

United States Senate
WASHINGTON, DC 20510

October 1, 2020

Christi A. Grimm
Principal Deputy Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
330 Independence Avenue, SW
Washington, DC 20201

Dear Principal Deputy Inspector General Grimm:

We are writing to express our alarm regarding reports of widespread and ongoing political interference in our nation's public health response to the COVID-19 pandemic, particularly at the Centers for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA). Last week, many of us introduced the Science and Transparency Over Politics (STOP) Act in order to ensure a thorough investigation into this political interference, a bill that must be swiftly enacted. In the interim, however, we ask that you immediately investigate whether, and to what extent, political interference has undermined the scientific and public health processes at the operating divisions of the Department of Health and Human Services (HHS) during the COVID-19 response, particularly CDC and FDA.

In the midst of a pandemic that has now claimed over 200,000 lives in the United States alone, the American people rely on the expertise of our federal agencies to keep them safe. Our communities, schools, health care providers, businesses, and families turn to agencies like the CDC and FDA for guidance on how to make important decisions: when people should get tested, how to protect children at home or in the classroom and workers on the job, and which treatments to use to save a life. Public confidence in the scientific process is especially critical as the FDA reviews COVID-19 vaccine candidates. The American people must trust the review process is rigorous, science-driven, and apolitical. Since April 2020, as concerns about political interference in our COVID-19 response have grown, the percentage of adults in the United States who say they will be willing to get vaccinated for COVID-19 has fallen by 21 points, from 72% to 51%.¹ Now more than ever, stopping political pressure from undermining public health experts is literally a matter of life and death.

Numerous public reports have revealed that political appointees at HHS and the White House have repeatedly interfered with, undermined, and even overruled career experts. In August, HHS Secretary Azar reportedly overruled the FDA when he revoked the agency's ability to regulate lab-developed diagnostic tests, including COVID-19 tests, potentially undermining the accuracy of the results that patients receive from these tests.² Also in August, the FDA paused its review

¹*A Trend That Worries Health Experts: As U.S. Gets Closer to COVID-19 Vaccine, Fewer People Say They'd Get One*, Morning Consult (Sept. 11, 2020) (<https://morningconsult.com/2020/09/11/vaccine-acceptance-public-poll/>).

²*HHS chief overrode FDA officials to ease testing rules*, Politico (Sept. 15, 2020) (<https://www.politico.com/news/2020/09/15/hhs-alex-azar-overrode-fda-testing-rules-415400>).

of convalescent plasma for the treatment of COVID-19 in response to requests from the National Institute of Health to continue looking at the data, but then rushed to issue an emergency use authorization (EUA) for the treatment following consistent and direct pressure from the President and White House officials, raising concerns that issuance of the EUA was premature and motivated by political pressure.³ That same month, guidance reportedly developed by HHS and the White House Coronavirus Task Force was published to the CDC's website—seemingly without approval from the CDC—recommending that asymptomatic individuals do not need to be tested, even after exposure to someone with COVID-19.⁴ This guidance contradicted clear advice from career CDC officials and other public health experts. Following public outcry, this guidance was reversed, but only after nearly a month during which COVID-19 may have further spread through our communities after the CDC appeared to be discouraging testing.⁵ We have now also learned that the White House may have pressured the CDC to “play down” the risk of bringing children back to school for in-person learning, including attempts to influence both CDC guidance and reports.⁶

Unfortunately, this political interference appears to be permeating the Department. Reports suggest political interference may have affected data reporting and the publication of scientific reports. In July 2020, without clear or sufficient justification, hospitals were directed to stop reporting COVID-19 health data to the CDC, the primary repository of the nation's public health data, and instead report the information to HHS.⁷ Further, according to public reports, political appointees at HHS have sought to review, alter, and delay the CDC's Morbidity and Mortality Weekly Reports (MMWR), which provide the latest information and recommendations on public health threats, including COVID-19.⁸ Health care providers, researchers, and public health professionals rely on the accurate, unbiased nature of these reports. According to public reports, MMWRs may have been altered or delayed for weeks or even months, withholding critical information from our nation's public health practitioners.

These political attacks appear to have extended even to individual scientists. According to records obtained by the *New York Times*, political officials at HHS, including in both the communications office and White House liaison's office, have lashed out at career CDC officials

³ *Trump Pressed for Plasma Therapy. Officials Worry, Is an Unvetted Vaccine Next?*, New York Times (Sept. 12, 2020) (<https://www.nytimes.com/2020/09/12/us/politics/trump-coronavirus-treatment-vaccine.html>).

⁴ *C.D.C. Testing Guidance Was Published Against Scientists' Objections*, New York Times (Sept. 17, 2020) (<https://www.nytimes.com/2020/09/17/health/coronavirus-testing-cdc.html>).

⁵ *CDC updates, again, guidelines on testing people without coronavirus symptoms*, CNN (Sept. 18, 2020) (<https://www.cnn.com/2020/09/18/health/covid-testing-guidance-update-cdc-bn/index.html>).

⁶ *Behind the White House Effort to Pressure the C.D.C. on School Openings*, New York Times (Sept. 28, 2020) (<https://www.nytimes.com/2020/09/28/us/politics/white-house-cdc-coronavirus-schools.html>).

⁷ Department of Health and Human Services, *COVID-19 Guidance for Hospital Reporting and FAQs For Hospitals, Hospital Laboratory, and Acute Care Facility Data Reporting* (July 29, 2020) (<https://www.hhs.gov/sites/default/files/covid-19-faqs-hospitals-hospital-laboratory-acute-care-facility-data-reporting.pdf>).

⁸ *Political Appointees Meddled in C.D.C.'s 'Hoiest of the Holy' Health Reports*, New York Times (Sept. 12, 2020) (<https://www.nytimes.com/2020/09/12/us/politics/trump-coronavirus-politics-cdc.html>); Centers for Disease Control and Prevention, *Morbidity and Mortality Weekly Report (MMWR)* (<https://www.cdc.gov/mmwr/publications/index.html>) (accessed Sept. 30, 2020).

for sharing basic facts about COVID-19 with the public.⁹ At least one public health expert—Rick Bright, the former Director of the Biomedical Advanced Research and Development Authority—has alleged that he was retaliated against for emphasizing the threat of COVID-19 and resisting political pressure in making certain purchases or approvals pushed by White House and other Administration officials.¹⁰ These actions have a profound chilling effect on our public health experts, undermining the response to COVID-19 and putting lives at risk.

Last week, after reports that the FDA was close to issuing guidance setting forth tougher criteria for authorizing COVID-19 vaccines for emergency use, President Trump suggested at a press conference that the plan “sounds like a political move,” and said the White House “may or may not” approve the guidance.¹¹ The White House has reportedly asked FDA to provide detailed justification for the guidance.¹² According to a top FDA official, White House objections may prevent the FDA from releasing the guidance.¹³

The consistent pattern running through these reports of political interference is the ongoing effort to minimize the seriousness of the virus. This message directly harms millions of Americans and jeopardizes public trust in science and our COVID-19 response. To safeguard the health and well-being of all Americans during this ongoing pandemic, we ask that you immediately open an investigation into political interference with the scientific work done by experts at HHS. As part of your review, we ask that you specifically address the following issues:

1. What is the extent of political interference at the CDC, FDA, and other key public health agencies involved in the response to COVID-19?
2. What impact has political interference had on the work of public health experts at HHS, including career officials at its operating divisions, and COVID-19 response efforts?
3. Has all public guidance issued on the CDC’s website or otherwise attributed to the CDC—including guidance pertaining to testing for the virus that causes COVID-19 and re-opening schools for in-person learning—been developed and approved by CDC personnel and gone through the standard CDC scientific review process?
4. How has the editorial and publication process for MMWRs changed from years past, and to what extent have political appointees attempted to alter or delay MMWRs? What has been the impact of these interventions on the timing and content of MMWR reports?

⁹ *Emails Detail Effort to Silence C.D.C. and Question Its Science*, New York Times (Sept. 18, 2020) (<https://www.nytimes.com/2020/09/18/us/politics/trump-cdc-coronavirus.html>).

¹⁰ *Ousted vaccine official alleges he was demoted for prioritizing ‘science and safety’*, Washington Post (May 5, 2020) (<https://www.washingtonpost.com/health/2020/05/05/rick-bright-hydroxychloroquine-whistleblower-complaint/>).

¹¹ *Trump says he may not approve stricter FDA guidelines for vaccine approval*, The Hill (Sept. 24, 2020) (<https://thehill.com/changing-america/well-being/prevention-cures/518005-trump-says-he-may-not-approve-stricter-fda>).

¹² *Trump, White House demand FDA justify tough standards for coronavirus vaccine, raising concerns of political interference*, Washington Post (Sept. 25, 2020) (<https://www.washingtonpost.com/politics/2020/09/25/coronavirus-vaccine-trump-interference/>).

¹³ *Top FDA vaccine official says vaccine guidance may never be released*, Politico (Sept. 28, 2020) (<https://www.politico.com/news/2020/09/28/fda-vaccine-guidance-may-not-be-released-422648>).

5. Have all applicable laws, rules, regulations, and policies—including the requirements of HHS's, CDC's, and FDA's scientific integrity and communications policies—been followed in the development and issuance of public guidance, reports, or policy changes?
6. Have any complaints been filed or issues been raised with the designated scientific integrity official regarding any of the events described above?
7. What role, if any, have entities outside of HHS—including the White House, the Office of Management and Budget, or the Office of Science and Technology Policy—played in developing, revising, and issuing guidance, reports, or policy changes at the CDC or FDA?

At a time when tens of thousands of Americans are dying from COVID-19 every month, we must do everything we can to ensure the federal government's response is effective, unbiased, and trustworthy. We thank you for your prompt attention to this matter.

Sincerely,



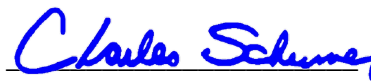
Gary C. Peters
United States Senator



Patty Murray
United States Senator



Elizabeth Warren
United States Senator



Charles E. Schumer
United States Senator

/s/ Mazie K. Hirono

Mazie K. Hirono
United States Senator

/s/ Ron Wyden

Ron Wyden
United States Senator

/s/ Chris Van Hollen

Chris Van Hollen
United States Senator

/s/ Tom Udall

Tom Udall
United States Senator

/s/ Debbie Stabenow

Debbie Stabenow
United States Senator

/s/ Edward J. Markey

Edward J. Markey
United States Senator

/s/ Kirsten Gillibrand

Kirsten Gillibrand
United States Senator

/s/ Sherrod Brown

Sherrod Brown
United States Senator

/s/ Robert Menendez

Robert Menendez
United States Senator

/s/ Richard Blumenthal

Richard Blumenthal
United States Senator

/s/ Jeanne Shaheen

Jeanne Shaheen
United States Senator

/s/ Tammy Baldwin

Tammy Baldwin
United States Senator

/s/ Benjamin L. Cardin

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United States Senator

/s/ Margaret Wood Hassan

Margaret Wood Hassan
United States Senator

/s/ Sheldon Whitehouse

Sheldon Whitehouse
United States Senator

/s/ Jack Reed

Jack Reed
United States Senator

/s/ Tammy Duckworth

Tammy Duckworth
United States Senator

/s/ Brian Schatz

Brian Schatz
United States Senator

/s/ Martin Heinrich

Martin Heinrich
United States Senator

/s/ Jacky Rosen

Jacky Rosen
United States Senator

/s/ Thomas R. Carper

Thomas R. Carper
United States Senator

/s/ Bernard Sanders

Bernard Sanders
United States Senator

/s/ Amy Klobuchar

Amy Klobuchar
United States Senator

/s/ Jeffrey A. Merkley

Jeffrey A. Merkley
United States Senator

/s/ Dick Durbin

Richard J. Durbin
United States Senator

/s/ Tina Smith

Tina Smith
United States Senator