

October 8, 2020

The Honorable Gene L. Dodaro
Comptroller General of the United States
Government Accountability Office
441 G Street, N.W.
Washington, D.C. 20548

Dear Mr. Dodaro:

In light of public reports that the Trump Administration has improperly exerted political influence on the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) since the onset of the coronavirus disease 2019 (COVID-19) pandemic, we request that the Government Accountability Office (GAO) conduct an investigation to determine whether the CDC and FDA's scientific integrity and communications policies have been violated and whether those policies are being implemented as intended to assure scientific integrity throughout the agency.

The CDC and FDA's independence as scientific agencies is crucial to safeguarding the public health and saving lives. These agencies must be able to develop, review, and disseminate public health data, guidelines, and other information that are based on science, facts, and medical principles—and not the political imperatives and moods of a president and his advisors. But the Trump Administration has reportedly pressured the CDC and FDA throughout the COVID-19 pandemic, repeatedly applying political pressure and imposing orders on career scientists that undermine the agencies' credibility and independence, including:

Centers for Disease Control and Prevention

- In March, the White House allegedly overruled CDC officials who “wanted to recommend that elderly and physically fragile Americans be advised not to fly on commercial airlines because of the new coronavirus.”¹
- In April, after the CDC announced an extension of its “No Sail” order which prohibited cruise ship voyages,² 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

¹ Associated Press, “Official: White House didn’t want to tell seniors not to fly,” Mike Stobbe, March 7, 2020, <https://apnews.com/921ad7f1f08d7634bf681ba785faf269>.

² 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>.

coronavirus outbreaks.³ This week, White House officials reportedly overruled Director Redfield when he pushed to extend the government’s ban on cruise ships until February 2021.⁴

- Since April, Department of Health and Human Services (HHS) political appointees have allegedly made significant efforts to edit, water down, and caveat CDC’s Morbidity and Mortality Weekly Reports (MMWR), CDC’s flagship scientific publication, which for decades has been exclusively authored by career scientists.⁵ According to *Politico*, political appointees “have attempted to add caveats to the CDC’s findings, including an effort to retroactively change agency reports that they said wrongly inflated the risks of Covid-19 and should have made clear that Americans sickened by the virus may have been infected because of their own behavior” and also “tried to halt the release of some CDC reports” altogether.⁶
- In May, the White House blocked the publishing of a detailed 17-page report titled, “Guidance for Implementing the Opening Up America Again Framework.”⁷ CDC scientists were apparently told that their work would “never see the light of day.”⁸ The CDC eventually published the report, but only after the White House required certain substantive changes.⁹
- In June, senior HHS officials accused the CDC of “undermining the President” when it released the latest information on pregnant women. According to the *Washington Post*, an HHS advisor criticized the CDC and said its latest report, “reads in a way to frighten women... as if the President and his administration can’t fix this and it is getting worse.”¹⁰
- In June, senior political appointees at HHS also reportedly “excoriated Anne Schuchat, CDC principal deputy director” in emails to the CDC Director and other agency officials

³ 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-chaoticfederal-response/2937001001/>.

⁴ Axios, “Scoop: CDC director overruled on cruise ship ban,” Jonathan Swan, September 29, 2020, <https://www.axios.com/scoop-white-house-overruled-cdc-cruise-ships-florida-91442136-1b8e-442e-a2a1-0b24e9a39fb6.html>

⁵ Politico, “Trump officials interfered with CDC reports on COVID-19,” Dan Diamond, September 11, 2020, <https://www.politico.com/news/2020/09/11/exclusive-trump-officials-interfered-with-cdc-reports-on-covid-19-412809>.

⁶ *Id.*

⁷ Associated Press, “Interim Guidance for Child Care Programs,” <https://www.documentcloud.org/documents/6883734-CDC-Business-Plans.html>.

⁸ Associated Press, “Trump administration buries detailed CDC advice on reopening,” Jason Dearen and Mike Stobbe, May 7, 2020, <https://apnews.com/7a00d5fba3249e573d2ead4bd323a4d4>.

⁹ Union of Concerned Scientists, “White House Buries CDC Report on COVID-19,” May 20, 2020, <https://www.ucsusa.org/resources/attacks-on-science/white-house-buries-cdc-report-covid-19>.

¹⁰ The Washington Post, “CDC feels pressure from Trump as rift grows over coronavirus response,” Lena H. Sun and Josh Dawsey, July 9, 2020, https://www.washingtonpost.com/health/trump-sidelines-public-health-advisers-in-growing-rift-over-coronavirus-response/2020/07/09/ad803218-c12a-11ea-9fdd-b7ac6b051dc8_story.html.

for remarks Dr. Schuchat made about the United States needing to take its virus response seriously, accusing her of being “duplicious” and undermining the President.¹¹

- In July, the White House ordered the CDC to stop collecting data on COVID-19 illness, hospitalizations, and deaths, instead filtering the data through a third-party contractor at HHS.¹² This announcement apparently “came as a shock at the C.D.C., according to two officials who spoke on the condition of anonymity.”¹³ Public health experts expressed significant concerns about transparency and objectivity with this policy change of moving control of the data away from the CDC to a political department. Significant issues with the quality, completeness, and transparency of data have persisted since the change.¹⁴
- In July, President Trump and Vice President Pence also exerted considerable public pressure on the CDC to revise its guidelines for schools. On July 8, President Trump 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!!!”¹⁵ 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,” which the White House reviewed and reportedly substantially edited.¹⁶ In response, three of the CDC’s former directors and one former acting director published an opinion piece declaring: “We ran the CDC. No president ever politicized its science the way Trump has.”¹⁷
- In August, highly-criticized testing recommendations for asymptomatic patients—which appeared to discourage COVID-19 testing—were posted on the CDC’s website.¹⁸ The *New York Times* revealed that this recommendation was “not written by C.D.C. scientists and was posted to the agency’s website despite their serious objections.”¹⁹ Reportedly, the “Department of Health and Human Services did the rewriting and then ‘dropped’ it into the C.D.C.’s public website, flouting the agency’s strict scientific review process.”²⁰

¹¹ The Washington Post, “Trump’s appointees sought to censor what government scientists said about the coronavirus, emails show,” Lena H. Sun, Yasmeen Abutaleb and Lenny Bernstein, September 18, 2020, <https://www.washingtonpost.com/health/2020/09/18/caputo-censored-cdc-officials/>.

¹² New York Times, “Trump Administration Strips C.D.C. of Control of Coronavirus Data,” Sheryl Gay Stolberg, July 14, 2020, <https://www.nytimes.com/2020/07/14/us/politics/trump-cdc-coronavirus.html>.

¹³ *Id.*

¹⁴ NPR, “COVID-19 Hospital Data System Plagued By Delays, Inaccuracies,” Pein Huang and Selena Simmons-Duffin, July 31, 2020, <https://www.npr.org/sections/health-shots/2020/07/31/897429054/covid-19-hospital-data-system-that-bypasses-cdc-plagued-by-delays-inaccuracies>.

¹⁵ Donald J. Trump, July 8, 2020, <https://twitter.com/realDonaldTrump/status/1280857657365200902>.

¹⁶ 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.

¹⁷ The Washington Post, “We ran the CDC. No president ever politicized its science the way Trump has,” Tom Frieden, Jeffrey Koplan, David Satcher, and Richard Besser, July 14, 2020, <https://www.washingtonpost.com/outlook/2020/07/14/cdc-directors-trump-politics/>.

¹⁸ New York Times, “C.D.C. Testing Guidance Was Published Against Scientists’ Objections,” Apoorva Mandavili, September 17, 2020, <https://www.nytimes.com/2020/09/17/health/coronavirus-testing-cdc.html>.

¹⁹ *Id.*

²⁰ *Id.*

According to officials quoted by the *New York Times*, the posted policy “does not reflect what many people at the C.D.C. feel should be the policy” and the document actually contained “elementary errors.”²¹ The recommendation has since been reversed.²²

The CDC updated its “Guidance on Scientific Integrity” in April 2016 to “strengthen scientific integrity in the conduct of CDC science, assure the public of the credibility of the agency’s scientific findings and results, and provide a transparent platform to demonstrate CDC’s commitment to a culture of scientific integrity.”²³ Through CDC’s core values of accountability, respect and integrity, CDC’s scientific integrity policy states that CDC employees “affirm a commitment to ensure that research and services are based on sound science, meet real public needs, and help achieve public health goals.”²⁴ Specifically, with regard to the “quality and objectivity of scientific research and information” the policy states that the **“CDC has a responsibility to conduct the best science and is committed to disseminating scientific findings and results without being influenced by policy or political issues.”**²⁵ With regard to its policies governing public communications, the agency’s scientific integrity policy states that “CDC is committed to ensuring that all information products authored by its staff members or published by CDC are released for public use in a timely manner, are of the highest quality and are scientifically sound, technically accurate, and useful to the intended audience.”²⁶

Food and Drug Administration

- In March, President Trump began tweeting about the benefits of hydroxychloroquine in treating COVID-19.²⁷ On March 28, the FDA issued an Emergency Use Authorization (EUA) for the drug, a decision widely criticized for lack of quality evidence.²⁸ In the months following authorization, studies failed to prove the drug was effective in treating COVID-19, and FDA revoked the EUA in June.²⁹ President Trump and White House officials have continued to advocate for use of hydroxychloroquine to treat and prevent COVID-19.³⁰

²¹ *Id.*

²² *New York Times*, “C.D.C. Reverses Testing Guidelines for People Without Covid-19 Symptoms,” Apoorva Mandavilli, September 18, 2020, <https://www.nytimes.com/2020/09/18/health/coronavirus-testing-cdc.html>.

²³ Centers for Disease Control and Prevention, “CDC Guidance on Scientific Integrity,” Office of the Associate Director for Science, April 2016, pp. 1.

²⁴ *Id.* pp. 3.

²⁵ *Id.* pp. 3.

²⁶ *Id.* pp. 15.

²⁷ *Forbes*, “All The Times Trump Has Promoted Hydroxychloroquine,” May 22, 2020, <https://www.forbes.com/sites/andrewsolender/2020/05/22/all-the-times-trump-promoted-hydroxychloroquine/#5eaa2bc24643>.

²⁸ *Science Magazine*, “Former FDA leaders decry emergency authorization of malaria drugs for coronavirus,” Charles Piller, April 7, 2020, <https://www.sciencemag.org/news/2020/04/former-fda-leaders-decry-emergency-authorization-malaria-drugs-coronavirus>.

²⁹ *Id.*; Food and Drug Administration, “FDA News Release: 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>.

³⁰ *ABC News*, “Hydroxychloroquine returns as wedge between President Trump, health advisers,” Lucien Bruggeman, July 28, 2020, <https://abcnews.go.com/Politics/hydroxychloroquine-returns-wedge-president-trump-health-advisers/story?id=72036996>.

- In August, FDA officials were considering issuing an EUA for convalescent plasma. After Dr. Anthony S. Fauci and Dr. Francis S. Collins reportedly voiced concerns that the data did not support it, the FDA placed the authorization on hold.³¹ President Trump then called Dr. Collins, demanding he “get it done by Friday,” and suggested at a news briefing that the FDA wanted to limit convalescent plasma use until after the election.³² On August 23, the FDA issued an EUA for convalescent plasma.³³
- 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.³⁴
- Also in August, President Trump lodged a clearly spurious claim that the “deep state” at the FDA is delaying potential COVID-19 treatments and vaccines until after the presidential election.³⁵
- Last month, reports emerged that the FDA was close to issuing guidance setting forth scientific criteria for authorization of COVID-19 vaccines for emergency use.³⁶ In public remarks, Dr. Peter Marks, the lead career official in charge of vaccine review, said an EUA for a COVID-19 vaccine would look more similar to a full approval, suggesting that FDA’s forthcoming guidance will set a higher bar for issuance of an EUA than the statutory floor for authorization.³⁷ President Trump suggested that the FDA’s plan to issue the guidance “sounds like a political move,” and said the White House “may or may not” approve the guidance.³⁸ The White House reportedly asked the FDA to provide

³¹ New York Times, “F.D.A.’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>.

³² New York Times, “Trump Pressed for Plasma Therapy. Officials Worry, Is an Unvetted Vaccine Next?,” Sharon LaFraniere, Noah Weiland and Michael Shear, September 12, 2020, <https://www.nytimes.com/2020/09/12/us/politics/trump-coronavirus-treatment-vaccine.html>.

³³ Stat News, “FDA, under pressure from Trump, authorizes blood plasma as Covid-19 treatment,” Nicholas Floriko, August 23, 2020, <https://www.statnews.com/2020/08/23/fda-under-pressure-from-trump-expected-to-authorize-blood-plasma-as-covid-19-treatment/>.

³⁴ Politico, “HHS chief overrode FDA officials to ease testing rules,” Adam Cancryn and Sarah Oweremohle, September 15, 2020, <https://www.politico.com/news/2020/09/15/hhs-alex-azar-overrode-fda-testing-rules-415400>.

³⁵ Reuters, “Exclusive: FDA commissioner disputes Trump, says no ‘deep state’ thwarting vaccine,” Jeff Mason, August 24, 2020, <https://www.reuters.com/article/us-health-coronavirus-usa-hahn-exclusive/exclusive-fda-commissioner-disputes-trump-says-no-deep-state-thwarting-vaccine-idUSKBN25L0A2>.

³⁶ Washington Post, “FDA poised to announce tougher standards for a covid-19 vaccine that make it unlikely one will be cleared by Election Day,” Laura McGinley and Carolyn Johnson, September 22, 2020, <https://www.washingtonpost.com/health/2020/09/22/fda-covid-vaccine-approval-standard/>.

³⁷ Bloomberg, “FDA Setting Higher Bar for Emergency Covid Vaccine Clearance,” Anna Edney, September 10, 2020, <https://www.bloomberg.com/news/articles/2020-09-10/fda-setting-higher-bar-for-emergency-covid-19-vaccine-clearance>.

³⁸ Reuters, “Trump says may block stricter FDA guidelines for COVID-19 vaccine,” Jeff Mason, September 23, 2020, <https://www.reuters.com/article/us-health-coronavirus-usa-vaccine-trump/trump-says-may-block-stricter-fda-guidelines-for-covid-19-vaccine-idUSKCN26E3M5>.

detailed justification for the guidance.³⁹ Then, earlier this week, the New York Times reported that the White House blocked the FDA from issuing the guidance.⁴⁰ Following this reporting, the Administration reversed course and allowed the FDA to issue the guidance.

The FDA issued a policy on scientific integrity in February 2012 to preserve and promote scientific integrity at the agency. As the policy notes, “[e]stablishing and maintaining integrity of the scientific process and of scientific data is crucial to the agency’s ability to arrive at sound decisions and to maintain public trust.”⁴¹ While FDA’s scientific experts may hold differing views, the agency notes that it promotes an environment where “scientific decisions are protected from political influence.”⁴² Key principles enshrined in the policy include **“shielding the agency’s science and its scientific staff from political influence”** and **“maintaining a firm commitment to science-based, data-driven decision-making.”**⁴³ With regards to its policies governing public communications, FDA and its parent agency HHS are **“committed to a culture of openness with the media and public that values the free exchange of ideas, data, and information and doing so in a manner that is timely, responsive, and accurate.”**⁴⁴

Any efforts by Trump Administration political officials to silence, modify, or delay public health information from the CDC or FDA may therefore constitute a violation of the CDC and FDA’s scientific integrity and communications policies. To determine the extent of this interference, we therefore request that, as part of GAO’s ongoing oversight work into the federal COVID-19 response pursuant to the Coronavirus Aid, Relief, and Economic Security Act, GAO audit the implementation of CDC and FDA’s scientific integrity and communications policies and understand the extent of any undue political influence at the CDC and FDA. Specifically we ask you to undertake an examination into the following:

- (1) Whether the CDC and FDA have identified violations of the scientific integrity and communications policies during the COVID-19 pandemic, and whether additional violations may have occurred;
- (2) The extent to which such violations involved and have impacted CDC and FDA scientists’ efforts to correct public statements made by Administration officials;

³⁹ Washington Post, “Trump, White House demand FDA justify tough standards for coronavirus vaccine, raising concerns of political interference,” Laurie McGinley, Yasmeen Abutaleb and Josh Dawsey, September 25, 2020, <https://www.washingtonpost.com/politics/2020/09/25/coronavirus-vaccine-trump-interference/>.

⁴⁰ New York Times, “White House Blocks New Coronavirus Vaccine Guidelines,” Sharon LaFraniere and Noah Weiland, October 5, 2020, <https://www.nytimes.com/2020/10/05/us/politics/coronavirus-vaccine-guidelines.html>.

⁴¹ Food and Drug Administration, “FDA Staff Manual Guides, Volume IV – Agency Program Directives: General or Multidiscipline: Scientific Integrity: Scientific Integrity at FDA,” February 3, 2012, pp. 1, <https://www.fda.gov/media/82932/download>.

⁴² Food and Drug Administration, “Scientific Integrity at FDA,” accessed October 1, 2020, <https://www.fda.gov/science-research/about-science-research-fda/scientific-integrity-fda>.

⁴³ Food and Drug Administration, “FDA Staff Manual Guides, Volume IV – Agency Program Directives: General or Multidiscipline: Scientific Integrity: Scientific Integrity at FDA,” February 3, 2012, pp. 2, <https://www.fda.gov/media/82932/download>.

⁴⁴ Department of Health and Human Services, “Guidelines on the Provision of Information to the News Media,” Office of the Assistant Secretary for Public Affairs, January 2017, pp. 2, https://www.hhs.gov/sites/default/files/media_policy.pdf; <https://www.fda.gov/news-events/fda-newsroom/news-media-policy>.


- (3) Policies, procedures, and training requirements for maintaining scientific integrity at the CDC and FDA related to political interference;
- (4) The nature of each violation of scientific integrity policies at the CDC and FDA during the COVID-19 pandemic related to political interference;
- (5) Employee awareness of the CDC and FDA's scientific integrity and communications policies, including the process for reporting potential violations;
- (6) Reasons potential violations may not be reported and the extent to which likely violations may be unreported; and
- (7) The adjudication process for allegations of scientific integrity violations related to political interference any concerns, such as with complaint resolution, timeliness of resolution, transparency, other process-related issues.


We also believe these communication issues raise a larger concern about independence of CDC, FDA, and other public health agencies. The independence of these agencies is critical to ensuring that Americans have fact-based information on public health risks and interventions so that they can make informed decisions for themselves, their families, and communities. The real or perceived political interference of these agencies' work or communication seeds confusion, erodes public confidence, and diminishes the agencies' credibility—a high cost to pay during a pandemic. Therefore, we ask GAO to conduct a fulsome review the independence of federal public health agencies to include the following:

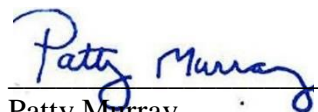
- (1) What current structures are in place at these agencies to allow them to independently carry out their missions?
- (2) What additional structures or steps could be taken to enhance the agencies' abilities to independently carry out their missions, free from political interference, while balancing the need for accountability?

Thank you for your consideration of this request.

Sincerely,


Elizabeth Warren
United States Senator


Gary C. Peters
Ranking Member, Committee on Homeland
Security & Governmental Affairs


Patty Murray
Ranking Member, Committee on Health,
Education, Labor & Pensions