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**From:** Olivarria, Frank [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C180721DB774423F99990DD86E67057C-FRANK.OLIVA]  
**Sent:** 8/21/2020 5:05:38 PM  
**To:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]; 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]

**Subject:** MEDIA HOLD: Sinclair Media (POC: Stephanie Caccomo)  
**Location:** WH

**Start:** 8/28/2020 10:30:00 AM  
**End:** 8/28/2020 1:00:00 PM  
**Show Time As:** Tentative

**Required Attendees:** Miller, Emily; Stephanie Caccomo; Felberbaum, Michael

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**From:** Olivarria, Frank [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C180721DB774423F99990DD86E67057C-FRANK.OLIVA]  
**Sent:** 8/21/2020 5:05:38 PM  
**To:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]; Miller, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=349ea636fe504b488adf664e48ce87e6-Emily.Mille]  
**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]  
**Subject:** Sinclair Media (POC: Stephanie Caccomo)  
**Location:** WH Studio (Rm. 459)  
**Start:** 8/27/2020 3:30:00 PM  
**End:** 8/27/2020 4:00:00 PM  
**Show Time As:** Busy

**Required Attendees:** Miller, Emily

Materials due: 8/26, 5 PM to Jakea Copeland, CC to Frank Olivarria  
Scheduling POC: Stephanie Caccomo  
Staffing Onsite: Emily Miller

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**From:** Jenkins, Yolanda [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F074311E73AA4061A2DFEE3827751964-YOLANDA.JEN]  
**Sent:** 8/21/2020 5:38:17 PM  
**To:** FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]; Commissioner FDA [CommissionerFDA@fda.hhs.gov]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Abernethy, Amy [Amy.Abernethy@fda.hhs.gov]; Franklin, Joseph [Joseph.Franklin@fda.hhs.gov]; Shah, Anand [Anand.Shah@fda.hhs.gov]; Lenihan, Keagan [Keagan.Lenihan@fda.hhs.gov]; Tobias, Lindsay [Lindsay.Tobias@fda.hhs.gov]; Zeta, Lowell [Lowell.Zeta@fda.hhs.gov]; Amin, Stacy [Stacy.Amin@fda.hhs.gov]; Beckerman, Peter [Peter.Beckerman@fda.hhs.gov]; Kropa, Halley [Halley.Kropa@fda.hhs.gov]; Abram, Anna [Anna.Abram@fda.hhs.gov]; Anderson, Erika [Erika.Anderson@fda.hhs.gov]; Rom, Colin [Colin.Rom@fda.hhs.gov]; Schiller, Lowell [Lowell.Schiller@fda.hhs.gov]; Tantillo, Andrew [Andrew.Tantillo@fda.hhs.gov]; Roth, Lauren [Lauren.Roth@fda.hhs.gov]; Wagner, John [John.Wolf.Wagner@fda.hhs.gov]; McBride, Maren [Maren.McBride@fda.hhs.gov]; Yiannas, Frank [Frank.Yiannas@fda.hhs.gov]; Boon, Caitlin [Caitlin.Boon@fda.hhs.gov]; Jenkins, Yolanda [Yolanda.Jenkins@fda.hhs.gov]; Mayne, Susan [Susan.Mayne@fda.hhs.gov]; Kavanaugh, Claudine [Claudine.Kavanaugh@fda.hhs.gov]; Stearn, Douglas [Douglas.Stearn@fda.hhs.gov]; Carroll, Laura [Laura.Carroll@fda.hhs.gov]; Kux, Leslie [Leslie.Kux@fda.hhs.gov]; McKinnon, Robin [Robin.McKinnon@fda.hhs.gov]; Dooren, Jennifer [Jennifer.Dooren@fda.hhs.gov]; Choiniere, Conrad [Conrad.Choiniere@fda.hhs.gov]; Balentine, Douglas [Douglas.Balentine@fda.hhs.gov]; Carey, Emily Rose [EmilyRose.Carey@fda.hhs.gov]; Taylor, Paige [Paige.Taylor@fda.hhs.gov]; Miller, Emily [Emily.Miller@fda.hhs.gov]; Rebello, Heidi [Heidi.Rebello@fda.hhs.gov]  
**CC:** Varnado, Martina [Martina.Varnado@fda.hhs.gov]; O'Neill, Jeff [Jeff.ONeill@fda.hhs.gov]

**Subject:** Commissioner Briefing: Nutrition Innovation Strategy  
**Attachments:** BriefingMemoNutrition\_Aug2020.Clean.docx; Tab A - Nutrition Innovation Strategy Briefing.docx; Tab B - Nutrition Innovation Strategy.docx; NISCommissionerHahnBriefing\_Aug2020\_CLEAN.pptx  
**Location:** Dial in: 1-866-507-5707; Passcode (b) (6)  
**Start:** 8/24/2020 9:15:00 AM  
**End:** 8/24/2020 10:15:00 AM  
**Show Time As:** Busy

**Required Attendees:** FDA Commissioner; Commissioner FDA; Hahn, Stephen (SH1@fda.hhs.gov); Abernethy, Amy; Franklin, Joseph; Shah, Anand; Lenihan, Keagan; Tobias, Lindsay; Zeta, Lowell; Amin, Stacy; Beckerman, Peter; Kropa, Halley; Abram, Anna; Anderson, Erika; Rom, Colin; Schiller, Lowell; Tantillo, Andrew; Roth, Lauren; Wagner, John; McBride, Maren; Yiannas, Frank; Boon, Caitlin; Jenkins, Yolanda; Mayne, Susan; Kavanaugh, Claudine; Stearn, Douglas; Carroll, Laura; Kux, Leslie; McKinnon, Robin; Dooren, Jennifer; Choiniere, Conrad; Balentine, Douglas; Carey, Emily Rose; Taylor, Paige; Miller, Emily; Rebello, Heidi

**See briefing materials attached.**

A briefing for the Commissioner to discuss Nutrition Innovation Strategy has been scheduled for Monday, August 24, from 9:15 AM – 10:15 AM.

**Date:** Monday, August 24, 2020  
**Time:** 9:15 AM – 10:15 AM

**Note:** Reminder to please be sure to mute your phone unless you are speaking.

**Call-in Information:**  
Dial in: 1-866-507-5707  
Passcode: (b) (6)

Please do not forward this invitation. If additional staff need to attend, please let me know.  
OC/Office of the Executive Secretariat Contact: Yolanda K. Jenkins, 240-447-1524

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**From:** Caccomo, Stephanie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=950C32CEBC4B4F80B302C50CF31C8524-STEPHANIE.C]  
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**CC:** Emily Miller (b) (6)  
**Subject:** Embargoed media briefing SH/PM \*\* call-in details added  
**Start:** 8/23/2020 3:00:00 PM  
**End:** 8/23/2020 3:30:00 PM  
**Show Time** Tentative  
**As:**

**Required Attendees:** Marks, Peter; Wagner, John; Miller, Emily; McNeill, Lorrie; Tierney, Julia; Frantz-Bohn, Susan; Felberbaum, Michael; McSeveney, Megan; Hahn, Stephen; Shah, Anand; Lenihan, Keagan

When it's time, join the Webex meeting here.

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**From:** Cacco, Stephanie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=950C32CEBC4B4F80B302C50CF31C8524-STEPHANIE.C]  
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**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  
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Access code: (b) (6)

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**From:** Cacco, Stephanie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=950C32CEBC4B4F80B302C50CF31C8524-STEPHANIE.C]  
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**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:** Cacco, 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

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Access code: (b) (6)



**From:** Jenkins, Yolanda [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F074311E73AA4061A2DFEE3827751964-YOLANDA.JEN]  
**Sent:** 8/21/2020 5:38:17 PM  
**To:** FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]; Commissioner FDA [CommissionerFDA@fda.hhs.gov]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Abernethy, Amy [Amy.Abernethy@fda.hhs.gov]; Franklin, Joseph [Joseph.Franklin@fda.hhs.gov]; Shah, Anand [Anand.Shah@fda.hhs.gov]; Lenihan, Keagan [Keagan.Lenihan@fda.hhs.gov]; Tobias, Lindsay [Lindsay.Tobias@fda.hhs.gov]; Zeta, Lowell [Lowell.Zeta@fda.hhs.gov]; Amin, Stacy [Stacy.Amin@fda.hhs.gov]; Beckerman, Peter [Peter.Beckerman@fda.hhs.gov]; Kropa, Halley [Halley.Kropa@fda.hhs.gov]; Abram, Anna [Anna.Abram@fda.hhs.gov]; Anderson, Erika [Erika.Anderson@fda.hhs.gov]; Rom, Colin [Colin.Rom@fda.hhs.gov]; Schiller, Lowell [Lowell.Schiller@fda.hhs.gov]; Tantillo, Andrew [Andrew.Tantillo@fda.hhs.gov]; Roth, Lauren [Lauren.Roth@fda.hhs.gov]; Wagner, John [John.Wolf.Wagner@fda.hhs.gov]; McBride, Maren [Maren.McBride@fda.hhs.gov]; Yiannas, Frank [Frank.Yiannas@fda.hhs.gov]; Boon, Caitlin [Caitlin.Boon@fda.hhs.gov]; Jenkins, Yolanda [Yolanda.Jenkins@fda.hhs.gov]; Mayne, Susan [Susan.Mayne@fda.hhs.gov]; Kavanaugh, Claudine [Claudine.Kavanaugh@fda.hhs.gov]; Stearn, Douglas [Douglas.Stearn@fda.hhs.gov]; Carroll, Laura [Laura.Carroll@fda.hhs.gov]; Kux, Leslie [Leslie.Kux@fda.hhs.gov]; McKinnon, Robin [Robin.McKinnon@fda.hhs.gov]; Dooren, Jennifer [Jennifer.Dooren@fda.hhs.gov]; Choiniere, Conrad [Conrad.Choiniere@fda.hhs.gov]; Balentine, Douglas [Douglas.Balentine@fda.hhs.gov]; Carey, Emily Rose [EmilyRose.Carey@fda.hhs.gov]; Taylor, Paige [Paige.Taylor@fda.hhs.gov]; Miller, Emily [Emily.Miller@fda.hhs.gov]; Rebello, Heidi [Heidi.Rebello@fda.hhs.gov]  
**CC:** Varnado, Martina [Martina.Varnado@fda.hhs.gov]; O'Neill, Jeff [Jeff.ONeill@fda.hhs.gov]  
**Subject:** Cancelled, to be Rescheduled - Commissioner Briefing: Nutrition Innovation Strategy  
**Attachments:** BriefingMemoNutrition\_Aug2020.Clean.docx; Tab A - Nutrition Innovation Strategy Briefing.docx; Tab B - Nutrition Innovation Strategy.docx; NISCommissionerHahnBriefing\_Aug2020\_CLEAN.pptx  
**Location:** Dial in: 1-866-507-5707; Passcode: (b) (6)  
**Start:** 8/24/2020 9:15:00 AM  
**End:** 8/24/2020 10:15:00 AM  
**Show Time As:** Tentative

**Required Attendees:** FDA Commissioner; Commissioner FDA; Hahn, Stephen (SH1@fda.hhs.gov); Abernethy, Amy; Franklin, Joseph; Shah, Anand; Lenihan, Keagan; Tobias, Lindsay; Zeta, Lowell; Amin, Stacy; Beckerman, Peter; Kropa, Halley; Abram, Anna; Anderson, Erika; Rom, Colin; Schiller, Lowell; Tantillo, Andrew; Roth, Lauren; Wagner, John; McBride, Maren; Yiannas, Frank; Boon, Caitlin; Jenkins, Yolanda; Mayne, Susan; Kavanaugh, Claudine; Stearn, Douglas; Carroll, Laura; Kux, Leslie; McKinnon, Robin; Dooren, Jennifer; Choiniere, Conrad; Balentine, Douglas; Carey, Emily Rose; Taylor, Paige; Miller, Emily; Rebello, Heidi

**(8/24) Update - Briefing is cancelled but will be rescheduled for a later date.**

**See briefing materials attached.**

A briefing for the Commissioner to discuss Nutrition Innovation Strategy has been scheduled for Monday, August 24, from 9:15 AM – 10:15 AM.

**Date:** Monday, August 24, 2020

**Time:** 9:15 AM – 10:15 AM

**Note:** Reminder to please be sure to mute your phone unless you are speaking.

**Call-in Information:**

Dial in: 1-866-507-5707

Passcode: (b) (6)

Please do not forward this invitation. If additional staff need to attend, please let me know.  
OC/Office of the Executive Secretariat Contact: Yolanda K. Jenkins, 240-447-1524

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**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.Lenihan]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-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

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**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](mailto:stephanie.caccomo@fda.hhs.gov)

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**From:** Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>

**Sent:** Tuesday, August 18, 2020 5:06 PM

**To:** Caccomo, Stephanie <[Stephanie.Caccomo@fda.hhs.gov](mailto:Stephanie.Caccomo@fda.hhs.gov)>; Hahn, Stephen <[SH1@fda.hhs.gov](mailto:SH1@fda.hhs.gov)>; Lenihan, Keagan <[Keagan.Lenihan@fda.hhs.gov](mailto:Keagan.Lenihan@fda.hhs.gov)>

**Cc:** Wagner, John <[John.Wolf.Wagner@fda.hhs.gov](mailto:John.Wolf.Wagner@fda.hhs.gov)>; Felberbaum, Michael <[Michael.Felberbaum@fda.hhs.gov](mailto: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

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**From:** Caccomo, Stephanie <[Stephanie.Caccomo@fda.hhs.gov](mailto:Stephanie.Caccomo@fda.hhs.gov)>

**Sent:** Tuesday, August 18, 2020 4:55 PM

**To:** Hahn, Stephen <[SH1@fda.hhs.gov](mailto:SH1@fda.hhs.gov)>; Lenihan, Keagan <[Keagan.Lenihan@fda.hhs.gov](mailto:Keagan.Lenihan@fda.hhs.gov)>; Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>

**Cc:** Wagner, John <[John.Wolf.Wagner@fda.hhs.gov](mailto:John.Wolf.Wagner@fda.hhs.gov)>; Felberbaum, Michael <[Michael.Felberbaum@fda.hhs.gov](mailto: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](mailto:stephanie.caccomo@fda.hhs.gov)

---

**From:** SH1@fda.hhs.gov [SH1@fda.hhs.gov]  
**Sent:** 8/21/2020 8:12:48 AM  
**To:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]  
**CC:** Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]  
**Subject:** RE: Personnel update for 9 a.m.

Just announce Emily

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Date:** August 20, 2020 at 12:59:10 PM EDT  
**To:** Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>  
**Cc:** Rom, Colin <Colin.Rom@fda.hhs.gov>  
**Subject:** RE: Personnel update for 9 a.m.

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**From:** Cacco, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]  
**Sent:** 8/23/2020 9:05:03 AM  
**To:** Cacco, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Marks, Peter; Wagner, John; Miller, Emily; McNeill, Lorrie; Tierney, Julia; Frantz-Bohn, Susan; Felberbaum, Michael; McSeveney, Megan; Hahn, Stephen; Shah, Anand; Lenihan, Keagan  
**Subject:** HOLD: Background media briefings SH/PM \*\*details to follow  
**Start:** 8/23/2020 3:00:00 PM  
**End:** 8/23/2020 3:30:00 PM  
**Show Time As:** Tentative

**Required Attendees:** Marks, Peter; Wagner, John; Miller, Emily; McNeill, Lorrie; Tierney, Julia; Frantz-Bohn, Susan; Felberbaum, Michael; McSeveney, Megan; Hahn, Stephen; Shah, Anand; Lenihan, Keagan



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**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)

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**From:** Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]  
**Sent:** 8/21/2020 5:05:38 PM  
**To:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]; 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]

**Subject:** [PENDING OMA RESPONSE] MEDIA HOLD: Sinclair Media (POC: Stephanie Caccomo)  
**Location:** HHS Studio

**Start:** 8/28/2020 11:00:00 AM  
**End:** 8/28/2020 1:00:00 PM  
**Show Time As:** Tentative

**Required Attendees:** Miller, Emily; Stephanie Caccomo; Felberbaum, Michael

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**From:** Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]  
**Sent:** 8/21/2020 5:05:38 PM  
**To:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]; Miller, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=349ea636fe504b488adf664e48ce87e6-Emily.Mille]  
**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]  
**Subject:** HOLD: Sinclair Media (POC: Stephanie Caccomo)  
**Location:** HHS Studio???

**Start:** 8/27/2020 5:30:00 PM  
**End:** 8/27/2020 6:00:00 PM  
**Show Time As:** Busy

**Required Attendees:** Miller, Emily

OMA: please try to move this to the HHS Studio for Thursday, August 27, 5:30pm (detailed email to follow)

Materials due: 8/26, 5 PM to Jakea Copeland, CC to Frank Olivarria  
Scheduling POC: Stephanie Caccomo  
Staffing Onsite: Emily Miller

**From:** Jenkins, Yolanda [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f074311e73aa4061a2dfce3827751964-Yolanda.Jen]  
**Sent:** 8/21/2020 5:38:17 PM  
**To:** FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]; Commissioner FDA [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e55e9a27325472887051a2c7f4f2f88-Commissione]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; 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]; Tobias, Lindsay [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a4766773c717470bbc55d204b5f067b2-Lindsay.Sto]; Zeta, Lowell [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c0fc7eb68244f4cb4260898d5dacadb-Lowell.Zeta]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Beckerman, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=182e3800db204bb88cf3863bad5259b6-PBeckerm]; Kropa, Halley [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40528285d20b46fc863c57101869448c-Halley.Krop]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Schiller, Lowell [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77949b06919e4f91aa788e9a616c50c7-Lowell.Schi]; Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Roth, Lauren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52bfd08572694f269a20c508f3c04a03-Lauren.Roth]; Wagner, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a481c74326041d0b268d42f2d70d9f5-John.Wagner]; McBride, Maren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]; Yiannas, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93cdf56a41324683ab173699c441fec8-Frank.Yiann]; Boon, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=11917eb34d5445c3802eef2a3999e2e3-Caitlin.Boo]; Jenkins, Yolanda [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f074311e73aa4061a2dfce3827751964-Yolanda.Jen]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Kavanaugh, Claudine [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e2bb33674f346b89bbe0b4ccc7b692-CKavanau]; Stearn, Douglas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1662d8003b3e4ed29367bb7b7aaf54ff-STEARN]; Carroll, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9cb6e346de33480889c94630f0a6ea55-Laura.Carro]; Kux, Leslie [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=9c5fbcdbce154860ab23e1750d503dba-LKux]; McKinnon, Robin  
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[o=ExchangeLabs/ou=Exchange Administrative Group  
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[o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=2f46091afaf2483abb72d8db96066f15-PTaylor]; Miller, Emily  
[o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=349ea636fe504b488adf664e48ce87e6-Emily.Mille]; Rebello, Heidi  
[o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]  
**CC:** Varnado, Martina [o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ad1d1bc50f7941718b0feeb194cbaff1-Martina.Var]; O'Neill, Jeff  
[o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=9a75446cda1244b3aa59af3b53cc2d4d-ONEILLJ]

**Subject:** Canceled: Cancelled, to be Rescheduled - Commissioner Briefing: Nutrition Innovation Strategy  
**Attachments:** BriefingMemoNutrition\_Aug2020.Clean.docx; Tab A - Nutrition Innovation Strategy Briefing.docx; Tab B - Nutrition Innovation Strategy.docx; NISCommissionerHahnBriefing\_Aug2020\_CLEAN.pptx  
**Location:** Dial in: 1-866-507-5707; Passcode: (b) (6)  
**Start:** 8/24/2020 9:15:00 AM  
**End:** 8/24/2020 10:15:00 AM  
**Show Time As:** Free  
**Importance:** High

**Required Attendees:** Commissioner FDA; Hahn, Stephen (SH1@fda.hhs.gov); Abernethy, Amy; Franklin, Joseph; Shah, Anand; Lenihan, Keagan; Tobias, Lindsay; Zeta, Lowell; Amin, Stacy; Beckerman, Peter; Kropa, Halley; Abram, Anna; Anderson, Erika; Rom, Colin; Schiller, Lowell; Tantillo, Andrew; Roth, Lauren; Wagner, John; McBride, Maren; Yiannas, Frank; Boon, Caitlin; Jenkins, Yolanda; Mayne, Susan; Kavanaugh, Claudine; Stearn, Douglas; Carroll, Laura; Kux, Leslie; McKinnon, Robin; Dooren, Jennifer; Choiniere, Conrad; Balentine, Douglas; Carey, Emily Rose; Taylor, Paige; Miller, Emily; Rebello, Heidi

*(8/24) Update - Briefing is cancelled but will be rescheduled for a later date.*

**See briefing materials attached.**

A briefing for the Commissioner to discuss Nutrition Innovation Strategy has been scheduled for Monday, August 24, from 9:15 AM – 10:15 AM.

**Date:** Monday, August 24, 2020  
**Time:** 9:15 AM – 10:15 AM

**Note:** Reminder to please be sure to mute your phone unless you are speaking.

**Call-in Information:**  
Dial in: 1-866-507-5707  
Passcode: (b) (6)

Please do not forward this invitation. If additional staff need to attend, please let me know.



---

**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*

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**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](mailto:john.wolf.wagner@fda.hhs.gov)





---

**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=fb77660891384232a7cd9086fcb1a3b-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".

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**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

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**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)

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**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)



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**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 and 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

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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)

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**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>  
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*Associate Commissioner*

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**Subject:** Re: CP strategic communications plan

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**Cc:** Miller, Emily <Emily.Miller@fda.hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
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**John 'Wolf' Wagner**  
Associate Commissioner

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**Sent:** Friday, August 21, 2020 8:50 PM

**To:** Hahn, Stephen <[SH1@fda.hhs.gov](mailto:SH1@fda.hhs.gov)>; Shah, Anand <[Anand.Shah@fda.hhs.gov](mailto:Anand.Shah@fda.hhs.gov)>; Lenihan, Keagan <[Keagan.Lenihan@fda.hhs.gov](mailto:Keagan.Lenihan@fda.hhs.gov)>; Wagner, John <[John.Wolf.Wagner@fda.hhs.gov](mailto:John.Wolf.Wagner@fda.hhs.gov)>

**Subject:** CP strategic communications plan

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Thanks, Emily

(b) (5)

(b) (5)



(b) (5)

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**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]; Caccamo, 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>; Caccamo, Stephanie <Stephanie.Caccamo@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>, Caccamo, Stephanie <Stephanie.Caccamo@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](mailto:john.wolf.wagner@fda.hhs.gov)



---

**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

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**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

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Thanks, Emily

(b) (5)

(b) (5)

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**From:** Felberbaum, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4819A643CA2945CDB1A2631B83E69673-MICHAEL.FEL]  
**Sent:** 8/19/2020 7:50:09 PM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]  
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**Subject:** FW: Trump suggests government scientists held back plasma therapy for political reasons

FYI

---

**From:** POLITICO Pro Health Care <politicoemail@politico.com>  
**Sent:** Wednesday, August 19, 2020 7:33 PM  
**To:** Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>  
**Subject:** Trump suggests government scientists held back plasma therapy for political reasons

### **Trump suggests government scientists held back plasma therapy for political reasons**

By Sarah Owerhohle, Zachary Brennan

08/19/2020 07:31 PM EDT

President Donald Trump on Wednesday accused government scientists of slow-walking a safe but unproven coronavirus therapy, convalescent plasma, for political reasons.

“You have lot of people over there that don't want to rush things. They want to do it after November 3rd,” he said in a White House press briefing.

Trump and other top administration officials have in recent weeks publicly urged Covid-19 survivors to donate their blood, which contains antibody-rich plasma, to help treat the sick.

But the FDA decided at the last minute to hold off on authorizing emergency use of the plasma after top scientists at the National Institutes of Health argued that data on the treatment's efficacy was still thin, [the New York Times reported Wednesday](#). While NIH has no role in approving therapies, the Times wrote that NIH Director Francis Collins and National Institute of Allergy and Infectious Disease Director Anthony Fauci raised alarms about the lack of definitive evidence.

More than 60,000 people in the U.S. have received plasma under a "compassionate use" program run by the Mayo Clinic, and clinical trials are ongoing. But there are no results yet from randomized, controlled studies, which are considered the gold standard in medical research.

Michael Caputo, assistant secretary of HHS for public affairs, told POLITICO, “NIH has no role in approving an EUA and the person quoted” — H. Clifford Lane, the clinical director at the National Institute of Allergy and Infectious Diseases, in the New York Times story — “did not attend key meetings on the topic.”

The FDA declined to comment on the matter. “Per policy, we are not able to comment on whether or not we will take any action regarding emergency use authorization for convalescent plasma and will render a decision at the appropriate time,” said Anand Shah, FDA’s Deputy Commissioner for Medical and Scientific Affairs.

He added that plasma is available through multiple pathways including clinical trials, compassionate use and

single-patient request to use it in an emergency.

NIH referred questions to NIAID, which did not respond to requests for comment. An NIH source told POLITICO that concerns about the lack of definitive data had been brewing after the president appeared to latch onto plasma in recent press briefings.

Plasma treatment involves giving sick patients blood plasma from volunteers who have recovered from the virus. The plasma contains antibodies that could help fight off the infection.

The treatment has been used for more than a century against diseases from diphtheria to Ebola with mixed success. But while the risk of using plasma is low, there is no definitive evidence it helps coronavirus patients. Large, randomized, controlled clinical trials are underway but could take months to produce results.

“I’ve heard fantastic things about convalescent plasma,” Trump told reporters. “And people are dying. And we should have it approved if it’s good, and I’m hearing it’s good.”

An expanded-access program to provide plasma to patients outside clinical trials will continue “while planning is under way to transition smoothly to Emergency Use Authorization of convalescent plasma,” a Mayo Clinic spokesman said.

The FDA this summer retracted an emergency use authorization for hydroxychloroquine — another drug touted by the president as a coronavirus cure — after randomized trials showed no benefit treating sick patients or preventing illness. The FDA had greenlighted the inexpensive drugs for emergency Covid-19 treatment after two limited studies, sparking criticism from health experts who accused the agency of caving to political pressure.

The plasma episode raises fresh questions about the FDA’s willingness to lower its standards for Covid-19 therapies and vaccines, said Rachel Sachs, an assistant professor of law at Washington University in St. Louis who studies drug regulation.

“We’ve seen [FDA Commissioner Stephen] Hahn be on a public relations campaign attempting to assure and convince the U.S. public that any vaccine will be safe and effective and at least one reason the agency has felt this need to embark on this campaign, is political interference,” she said. “This situation raises the possibility that the agency may seek to approve a product that doesn’t meet its rigorous safety and efficacy standards.”

*To view online:*

<https://subscriber.politicopro.com/health-care/article/2020/08/trump-suggests-political-motivations-in-stalled-convalescent-plasma-clearance-1982243>

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This email was sent to [michael.felberbaum@fda.hhs.gov](mailto:michael.felberbaum@fda.hhs.gov) by:

POLITICO, LLC

1000 Wilson Blvd.

Arlington, VA 22209

USA



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**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 8/18/2020 2:31:42 PM  
**To:** Wagner, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a481c74326041d0b268d42f2d70d9f5-John.Wagner]; Caccamo, 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]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Miller, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=349ea636fe504b488adf664e48ce87e6-Emily.Mille]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]  
**Subject:** RE: Tom Burton's story on testing

Thx

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**From:** Wagner, John <John.Wolf.Wagner@fda.hhs.gov>  
**Date:** August 18, 2020 at 11:14:28 AM MDT  
**To:** Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>, Miller, Emily <Emily.Miller@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>  
**Subject:** RE: Tom Burton's story on testing

Link:

[https://www.wsj.com/articles/us-coronavirus-covid-testing-delay-11597267543?mod=hp\\_lead\\_pos5](https://www.wsj.com/articles/us-coronavirus-covid-testing-delay-11597267543?mod=hp_lead_pos5)

**John 'Wolf' Wagner**  
*Associate Commissioner*

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**From:** Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>  
**Sent:** Tuesday, August 18, 2020 1:01 PM  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Wagner, John <John.Wolf.Wagner@fda.hhs.gov>; Miller, Emily <Emily.Miller@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>  
**Subject:** Tom Burton's story on testing

Tom's story. Generally ok/balanced concerning FDA's role.

# How Three Lost Weeks Held Back America's Covid-19 Testing Ability

**The coronavirus spread unchecked for 21 critical February days while problems plagued the federal test for the pathogen; 'We quickly got behind'**

Aug. 18, 2020 12:20 pm ET

Alex Azar's face reddened when he heard the news: The only federally authorized tests to detect whether Americans were infected with the new coronavirus were flawed, and officials couldn't identify what was causing the problem.

The Health and Human Services secretary listened on a speaker phone with advisers on Feb. 18, according to an attendee, as a senior Centers for Disease Control and Prevention official told him the agency hadn't yet found a fix to the problem in the CDC-designed test.

This was a serious complication. Some public-health authorities feared the virus might be spreading in the U.S. Mr. Azar asked if the CDC could go faster.

"You've got to do this," he told the CDC official, said the attendee.

It took 21 days for testing to take off—from Feb. 8 when state and city public-health labs detected a problem, until Feb. 29, when federal officials offered a broad solution.

The lost days stemmed in part from missteps by U.S. health leaders. They dismissed other solutions that could have led to national testing, underestimated the risk of the virus spreading and were overly confident they could fix the problem, according to interviews with people familiar with the testing crisis, previously undisclosed emails and other correspondence reviewed by The Wall Street Journal.

There were already more than 50 mostly hidden infections a day in the U.S. by mid-February, suggesting that community transmission probably began in January, according to estimates from Northeastern University.

During the 21-day delay, the virus continued to move undetected, on the way to making the U.S. the world leader in coronavirus cases. More than 5.4 million Americans have been infected and more than 170,500 have died as of Tuesday morning, data compiled by Johns Hopkins University show.

The delay set back testing, a critical tool to control the spread of a virus. The lack of adequate testing meant public-health officials couldn't identify and isolate infected individuals and track down people they exposed to the virus. The lack of measures to control the virus enabled cases to surge early on in some parts of the country, outpacing health officials' ability to control it.

"Once we really started to have more widespread disease, we quickly got behind," said Marcus Plescia, chief medical officer of the Association of State and Territorial Health Officials, a nonprofit organization representing public health departments. "We quickly found ourselves in a situation with communitywide transmission."

It still isn't clear what caused the initial problem, which involved just one component of the test. A report by the HHS Office of the General Counsel identified contamination as the likely cause. But a federal official said difficulties the CDC encountered remaking the component suggest the problem might have been due instead to a design flaw.

No one suggests America could have avoided the pandemic. But the 21-day delay prevented testing that might have limited the spread and alerted cities like New York and Seattle to shut down sooner, many public-health authorities say. The delay was a bigger error than the technical glitch in the CDC test itself, said Ashish Jha, faculty director of the Harvard Global Health Institute, and a quicker fix could also have led to more-limited lockdowns, which "could have been more effective and better received and tolerated by the public."

A comparison with South Korea is instructive. Both governments authorized their first Covid-19 tests Feb. 4. Within three days, a South Korean company was distributing tests—around the time the CDC started shipping kits to states—and several South Korean suppliers soon followed. By the time the U.S. figured out how to handle its testing snag, South Korea had completed more than 58,000 tests, and the country’s response is widely considered a success, though there has been a recent uptick in cases.

Officials at the HHS, which includes the Food and Drug Administration and CDC, disagree that testing delays worsened the pandemic. “While developing this first test is paramount to any pandemic response, the CDC and our public-health labs were not intended to bear the weight or capacity of nationwide testing on this scale,” said HHS spokesman Michael Caputo.

“This administration built a comprehensive diagnostic testing system from scratch” he said, and “now has the world’s most robust public-private testing system and is better prepared to respond to future global health threats.” The HHS said Mr. Azar wanted the testing delay to be fixed immediately. The CDC didn’t respond to requests for an interview with its director, Robert Redfield.

It wasn’t until Feb. 26 that the FDA conveyed a solution to public-health labs: They could run the tests without relying on the faulty component. Three days later, the FDA opened the doors for hundreds of hospital labs to begin tests without waiting for regulatory approval.

Mr. Azar assumed the role overseeing the U.S. response after the CDC alerted him to the coronavirus threat on Jan. 3. Early on, said people familiar with internal discussions, he appeared confident he could handle the situation.

The HHS could have used a German-designed test promoted by the World Health Organization and reliably used by many countries. Instead, Mr. Azar in January supported the creation of a CDC test he envisioned as the nation’s gold standard, the people said. The CDC normally develops the first test for new pathogens causing outbreaks and distributes it to public-health labs.

Some FDA officials in January worried that relying exclusively on public-health labs before engaging commercial and academic labs would take too long, said FDA officials familiar with the discussions. Behind the scenes, they began putting commercial and hospital labs in touch with Biodefense and Emerging Infections Research Resources Repository, a government contractor that could help them build testing kits, the FDA officials said.

It wasn’t until late February that the commercial labs started to make their own tests. Some federal officials believed it was important for the CDC to develop its test first, which was the standard process.

Mr. Azar in a statement said he “encouraged FDA to reach out to industry from the earliest days of the response.” Mr. Azar, who declined to comment further, said in an April interview with the Journal that the CDC typically develops tests for novel pathogens because commercial testing can take months to develop.

An FDA spokeswoman said the agency reached out to labs early to build up a robust testing system.

Complicating matters for commercial and hospital labs, a public-health emergency Mr. Azar declared Jan. 31 created a new regulatory hurdle: They would soon have to seek emergency-use authorization from the FDA, a potentially time-consuming process, before their tests could be used. In a nonemergency, hospital and academic labs are typically allowed to design and implement their own in-house tests without much regulatory oversight. The FDA spokeswoman said that, in many cases, the FDA can do this review in as little as a day.

All this meant everything was riding on the CDC going into February. The agency created its test in just over a week.

The CDC test, which the FDA authorized Feb. 4, shipped by Feb. 6 to 33 states and 70 labs in 66 countries, according to an HHS report.

The test consisted of three components, each of which detected a different string of the virus’s genetic code. The first two parts identified sequences unique to the new coronavirus. The third component looked for a chunk of genetic material present in a wider swath of coronaviruses, a catchall in case the virus mutated.

State and local public-health officials were eager to get the kits, and some pulled scientists in to work over the weekend of Saturday, Feb. 8, to speed the validation process.

That day, Minnesota infectious-disease lab manager Sara Vetter was making decorations for her daughter's Harry Potter-theme birthday party when a lab supervisor texted, alerting her about a problem.

Lab specialists had put the test through a standard validation process, including running it on confirmed positive virus samples and on a "negative control" sample, such as sterile water, to ensure it was working. But in the third component, the negative control was somehow turning up positive.

Dr. Vetter soon heard grumblings from other public-health labs showing they weren't alone. That "gave us a little bit of comfort, because at least we knew it wasn't just us," she said. "But then we were left with this horrible feeling of 'what do we do?'"

When New York state's health department received the test that Saturday, it found problems with the first and third parts of the test. The testing-chemical mixture was contaminated, New York state health officials said later.

Jennifer Rakeman-Cagno, director of the public-health laboratory for the New York City Department of Health and Mental Hygiene, emailed the deputy commissioner that day saying the third sequence "is coming up 'positive' very late in the cycle on the negative controls. This makes the test invalid. This is being seen at multiple labs." A spokesman for Dr. Rakeman-Cagno didn't respond to requests for comment.

Scott Becker, chief executive of the Association of Public Health Laboratories, a nonprofit that represents state and local governmental health labs, on Sunday morning, Feb. 9, saw his phone light up with emails from lab directors saying the tests weren't working right.

"This really can't be happening," Mr. Becker said he thought. "Our only tool was testing. And otherwise we are flying blind."

The FDA learned Feb. 10 that 10% of the public-health labs found problems with the third test component's accuracy, said agency officials.

Taken by surprise, the CDC set out to remake the third component, a process that would take a week or more. The agency was confident it could fix the test, which worked in its own labs. On Feb. 11, the public-lab association told its members the CDC was remanufacturing the third component to ship out as a replacement. Some labs that didn't encounter the problem started testing patients. Most went on pause.

Mr. Azar in a speech that day praised the tests, saying, "these test kits are now available for order by U.S. state and local public-health laboratories, Defense Department laboratories, and select international laboratories."

CDC officials told public-health lab representatives that the new component would be available the following week, according to a Feb. 12 written summary of a call between those parties.

By Feb. 16, the FDA learned that 26 public-health labs out of 100 had found problems, said FDA officials.

Mr. Azar wanted a fast solution, said people familiar with the discussions. In the Feb. 18 meeting with Mr. Azar at the HHS conference room, Daniel Jernigan, who heads the CDC's influenza division, told Mr. Azar the CDC didn't know what was causing the problem in the third sequence, said the attendee at the meeting, which included officials from the National Institutes of Health, the FDA and other agency leaders listening by phone.

Mr. Azar asked, "Well, how important is it?" and Dr. Jernigan responded that the sequence was essential, the attendee said.

That's when Mr. Azar asked if the CDC could move more quickly.

Dr. Jernigan didn't respond to requests for comment.

The CDC's Dr. Redfield told Mr. Azar the agency was working on a fix, said people familiar with the discussions. Over the following days, Dr. Redfield assured him they could remake the faulty third component, they said.

Mr. Azar initially didn't think a short testing delay would be a problem because he believed the risk of spread was low, but he was frustrated and urged a fix, people familiar with the discussions said.

Dr. Redfield kept changing the timeline of when the test could be fixed, people familiar with the discussions said, pushing it later and later. Mr. Azar was told on Feb. 18 the test might not be ready until March 12, they said.

On Feb. 19, knowing that some labs had also had problems with the first component of the test, the CDC told public-health labs it would replace all the test chemicals and send out new kits, according to a written summary of a call between the CDC and public-health labs. The CDC now said it couldn't say when the new kits would be ready.

By then, lab specialists at the agency had tried at least two ways to manufacture a new third component, according to a federal official. But they couldn't get it to work. That suggested that contamination might not be the problem. Inside the agency's labs, the mood shifted from confidence to feeling under pressure.

Meanwhile, the virus was spreading. Two people died at home on Feb. 6 and Feb. 17 in Santa Clara County, Calif. In April, autopsies determined they were Covid-19 positive. Neither had any travel history.

About a million people gathered in New Orleans for Mardi Gras, which fell on Feb. 25. Attendees infected there seeded cases in other states, CDC reports in April and May found.

Given continued problems with the third component, officials worked on other options. CDC scientists scrambled to analyze test data using just the first two components. On Feb. 21, it looked that one solution worked; three days later, it didn't, said FDA officials.

Timothy Stenzel, the FDA official in charge of lab diagnostics, flew to the CDC's Respiratory Virus Diagnostic Lab in Atlanta, where the test was developed, on Feb. 22.

What he saw there was alarming, his boss Jeffrey Shuren, the FDA's medical-device center director, said in a later HHS conference call recounted by a senior administration official. In the call, Dr. Shuren described the lab as "filthy"—meaning it had the potential to contaminate—the official said. If it had been any other lab, Dr. Shuren told CDC officials on the call, the FDA would have shut it down, the official said. FDA spokeswoman Stephanie Caccamo declined to comment on the conference call.

Dr. Stenzel concluded the test's design was probably adequate but something had gone wrong in the manufacture of its early version, FDA officials said. He didn't determine exactly what had gone wrong, they said.

A later test made by commercial lab company [Laboratory Corp. of America](#) used the same CDC design and didn't have the same accuracy problems, the FDA officials said. [LabCorp](#) developed its test with published information about the CDC's design and adapted it to work with different chemicals and on high-throughput instruments, said Pattie Kushner, LabCorp's chief communications officer. The test is highly accurate, she said.

The CDC said in an article in the journal *Emerging Infectious Diseases* that its test performed adequately in its own labs in January and February on nearly 3,000 specimens.

Alarm about the virus and testing woes hit a crescendo in late February. Mr. Becker and Grace Kubin—a lab director at the Texas Department of State Health Services and then-president of the public-lab association—wrote FDA Commissioner Stephen Hahn a Feb. 24 letter pleading with the commissioner to let public-health labs bypass the authorization process and design and implement their own tests.

"We are now many weeks into the response," they wrote, "with still no diagnostic or surveillance test available outside of CDC for the vast majority of our member laboratories."

Nancy Messonnier, the CDC's top respiratory-diseases official, said in a press call that community spread of the virus was a question of when, not if, and that disruption to everyday life could be severe. The stock market cratered.

A furious Mr. Trump called Mr. Azar and considered having Dr. Messonnier fired, said people familiar with the discussion. Mr. Trump announced Vice President Mike Pence would assume primary control of the task force. The White House declined to comment.

On Feb. 26—18 days after the problem first emerged—public-health labs began hearing the FDA was likely to let them use some version of the original test after all.

The subject line of an email that day from Dr. Stenzel to the public-lab association read: “Do not destroy your current CDC 2019 nCoV Coronavirus EUA Kits,” and “Please hold for additional follow on information.”

“Here we go again! I hope we have not destroyed the earlier kit,” Sandip Shah, director of Michigan’s state public-health lab, wrote to his staff, forwarding the email.

A microbiologist responded: “We have not destroyed the kit!”

Another lab member, quoting from the baseball movie “The Sandlot,” in which a boy is exasperated his friend Scotty Smalls didn’t have essential childhood skills, emailed: “you are killing me Smalls.”

That day, the FDA gave the go-ahead for the abbreviated test—dropping the third component—after determining it could work.

The HHS initiated a conference call with some members of the task force and Brian Harrison, Mr. Azar’s chief of staff, said a person familiar with the discussion. Mr. Harrison urged them to get the remade CDC tests out quickly, the person said.

The public-health labs still would have to submit for and get FDA emergency-use authorization for new tests of their own creation. But they could do so in a single application. Public-health labs wanting to use the CDC kit could eliminate the third component and get started immediately.

“From the beginning of the Covid-19 response, Secretary Azar and Brian Harrison insisted that accurate testing be widely proliferated as quickly as possible,” an HHS spokeswoman said on Mr. Harrison’s behalf.

On a Feb. 26 call with the CDC, FDA and other public-health labs to go over the solution, Jill Taylor, director of New York’s Wadsworth Center, the state’s research and public-health laboratory, expressed frustration at not having a usable test. New York was among a small number of labs that would still have to wait for a new CDC test because it had not been able to get the first component to work.

“This is completely unacceptable,” Dr. Taylor said, according to a person on the call. “We need to do something.”

She told the FDA that Wadsworth had developed its own test. The FDA promised to expedite a review New York state submitted on behalf of the state and New York City. The FDA confirmed the account, and a state health-department spokesman said Dr. Taylor verified the account.

Wadsworth officials had made their test because they worried it could take a long time to fix the CDC test and that materials would be in short supply, said Gareth Rhodes, a state official on New York’s coronavirus task force in charge of testing.

At the time, some federal officials continued to dismiss the severity of the crisis. President Trump in a Feb. 26 press conference said spread of the virus in the U.S. wasn’t inevitable and that “the risk to the American public remains very low.”

On Feb. 27, the CDC’s contractor produced the two-component test and shipped it to seven public-health labs for validation, to make sure it worked. Once it did, tests went out to 40 more public-health labs on Feb. 28.

On Feb. 29, FDA officials let hundreds of academic hospital labs know they could use their own tests and said the agency would give them retroactive proof of accuracy. Within two weeks, Roche Molecular Systems Inc. had the first authorized commercial coronavirus test. Companies including Thermo Fisher Scientific Inc., Hologic Inc. and LabCorp quickly followed suit.

Testing exploded, with labs able to test more than 100,000 people a day by the end of March, according to the Covid Tracking Project. So did the number of infections detected.

The Life Care Center of Kirkland, a nursing home in Kirkland, Wash., had noticed an outbreak of a severe respiratory illness and had notified the state. Washington state began testing locally on Feb. 28. The next day, local and federal health officials reported two cases linked to the facility and the first known Covid-19 death in the U.S.

New York's health department received FDA authorization for its test Feb. 29. Within a couple of hours, the state had its first positive case.

With the virus out of control, the punishing nationwide lockdown was about to begin.

—Rebecca Ballhaus contributed to this article.

—Illustration at top by Jessica Kuronen/WSJ.

**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](mailto:stephanie.caccomo@fda.hhs.gov)

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**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.Lenihan]; 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

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**From:** Caccamo, Stephanie <Stephanie.Caccamo@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](mailto:stephanie.caccomo@fda.hhs.gov)

---

**From:** Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>

**Sent:** Tuesday, August 18, 2020 5:06 PM

**To:** Caccomo, Stephanie <[Stephanie.Caccomo@fda.hhs.gov](mailto:Stephanie.Caccomo@fda.hhs.gov)>; Hahn, Stephen <[SH1@fda.hhs.gov](mailto:SH1@fda.hhs.gov)>; Lenihan, Keagan <[Keagan.Lenihan@fda.hhs.gov](mailto:Keagan.Lenihan@fda.hhs.gov)>

**Cc:** Wagner, John <[John.Wolf.Wagner@fda.hhs.gov](mailto:John.Wolf.Wagner@fda.hhs.gov)>; Felberbaum, Michael <[Michael.Felberbaum@fda.hhs.gov](mailto: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](mailto:Stephanie.Caccomo@fda.hhs.gov)>

**Sent:** Tuesday, August 18, 2020 4:55 PM

**To:** Hahn, Stephen <[SH1@fda.hhs.gov](mailto:SH1@fda.hhs.gov)>; Lenihan, Keagan <[Keagan.Lenihan@fda.hhs.gov](mailto:Keagan.Lenihan@fda.hhs.gov)>; Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>

**Cc:** Wagner, John <[John.Wolf.Wagner@fda.hhs.gov](mailto:John.Wolf.Wagner@fda.hhs.gov)>; Felberbaum, Michael <[Michael.Felberbaum@fda.hhs.gov](mailto: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](mailto: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 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

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**From:** Shah, Anand <[Anand.Shah@fda.hhs.gov](mailto:Anand.Shah@fda.hhs.gov)>  
**Sent:** Wednesday, August 19, 2020 3:19 PM  
**To:** Caccomo, Stephanie <[Stephanie.Caccomo@fda.hhs.gov](mailto:Stephanie.Caccomo@fda.hhs.gov)>; Amin, Stacy <[Stacy.Amin@fda.hhs.gov](mailto:Stacy.Amin@fda.hhs.gov)>; Wagner, John <[John.Wolf.Wagner@fda.hhs.gov](mailto:John.Wolf.Wagner@fda.hhs.gov)>; Hahn, Stephen <[SH1@fda.hhs.gov](mailto:SH1@fda.hhs.gov)>; Lenihan, Keagan <[Keagan.Lenihan@fda.hhs.gov](mailto:Keagan.Lenihan@fda.hhs.gov)>; Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>  
**Cc:** Miller, Emily <[Emily.Miller@fda.hhs.gov](mailto:Emily.Miller@fda.hhs.gov)>; Felberbaum, Michael <[Michael.Felberbaum@fda.hhs.gov](mailto:Michael.Felberbaum@fda.hhs.gov)>; Zeta, Lowell <[Lowell.Zeta@fda.hhs.gov](mailto: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](mailto:Stephanie.Caccomo@fda.hhs.gov)>  
**Sent:** Wednesday, August 19, 2020 3:11 PM  
**To:** Amin, Stacy <[Stacy.Amin@fda.hhs.gov](mailto:Stacy.Amin@fda.hhs.gov)>; Shah, Anand <[Anand.Shah@fda.hhs.gov](mailto:Anand.Shah@fda.hhs.gov)>; Wagner, John <[John.Wolf.Wagner@fda.hhs.gov](mailto:John.Wolf.Wagner@fda.hhs.gov)>; Hahn, Stephen <[SH1@fda.hhs.gov](mailto:SH1@fda.hhs.gov)>; Lenihan, Keagan <[Keagan.Lenihan@fda.hhs.gov](mailto:Keagan.Lenihan@fda.hhs.gov)>; Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>  
**Cc:** Miller, Emily <[Emily.Miller@fda.hhs.gov](mailto:Emily.Miller@fda.hhs.gov)>; Felberbaum, Michael <[Michael.Felberbaum@fda.hhs.gov](mailto:Michael.Felberbaum@fda.hhs.gov)>; Zeta, Lowell <[Lowell.Zeta@fda.hhs.gov](mailto: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](mailto:stephanie.caccomo@fda.hhs.gov)

---

**From:** Amin, Stacy <[Stacy.Amin@fda.hhs.gov](mailto:Stacy.Amin@fda.hhs.gov)>  
**Sent:** Wednesday, August 19, 2020 2:15 PM  
**To:** Caccomo, Stephanie <[Stephanie.Caccomo@fda.hhs.gov](mailto:Stephanie.Caccomo@fda.hhs.gov)>; Shah, Anand <[Anand.Shah@fda.hhs.gov](mailto:Anand.Shah@fda.hhs.gov)>; Wagner, John <[John.Wolf.Wagner@fda.hhs.gov](mailto:John.Wolf.Wagner@fda.hhs.gov)>; Hahn, Stephen <[SH1@fda.hhs.gov](mailto:SH1@fda.hhs.gov)>; Lenihan, Keagan <[Keagan.Lenihan@fda.hhs.gov](mailto:Keagan.Lenihan@fda.hhs.gov)>; Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>  
**Cc:** Miller, Emily <[Emily.Miller@fda.hhs.gov](mailto:Emily.Miller@fda.hhs.gov)>; Felberbaum, Michael <[Michael.Felberbaum@fda.hhs.gov](mailto:Michael.Felberbaum@fda.hhs.gov)>; Zeta, Lowell <[Lowell.Zeta@fda.hhs.gov](mailto: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](mailto:Stephanie.Caccomo@fda.hhs.gov)>  
**Sent:** Wednesday, August 19, 2020 1:51 PM  
**To:** Amin, Stacy <[Stacy.Amin@fda.hhs.gov](mailto:Stacy.Amin@fda.hhs.gov)>; Shah, Anand <[Anand.Shah@fda.hhs.gov](mailto:Anand.Shah@fda.hhs.gov)>; Wagner, John <[John.Wolf.Wagner@fda.hhs.gov](mailto:John.Wolf.Wagner@fda.hhs.gov)>; Hahn, Stephen <[SH1@fda.hhs.gov](mailto:SH1@fda.hhs.gov)>; Lenihan, Keagan <[Keagan.Lenihan@fda.hhs.gov](mailto:Keagan.Lenihan@fda.hhs.gov)>; Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>  
**Cc:** Miller, Emily <[Emily.Miller@fda.hhs.gov](mailto:Emily.Miller@fda.hhs.gov)>; Felberbaum, Michael <[Michael.Felberbaum@fda.hhs.gov](mailto:Michael.Felberbaum@fda.hhs.gov)>; Zeta, Lowell <[Lowell.Zeta@fda.hhs.gov](mailto: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](mailto:stephanie.caccomo@fda.hhs.gov)

---

**From:** Amin, Stacy <[Stacy.Amin@fda.hhs.gov](mailto:Stacy.Amin@fda.hhs.gov)>  
**Sent:** Wednesday, August 19, 2020 1:30 PM  
**To:** Shah, Anand <[Anand.Shah@fda.hhs.gov](mailto:Anand.Shah@fda.hhs.gov)>; Wagner, John <[John.Wolf.Wagner@fda.hhs.gov](mailto:John.Wolf.Wagner@fda.hhs.gov)>; Caccomo, Stephanie <[Stephanie.Caccomo@fda.hhs.gov](mailto:Stephanie.Caccomo@fda.hhs.gov)>; Hahn, Stephen <[SH1@fda.hhs.gov](mailto:SH1@fda.hhs.gov)>; Lenihan, Keagan <[Keagan.Lenihan@fda.hhs.gov](mailto:Keagan.Lenihan@fda.hhs.gov)>; Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>  
**Cc:** Miller, Emily <[Emily.Miller@fda.hhs.gov](mailto:Emily.Miller@fda.hhs.gov)>; Felberbaum, Michael <[Michael.Felberbaum@fda.hhs.gov](mailto:Michael.Felberbaum@fda.hhs.gov)>; Zeta, Lowell <[Lowell.Zeta@fda.hhs.gov](mailto: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](mailto:Anand.Shah@fda.hhs.gov)>  
**Sent:** Wednesday, August 19, 2020 12:33 PM  
**To:** Wagner, John <[John.Wolf.Wagner@fda.hhs.gov](mailto:John.Wolf.Wagner@fda.hhs.gov)>; Caccomo, Stephanie <[Stephanie.Caccomo@fda.hhs.gov](mailto:Stephanie.Caccomo@fda.hhs.gov)>; Hahn, Stephen <[SH1@fda.hhs.gov](mailto:SH1@fda.hhs.gov)>; Lenihan, Keagan <[Keagan.Lenihan@fda.hhs.gov](mailto:Keagan.Lenihan@fda.hhs.gov)>; Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>; Amin, Stacy <[Stacy.Amin@fda.hhs.gov](mailto:Stacy.Amin@fda.hhs.gov)>  
**Cc:** Miller, Emily <[Emily.Miller@fda.hhs.gov](mailto:Emily.Miller@fda.hhs.gov)>; Felberbaum, Michael <[Michael.Felberbaum@fda.hhs.gov](mailto:Michael.Felberbaum@fda.hhs.gov)>; Zeta, Lowell <[Lowell.Zeta@fda.hhs.gov](mailto: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](mailto:John.Wolf.Wagner@fda.hhs.gov)>; Caccomo, Stephanie <[Stephanie.Caccomo@fda.hhs.gov](mailto:Stephanie.Caccomo@fda.hhs.gov)>; Hahn, Stephen <[SH1@fda.hhs.gov](mailto:SH1@fda.hhs.gov)>; Lenihan, Keagan <[Keagan.Lenihan@fda.hhs.gov](mailto:Keagan.Lenihan@fda.hhs.gov)>; Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>; Amin, Stacy <[Stacy.Amin@fda.hhs.gov](mailto:Stacy.Amin@fda.hhs.gov)>  
**Cc:** Miller, Emily <[Emily.Miller@fda.hhs.gov](mailto:Emily.Miller@fda.hhs.gov)>; Felberbaum, Michael <[Michael.Felberbaum@fda.hhs.gov](mailto: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](mailto:John.Wolf.Wagner@fda.hhs.gov)>  
**Sent:** Wednesday, August 19, 2020 12:22 PM  
**To:** Caccomo, Stephanie <[Stephanie.Caccomo@fda.hhs.gov](mailto:Stephanie.Caccomo@fda.hhs.gov)>; Hahn, Stephen <[SH1@fda.hhs.gov](mailto:SH1@fda.hhs.gov)>; Lenihan, Keagan <[Keagan.Lenihan@fda.hhs.gov](mailto:Keagan.Lenihan@fda.hhs.gov)>; Shah, Anand <[Anand.Shah@fda.hhs.gov](mailto:Anand.Shah@fda.hhs.gov)>; Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>; Amin, Stacy <[Stacy.Amin@fda.hhs.gov](mailto:Stacy.Amin@fda.hhs.gov)>  
**Cc:** Miller, Emily <[Emily.Miller@fda.hhs.gov](mailto:Emily.Miller@fda.hhs.gov)>; Felberbaum, Michael <[Michael.Felberbaum@fda.hhs.gov](mailto: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](mailto:john.wolf.wagner@fda.hhs.gov)



Sent from my mobile device

---

**From:** Caccomo, Stephanie <[Stephanie.Caccomo@fda.hhs.gov](mailto:Stephanie.Caccomo@fda.hhs.gov)>  
**Date:** August 19, 2020 at 12:15:59 PM EDT  
**To:** Hahn, Stephen <[SH1@fda.hhs.gov](mailto:SH1@fda.hhs.gov)>, Lenihan, Keagan <[Keagan.Lenihan@fda.hhs.gov](mailto:Keagan.Lenihan@fda.hhs.gov)>, Shah, Anand <[Anand.Shah@fda.hhs.gov](mailto:Anand.Shah@fda.hhs.gov)>, Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>, Amin, Stacy <[Stacy.Amin@fda.hhs.gov](mailto:Stacy.Amin@fda.hhs.gov)>  
**Cc:** Wagner, John <[John.Wolf.Wagner@fda.hhs.gov](mailto:John.Wolf.Wagner@fda.hhs.gov)>, Miller, Emily <[Emily.Miller@fda.hhs.gov](mailto:Emily.Miller@fda.hhs.gov)>, Felberbaum, Michael <[Michael.Felberbaum@fda.hhs.gov](mailto: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:** 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)

(b) (5)

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

Thank you.

---

**From:** Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]  
**Sent:** 8/23/2020 12:56:37 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]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]  
**Subject:** Re: Meadows re Hahn/FDA on ABC

I really don't think this is that bad. He dragged NIH into it rightfully and gave SH a shout out for not cutting corners. Meadows has to protect POTUS (b) (5)

[REDACTED]. SH can pivot from those types of questions to talk about the great announcement they are making today.

---

**From:** Miller, Emily <Emily.Miller@fda.hhs.gov>  
**Date:** August 23, 2020 at 12:44:45 PM EDT  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>  
**Subject:** Meadows re Hahn/FDA on ABC

Transcript below of Meadows comment about FDA and Hahn specially. It's all over the place in media and we get a lot of calls (not responding.)

I recommend (b) (5)

STEPHANOPOULOS: Let's turn to the COVID crisis. In a tweet yesterday morning --

MEADOWS: Sure.

STEPHANOPOULOS: -- the president leveled a pretty serious charge against the FDA. I want to read it. Putting it up on the screen right now. The deep state or whoever over at the FDA is making it very difficult for drug companies to get people in order to test the vaccines and therapeutics. Obviously they are hoping to delay the answer until after November 3rd. Let's focus on speed and saving lives.

What evidence does the president have that the FDA is manipulating this process -- this approval process for political reasons?

MEADOWS: Well, I -- your words are manipulating it, George. I don't think he said they were manipulating. But I can't --

(CROSSTALK)

STEPHANOPOULOS: -- the obvious --

MEADOWS: Well, hold on. I can --

(CROSSTALK)

MEADOWS: I can help you. I've been personally involved in this so I'll be glad to tell you. Here's what we continue to look at -- and it's not just the FDA. It's NIH and others. As we look at the protocols and Dr. Hahn was very right to say we're not going to cut any corners because we're not cutting any corners.

But what we have is we have a China virus that came here. We've got to deliver answers and the president each and everyday is saying why don't we have an answer today, why don't we have an answer tomorrow. And so what happens is is that we continue to look at some of the trials and what's happening and we want to wear a belt and suspenders the way that some of these bureaucrats want to look at it.

They want to do things the way they've always done it. This president is about cutting red tape. That's what the tweet was all about. And I think you're going to hear an announcement later today which really -- he had to make sure that they felt the heat. If they don't see the light, they need to feel the heat because the American people are suffering. This president knows it and he's going to put it on wherever (ph) it is -- the FDA or at NIH or anybody else to make sure that we deliver on behalf of the American people.

STEPHANOPOULOS: His exact words obviously they're --

MEADOWS: Yes.

STEPHANOPOULOS: -- hoping to delay the answer until after November 3rd. If he believes that the FDA is doing that, again, for political reasons until after the election, why wouldn't he fire the FDA Commissioner?

MEADOWS: Well, I can tell you that we've looked at a number of people that are not being as diligent as they should be in terms of getting to the bottom of it. We've actually had people that have been relocated. You've covered that on your show.

When we -- when we -- look, it's almost impossible to fire a federal employee regardless of what they do wrong. You -- we need real civil service reform. But this president wants to make sure that we hold them accountable. And I can tell you that Secretary Azar was on the phone with the president and me yesterday as we were working through this.

But it's not just on the announcement that's coming today. It's more announcements that are coming this week and the week to follow. But we really need to make sure that we have good science and the proper protocol. But we also can't wait around and assume that this virus is going to go away. This president wants real results and that's why he took to Twitter. But it wasn't just Twitter.

I've answered a number of phone calls from the president and had a number of meetings this last week to sure that we move it forward.

STEPHANOPOULOS: So he does believe there are those in the FDA who are trying to delay approvals for political purposes, until after the elections.

MEADOWS: Well, I believe there are a number of people that do not see the same sense of urgency as he sees. And that as we start to look at it, they know that some kind of result today is good for the American people. And he just wants to make sure that they feel the same urgency.

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

---

**From:** Miller, Emily [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]  
**Sent:** 8/21/2020 8:42:00 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:** Fwd: Ring Light

See below. (b) (5)

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**From:** Wagner, John <John.Wolf.Wagner@fda.hhs.gov>  
**Date:** August 21, 2020 at 7:13:43 AM EDT  
**To:** Miller, Emily <Emily.Miller@fda.hhs.gov>  
**Subject:** RE: Ring Light

Emily-

I ordered this done previously. There is an effort to get his office area set up for Zoom and 4k briefings with existing equipment underway. (b) (6)

Call me this morning

**John 'Wolf' Wagner**  
*Associate Commissioner*

---

**From:** Miller, Emily <Emily.Miller@fda.hhs.gov>  
**Sent:** Thursday, August 20, 2020 4:59 PM  
**To:** Saunders, Shelisha <Shelisha.Saunders@fda.hhs.gov>; Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>  
**Cc:** Wagner, John <John.Wolf.Wagner@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>  
**Subject:** RE: Ring Light

Let's hold on buying any equipment. (b) (5)

---

**From:** Saunders, Shelisha <Shelisha.Saunders@fda.hhs.gov>  
**Sent:** Wednesday, August 19, 2020 2:15 PM  
**To:** Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>  
**Cc:** Wagner, John <John.Wolf.Wagner@fda.hhs.gov>; Miller, Emily <Emily.Miller@fda.hhs.gov>  
**Subject:** RE: Ring Light

(b) (5)

Thanks



---

**From:** Caccomo, Stephanie <[Stephanie.Caccomo@fda.hhs.gov](mailto:Stephanie.Caccomo@fda.hhs.gov)>  
**Sent:** Wednesday, August 19, 2020 2:14 PM  
**To:** Saunders, Shelisha <[Shelisha.Saunders@fda.hhs.gov](mailto:Shelisha.Saunders@fda.hhs.gov)>; Kimberly, Brad <[Brad.Kimberly@fda.hhs.gov](mailto:Brad.Kimberly@fda.hhs.gov)>  
**Cc:** Wagner, John <[John.Wolf.Wagner@fda.hhs.gov](mailto:John.Wolf.Wagner@fda.hhs.gov)>; Miller, Emily <[Emily.Miller@fda.hhs.gov](mailto:Emily.Miller@fda.hhs.gov)>  
**Subject:** RE: Ring Light

Hi! Can we hold on this, (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](mailto:stephanie.caccomo@fda.hhs.gov)

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**From:** Saunders, Shelisha <[Shelisha.Saunders@fda.hhs.gov](mailto:Shelisha.Saunders@fda.hhs.gov)>  
**Sent:** Wednesday, August 19, 2020 8:36 AM  
**To:** Kimberly, Brad <[Brad.Kimberly@fda.hhs.gov](mailto:Brad.Kimberly@fda.hhs.gov)>  
**Cc:** Wagner, John <[John.Wolf.Wagner@fda.hhs.gov](mailto:John.Wolf.Wagner@fda.hhs.gov)>; Caccomo, Stephanie <[Stephanie.Caccomo@fda.hhs.gov](mailto:Stephanie.Caccomo@fda.hhs.gov)>  
**Subject:** RE: Ring Light

I will look into this.

---

**From:** Kimberly, Brad <[Brad.Kimberly@fda.hhs.gov](mailto:Brad.Kimberly@fda.hhs.gov)>  
**Sent:** Wednesday, August 19, 2020 8:34 AM  
**To:** Saunders, Shelisha <[Shelisha.Saunders@fda.hhs.gov](mailto:Shelisha.Saunders@fda.hhs.gov)>  
**Cc:** Wagner, John <[John.Wolf.Wagner@fda.hhs.gov](mailto:John.Wolf.Wagner@fda.hhs.gov)>; Caccomo, Stephanie <[Stephanie.Caccomo@fda.hhs.gov](mailto:Stephanie.Caccomo@fda.hhs.gov)>  
**Subject:** Ring Light

Shelisha, on this morning's check-in, (b) (5)

Copying Wolf on this email just so we're all on the same page.

**Brad Kimberly**  
*Director, Social Media*

Office of Media Affairs  
Office of External Affairs  
U.S. Food and Drug Administration  
Tel: 240-402-1002 | Cell: 240-750-9302  
[brad.kimberly@fda.hhs.gov](mailto:brad.kimberly@fda.hhs.gov)



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**From:** Kimberly, Brad  
**Sent:** Monday, August 17, 2020 8:25 AM  
**To:** Caccomo, Stephanie <[Stephanie.Caccomo@fda.hhs.gov](mailto:Stephanie.Caccomo@fda.hhs.gov)>; Wagner, John <[John.Wolf.Wagner@fda.hhs.gov](mailto:John.Wolf.Wagner@fda.hhs.gov)>;

Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Hatch, Shannon <Shannon.Hatch@fda.hhs.gov>

**Subject:** RE: OMA check-in with Wolf

Hey, Wolf... this is the one we have at home.

[https://www.amazon.com/QIAYA-Selfie-Photography-Lighting-Rechargeable/dp/B01HXTHPXU?ref=ast\\_sto\\_dp](https://www.amazon.com/QIAYA-Selfie-Photography-Lighting-Rechargeable/dp/B01HXTHPXU?ref=ast_sto_dp)

**Brad Kimberly**

*Director, Social Media*

Office of Media Affairs  
Office of External Affairs  
U.S. Food and Drug Administration  
Tel: 240-402-1002 | Cell: 240-750-9302  
[brad.kimberly@fda.hhs.gov](mailto:brad.kimberly@fda.hhs.gov)



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**From:** Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]  
**Sent:** 8/23/2020 12:18:49 PM  
**To:** Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Miller, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=349ea636fe504b488adf664e48ce87e6-Emily.Mille]  
**CC:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Wagner, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a481c74326041d0b268d42f2d70d9f5-John.Wagner]; Pines, Wayne \* [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e9f5ce0254041a48966c10d0c38bef5-Wayne.Pines]  
**Subject:** RE: Hahn talkers

PRE-DECISIONAL, DELIBERATIVE, CONFIDENTIAL

Colin – additional edits from Steve below. Please use this version.

(b) (5)

(b) (5)

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**From:** Shah, Anand  
**Sent:** Sunday, August 23, 2020 11:53 AM  
**To:** Rom, Colin <Colin.Rom@fda.hhs.gov>; Miller, Emily <Emily.Miller@fda.hhs.gov>  
**Cc:** Hahn, Stephen <SH1@fda.hhs.gov>; Wagner, John <John.Wolf.Wagner@fda.hhs.gov>; Pines, Wayne \* <Wayne.Pines@fda.hhs.gov>  
**Subject:** RE: Hahn talkers

Yes

---

**From:** Rom, Colin <Colin.Rom@fda.hhs.gov>  
**Sent:** Sunday, August 23, 2020 11:28 AM  
**To:** Miller, Emily <Emily.Miller@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>  
**Cc:** Hahn, Stephen <SH1@fda.hhs.gov>; Wagner, John <John.Wolf.Wagner@fda.hhs.gov>; Pines, Wayne \* <Wayne.Pines@fda.hhs.gov>  
**Subject:** RE: Hahn talkers

Sounds good. Anand is this final?

---

**From:** Miller, Emily <Emily.Miller@fda.hhs.gov>  
**Date:** August 23, 2020 at 11:02:05 AM EDT  
**To:** Rom, Colin <Colin.Rom@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>  
**Cc:** Hahn, Stephen <SH1@fda.hhs.gov>, Wagner, John <John.Wolf.Wagner@fda.hhs.gov>, Pines, Wayne \* <Wayne.Pines@fda.hhs.gov>  
**Subject:** RE: Hahn talkers

I would like to mark up the final version so it's TV friendly and notes when to look up and pause etc. Let me know when the final runs through and I'll send you one that can be printed for him to hold and take to podium.

---

**From:** Rom, Colin <Colin.Rom@fda.hhs.gov>  
**Sent:** Sunday, August 23, 2020 11:01 AM  
**To:** Shah, Anand <Anand.Shah@fda.hhs.gov>  
**Cc:** Hahn, Stephen <SH1@fda.hhs.gov>; Wagner, John <John.Wolf.Wagner@fda.hhs.gov>; Miller, Emily <Emily.Miller@fda.hhs.gov>; Pines, Wayne \* <Wayne.Pines@fda.hhs.gov>  
**Subject:** RE: Hahn talkers

On it-- will make sure he has these at the WH

---

**From:** Shah, Anand <[Anand.Shah@fda.hhs.gov](mailto:Anand.Shah@fda.hhs.gov)>

**Sent:** Sunday, August 23, 2020 10:32 AM

**To:** Rom, Colin <[Colin.Rom@fda.hhs.gov](mailto:Colin.Rom@fda.hhs.gov)>

**Cc:** Hahn, Stephen <[SH1@fda.hhs.gov](mailto:SH1@fda.hhs.gov)>; Wagner, John <[John.Wolf.Wagner@fda.hhs.gov](mailto:John.Wolf.Wagner@fda.hhs.gov)>; Miller, Emily <[Emily.Miller@fda.hhs.gov](mailto:Emily.Miller@fda.hhs.gov)>; Pines, Wayne \* <[Wayne.Pines@fda.hhs.gov](mailto:Wayne.Pines@fda.hhs.gov)>

**Subject:** Hahn talkers

PRE-DECISIONAL, DELIBERATIVE, CONFIDENTIAL

Colin – this has been approved by Steve. can you coordinate getting these to SH, hard copy, enlarged font for ease of reading? I am now working on reactive Q/A

(b) (5)

(b) (5)

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**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](mailto:john.wolf.wagner@fda.hhs.gov)



---

**From:** Rebello, Heidi [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2834CE193CA949799EF063E34A2CFA0B-HEIDI.REBEL]  
**Sent:** 8/21/2020 8:19:41 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]  
**CC:** Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]  
**Subject:** RE: Personnel update for 9 a.m.  
**Attachments:** All Hands OMA - OC.docx

This is what will be going out. Same content as previously shared but just about Emily. TY.

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Sent:** Friday, August 21, 2020 8:13 AM  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>  
**Cc:** Rom, Colin <Colin.Rom@fda.hhs.gov>  
**Subject:** RE: Personnel update for 9 a.m.

Got it.

---

**From:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Date:** August 21, 2020 at 8:12:41 AM EDT  
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>  
**Cc:** Rom, Colin <Colin.Rom@fda.hhs.gov>  
**Subject:** RE: Personnel update for 9 a.m.

Just announce Emily

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Date:** August 20, 2020 at 12:59:10 PM EDT  
**To:** Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>  
**Cc:** Rom, Colin <Colin.Rom@fda.hhs.gov>  
**Subject:** RE: Personnel update for 9 a.m.

So we could announce Emily and leave it there (b) (5).

---

**From:** Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>  
**Sent:** Thursday, August 20, 2020 9:43 AM  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>  
**Subject:** RE: Personnel update for 9 a.m.

We did announce Wolf. It was in the same communication as Laura Caliguri's departure.

---

**From:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Sent:** Thursday, August 20, 2020 9:35 AM  
**To:** Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>



**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>

**Subject:** Re: Personnel update for 9 a.m.

I think everyone should be handled the same way. If we didn't send an all hands on the others, we shouldn't send an all hands on Emily.

Did we send an all hands for Wolf?

Steve

---

**From:** Heidi Rebello <Heidi.Rebello@fda.hhs.gov>

**Date:** Thursday, August 20, 2020 at 9:34 AM

**To:** Stephen Hahn <SH1@fda.hhs.gov>

**Cc:** Keagan Lenihan <Keagan.Lenihan@fda.hhs.gov>, Colin Rom <Colin.Rom@fda.hhs.gov>

**Subject:** RE: Personnel update for 9 a.m.

Do you want to send All Hands on just Emily then? I can send you updated version with just her info.

---

**From:** Hahn, Stephen <SH1@fda.hhs.gov>

**Sent:** Thursday, August 20, 2020 9:33 AM

**To:** Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>

**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>

**Subject:** Re: Personnel update for 9 a.m.

Thanks, Heidi (b) (5)

Steve

---

**From:** Heidi Rebello <Heidi.Rebello@fda.hhs.gov>

**Date:** Thursday, August 20, 2020 at 9:32 AM

**To:** Stephen Hahn <SH1@fda.hhs.gov>

**Cc:** Keagan Lenihan <Keagan.Lenihan@fda.hhs.gov>, Colin Rom <Colin.Rom@fda.hhs.gov>

**Subject:** RE: Personnel update for 9 a.m.

(b) (5)

---

**From:** Hahn, Stephen <SH1@fda.hhs.gov>

**Sent:** Thursday, August 20, 2020 9:30 AM

**To:** Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>

**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>

**Subject:** Re: Personnel update for 9 a.m.

Hi Heidi,

(b) (5)

Steve

---

**From:** Heidi Rebello <Heidi.Rebello@fda.hhs.gov>

**Date:** Wednesday, August 19, 2020 at 4:37 PM

**To:** Stephen Hahn <SH1@fda.hhs.gov>

**Cc:** Keagan Lenihan <Keagan.Lenihan@fda.hhs.gov>, Colin Rom <Colin.Rom@fda.hhs.gov>

**Subject:** RE: Personnel update for 9 a.m.

Sir, just checking back on this All Hands. Thank you.

---

**From:** Rebello, Heidi  
**Sent:** Wednesday, August 19, 2020 9:00 AM  
**To:** Hahn, Stephen <[sh1@fda.hhs.gov](mailto:sh1@fda.hhs.gov)>  
**Cc:** Lenihan, Keagan <[Keagan.Lenihan@fda.hhs.gov](mailto:Keagan.Lenihan@fda.hhs.gov)>; Rom, Colin <[Colin.Rom@fda.hhs.gov](mailto:Colin.Rom@fda.hhs.gov)>  
**Subject:** RE: Personnel update for 9 a.m.

Here is the all hands to accompany the announcement once you approve of it. (b) (5)  
[REDACTED]. Please let me know if you have any edits. Plan is to send it out FDA wide after 9.

---

**From:** Rebello, Heidi  
**Sent:** Wednesday, August 19, 2020 8:54 AM  
**To:** Hahn, Stephen <[sh1@fda.hhs.gov](mailto:sh1@fda.hhs.gov)>  
**Cc:** Lenihan, Keagan <[Keagan.Lenihan@fda.hhs.gov](mailto:Keagan.Lenihan@fda.hhs.gov)>  
**Subject:** Personnel update for 9 a.m.

TPs for 9 a.m. meeting, 8/19 (Wed.)

(b) (5)

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**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]; Caccamo, 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>; Caccamo, Stephanie <Stephanie.Caccamo@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)

John 'Wolf' Wagner  
Associate Commissioner

---

**From:** Shah, Anand <[Anand.Shah@fda.hhs.gov](mailto:Anand.Shah@fda.hhs.gov)>

**Sent:** Wednesday, August 19, 2020 3:19 PM

**To:** Caccomo, Stephanie <[Stephanie.Caccomo@fda.hhs.gov](mailto:Stephanie.Caccomo@fda.hhs.gov)>; Amin, Stacy <[Stacy.Amin@fda.hhs.gov](mailto:Stacy.Amin@fda.hhs.gov)>; Wagner, John <[John.Wolf.Wagner@fda.hhs.gov](mailto:John.Wolf.Wagner@fda.hhs.gov)>; Hahn, Stephen <[SH1@fda.hhs.gov](mailto:SH1@fda.hhs.gov)>; Lenihan, Keagan <[Keagan.Lenihan@fda.hhs.gov](mailto:Keagan.Lenihan@fda.hhs.gov)>; Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>

**Cc:** Miller, Emily <[Emily.Miller@fda.hhs.gov](mailto:Emily.Miller@fda.hhs.gov)>; Felberbaum, Michael <[Michael.Felberbaum@fda.hhs.gov](mailto:Michael.Felberbaum@fda.hhs.gov)>; Zeta, Lowell <[Lowell.Zeta@fda.hhs.gov](mailto: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](mailto:Stephanie.Caccomo@fda.hhs.gov)>

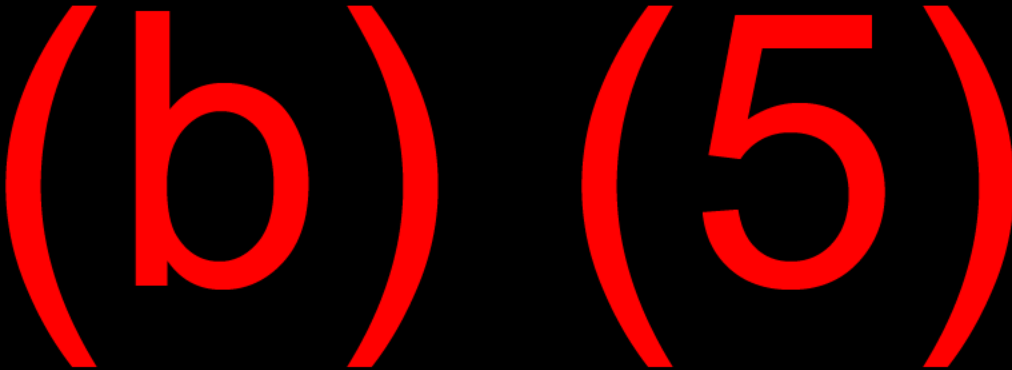

**Sent:** Wednesday, August 19, 2020 3:11 PM

**To:** Amin, Stacy <[Stacy.Amin@fda.hhs.gov](mailto:Stacy.Amin@fda.hhs.gov)>; Shah, Anand <[Anand.Shah@fda.hhs.gov](mailto:Anand.Shah@fda.hhs.gov)>; Wagner, John <[John.Wolf.Wagner@fda.hhs.gov](mailto:John.Wolf.Wagner@fda.hhs.gov)>; Hahn, Stephen <[SH1@fda.hhs.gov](mailto:SH1@fda.hhs.gov)>; Lenihan, Keagan <[Keagan.Lenihan@fda.hhs.gov](mailto:Keagan.Lenihan@fda.hhs.gov)>; Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>

**Cc:** Miller, Emily <[Emily.Miller@fda.hhs.gov](mailto:Emily.Miller@fda.hhs.gov)>; Felberbaum, Michael <[Michael.Felberbaum@fda.hhs.gov](mailto:Michael.Felberbaum@fda.hhs.gov)>; Zeta, Lowell <[Lowell.Zeta@fda.hhs.gov](mailto:Lowell.Zeta@fda.hhs.gov)>

**Subject:** RE: FOR URGENT REVIEW: Response on NYT/ Plasma EUA Statement

How about below, please note (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](mailto:stephanie.caccomo@fda.hhs.gov)

---

**From:** Amin, Stacy <[Stacy.Amin@fda.hhs.gov](mailto:Stacy.Amin@fda.hhs.gov)>

**Sent:** Wednesday, August 19, 2020 2:15 PM

**To:** Caccomo, Stephanie <[Stephanie.Caccomo@fda.hhs.gov](mailto:Stephanie.Caccomo@fda.hhs.gov)>; Shah, Anand <[Anand.Shah@fda.hhs.gov](mailto: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)

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**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*

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Office of External Affairs  
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Desk: 301.348.1956  
Cell: 240.762.8873  
[stephanie.caccomo@fda.hhs.gov](mailto: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](mailto:John.Wolf.Wagner@fda.hhs.gov)>; Caccomo, Stephanie <[Stephanie.Caccomo@fda.hhs.gov](mailto:Stephanie.Caccomo@fda.hhs.gov)>; Hahn, Stephen <[SH1@fda.hhs.gov](mailto:SH1@fda.hhs.gov)>; Lenihan, Keagan <[Keagan.Lenihan@fda.hhs.gov](mailto:Keagan.Lenihan@fda.hhs.gov)>; Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>; Amin, Stacy <[Stacy.Amin@fda.hhs.gov](mailto:Stacy.Amin@fda.hhs.gov)>  
**Cc:** Miller, Emily <[Emily.Miller@fda.hhs.gov](mailto:Emily.Miller@fda.hhs.gov)>; Felberbaum, Michael <[Michael.Felberbaum@fda.hhs.gov](mailto: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...

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**From:** Wagner, John <[John.Wolf.Wagner@fda.hhs.gov](mailto:John.Wolf.Wagner@fda.hhs.gov)>  
**Sent:** Wednesday, August 19, 2020 12:22 PM  
**To:** Caccomo, Stephanie <[Stephanie.Caccomo@fda.hhs.gov](mailto:Stephanie.Caccomo@fda.hhs.gov)>; Hahn, Stephen <[SH1@fda.hhs.gov](mailto:SH1@fda.hhs.gov)>; Lenihan, Keagan <[Keagan.Lenihan@fda.hhs.gov](mailto:Keagan.Lenihan@fda.hhs.gov)>; Shah, Anand <[Anand.Shah@fda.hhs.gov](mailto:Anand.Shah@fda.hhs.gov)>; Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>; Amin, Stacy <[Stacy.Amin@fda.hhs.gov](mailto:Stacy.Amin@fda.hhs.gov)>  
**Cc:** Miller, Emily <[Emily.Miller@fda.hhs.gov](mailto:Emily.Miller@fda.hhs.gov)>; Felberbaum, Michael <[Michael.Felberbaum@fda.hhs.gov](mailto: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](mailto:john.wolf.wagner@fda.hhs.gov)



Sent from my mobile device

---

**From:** Caccomo, Stephanie <[Stephanie.Caccomo@fda.hhs.gov](mailto:Stephanie.Caccomo@fda.hhs.gov)>  
**Date:** August 19, 2020 at 12:15:59 PM EDT  
**To:** Hahn, Stephen <[SH1@fda.hhs.gov](mailto:SH1@fda.hhs.gov)>, Lenihan, Keagan <[Keagan.Lenihan@fda.hhs.gov](mailto:Keagan.Lenihan@fda.hhs.gov)>, Shah, Anand <[Anand.Shah@fda.hhs.gov](mailto:Anand.Shah@fda.hhs.gov)>, Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>, Amin, Stacy <[Stacy.Amin@fda.hhs.gov](mailto:Stacy.Amin@fda.hhs.gov)>  
**Cc:** Wagner, John <[John.Wolf.Wagner@fda.hhs.gov](mailto:John.Wolf.Wagner@fda.hhs.gov)>, Miller, Emily <[Emily.Miller@fda.hhs.gov](mailto:Emily.Miller@fda.hhs.gov)>, Felberbaum, Michael <[Michael.Felberbaum@fda.hhs.gov](mailto: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)

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**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](mailto: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)

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



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**From:** Caccomo, Stephanie <[Stephanie.Caccomo@fda.hhs.gov](mailto:Stephanie.Caccomo@fda.hhs.gov)>

**Sent:** Friday, August 21, 2020 11:01 AM

**To:** Hahn, Stephen <[SH1@fda.hhs.gov](mailto:SH1@fda.hhs.gov)>; Lenihan, Keagan <[Keagan.Lenihan@fda.hhs.gov](mailto:Keagan.Lenihan@fda.hhs.gov)>; Shah, Anand <[Anand.Shah@fda.hhs.gov](mailto:Anand.Shah@fda.hhs.gov)>; Abram, Anna <[Anna.Abram@fda.hhs.gov](mailto:Anna.Abram@fda.hhs.gov)>

**Cc:** Wagner, John <[John.Wolf.Wagner@fda.hhs.gov](mailto:John.Wolf.Wagner@fda.hhs.gov)>; Miller, Emily <[Emily.Miller@fda.hhs.gov](mailto:Emily.Miller@fda.hhs.gov)>; Felberbaum, Michael <[Michael.Felberbaum@fda.hhs.gov](mailto: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](mailto:stephanie.caccomo@fda.hhs.gov)

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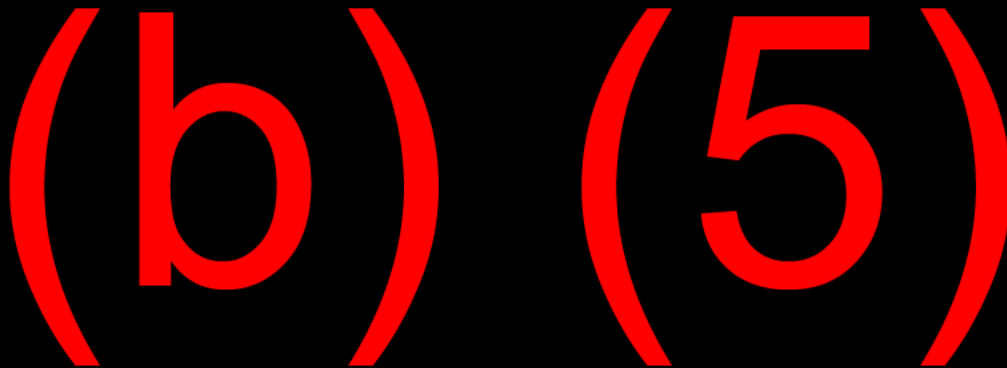
**From:** Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]  
**Sent:** 8/19/2020 3:13:31 PM  
**To:** Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; 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

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Office of External Affairs  
U.S. Food and Drug Administration  
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**To:** Caccomo, Stephanie <[Stephanie.Caccomo@fda.hhs.gov](mailto:Stephanie.Caccomo@fda.hhs.gov)>; Shah, Anand <[Anand.Shah@fda.hhs.gov](mailto:Anand.Shah@fda.hhs.gov)>; Wagner, John <[John.Wolf.Wagner@fda.hhs.gov](mailto:John.Wolf.Wagner@fda.hhs.gov)>; Hahn, Stephen <[SH1@fda.hhs.gov](mailto:SH1@fda.hhs.gov)>; Lenihan, Keagan <[Keagan.Lenihan@fda.hhs.gov](mailto:Keagan.Lenihan@fda.hhs.gov)>; Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>  
**Cc:** Miller, Emily <[Emily.Miller@fda.hhs.gov](mailto:Emily.Miller@fda.hhs.gov)>; Felberbaum, Michael <[Michael.Felberbaum@fda.hhs.gov](mailto:Michael.Felberbaum@fda.hhs.gov)>; Zeta, Lowell <[Lowell.Zeta@fda.hhs.gov](mailto:Lowell.Zeta@fda.hhs.gov)>  
**Subject:** RE: FOR URGENT REVIEW: Response on NYT/ Plasma EUA Statement

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**Cc:** Miller, Emily <[Emily.Miller@fda.hhs.gov](mailto:Emily.Miller@fda.hhs.gov)>; Felberbaum, Michael <[Michael.Felberbaum@fda.hhs.gov](mailto:Michael.Felberbaum@fda.hhs.gov)>; Zeta, Lowell <[Lowell.Zeta@fda.hhs.gov](mailto: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](mailto:stephanie.caccomo@fda.hhs.gov)

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**From:** Amin, Stacy <[Stacy.Amin@fda.hhs.gov](mailto:Stacy.Amin@fda.hhs.gov)>  
**Sent:** Wednesday, August 19, 2020 1:30 PM  
**To:** Shah, Anand <[Anand.Shah@fda.hhs.gov](mailto:Anand.Shah@fda.hhs.gov)>; Wagner, John <[John.Wolf.Wagner@fda.hhs.gov](mailto:John.Wolf.Wagner@fda.hhs.gov)>; Caccomo, Stephanie <[Stephanie.Caccomo@fda.hhs.gov](mailto:Stephanie.Caccomo@fda.hhs.gov)>; Hahn, Stephen <[SH1@fda.hhs.gov](mailto:SH1@fda.hhs.gov)>; Lenihan, Keagan <[Keagan.Lenihan@fda.hhs.gov](mailto:Keagan.Lenihan@fda.hhs.gov)>; Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>  
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(b) (5)

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**Subject:** RE: FOR URGENT REVIEW: Response on NYT/ Plasma EUA Statement

My edits attached – thank you

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**Cc:** Miller, Emily <[Emily.Miller@fda.hhs.gov](mailto:Emily.Miller@fda.hhs.gov)>; Felberbaum, Michael <[Michael.Felberbaum@fda.hhs.gov](mailto:Michael.Felberbaum@fda.hhs.gov)>  
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**Cc:** Miller, Emily <[Emily.Miller@fda.hhs.gov](mailto:Emily.Miller@fda.hhs.gov)>; Felberbaum, Michael <[Michael.Felberbaum@fda.hhs.gov](mailto: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](mailto:john.wolf.wagner@fda.hhs.gov)



Sent from my mobile device

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**Date:** August 19, 2020 at 12:15:59 PM EDT  
**To:** Hahn, Stephen <[SH1@fda.hhs.gov](mailto:SH1@fda.hhs.gov)>, Lenihan, Keagan <[Keagan.Lenihan@fda.hhs.gov](mailto:Keagan.Lenihan@fda.hhs.gov)>, Shah, Anand <[Anand.Shah@fda.hhs.gov](mailto:Anand.Shah@fda.hhs.gov)>, Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>, Amin, Stacy <[Stacy.Amin@fda.hhs.gov](mailto:Stacy.Amin@fda.hhs.gov)>  
**Cc:** Wagner, John <[John.Wolf.Wagner@fda.hhs.gov](mailto:John.Wolf.Wagner@fda.hhs.gov)>, Miller, Emily <[Emily.Miller@fda.hhs.gov](mailto:Emily.Miller@fda.hhs.gov)>, Felberbaum, Michael <[Michael.Felberbaum@fda.hhs.gov](mailto: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:** 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]; Caccamo, 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:** Caccamo, Stephanie <Stephanie.Caccamo@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)

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**From:** Caccamo, Stephanie <Stephanie.Caccamo@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*

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**Subject:** RE: FOR URGENT REVIEW: Response on NYT/ Plasma EUA Statement

**(b) (5)**

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**Cc:** Miller, Emily <[Emily.Miller@fda.hhs.gov](mailto:Emily.Miller@fda.hhs.gov)>; Felberbaum, Michael <[Michael.Felberbaum@fda.hhs.gov](mailto:Michael.Felberbaum@fda.hhs.gov)>

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**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](mailto:john.wolf.wagner@fda.hhs.gov)



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**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)

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**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

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Thanks,  
Emily

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**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)



**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](mailto: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)

---

**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:

(b) (5)

(b) (5) 35% increase in survival?

Kevin

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**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

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**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:** Caccamo, Stephanie <Stephanie.Caccamo@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

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(b) (5)

**Stephanie Caccomo**

*Media Relations Director*

Office of Media Affairs  
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Desk: 301.348.1956  
Cell: 240.762.8873  
[stephanie.caccomo@fda.hhs.gov](mailto:stephanie.caccomo@fda.hhs.gov)

---

**From:** Miller, Emily [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]  
**Sent:** 8/20/2020 7:39:05 PM  
**To:** 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]; Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]  
**Subject:** Reuters 8pm deadline

Commissioner — Below is email from Reuters that appears to be a hit piece from someone (b) (5) Stephanie talked to Peter and he knows about it - I assume it's true - and said no comment about it. (b) (5)

(b) (5)

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**From:** Levine, Daniel R. (Reuters) <Dan.Levine@thomsonreuters.com>  
**Sent:** Thursday, August 20, 2020 6:50 PM  
**To:** Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>  
**Cc:** Taylor, Marisa (Reuters) <Marisa.Taylor@thomsonreuters.com>  
**Subject:** Reuters seeking comment ASAP

Hi, Stephanie. We are Reuters News reporters, preparing a story about the approval process for potential coronavirus vaccines.

We have learned that on an NIH working group call last week, CBER chief Peter Marks said he would resign if FDA ever approved a vaccine candidate that had not been shown by data to be safe and effective. This was in response to concerns raised on the call about the potential for politics to influence any FDA decisionmaking. Please let us know if you have any comment.

In addition, federal law gives the FDA commissioner authority to issue emergency use authorizations for a vaccine. Will Commissioner Hahn defer to whatever guidance he receives from career staff, including Marks?



Our deadline is ASAP. Thanks so much.

Best,  
Dan

**Dan Levine**  
Correspondent  
Reuters News

Phone: +1 415 348 4726  
Mobile: +(b) (6)

[dan.levine@thomsonreuters.com](mailto:dan.levine@thomsonreuters.com)  
<http://www.reuters.com/>

LinkedIn: [www.linkedin.com/in/dlevine1](http://www.linkedin.com/in/dlevine1)

This e-mail is for the sole use of the intended recipient and contains information that may be privileged and/or confidential. If you are not an intended recipient, please notify the sender by return e-mail and delete this e-mail and any attachments. Certain required legal entity disclosures can be accessed on our website:  
<https://www.thomsonreuters.com/en/resources/disclosures.html>

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**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.Guevara]; 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*

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**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](mailto:John.Wolf.Wagner@fda.hhs.gov)>

**Date:** August 23, 2020 at 8:32:31 AM EDT

**To:** Hahn, Stephen <[SH1@fda.hhs.gov](mailto:SH1@fda.hhs.gov)>, Shah, Anand <[Anand.Shah@fda.hhs.gov](mailto:Anand.Shah@fda.hhs.gov)>, Lenihan, Keagan <[Keagan.Lenihan@fda.hhs.gov](mailto:Keagan.Lenihan@fda.hhs.gov)>

**Cc:** Miller, Emily <[Emily.Miller@fda.hhs.gov](mailto:Emily.Miller@fda.hhs.gov)>, Caccomo, Stephanie <[Stephanie.Caccomo@fda.hhs.gov](mailto:Stephanie.Caccomo@fda.hhs.gov)>, Felberbaum, Michael <[Michael.Felberbaum@fda.hhs.gov](mailto:Michael.Felberbaum@fda.hhs.gov)>, Guevara, Bessy <[Bessy.Guevara@fda.hhs.gov](mailto:Bessy.Guevara@fda.hhs.gov)>, Rom, Colin <[Colin.Rom@fda.hhs.gov](mailto:Colin.Rom@fda.hhs.gov)>, Olivarria, Frank <[Frank.Olivarria@fda.hhs.gov](mailto:Frank.Olivarria@fda.hhs.gov)>, Sheehy, Janice <[Janice.Sheehy@fda.hhs.gov](mailto: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](mailto:john.wolf.wagner@fda.hhs.gov)



---

**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

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**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](mailto:stephanie.caccomo@fda.hhs.gov)

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**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*

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**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

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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](mailto:john.wolf.wagner@fda.hhs.gov)



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**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...

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**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](mailto:john.wolf.wagner@fda.hhs.gov)

Sent from my mobile device

---

**From:** Cacco, Stephanie <[Stephanie.Caccoma@fda.hhs.gov](mailto:Stephanie.Caccoma@fda.hhs.gov)>

**Date:** August 19, 2020 at 12:15:59 PM EDT

**To:** Hahn, Stephen <[SH1@fda.hhs.gov](mailto:SH1@fda.hhs.gov)>, Lenihan, Keagan <[Keagan.Lenihan@fda.hhs.gov](mailto:Keagan.Lenihan@fda.hhs.gov)>, Shah, Anand <[Anand.Shah@fda.hhs.gov](mailto:Anand.Shah@fda.hhs.gov)>, Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>, Amin, Stacy <[Stacy.Amin@fda.hhs.gov](mailto:Stacy.Amin@fda.hhs.gov)>

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**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)



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**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>  
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Best Regards,  
Peter

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**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

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(b) (5)

**Stephanie Caccomo**  
*Media Relations Director*

Office of Media Affairs  
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Desk: 301.348.1956  
Cell: 240.762.8873  
[stephanie.caccomo@fda.hhs.gov](mailto:stephanie.caccomo@fda.hhs.gov)

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**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

---

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(b) (5)

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Cell: 240.762.8873  
[stephanie.caccomo@fda.hhs.gov](mailto:stephanie.caccomo@fda.hhs.gov)

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**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=fb77660891384232a7cd9086fcb1a3b-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:** Caccamo, Stephanie <Stephanie.Caccamo@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*

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**CC:** Emily Miller [emilymiller.miller@gmail.com]  
**Subject:** Embargoed media briefing SH/PM \*\* call-in details added  
**Start:** 8/23/2020 3:00:00 PM  
**End:** 8/23/2020 3:30:00 PM  
**Show Time** Busy  
**As:**

**Required Attendees:** Marks, Peter; Wagner, John; Miller, Emily; McNeill, Lorrie; Tierney, Julia; Frantz-Bohn, Susan; Felberbaum, Michael; McSeveney, Megan; Hahn, Stephen; Shah, Anand; Lenihan, Keagan

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**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)

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**From:** Secretary Scheduler (OS/IOS) [Secretary.Scheduler@hhs.gov]  
**Sent:** 8/23/2020 7:55:08 AM  
**To:** Secretary Scheduler (OS/IOS) [Secretary.Scheduler@hhs.gov]; 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:** FW: AMA Prep  
**Location:** 877-314-0340, (b) (6)

**Start:** 8/23/2020 8:15:00 AM  
**End:** 8/23/2020 9:00:00 AM  
**Show Time As:** Tentative

**Recurrence:** (none)

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**From:** Secretary Scheduler (OS/IOS)  
**Sent:** Sunday, August 23, 2020 12:32:23 AM UTC  
**To:** Secretary Scheduler (OS/IOS); (b) (6) (OS/IOS); Apple, Matthew (HHS/IOS); Harrison, Brian (HHS/IOS); Lukens IV, Mel (HHS/IOS); Morris, Katy (HHS/IOS); Mango, Paul (HHS/IOS); Pusan, Cesar (HHS/OS/IOS); Stecker, Judy (OS/IOS); Tignor, Beth (HHS/IOS); Brennan, Patrick (OS/ASPA); Pence, Laura (HHS/IOS); Steele, Danielle (HHS/IOS); Caputo, Michael (HHS/ASPA); Hubbard, Madeleine (OS/ASPA); Murphy, Ryan (OS/ASPA); Pratt, Michael (OS/ASPA)  
**Subject:** AMA Prep  
**When:** Sunday, August 23, 2020 12:15 PM-1:00 PM.  
**Where:** 877-314-0340,,8782239#

877-314-0340, (b) (6)  
**Leader:** (b) (6) -Judy