

United States Senate
WASHINGTON, DC 20510

August 25, 2020

Dr. Stephen M. Hahn, M.D.
Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Hahn:

We write regarding the U.S. Food and Drug Administration's (FDA) troubling decision earlier this week to issue an Emergency Use Authorization (EUA) for convalescent plasma as a treatment for coronavirus disease 2019 (COVID-19).¹ Reports suggest that the FDA granted the EUA amid intense political pressure from President Trump and other Administration officials, despite limited evidence of convalescent plasma's effectiveness as a COVID-19 treatment.² To help us better understand whether the issuance of the blood plasma EUA was motivated by politics, we request copies of any and all communications between FDA and White House officials regarding the blood plasma EUA.

Convalescent plasma—the liquid component of blood from a recovering disease patient that contains antibodies—can be used to treat certain infections.³ Since the start of the COVID-19 pandemic, scientists have examined the possibility of using convalescent plasma as a treatment for COVID-19, and a recent study of 20,000 COVID-19 patients found that COVID-19 plasma treatment is safe to use.⁴ The FDA has spent recent weeks assessing whether it should grant an EUA for convalescent plasma as a COVID-19 treatment. Under the *Federal Food, Drug, and Cosmetic Act*, the FDA Commissioner may issue EUAs, which “allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases... when there are no adequate, approved, and available alternatives.”⁵

¹ Politico, “FDA authorizes plasma treatment despite scientists’ objections,” Zachary Brennan and Sarah Oermohle, August 23, 2020, <https://www.politico.com/news/2020/08/23/plasma-treatment-coronavirus-fda-trump-400390>.

² *Id.*

³ U.S. Food and Drug Administration, “Donate COVID-19 Plasma,” August 23, 2020, <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/donate-covid-19-plasma>; New York Times, “FDA’s Emergency Approval of Blood Plasma Is Now on Hold,” Noah Weiland, Sharon LaFraniere, and Sheri Fink, August 19, 2020, <https://www.nytimes.com/2020/08/19/us/politics/blood-plasma-covid-19.html>.

⁴ Stat, “Is convalescent plasma safe and effective? We answer the major questions about the Covid-19 treatment,” Lev Facher, August 23, 2020, <https://www.statnews.com/2020/08/23/is-convalescent-plasma-safe-and-effective/>.

⁵ 21 U.S.C. 360bbb-3; U.S. Food and Drug Administration, “Coronavirus (COVID-19) Update: FDA Issues Emergency Use Authorization for Potential COVID-19 Treatment,” May 1, 2020, <https://www.fda.gov/news->

Though plasma will not harm patients, there is not scientific consensus on how to interpret existing data on plasma's efficacy as a COVID-19 treatment. Though one study, released on August 13th, found that plasma treatment could reduce COVID-19 mortality, that study was not peer reviewed and did not have a control group—making it hard to determine whether the treatment actually made a difference in patients' outcomes.⁶ Just last week, citing limited evidence of plasma's effectiveness as a COVID-19 treatment, top government scientists—including Dr. Anthony Fauci and Dr. Francis Collins—urged the FDA to refrain from issuing an EUA for a plasma treatment without more convincing effectiveness data.⁷

The warnings from Dr. Fauci and Dr. Collins came several days after Dr. Peter Navarro, a key White House official, reportedly accused FDA scientists of serving the “Deep State,” a conservative conspiracy theory suggesting that career government officials are actively working to undermine President Trump, by failing to rapidly approve COVID-19 vaccines and therapeutics.⁸ And three days after the warning from Dr. Fauci and Dr. Collins, on Saturday, President Trump accused FDA officials of “slow-walking the therapy to harm his reelection chances.”⁹ The FDA then issued an EUA for convalescent plasma as a COVID-19 treatment on August 23,¹⁰ touting it as “another achievement in [the] Administration's fight against [the] pandemic.”¹¹ After the FDA issued its EUA, public health officials expressed concerns that “the scientific integrity of FDA may be significantly compromised” and that “science lost” while “politics won.”¹²

It is essential for public health that COVID-19 patients have access to effective vaccines and treatments as quickly as possible. However, it is also critical that the FDA's drug approval process—which serves as the gold standard around the world—is guided by science, not partisan or political whims. Protecting the integrity of the FDA's approval process is even more critical given that the agency will soon be asked to approve one or more vaccines under intense political pressure, and because of its decision to issue and then revoke a rushed EUA for

[events/press-announcements/coronavirus-covid-19-update-fda-issues-emergency-use-authorization-potential-covid-19-treatment](https://www.fda.gov/oc/2020/08/23/fda-issues-emergency-use-authorization-potential-covid-19-treatment).

⁶ Stat, “Is convalescent plasma safe and effective? We answer the major questions about the Covid-19 treatment,” Lev Facher, August 23, 2020, <https://www.statnews.com/2020/08/23/is-convalescent-plasma-safe-and-effective/>.

⁷ New York Times, “FDA's Emergency Approval of Blood Plasma Is Now on Hold,” Noah Weiland, Sharon LaFraniere, and Sheri Fink, August 19, 2020, <https://www.nytimes.com/2020/08/19/us/politics/blood-plasma-covid-19.html>.

⁸ Axios, “Scoop: The Trump-Navarro mind meld on the FDA,” Jonathan Swan, August 23, 2020, https://www.axios.com/trump-peter-navarro-fda-deep-state-12563e41-de4a-4635-9319-ff0eca41f126.html?utm_source=newsletter&utm_medium=email&utm_campaign=newsletter_axiosvitals&stream=top.

⁹ Politico, “FDA authorizes plasma treatment despite scientists' objections,” Zachary Brennan and Sarah Owerhohle, August 23, 2020, <https://www.politico.com/news/2020/08/23/plasma-treatment-coronavirus-fda-trump-400390>.

¹⁰ *Id.*

¹¹ Twitter, “PRESS RELEASE: FDA Issues Emergency Use Authorization for Convalescent Plasma as Potential Promising #COVID19 Treatment, Another Achievement in Administration's Fight Against Pandemic,” @FDAMedia, August 23, 2020, <https://twitter.com/FDAMedia/status/1297641562860589057>.

¹² CNBC, “Scientists doubt convalescent plasma touted by Trump is a ‘breakthrough’ coronavirus treatment,” Berkeley Lovelace Jr., August 24, 2020, <https://www.cnbc.com/2020/08/24/scientists-doubt-convalescent-plasma-touted-by-trump-is-a-breakthrough-coronavirus-treatment.html>.

hydroxychloroquine for COVID-19 treatment. Hydroxychloroquine was found to cause “serious heart rhythm problems and other safety issues, including blood and lymph system disorders, kidney injuries, and liver problems and failure”—forcing the FDA to revoke its EUA.¹³

To help us better understand the FDA’s decision to issue an EUA for convalescent blood plasma to treat COVID-19, as well as to help us determine whether the decision was politically motivated, please provide us with the following no later than September 8, 2020:

1. A copy of all emails, and other written communications, between FDA officials and White House officials containing the words “COVID-19” and “convalescent plasma” sent between January 1, 2020 and August 24, 2020;
2. A description of any and all phone calls, meetings, and other verbal communications at which you, or other senior FDA officials, and White House officials were present that took place between January 1, 2020 and August 24, 2020; and
3. A detailed timeline of the EUA approval process for convalescent plasma as a COVID-19 treatment.

Thank you for your attention to this matter.

Sincerely,

/s/ Elizabeth Warren
Elizabeth Warren
United States Senator

/s/ Edward J. Markey
Edward J. Markey
United States Senator

¹³ U.S. Food and Drug Administration, “DA cautions against use of hydroxychloroquine or chloroquine for COVID-19 outside of the hospital setting or a clinical trial due to risk of heart rhythm problems,” July 1, 2020, <https://www.fda.gov/drugs/drug-safety-and-availability/fda-cautions-against-use-hydroxychloroquine-or-chloroquine-covid-19-outside-hospital-setting-or>.