From: Miller, Emily <Emily.Miller@fda.hhs.gov>
Date: August 23, 2020 at 4:14:34 PM EDT
To: Rom, Colin <Colin.Rom@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>, Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Wagner, John <John.Wolf.Wagner@fda.hhs.gov>, Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: RE: FINAL - Hahn remarks at White House today

Colin- As we discussed, attached is the version that is used for TV appearances. I know he's not used to it, so just ask him to try to practice reading it out loud from this. If it throws him, stick to the scripted kind.

From: Rom, Colin <Colin.Rom@fda.hhs.gov>
Sent: Sunday, August 23, 2020 3:51 PM
To: Miller, Emily <Emily.Miller@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Wagner, John <John.Wolf.Wagner@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: Re: FINAL - Hahn remarks at White House today

Thanks Emily. Getting to SH now

From: Miller, Emily <Emily.Miller@fda.hhs.gov>
Date: August 23, 2020 at 3:48:45 PM EDT
To: Rom, Colin <Colin.Rom@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>, Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Wagner, John <John.Wolf.Wagner@fda.hhs.gov>, Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: FINAL - Hahn remarks at White House today

Colin – Final remarks attached. I'll send a copy to you with TV ready breaks and not scripted grammatically. But still give him this one as he is used to the format.

Thanks,
Emily

From: Marks, Peter [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DFBB2B5BD38445CB9C9ADCA3F72DF53A-MARKSP]
Sent: 8/19/2020 3:10:20 PM
To: Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Wagner, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a481c74326041d0b268d42f2d70d9f5-John.Wagner]; 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: Miller, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=349ea636fe504b488adf664e48ce87e6-Emily.Mille]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Zeta, Lowell [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c0fc7eb68244f4cb4260898d5dacadb-Lowell.Zeta]
Subject: RE: FOR URGENT REVIEW: Response on NYT/ Plasma EUA Statement

Dear Stacy,

FDA continues to get data regarding the EAP, since it is an ongoing program, and since there are many analyses ongoing. Although we have shared all of the most substantive information, there is some additional positive information that has come in recently that has not yet been shared. We do not intend to change the outcome of anything based on these data. There will be confirmatory data from the Mayo, which we will have shortly that should also not change anything in the wording of the EUA. How much of that we share with NIH is up to the Commissioner.

Best Regards,
Peter

From: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Sent: Wednesday, August 19, 2020 2:15 PM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Wagner, John <John.Wolf.Wagner@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Miller, Emily <Emily.Miller@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Zeta, Lowell <Lowell.Zeta@fda.hhs.gov>
Subject: RE: FOR URGENT REVIEW: Response on NYT/ Plasma EUA Statement

(b) (5)

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Wednesday, August 19, 2020 1:51 PM
To: Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Wagner, John <John.Wolf.Wagner@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Miller, Emily <Emily.Miller@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Zeta, Lowell

<Lowell.Zeta@fda.hhs.gov>
Subject: RE: FOR URGENT REVIEW: Response on NYT/ Plasma EUA Statement

Yes, there was additional data.

Heard feedback from Amanda to just make one edit, good from OCC?

Stephanie Caccomo
Media Relations Director

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: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Sent: Wednesday, August 19, 2020 1:30 PM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Wagner, John <John.Wolf.Wagner@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Miller, Emily <Emily.Miller@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Zeta, Lowell <Lowell.Zeta@fda.hhs.gov>
Subject: RE: FOR URGENT REVIEW: Response on NYT/ Plasma EUA Statement

(b) (5)

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Wednesday, August 19, 2020 12:33 PM
To: Wagner, John <John.Wolf.Wagner@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Cc: Miller, Emily <Emily.Miller@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Zeta, Lowell <Lowell.Zeta@fda.hhs.gov>
Subject: RE: FOR URGENT REVIEW: Response on NYT/ Plasma EUA Statement

My edits attached – thank you

From: Shah, Anand
Sent: Wednesday, August 19, 2020 12:23 PM
To: Wagner, John <John.Wolf.Wagner@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Cc: Miller, Emily <Emily.Miller@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: RE: FOR URGENT REVIEW: Response on NYT/ Plasma EUA Statement

I'll have a few proposed edits in Word momentarily…

From: Wagner, John <John.Wolf.Wagner@fda.hhs.gov>
Sent: Wednesday, August 19, 2020 12:22 PM

To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Cc: Miller, Emily <Emily.Miller@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: Re: FOR URGENT REVIEW: Response on NYT/ Plasma EUA Statement

Doc is good. We're good. Get this to occ and ASPA ASPA for super expedited clearance please

John 'Wolf' Wagner

Associate Commissioner

Office of External Affairs
U.S. Food and Drug Administration
john.wolf.wagner@fda.hhs.gov

U.S. FOOD & DRUG ADMINISTRATION

Sent from my mobile device

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Date: August 19, 2020 at 12:15:59 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Marks, Peter <Peter.Marks@fda.hhs.gov>, Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Cc: Wagner, John <John.Wolf.Wagner@fda.hhs.gov>, Miller, Emily <Emily.Miller@fda.hhs.gov>, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: FOR URGENT REVIEW: Response on NYT/ Plasma EUA Statement
Importance: High

Hi—

Updated language below to use responsively on CP EUA. We propose to share with WaPo first, but will share with other outlets. Many reporters are pinging about story, so would appreciate ok asap!

Statement attributable to Anand Shah, M.D., FDA's Deputy Commissioner for Medical and Scientific Affairs:

From: Rom, Colin [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F59636221F4340D697DBD43EE27255FB-COLIN.ROM]
Sent: 8/23/2020 3:52:03 PM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
Subject: Fwd: FINAL - Hahn remarks at White House today
Attachments: SH remarks at WH on CP -- FINAL.docx

Remarks attached. Will be printed for you at the WH

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 8/23/2020 3:50:15 PM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
Subject: Fwd: FINAL - Hahn remarks at White House today
Attachments: SH remarks at WH on CP -- FINAL.docx

Stacy had a couple minor legal edits. Final attached.

From: Miller, Emily <Emily.Miller@fda.hhs.gov>
Date: August 23, 2020 at 3:48:45 PM EDT
To: Rom, Colin <Colin.Rom@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>, Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Wagner, John <John.Wolf.Wagner@fda.hhs.gov>, Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: FINAL - Hahn remarks at White House today

Colin – Final remarks attached. I'll send a copy to you with TV ready breaks and not scripted grammatically. But still give him this one as he is used to the format.

Thanks,
Emily

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 8/18/2020 6:02:55 PM
To: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; 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: Wagner, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a481c74326041d0b268d42f2d70d9f5-John.Wagner]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]
Subject: RE: Flag, NYT Qs on CP EUA

Agree on response.

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Date: August 18, 2020 at 5:05:45 PM EDT
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Wagner, John <John.Wolf.Wagner@fda.hhs.gov>, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: RE: Flag, NYT Qs on CP EUA

Dear Stephanie,

What you propose to get back to the reporter with is absolutely fine with me.

There is a much more disturbing aspect to me about this, aside from the fact that it is FDA and not NIH that determines whether or not something meets the standard for EUA: this was yet another leak of information from a meeting that should have been a confidential one, and could undermine the type of open dialogue that would optimally take place.

Best Regards,
Peter

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Tuesday, August 18, 2020 4:55 PM
To: Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Wagner, John <John.Wolf.Wagner@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: Flag, NYT Qs on CP EUA

Noah Weiland at NYT reached out about the CP EUA.

From reporter:
I'm working on a story with a few colleagues today about the convalescent plasma EUA. We've heard from senior officials that the EUA was ready to go late last week, but that several health officials, including Francis Collins and Tony Fauci, intervened, worried that the data from the Mayo Clinic expanded access program was

too weak to use as a foundation of the EUA. The FDA decided to put the EUA on hold for now as it reevaluates data from that program and other studies. We report that the EUA could still come in the near future. A draft of it, we report, included references to the history of success plasma has had in other disease outbreaks, plasma in animal models and a group of plasma studies conducted during the coronavirus pandemic.

(b) (5)

[redacted].

Stephanie Caccomo
Media Relations Director

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: Miller, Emily [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]
Sent: 8/23/2020 3:37:17 PM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Bugin, Kevin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=735d396f29ce480a88de9e6c2b0f424e-BUGINK]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
Subject: RE: Update TPs

Message positive always. And can phrase it in real language as "(b) (5) [redacted]

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Sunday, August 23, 2020 3:06 PM
To: Bugin, Kevin <Kevin.Bugin@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Miller, Emily <Emily.Miller@fda.hhs.gov>
Subject: Re: Update TPs

Yes, you are absolutely right. I like 35% increase in survival.
Steve

From: "Bugin, Kevin" <Kevin.Bugin@fda.hhs.gov>
Date: Sunday, August 23, 2020 at 3:04 PM
To: Stephen Hahn <SH1@fda.hhs.gov>, Anand Shah <Anand.Shah@fda.hhs.gov>, "Miller, Emily" <Emily.Miller@fda.hhs.gov>
Subject: Re: Update TPs

Hi Steve,
In this bullet:

[redacted]

(b) (5) [redacted] 35% increase in survival?

Kevin

From: Hahn, Stephen <SH1@fda.hhs.gov>
Date: August 23, 2020 at 2:40:18 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Miller, Emily <Emily.Miller@fda.hhs.gov>, Bugin, Kevin <Kevin.Bugin@fda.hhs.gov>
Subject: Update TPs

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 8/18/2020 6:02:26 PM
To: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
Subject: Re: confidential and pre-decisional

Equally as disappointed, Peter. We should be extra careful going forward.

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Date: August 18, 2020 at 5:10:13 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: confidential and pre-decisional

Dear Commissioner and Keagan,

QED

I am greatly troubled and saddened by the fact that somebody keeps taking it upon themselves to leak confidential conversations regarding our regulatory deliberations. That said – knowing that this likely would happen is why we could certainly not proceed with a regulatory action last week after Dr. Collins remark.

Best Regards,
Peter

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Tuesday, August 18, 2020 4:55 PM
To: Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Wagner, John <John.Wolf.Wagner@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: Flag, NYT Qs on CP EUA

Noah Weiland at NYT reached out about the CP EUA.

From reporter:
I'm working on a story with a few colleagues today about the convalescent plasma EUA. We've heard from senior officials that the EUA was ready to go late last week, but that several health officials, including Francis Collins and Tony Fauci, intervened, worried that the data from the Mayo Clinic expanded access program was too weak to use as a foundation of the EUA. The FDA decided to put the EUA on hold for now as it reevaluates data from that program and other studies. We report that the EUA could still come in the near future. A draft of it, we report, included references to the history of success plasma has had in other disease outbreaks, plasma in animal models and a group of plasma studies conducted during the coronavirus pandemic.

(b) (5)

Stephanie Caccomo
Media Relations Director

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: Wagner, John [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8A481C74326041D0B268D42F2D70D9F5-JOHN.WAGNER]
Sent: 8/23/2020 8:54:11 AM
To: Miller, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=349ea636fe504b488adf664e48ce87e6-Emily.Mille]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Guevara, Bessy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58097ba8edea47afb3338e671a43dc04-Bessy.Gueva]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]
Subject: RE: tentative timeline for CP rollout based on info 0800am

It would be OTR if we hold it.

It would be for select media and those that cover FDA- we could send out once approved by WH Comms. We've not received that yet. As we told Sec Azar, that's where the tech detail would come out.

John 'Wolf' Wagner
Associate Commissioner

From: Miller, Emily <Emily.Miller@fda.hhs.gov>
Sent: Sunday, August 23, 2020 8:47 AM
To: Wagner, John <John.Wolf.Wagner@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Guevara, Bessy <Bessy.Guevara@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>
Subject: Re: tentative timeline for CP rollout based on info 0800am

Is the 3pm media call on the record or on background?

Are we sending out media advisory for it or WH?

Emily Miller
FDA Assistant Commissioner for Media Affairs
Text/call: (240) 805-3909

From: Wagner, John <John.Wolf.Wagner@fda.hhs.gov>
Date: August 23, 2020 at 8:32:31 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Miller, Emily <Emily.Miller@fda.hhs.gov>, Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>, Guevara, Bessy <Bessy.Guevara@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>, Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>, Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>
Subject: tentative timeline for CP rollout based on info 0800am

BLUF: WH Rose Garden event on Convalescent Plasma, 6pm Sunday 23 August 2020
ALL subject to WH/CoS approval. ASPA working with WH comms to confirm.

0815: Sec Azar prep call
0930: Rollout Team / FDA planning call
1100: Prep call for Dr Marks / FDA, ASPA, WH Comms
1400: prep call for Dr Hahn / FDA/ASPA team
1500: Media roundtable call for Dr Marks/Dr Hahn

1600: Dr Hahn movement to WH/Testing/Security
1700: Prep time at WH
1800: GO time for Rose Garden event
1800: package posts on FDA site
1815: FDA press release posts

John 'Wolf' Wagner
Associate Commissioner

Office of External Affairs
U.S. Food and Drug Administration
john.wolf.wagner@fda.hhs.gov

FDA U.S. FOOD & DRUG ADMINISTRATION

From: Abram, Anna [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FB77660891384232A7CD9086FCBB1A3B-ANNA.ABRAM]
Sent: 8/21/2020 12:09:13 PM
To: 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]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
CC: Wagner, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a481c74326041d0b268d42f2d70d9f5-John.Wagner]; Miller, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=349ea636fe504b488adf664e48ce87e6-Emily.Mille]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]
Subject: RE: CP EUA press release
Attachments: 082020 FDA Press Release CP EUA_SCAA.docx

Thanks, Stephanie. This looks good overall. See my suggested edits in the attached. Thanks!

Internal confidential

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Friday, August 21, 2020 11:01 AM
To: Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>
Cc: Wagner, John <John.Wolf.Wagner@fda.hhs.gov>; Miller, Emily <Emily.Miller@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: CP EUA press release

Good morning!

Attaching for your review is the convalescent plasma EUA press release. CBER and OCC cleared.

We plan to move this to HHS later today so PR can be ready to go by Monday. Of note--Azar quote is proposed by FDA, so we'll flag any changes his staff make to his quote. If you have any concerns or edits, please let us know today.

Thank you so much!

Stephanie Caccomo
Media Relations Director

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: Caccomo, Stephanie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=950C32CEBC4B4F80B302C50CF31C8524-STEPHANIE.C]
Sent: 8/23/2020 8:42:37 AM
To: Wagner, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a481c74326041d0b268d42f2d70d9f5-John.Wagner]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Miller, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=349ea636fe504b488adf664e48ce87e6-Emily.Mille]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Guevara, Bessy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58097ba8edea47afb3338e671a43dc04-Bessy.Gueva]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]
Subject: RE: tentative timeline for CP rollout based on info 0800am

What time are we thinking for EUA to actually get signed? Hopefully 3pm? And then post to website at 6pm?

Stephanie Caccomo
Media Relations Director

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: Wagner, John <John.Wolf.Wagner@fda.hhs.gov>
Sent: Sunday, August 23, 2020 8:32 AM
To: Hahn, Stephen <SH1@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Miller, Emily <Emily.Miller@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Guevara, Bessy <Bessy.Guevara@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>
Subject: tentative timeline for CP rollout based on info 0800am

BLUF: WH Rose Garden event on Convalescent Plasma, 6pm Sunday 23 August 2020
ALL subject to WH/CoS approval. ASPA working with WH comms to confirm.

0815: Sec Azar prep call
0930: Rollout Team / FDA planning call
1100: Prep call for Dr Marks / FDA, ASPA, WH Comms
1400: prep call for Dr Hahn / FDA/ASPA team
1500: Media roundtable call for Dr Marks/Dr Hahn

1600: Dr Hahn movement to WH/Testing/Security
1700: Prep time at WH
1800: GO time for Rose Garden event
1800: package posts on FDA site
1815: FDA press release posts

John 'Wolf' Wagner
Associate Commissioner

Office of External Affairs
U.S. Food and Drug Administration
john.wolf.wagner@fda.hhs.gov

From: Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]
Sent: 8/19/2020 12:32:57 PM
To: Wagner, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a481c74326041d0b268d42f2d70d9f5-John.Wagner]; 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]; 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]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]
CC: Miller, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=349ea636fe504b488adf664e48ce87e6-Emily.Mille]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Zeta, Lowell [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c0fc7eb68244f4cb4260898d5dacadb-Lowell.Zeta]
Subject: RE: FOR URGENT REVIEW: Response on NYT/ Plasma EUA Statement
Attachments: Wolf.docx

My edits attached – thank you

From: Shah, Anand
Sent: Wednesday, August 19, 2020 12:23 PM
To: Wagner, John <John.Wolf.Wagner@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Cc: Miller, Emily <Emily.Miller@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: RE: FOR URGENT REVIEW: Response on NYT/ Plasma EUA Statement

I'll have a few proposed edits in Word momentarily…

From: Wagner, John <John.Wolf.Wagner@fda.hhs.gov>
Sent: Wednesday, August 19, 2020 12:22 PM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Cc: Miller, Emily <Emily.Miller@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: Re: FOR URGENT REVIEW: Response on NYT/ Plasma EUA Statement

Doc is good. We're good. Get this to occ and ASPA ASPA for super expedited clearance please

John 'Wolf' Wagner

Associate Commissioner

Office of External Affairs
U.S. Food and Drug Administration
john.wolf.wagner@fda.hhs.gov

U.S. FOOD & DRUG ADMINISTRATION

Sent from my mobile device

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Date: August 19, 2020 at 12:15:59 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Marks, Peter <Peter.Marks@fda.hhs.gov>, Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Cc: Wagner, John <John.Wolf.Wagner@fda.hhs.gov>, Miller, Emily <Emily.Miller@fda.hhs.gov>, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: FOR URGENT REVIEW: Response on NYT/ Plasma EUA Statement
Importance: High

Hi—

Updated language below to use responsively on CP EUA. We propose to share with WaPo first, but will share with other outlets. Many reporters are pinging about story, so would appreciate ok asap!

Statement attributable to Anand Shah, M.D., FDA's Deputy Commissioner for Medical and Scientific Affairs:

(b) (5)

From: Wagner, John [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8A481C74326041D0B268D42F2D70D9F5-JOHN.WAGNER]
Sent: 8/19/2020 7:27:48 AM
To: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; 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]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]
Subject: RE: Flag, NYT Qs on CP EUA

100% correct Peter. We need to address this offline.

John 'Wolf' Wagner
Associate Commissioner

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Tuesday, August 18, 2020 5:06 PM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Wagner, John <John.Wolf.Wagner@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: RE: Flag, NYT Qs on CP EUA

Dear Stephanie,

What you propose to get back to the reporter with is absolutely fine with me.

There is a much more disturbing aspect to me about this, aside from the fact that it is FDA and not NIH that determines whether or not something meets the standard for EUA: this was yet another leak of information from a meeting that should have been a confidential one, and could undermine the type of open dialogue that would optimally take place.

Best Regards,
Peter

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Tuesday, August 18, 2020 4:55 PM
To: Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Wagner, John <John.Wolf.Wagner@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: Flag, NYT Qs on CP EUA

Noah Weiland at NYT reached out about the CP EUA.

From reporter:
I'm working on a story with a few colleagues today about the convalescent plasma EUA. We've heard from senior officials that the EUA was ready to go late last week, but that several health officials, including Francis

Collins and Tony Fauci, intervened, worried that the data from the Mayo Clinic expanded access program was too weak to use as a foundation of the EUA. The FDA decided to put the EUA on hold for now as it reevaluates data from that program and other studies. We report that the EUA could still come in the near future. A draft of it, we report, included references to the history of success plasma has had in other disease outbreaks, plasma in animal models and a group of plasma studies conducted during the coronavirus pandemic.

(b) (5)

Stephanie Caccomo
Media Relations Director

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: Wagner, John [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8A481C74326041D0B268D42F2D70D9F5-JOHN.WAGNER]
Sent: 8/19/2020 7:27:03 AM
To: 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]; 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: Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]
Subject: RE: Flag, NYT Qs on CP EUA

I'm good with that response.

John 'Wolf' Wagner
Associate Commissioner

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Tuesday, August 18, 2020 4:55 PM
To: Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Wagner, John <John.Wolf.Wagner@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: Flag, NYT Qs on CP EUA

Noah Weiland at NYT reached out about the CP EUA.

From reporter:
I'm working on a story with a few colleagues today about the convalescent plasma EUA. We've heard from senior officials that the EUA was ready to go late last week, but that several health officials, including Francis Collins and Tony Fauci, intervened, worried that the data from the Mayo Clinic expanded access program was too weak to use as a foundation of the EUA. The FDA decided to put the EUA on hold for now as it reevaluates data from that program and other studies. We report that the EUA could still come in the near future. A draft of it, we report, included references to the history of success plasma has had in other disease outbreaks, plasma in animal models and a group of plasma studies conducted during the coronavirus pandemic.

(b) (5)

Stephanie Caccomo
Media Relations Director

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: Marks, Peter [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DFBB2B5BD38445CB9C9ADCA3F72DF53A-MARKSP]
Sent: 8/22/2020 10:16:42 PM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
CC: Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]
Subject: EUA Update - confidential and predecisional

Dear Commissioner,

The EUA should be signed off by Denise by about 10 AM tomorrow. The ASPR is doing a final review of their revised submission based on OCC review, and then Denise can sign.

Though the dataset that came in from the Mayo is smaller than we would have liked due to the clinical follow up that they had in their database, the analysis of the new samples does reach statistical significance. In the overall data set, though there may be benefit for all non-intubated patients, as previously, the strongest data are in non-intubated patients less that 80 years of age treated within 3 days of diagnosis with high titer convalescent plasma – at 7 days there is a 35% improvement in survival, and it doesn't fall off too badly – at 100 days there is a 25% improvement in survival. This is not too far off from other interventions for specific populations such as dexamethasone and remdesivir. Looking at the totality of the evidence, the various titering methods, and various sample sets used to get to essentially the same results, our statisticians feel very confident in the robust nature of this analysis.

From my perspective it is a definite go. Look forward to discussing further tomorrow.

Safe travels!

Best Regards,
Peter

From: Marks, Peter [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DFBB2B5BD38445CB9C9ADCA3F72DF53A-MARKSP]
Sent: 8/21/2020 8:30:21 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: Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
Subject: RE: CBER Update - 8/21/2020

Dear Commissioner,

It will likely be coming in on a rolling basis every several hundred patients, but it will still be over the weekend. That said, I can show you some nice data below from (b) (4) – if you have a moment could you call?

(b) (4)

Best Regards,
Peter

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Friday, August 21, 2020 8:08 AM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Abram, Anna <Anna.Abram@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: Re: CBER Update - 8/21/2020

Thx Peter
Can Mayo send us the data on a rolling basis? Wouldn't it be much better than one large data dump this weekend?
Steve

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Date: August 21, 2020 at 4:48:13 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Cc: Abram, Anna <Anna.Abram@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>, Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: CBER Update - 8/21/2020

Dear Commissioner,

Here is today's CBER update.

Convalescent plasma and hyperimmune globulin

Data

1. EAP numbers for 8/19/2020: (b) (4) [redacted]
2. (b) (4) [redacted] eINDs for convalescent plasma issued
3. (b) (4) [redacted]
4. (b) (4) [redacted]
5. [redacted]
6. (b) (4) [redacted]

Actions/Decisions Needed

7. Will work to facilitate completion of EUA – major issue today is to work with OCC on clearance
8. Will contact Commissioner Hahn on Sunday with results of analysis when available

Vaccine Development

Data

1. Enrollment in (b) (4) [redacted]

Actions/Decisions Needed

1. Continuing work on advisory committee meeting planning
2. Continuing to monitor status of trials.

Best Regards,
Peter

From: Marks, Peter [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DFBB2B5BD38445CB9C9ADCA3F72DF53A-MARKSP]
Sent: 8/19/2020 4:54:11 AM
To: FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]; 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]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; 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]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
CC: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; Jenkins, Charlene [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e722b6438b04d2e9029c72543639a67-Charlene.Je]
Subject: RE: Telecon: Weekly CBER Meeting with the Commissioner

Dear All,

My apologies for the late agenda. Please let me know if there are topics that you would like to add:

1. Update on (b) (4)
2. Progress on convalescent plasma EUA
3. (b) (4)
4. Potential logistics of an EUA and VRBPAC AC meeting planning

a. Committee composition
b. Meeting dates
c. Webcasting

We have an addition 15 minutes on the calendar on August 20 in the event that we do not get through the AC agenda.

Best Regards,
Peter

-----Original Appointment-----
From: FDA Commissioner <Stephen.Hahn@fda.hhs.gov>
Sent: Friday, April 17, 2020 11:18 PM
To: FDA Commissioner; Hahn, Stephen; Lenihan, Keagan; Abram, Anna; Marks, Peter; Witten, Celia (CBER); Tierney, Julia; Shah, Anand
Cc: Rom, Colin
Subject: Telecon: Weekly CBER Meeting with the Commissioner
When: Wednesday, August 19, 2020 11:00 AM-11:30 AM (UTC-05:00) Eastern Time (US & Canada).
Where: 1-877-465-7975,,(b) (6)

From: Marks, Peter [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DFBB2B5BD38445CB9C9ADCA3F72DF53A-MARKSP]
Sent: 8/19/2020 10:07:53 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: Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]
Subject: FW: Flag, NYT Qs on CP EUA

Dear Commissioner and Keagan,

I would like to at least touch upon this at our meeting today. Thanks.

Best Regards,
Peter

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Wednesday, August 19, 2020 9:38 AM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Wagner, John <John.Wolf.Wagner@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Miller, Emily <Emily.Miller@fda.hhs.gov>
Subject: RE: Flag, NYT Qs on CP EUA

Peter—the source was Dr. Lane from NIAID. On the record.

Story from NYT posted:

WASHINGTON — Last week, just as the Food and Drug Administration was preparing to issue an emergency authorization for blood plasma as a Covid-19 treatment, a group of top federal health officials including Dr. Francis S. Collins and Dr. Anthony S. Fauci intervened, arguing that emerging data on the treatment was too weak, according to two senior administration officials.

The authorization is on hold for now as more data is reviewed, according to H. Clifford Lane, the clinical director at the National Institute of Allergy and Infectious Diseases. An emergency approval could still be issued in the near future, he said.

Donated by people who have survived the disease, antibody-rich plasma is considered safe. President Trump has hailed it as a "beautiful ingredient" in the veins of people who have survived Covid-19.

But clinical trials have not proved whether plasma can help people fighting the coronavirus.

Several top health officials — led by Dr. Collins, the director of the National Institutes of Health; Dr. Fauci, the government's top infectious disease expert; and Dr. Lane — urged their colleagues last week to hold off, citing recent data from the country's largest plasma study, run by the Mayo Clinic. They thought the study's data to date was not strong enough to warrant an emergency approval.

"The three of us are pretty aligned on the importance of robust data through randomized control trials, and that a pandemic does not change that," Dr. Lane said in an interview on Tuesday.

The drafted emergency authorization leaned on the history of plasma's use in other disease outbreaks and on animal research and a spate of plasma studies, including the Mayo Clinic's program, which has given infusions to more than 66,000 Covid-19 patients thanks to financing from the federal government.

An F.D.A. spokeswoman declined to comment.

Plasma, the pale yellow liquid leftover after blood is stripped of its red and white cells, has been the subject of months of intense enthusiasm from scientists, celebrities and Mr. Trump, part of the administration's push for coronavirus treatments as a stopgap while pharmaceutical companies race to complete dozens of clinical trials for coronavirus vaccines.

Emergency authorizations, which do not require the same level of evidence as a full F.D.A. approval would, have been a fraught subject for the government during the pandemic. The agency gave one to the malaria drugs hydroxychloroquine and chloroquine only to rescind it months later after the drugs were found to be ineffective against the coronavirus, and potentially harmful. An emergency authorization for blood plasma would most likely ease the clerical burdens on hospitals in conducting infusions.

Senior health officials have privately expressed concern about the rapid growth of the Mayo program and the perceived rush to declare plasma effective without the affirmation of results from randomized trials, which scientists have long relied on as the gold standard of evidence. Skyrocketing enrollment in the program has prompted a debate among researchers about what kind of empirical certainty is needed in treating patients in a public health emergency.

An emergency approval now would "change the way people view trials," said Dr. Mila B. Ortigoza, an infectious disease specialist at N.Y.U. Langone Health who started a trial with colleagues at Montefiore Medical Center.

"We want to make sure that when we say it works, we are confident, with indisputable evidence," she said. "We're dealing with patients' lives here."

Unlike the malaria drugs, plasma, which has been used since the 1890s to treat infectious diseases, has earned the attention of a highly credentialed community of microbiologists and immunologists eager to prove its usefulness. The Mayo Clinic has already published analysis on tens of thousands of patients in its expanded access program showing that plasma is safe.

The most recent batch of data from the program included more than 35,000 Covid-19 patients, many of them in intensive care and on ventilators, and suggested that plasma administered within three days of a diagnosis reduced mortality rates. When calculated a month after the infusions, the death rate of patients who received plasma within three days of diagnosis was lower (21.6 percent) than it was for those who received plasma later (26.7 percent).

Coronavirus Schools Briefing: The pandemic is upending education. Get the latest news and tips as students go back to school.

But the study did not have a control group of patients given a placebo to compare with those given plasma, making it difficult for scientists to assess whether the treatment really worked. And given the limited supply of plasma, it is not clear how realistic treating patients within three days of diagnosis would be.

The program's enrollment has surged to more than 30 times as high as initially expected, complicating the ability of scientists to recruit sick patients to randomized trials.

It "ballooned to a degree that, you know, is becoming unmanageable," Dr. Lane said.

Statisticians at the F.D.A. are now examining the Mayo data to better understand what factors other than the treatment might have influenced patient responses, such as higher-quality care in the hospital, Dr. Lane said.

A research team from Houston Methodist hospitals also published preliminary results from a plasma trial last week. Their study of hospitalized Covid-19 patients in the American Journal of Pathology reported that a group of 136 patients who received the treatment were more likely to be alive four weeks later compared with 251 patients who did not receive it. That study found a statistically significant benefit only when patients were treated within three days of admission and when the plasma contained a high concentration of antibodies.

The Houston study was not randomized, meaning that all of the patients enrolled received the treatment and none received a placebo. (The researchers later compared their outcomes to records from other Covid-19 patients who were not in the study but were matched to be similar to them.)

A surge in cases in Texas this summer quickly brought the hospital system to its enrollment cap, and doctors there have not been able to provide the experimental treatment since mid-July. If the F.D.A. gave an emergency authorization, doctors at the hospital could possibly begin administering it again, said Dr. Eric Salazar, the study's principal investigator.

But an emergency authorization could have the unintended effect of making it harder for rigorous clinical trials to definitively show whether plasma works. Scientists have struggled to recruit patients for randomized trials, as many patients and their doctors — knowing they could get the treatment under the Mayo program — have been unwilling to risk receiving a placebo.

Last month, one such trial in the Netherlands was stopped when researchers realized that patients given plasma showed no difference in mortality, length of hospital stay or disease severity compared with those given a placebo. Most of the patients had already developed their own antibodies by the time they entered the study, the researchers noted.

At least 10 randomized trials in the United States have collectively enrolled only a few hundred people. They have also been stymied by the waning of the virus outbreak in many cities, complicating the ability of researchers to recruit sick people. Dr. Collins has encouraged a strategy of pooling the results from randomized trials, an idea that has met resistance from some researchers.

Dr. R. Scott Wright, who is helping oversee the Mayo Clinic's plasma program, was an early proponent of conducting randomized trials. But he said in a recent interview that the mechanics of setting up large studies were complicated by early shortages of plasma, coordination via videoconference calls and the difficulty of predicting where the virus would spread next.

If the F.D.A. does grant the emergency authorization, it could make it even harder to get answers, said Dr. Ortigoza of N.Y.U.

"We will keep going, because we're in desperate need of a randomized placebo-controlled trial for convalescent plasma," she said. "This is something our country and the world really needs right now."

Stephanie Caccomo
Media Relations Director

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: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Tuesday, August 18, 2020 5:06 PM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Wagner, John <John.Wolf.Wagner@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: RE: Flag, NYT Qs on CP EUA

Dear Stephanie,

What you propose to get back to the reporter with is absolutely fine with me.

There is a much more disturbing aspect to me about this, aside from the fact that it is FDA and not NIH that determines whether or not something meets the standard for EUA: this was yet another leak of information from a meeting that should have been a confidential one, and could undermine the type of open dialogue that would optimally take place.

Best Regards,
Peter

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Tuesday, August 18, 2020 4:55 PM
To: Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Wagner, John <John.Wolf.Wagner@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: Flag, NYT Qs on CP EUA

Noah Weiland at NYT reached out about the CP EUA.

From reporter:
I'm working on a story with a few colleagues today about the convalescent plasma EUA. We've heard from senior officials that the EUA was ready to go late last week, but that several health officials, including Francis Collins and Tony Fauci, intervened, worried that the data from the Mayo Clinic expanded access program was too weak to use as a foundation of the EUA. The FDA decided to put the EUA on hold for now as it reevaluates data from that program and other studies. We report that the EUA could still come in the near future. A draft of it, we report, included references to the history of success plasma has had in other disease outbreaks, plasma in animal models and a group of plasma studies conducted during the coronavirus pandemic.

(b) (5)

Stephanie Caccomo
Media Relations Director

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: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
Sent: 8/23/2020 8:12:28 AM
To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Wagner, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a481c74326041d0b268d42f2d70d9f5-John.Wagner]; Miller, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=349ea636fe504b488adf664e48ce87e6-Emily.Mille]; Pratt, Michael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=facc5c0e27c74fd4964699547a71849d-HHS-Michael]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Caputo, Michael R (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dac6080dfebe436da01db07986b63377-HHS-Michael]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
CC: Emily Miller [emilymiller.miller@gmail.com]; Pines, Wayne * [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e9f5ce0254041a48966c10d0c38bef5-Wayne.Pines]

Subject: CP rollout prep for SH

Start: 8/23/2020 2:00:00 PM
End: 8/23/2020 2:30:00 PM
Show Time As: Busy

Required Attendees: Caccomo, Stephanie; Lenihan, Keagan; Shah, Anand; Wagner, John; Miller, Emily; Pratt, Michael (OS); Marks, Peter; Murphy, Ryan (OS); Caputo, Michael R (OS); Felberbaum, Michael; Hahn, Stephen

Join by phone
210-795-0506 US Toll
877-465-7975 US Toll Free
Access code (b) (6)

From: Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]
Sent: 8/23/2020 10:30:07 AM
To: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]

Subject: Rose Garden Press Event

Start: 8/23/2020 6:00:00 PM
End: 8/23/2020 7:00:00 PM
Show Time As: Busy

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 8/19/2020 8:47:43 AM
To: 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]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Witten, Celia (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fc08ebb3ac61486da9f1b4046757c5cf-Witten]
Subject: Re: early EHR data

Thanks, Peter. Really helpful.

Steve

Sent from my iPad

On Aug 19, 2020, at 8:07 AM, Marks, Peter <Peter.Marks@fda.hhs.gov> wrote:

Dear Commissioner,

Though it is only supportive, please see the figure by Mayo collaborators developed below from EHR data on the optimal patient population that we described (n=124 convalescent plasma, 1040 matched controls).

Best Regards,
Peter

From: Joyner, Michael J., M.D. <joyner.michael@mayo.edu>
Sent: Tuesday, August 18, 2020 5:58 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Carter, Rickey E., Ph.D. <Carter.Rickey@mayo.edu>; Nigel Paneth (paneth@epi.msu.edu) <paneth@epi.msu.edu>; Arturo Casadevall (acasade1@jhu.edu) <acasade1@jhu.edu>; Wright, R. Scott, M.D. <wright.scott@mayo.edu>
Subject: early EHR data
Importance: High

Peter, this is a first look at some EHR data mining mostly early in the pandemic from the NYC area. This is less than 3 days no vent, matched etc. It is pretty consistent….. Long way to go on this, but consistent with other signals.

Mike

<image003.png>