

United States Senate

WASHINGTON, DC 20510

August 28, 2020

The Honorable Alex M. Azar II
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Secretary Azar,

We write to express our serious concern with reports of political interference in recent decisions on scientific matters by agencies within the Department of Health and Human Services (the Department). These decisions, which involve the authorization of experimental COVID-19 treatments and guidance for COVID-19 testing, should be driven solely by science and public health. Instead, it appears the Trump Administration again has allowed political interference in its scientific decision making, placing lives and livelihoods at risk across the country.

The timing of this interference is particularly troubling, as people across the country are waiting anxiously for a safe and effective vaccine to COVID-19. More than ever, public trust in our core public health agencies must be fiercely protected. We will not beat this pandemic without that trust, and allowing political interference in these processes is harmful to the trust in our world-class scientific institutions and ultimately the health of our population. As such, the Administration's actions this week have set off alarms among experts and former leaders of these agencies. It is your responsibility, as head of the Department that researches, approves, and disseminates diagnostics, therapeutics, and vaccines, as well as critical information about the pandemic, to safeguard the integrity of the agencies under your control.

This Sunday, you joined President Trump and Food and Drug Administration (FDA) Commissioner Stephen Hahn to announce authorization for emergency use of convalescent plasma as a treatment for COVID-19, hailing it as a "dream in drug development." Many experts, including Director of the National Institutes of Health, Dr. Francis Collins, and Director of the National Institute for Allergy and Infectious Diseases, Dr. Anthony Fauci, have cautioned the evidence on this therapy is not strong enough to warrant issuance of an emergency use authorization (EUA).¹ Yet, in announcing this regulatory action, you and Commissioner Hahn made unsubstantiated claims about the efficacy of the treatment, which the Commissioner has since walked back.² At that same press conference, the President attacked the integrity of the FDA.³

The announcement came after several senior Administration officials and the President himself issued unsubstantiated accusations, akin to conspiracy theories, that FDA's career public

1 <https://www.nytimes.com/2020/08/19/us/politics/blood-plasma-covid-19.html>

2 <https://www.statnews.com/2020/08/23/fda-under-pressure-from-trump-expected-to-authorize-blood-plasma-as-covid-19-treatment/>;
<https://abcnews.go.com/Health/wireStory/fda-commissioner-overstated-effects-virus-therapy-72595122>

3 <https://www.nytimes.com/2020/08/23/us/politics/fda-plasma-coronavirus.html>; https://www.washingtonpost.com/opinions/the-fda-must-stand-up-for-itself-and-for-science-not-politics/2020/08/25/7c253742-e70c-11ea-bc79-834454439a44_story.html

servants are trying to stop treatments and vaccines for COVID-19 from reaching the public.⁴ There is no evidence to support these claims, as former FDA Commissioner Dr. Scott Gottlieb – whom the President nominated – has made clear.

The following day, the Centers for Disease Control and Prevention (CDC) quietly issued updates to its guidelines on COVID-19 testing in asymptomatic individuals exposed to the virus, recommending that such individuals may not need testing.⁵ By doing so, CDC contradicted its previous recommendation, and at this writing, the agency and Department have provided no scientific explanation for the decision. These changes raised alarm among public health experts, who called the moves “potentially dangerous” because they minimize the role that asymptomatic individuals play in spreading the disease.⁶ Dr. Fauci commented he is “worried it will give people the incorrect assumption that asymptomatic spread is not of great concern. In fact it is.”⁷ It has been reported the decision resulted from “pressure from the upper ranks of the Trump administration” and that CDC “was instructed by higher-ups within the Trump administration to modify its coronavirus testing guidelines.”⁸

Yesterday, CDC Director Dr. Robert Redfield walked back these changes, stating that “testing may be considered for all close contacts of confirmed or probable COVID-19 patients.”⁹ While we understand the science around this novel pathogen is evolving, unnecessary – and potentially political – changes to public health guidance that are not supported by evidence create confusion and may contribute to further spread and death.

These incidents, while troubling in isolation, follow what unfortunately has become common Administration practice: political interference in scientific decision making. The Trump Administration has repeatedly interfered with scientific decisions, including the emergency authorization of hydroxychloroquine, pushing other unproven therapies, and withholding and censoring guidelines from the CDC meant to help communities re-open safely.^{10 11} This constant political interference is dangerous and unacceptable.

We would like to better understand the role of the White House and senior political officials in the Department in the recent actions around testing guidelines and the authorization of convalescent plasma. Please provide a written response no later than September 4, 2020.

1. What is the process by which HHS and its agencies incorporate feedback from political leadership, and specifically members of the White House Coronavirus Task Force, into scientific or public health decisions? How are such considerations weighed against evidence in support of or opposition to a decision?

4 <https://www.axios.com/trump-peter-navarro-fda-deep-state-12563e41-de4a-4635-9319-ff0eca41f126.html>;

<https://twitter.com/realDonaldTrump/status/1297138862108663808?s=20>

5 <https://www.cnn.com/2020/08/26/health/cdc-guidelines-coronavirus-testing/index.html>.

6 <https://www.nytimes.com/2020/08/25/health/covid-19-testing-cdc.html>.

7 <https://www.cnn.com/2020/08/26/politics/cdc-coronavirus-testing-guidance/index.html>

8 <https://www.cnn.com/2020/08/26/politics/cdc-coronavirus-testing-guidance/index.html>; <https://www.nytimes.com/2020/08/26/world/covid-19-coronavirus.html#link-75471d37>

9 <https://www.nytimes.com/2020/08/27/world/covid-19-coronavirus.html?action=click&module=Top%20Stories&pgtype=Homepage#link-5fab7b72>

10 <https://www.axios.com/trump-covid-oleandrin-9896f570-6cd8-4919-af3a-65ebad113d41.html>

11 <https://www.cnn.com/2020/05/19/politics/cdc-reopening-guidance-released/index.html>

2. Please describe the involvement of political leadership in the decision to authorize convalescent plasma, including your personal role and involvement.
3. Given continued concerns about the effectiveness of convalescent plasma in treating COVID-19, please provide a detailed description of the basis NIH officials provided for delaying the authorization and an explanation for the decision to issue the August 23 EUA without waiting for additional evidence.
4. Please describe the role of each of the following agencies or offices in providing evidence, information, or feedback about the convalescent plasma EUA:
 - a. The Office of the Secretary;
 - b. The Office of the Assistant Secretary for Health;
 - c. NIH;
 - d. Office of the Assistant Secretary for Preparedness and Response; and
 - e. FDA.
5. Please describe the involvement of political leadership in the decision to revise CDC's guidelines for testing asymptomatic individuals exposed to COVID-19, including your personal role and involvement.
6. Please provide the scientific basis to support CDC's decision to remove the recommendation for asymptomatic individuals who were exposed to COVID-19 to be tested for the disease.

We look forward to your responses.

Please contact Andi Fristedt or Katlin McKelvie Backfield of the Senate HELP Committee staff with any questions.

Sincerely,



Patty Murray
United States Senator



Charles E. Schumer
United States Senator



Elizabeth Warren
United States Senator



Jacky Rosen
United States Senator



Tim Kaine
United States Senator

/s/ Thomas R. Carper

Thomas R. Carper
United States Senator

/s/ Martin Heinrich

Martin Heinrich
United States Senator



Sherrod Brown
United States Senator



Robert Menendez
United States Senator

/s/ Chris Van Hollen

Chris Van Hollen
United States Senator

/s/ Robert P. Casey, Jr.

Robert P. Casey, Jr.
United States Senator



Debbie Stabenow
United States Senator



Richard Blumenthal
United States Senator



Edward J. Markey
United States Senator

/s/ Mazie K. Hirono

Mazie K. Hirono
United States Senator



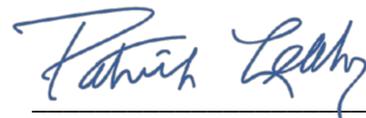
Jeffrey A. Merkley
United States Senator



Ron Wyden
United States Senator



Kirsten Gillibrand
United States Senator



Patrick Leahy
United States Senator

/s/ Jack Reed

Jack Reed
United States Senator



Jeanne Shaheen
United States Senator



Tina Smith
United States Senator



Christopher S. Murphy
United States Senator



Tammy Baldwin
United States Senator

/s/ Dick Durbin

Richard J. Durbin
United States Senator



Bernard Sanders
United States Senator



Tammy Duckworth
United States Senator

/s/ Doug Jones

Doug Jones
United States Senator



Gary C. Peters
United States Senator



Angus S. King, Jr.
United States Senator



Tom Udall
United States Senator



Margaret Wood Hassan
United States Senator

/s/ Brian Schatz

Brian Schatz
United States Senator