

United States Senate
WASHINGTON, DC 20510

August 28, 2020

Senator Lamar Alexander
Chairman
Senate Committee on Health, Education, Labor, and Pensions
428 Senate Dirksen Office Building
Washington, D.C. 20510

Senator Patty Murray
Ranking Member
Senate Committee on Health, Education, Labor, and Pensions
428 Senate Dirksen Office Building
Washington, D.C. 20510

Dear Chairman Alexander and Ranking Member Murray:

We write to request that you immediately call on U.S. Food and Drug Administration (FDA) Commissioner Stephen M. Hahn and U.S. Centers for Disease Control and Prevention (CDC) Director Robert R. Redfield to testify before the Senate Committee on Health, Education, Labor, and Pensions (HELP) for a hearing regarding the Trump Administration's politicization of the coronavirus disease 2019 (COVID-19) pandemic response and the undue political influence of the White House on these public health agencies.

It is essential that the federal government develop and implement public health policies that are guided by science, facts, and medical principles—not the political whims of the President. Yet, throughout the COVID-19 pandemic, the Trump Administration has reportedly repeatedly pressured the FDA and CDC into decisions based on political motivations rather than sound public health principles and scientific evidence.

This past week, in which the FDA issued an Emergency Use Authorization under questionable circumstances for the use of convalescent plasma to treat COVID-19, and the CDC released new guidelines – “in contravention of common sense ... [that] contradict what we know about how to stem the spread of the pandemic”¹ – appears to represent a low point for the Administration's ability to let sound public health principles and science guide the response to the pandemic. This politicized decision process has resulted in an ongoing, tragic failure to contain the virus, costing tens of thousands of American lives, plunging the economy into a recession, and compromising the integrity of the CDC and FDA as these agencies make critical decisions about COVID-19 treatments and vaccines.

¹ Washington Post, “The CDC's covid-19 advice is wrong. If you've been exposed, you should be tested,” Leana S. Wen, August 26 2020, <https://www.washingtonpost.com/opinions/2020/08/26/governments-new-advice-is-wrong-if-youve-been-exposed-you-should-be-tested/>.

Political Pressures Appear to Have Affected CDC Guidance on Testing and Other Key Public Health Actions

COVID-19 Testing Guidelines. President Trump has repeatedly pushed to “Slow the testing down”² and downplay the importance of COVID-19 testing. He appears to have prioritized artificially lowering the official COVID-19 case count over enacting proven public health measures to contain the spread of the virus—saying “testing is a double-edged sword” and explaining that “when you do testing to that extent, you’re going to find more people; you’re going to find more cases.”³ Now, this week, the CDC issued new testing guidance calling for significantly fewer people to get tested.⁴ Public health experts have deemed this guidance “potentially dangerous,” a “step in the wrong direction,” and a “walk-back” that could reduce visibility into COVID-19’s spread.⁵

Asymptomatic patients (people infected with the virus who do not show symptoms) and pre-symptomatic patients (people infected with the virus who have not yet started showing symptoms) can be significant vectors for the spread of COVID-19 to others. In April, researchers analyzing a set of COVID-19 patients found that 44 percent were infected from pre-symptomatic cases.⁶ Meanwhile, the World Health Organization states that “transmission can... occur from people who... remain asymptomatic.”⁷ Identifying and isolating pre- and asymptomatic COVID-19 carriers is critical to containing the virus, and one former health commissioner noted that “these are exactly the people who should be tested.”⁸ Indeed, public health experts have consistently indicated that a robust testing program that can identify asymptomatic or pre-symptomatic individuals is critical to controlling the disease.⁹

CDC guidance on COVID-19 testing previously reflected the reality that asymptomatic patients can carry and transmit the virus. The previous guidance, last updated on July 17th, included both “asymptomatic individuals with recent known or suspected exposure to SARS-CoV-2 transmission” and “asymptomatic individuals without known or suspected exposure to SARS-CoV-2 for early identification in special settings” on a list of “five populations for which SARS-

² Vox, “Trump’s catastrophic failure on testing is no joke,” Matthew Yglesias, June 23, 2020, <https://www.vox.com/2020/6/23/21299438/trump-testing-joke-failure>.

³*Id.*

⁴ Vox, “Trump asked for fewer Covid-19 tests. Now the CDC is recommending less testing,” German Lopez, August 26, 2020, <https://www.vox.com/2020/8/26/21403000/trump-covid-coronavirus-testing-cdc-hhs>.

⁵ New York Times, “CDC Now Says People Without Covid-19 Symptoms Do Not Need Testing,” Katherine J. Wu, August 25, 2020, <https://www.nytimes.com/2020/08/25/health/covid-19-testing-cdc.html>.

⁶ Nature Medicine, “Temporal dynamics in viral spreading and transmissibility of COVID-19,” Xi He et al, April 15, 2020, <https://www.nature.com/articles/s41591-020-0869-5>.

⁷ World Health Organization, “Transmission of SARS-CoV-2: implications for infection prevention precautions,” July 9, 2020, <https://www.who.int/news-room/commentaries/detail/transmission-of-sars-cov-2-implications-for-infection-prevention-precautions>.

⁸ CNN, “Updated CDC guidelines now say people exposed to coronavirus may not need to be tested,” Jamie Gumbrecht, Maggie Fox, and Michael Nedelman, August 26, 2020, <https://www.cnn.com/2020/08/26/health/cdc-guidelines-coronavirus-testing/index.html>.

⁹ STAT, “New Covid-19 testing guidelines, crafted at the White House, alarm public health experts,” Helen Branswell and Kate Sheridan, August 26, 2020, <https://www.statnews.com/2020/08/26/new-covid19-testing-guidelines-crafted-at-white-house-alarm-public-health-experts/>.

CoV-2 [the virus that causes COVID-19] testing with viral tests...is appropriate.”¹⁰ On August 24th, however, the CDC updated its guidance, which now states that individuals that “have been in close contact (within 6 feet) of a person with a COVID-19 infection for at least 15 minutes but do not have symptoms...do not necessarily need a test.”¹¹

Initially, the CDC has not provided an explanation for these testing guideline changes, instead referring inquiries to the Department of Health and Human Services (HHS). In response, Dr. Brett Giroir, the Assistant Secretary for Health at HHS and the Administration official responsible for testing, stated that the guidance “received appropriate attention, consultation and input from task force experts,”¹² and was “updated to reflect current evidence and best public health practices.”¹³ HHS, however, “has not specified what change in ‘current evidence’ may have driven the change;” meanwhile, a CDC official has told the press that the change “[came] from the top down” and was driven by “pressure from the upper ranks of the Trump Administration.”¹⁴ After the criticism, Director Redfield issued a statement walking back the new guidelines but did not formally reverse them, leading to even more confusion.¹⁵

CDC’s Re-opening Guidance on Other Matters. The updated testing guidance is not the first time that the agency has modified or revoked public health guidelines under pressure from President Trump or other Administration officials. In April, for example, the CDC announced an extension of its “No Sail” order, which prohibited cruise ship voyages to mitigate COVID-19’s spread.¹⁶ Vice President Pence reportedly ordered the CDC to remove the announcements of the extension from its website, then interfered to shorten the duration of the order, despite substantial evidence that cruise ships have been a major source of coronavirus outbreaks.¹⁷ In May, the Administration reportedly under pressure from Administration officials, shelved draft CDC guidance for churches and other places of worship that called for mitigation efforts, such as limiting the size of in-person gatherings, maintaining distance between attendees, and reopening

¹⁰ U.S. Centers for Disease Control and Prevention, “Overview of Testing for SARS-CoV-2,” updated July 17, 2020, Wayback Machine, <https://web.archive.org/web/20200822095711/https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing-overview.html>.

¹¹ U.S. Centers for Disease Control and Prevention, “Overview of Testing for SARS-CoV-2 (COVID-19),” updated August 24, 2020, <https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing-overview.html>.

¹² CNN, “CDC director says new testing guidance reflects ‘updated recommendations’ from the White House,” Nick Valencia and Maggie Fox, August 26, 2020, https://www.cnn.com/world/live-news/coronavirus-pandemic-08-27-20-intl/h_31c1a72fd4fd73041f78b8b4788a5dd6.

¹³ CNN, “CDC was pressure ‘from the top down’ to change coronavirus testing guidance, official says,” Nick Valencia, Sara Murray, and Kristen Holmes, August 26, 2020, <https://www.cnn.com/2020/08/26/politics/cdc-coronavirus-testing-guidance/index.html>.

¹⁴ *Id.*

¹⁵ Daily Beast, “CDC Director Walks Back COVID-19 Testing Guidelines Amid Outcry,” Justin Baragona, August 27, 2020, <https://www.thedailybeast.com/cdc-director-robert-redfield-walks-back-covid-19-testing-guidelines-amid-outcry>.

¹⁶ Centers for Disease Control and Prevention, “CDC Announces Modifications and Extension of No Sail Order for All Cruise Ships,” April 9, 2020, <https://www.cdc.gov/media/releases/2020/s0409-modifications-extension-no-sail-ships.html>.

¹⁷ USA Today, “White House task force quietly softened cruise ship no-sail restrictions after months of industry deference,” Curtis Tate, Morgan Hines, Cara Kelly, and Brett Murphy, April 13, 2020, <https://www.usatoday.com/story/travel/cruises/2020/04/13/coronavirus-cruise-ships-saw-red-flags-amid-chaotic-federal-response/2937001001/>.

in phases, then abruptly reversed course after President Trump warned them that “You better put it out.”¹⁸

And in July, President Trump and Vice President Pence once again exerted public pressure on the CDC to revise its guidelines, this time for schools. On July 7, President Trump stated, “we’re very much going to put pressure on governors and everybody else to open the schools...Get open in the fall. We want your schools open.”¹⁹ On July 8, he tweeted, “I disagree with @CDCgov on their very tough & expensive guidelines for opening schools. While they want them open, they are asking schools to do very impractical things. I will be meeting with them!!!”²⁰ In response, the CDC issued new guidance documents for schools on July 23, including a statement entitled, “The Importance of Reopening America’s Schools this Fall.”²¹ The White House reviewed this statement and reportedly substantially edited at least one of the updated documents.²² As with the changes to guidelines for cruise ships and houses of worship, the Administration appears to have prioritized its political interest in reopening over the advice of the CDC’s public health experts, undermining the public credibility of the guidance issued by the agency and making the ongoing pandemic significantly worse. Director Redfield permitted these changes.

Political Pressures May Have Also Influenced Certain Authorizations at the FDA

Hydroxychloroquine. In March 2020, the FDA issued an emergency use authorization (EUA) for the malaria drug hydroxychloroquine’s use as a treatment for COVID-19 after receiving pressure to do so from President Trump. In March, President Trump declared the malaria drug hydroxychloroquine a “game changer” against COVID-19 and asked the FDA to fast-track its approval.²³ The FDA issued an EUA for the drug on March 28, but less than a month later, on April 24, it warned that hydroxychloroquine is “has not been shown to be safe and effective” for treating COVID-19 and should not be used outside of hospitals and clinical trials, and it revoked the EUA altogether on June 15.²⁴

¹⁸ Associated Press, “In reversal, White House tells CDC to post church guidance,” Zeke Miller and Mike Stobbe, May 21, 2020, <https://apnews.com/92a389588798ef5fec4a722d6d073955>.

¹⁹ NPR, “Trump Pledges to ‘Pressure’ Governors to Reopen Schools Despite Health Concerns,” Barbara Sprunt, July 7, 2020, <https://www.npr.org/2020/07/07/888157257/white-house-pushes-to-reopen-schools-despite-a-surge-in-coronavirus-cases>.

²⁰ Donald J. Trump, July 8, 2020, <https://twitter.com/realDonaldTrump/status/1280857657365200902>.

²¹ Centers for Disease Control and Prevention, “Statement on the Importance of Reopening America’s Schools this Fall,” Updated July 23, 2020, <https://www.cdc.gov/coronavirus/2019-ncov/community/schools-childcare/index.html>.

²² Washington Post, “CDC director concedes schools in ‘hot spots’ face tougher call on reopening,” Laura Meckler and Rachel Weiner, July 24, 2020, https://www.washingtonpost.com/education/cdc-director-concedes-schools-in-hot-spots-face-tougher-call-on-reopening/2020/07/24/273ee068-cdd8-11ea-b0e3-d55bda07d66a_story.html.

²³ ABC News, “Timeline: Tracking Trump alongside scientific developments on hydroxychloroquine,” Libby Cathey, August 8, 2020, <https://abcnews.go.com/Health/timeline-tracking-trump-alongside-scientific-developments-hydroxychloroquine/story?id=72170553>.

²⁴ U.S. Food and Drug Administration, “Coronavirus (COVID-19) Update: FDA Revokes Emergency Use Authorization for Chloroquine and Hydroxychloroquine,” June 15, 2020, <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-revokes-emergency-use-authorization-chloroquine-and>.

Convalescent Plasma. Convalescent plasma—the liquid component of blood from a recovering disease patient that contains antibodies—can be used to treat certain infections.²⁵ 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.²⁶ Though plasma may not harm patients, however the FDA initially chose to hold off on issuing an EUA for blood plasma after top government scientists—including Dr. Anthony Fauci and Dr. Francis Collins—publicly urged the FDA to wait before reviewing more convincing effectiveness data.²⁷

But after Dr. Peter Navarro, a key White House official, reportedly accused FDA scientists of serving the “Deep State,”²⁸ and President Trump accused FDA officials of “slow-walking the therapy to harm his reelection chances,”²⁹ the FDA issued an EUA for convalescent plasma as a COVID-19 treatment on August 23.³⁰ 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.”³¹

The politicization of our nation’s science agencies is dangerous. It has resulted in a failed response to the pandemic, costing thousands of American lives. And it has caused Americans to lose confidence in the integrity of these agencies – meaning that already fraught agency decisions about vaccines, treatments, and other efforts to stop the pandemic will be made even more difficult. The Senate HELP Committee must seek answers from Dr. Hahn and Dr. Redfield about undue political influence in the COVID-19 response. We request that you hold a hearing immediately.

Sincerely,

²⁵ 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>.

²⁶ 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/>.

²⁷ 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>.

²⁸ Reuters, “Trump says without proof that FDA ‘deep state’ slowing COVID trials,” Linda So, August 22, 2020, <https://www.reuters.com/article/us-health-coronavirus-trump-fda/trump-says-without-proof-that-fda-deep-state-slowing-covid-trials-idUSKBN2510LF>.

²⁹ 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>.

³⁰ *Id.*

³¹ 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>.

_____/s/
Elizabeth Warren
United States Senator

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Tim Kaine
United States Senator

_____/s/
Tammy Baldwin
United States Senator

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Tina Smith
United States Senator

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Margaret Wood Hassan
United States Senator

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Doug Jones
United States Senator

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Christopher S. Murphy
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Robert P. Casey Jr.
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Jacky Rosen
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