



September 2023

CARES ACT

Experts Identified Safeguards to Help Selected HHS Agencies Protect Against Potential Political Interference

GAO Highlights

Highlights of [GAO-23-106529](#), a report to congressional requesters

Why GAO Did This Study

Recent reports have identified shortcomings in HHS's response to the COVID-19 pandemic, including allegations of political interference. In April 2022, GAO made recommendations to HHS and agency heads, including that they develop procedures for reporting and addressing allegations of political interference and train staff on how to report such allegations. This report examines further actions selected agencies—CDC, FDA, NIH, and ASPR—could take to protect against such interference. GAO selected these agencies because of the key roles they played in the COVID-19 response.

GAO convened a roundtable of 11 experts to discuss actions selected HHS agencies could take to protect against potential political interference. GAO contracted with the National Academies of Sciences, Engineering, and Medicine to help identify individuals with expertise in this topic area. The selected experts represented a range of perspectives and experiences, including working in the federal government; various academic areas, including political science; and the non-profit sector. GAO also reviewed federal guidance related to scientific integrity and interviewed HHS officials.

What GAO Recommends

HHS is taking steps to address the recommendations GAO made in April 2022. For example, HHS is updating its scientific integrity policy to include specific provisions prohibiting political interference, among other things, and developing training for staff. GAO will continue to monitor implementation.

View [GAO-23-106529](#). For more information, contact Jessica Farb at (202) 512-7114 or farbj@gao.gov.

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What GAO Found

Department of Health and Human Services (HHS) agencies—including the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the National Institutes of Health (NIH), and the Administration for Strategic Preparedness and Response (ASPR)—have been at the forefront of the federal government's response to the COVID-19 pandemic. Like most federal agencies, HHS leadership consists of both political appointees and career officials who work together to oversee agency operations and implement the administration's policy priorities. Political involvement or undue external influence becomes interference when it seeks to undermine an agency's impartiality, nonpartisanship, and professional judgment, according to the National Academies of Sciences, Engineering, and Medicine.

Experts participating in a roundtable convened by GAO identified safeguards in three areas that could help selected HHS agencies protect against potential political interference.

Safeguards Identified by Experts to Help Selected Department of Health and Human Services Agencies Protect Against Potential Political Interference

Agency processes



Experts told GAO that agency processes should include certain safeguards to protect against potential political interference, including scientific integrity policies, transparency, and clear documentation of the decision-making process.

Training



Experts told GAO that training agency staff, including political appointees and career officials, on scientific integrity processes could increase agency officials' comprehension of political appointees' appropriate role in an agency.

Institutional structures



Experts told GAO that agencies' institutional structures could be strengthened through safeguards such as using advisory committees, limiting the number of political appointees at an agency, and designating a scientific integrity liaison.

Source: GAO roundtable discussion with 11 experts; GAO (illustrations). | GAO-23-106529

Selected HHS agencies have taken, or are in the process of taking, steps related to some of these safeguards. For example, HHS officials told GAO that the department is updating its existing scientific integrity policy, as required by a presidential memorandum issued in January 2021. According to officials, the updated HHS policy will include specific provisions prohibiting political interference and clear procedures for reporting and handling allegations of political interference, among other things. In another example, HHS has designated an interim scientific integrity official dedicated to ensuring scientific integrity at HHS.

While establishing safeguards against potential political interference is important, experts noted no agency is fully insulated from political influence and there is an appropriate role for political appointees and elected officials in agency processes. For example, experts told GAO it is appropriate for a political appointee or elected official to encourage an agency to expedite or prioritize a project. However, experts said it would be inappropriate to exert influence in a manner that interferes with the scientific integrity of the process or seeks to distort or misuse the science behind a decision.

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Abbreviations

ASPR	Administration for Strategic Preparedness and Response
BARDA	Biomedical Advanced Research and Development Authority
CDC	Centers for Disease Control and Prevention
EUA	emergency use authorization
FDA	Food and Drug Administration
HHS	Department of Health and Human Services
<i>MMWR</i>	<i>Morbidity and Mortality Weekly Report</i>
NIH	National Institutes of Health
OSTP	Office of Science and Technology Policy

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September 14, 2023

Congressional Requesters

Department of Health and Human Services (HHS) agencies—including the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the National Institutes of Health (NIH), and the Administration for Strategic Preparedness and Response (ASPR)—have been at the forefront of the federal government’s efforts to combat the COVID-19 pandemic. Like most federal agencies, HHS leadership consists of both political appointees, selected by the President, and career officials who work together to oversee agency operations and implement the administration’s policy priorities. Political involvement or other undue external influence becomes interference when it seeks to undermine an agency’s impartiality, nonpartisanship, and professional judgment, according to the National Academies of Sciences, Engineering, and Medicine (National Academies).¹

Recent reports have identified shortcomings in HHS’s response to the COVID-19 pandemic, including allegations of political interference. For example, in March 2020, FDA issued an emergency use authorization (EUA) for hydroxychloroquine and chloroquine for the treatment of COVID-19, a decision that was criticized by government scientists and others as lacking in scientific integrity; the EUA was revoked about 3 months after issuance.² Additionally, members of Congress and experts

¹According to the National Academies, it provides independent, objective analysis and advice to the nation, including the federal government, and conducts other activities to solve complex problems and inform public policy decisions.

For the purposes of this report, we adapted a definition of “political interference” from a 2017 report by the National Academies, which states that undue external influences are those from outside an agency that seek to undermine its impartiality, nonpartisanship, and professional judgment. See National Academies of Sciences, Engineering, and Medicine, *Principles and Practices for a Federal Statistical Agency: Sixth Edition*. (Washington, D.C.: 2017).

²The Secretary of Health and Human Services may declare that circumstances, prescribed by statute, exist justifying the emergency use of certain medical products. Once a declaration has been made, FDA may temporarily allow the use of unapproved medical products or unapproved use of approved medical products by issuing an EUA, provided certain statutory criteria are met. See 21 U.S.C. § 360bbb-3.

alleged that political pressure influenced CDC's decision to change its mask guidance in May 2021, which the agency subsequently reversed in July 2021. In April 2022, we reported that agency respondents from CDC, FDA, and NIH told us that they observed instances of potential political interference that may have compromised the scientific integrity of certain aspects of the COVID-19 pandemic response.³

Allegations of political interference affecting scientific decision-making within federal agencies are not unique to the COVID-19 pandemic response, though they appear to be increasing in frequency, according to a recent analysis examining reports of scientific integrity violations in federal policymaking from the 1950s to 2018.⁴ Additionally, research indicates that the potential political interference reported in the media and in congressional inquiries during the COVID-19 pandemic may have reduced trust in public health institutions.⁵

You asked us to examine actions selected agencies could take to protect against such interference. We selected four agencies within HHS that

For the purposes of this report, the term “scientific integrity” refers to the use of scientific evidence and data to make policy decisions that are based on established scientific methods and processes and are not inappropriately influenced by political considerations. When appropriate, these decisions are then shared openly with the public. This definition is consistent with our prior reports and was developed based on our review of existing scientific integrity guidance for agencies. In NIH policy, the agency defines scientific integrity as “maintaining the quality and objectivity of the research activities that [NIH] funds and conducts, such that they are sound and worthy of the public’s confidence.” NIH, *NIH Policies and Procedures for Promoting Scientific Integrity*, (November 2012).

For example, see Charles Piller, “Former FDA Leaders Decry Emergency Authorization of Malaria Drugs for Coronavirus,” *Science* (Apr. 7, 2020).

³See GAO, *Scientific Integrity, HHS Agencies Need to Develop Procedures and Train Staff on Reporting and Addressing Political Interference*, [GAO-22-104613](#). (Washington, D.C.: Apr. 20, 2022).

⁴See Emily Berman and Jacob Carter. “Policy Analysis: Scientific Integrity in Federal Policymaking Under Past and Present Administrations,” *Journal of Science Policy and Governance*, vol. 13, no. 1 (Sept. 2018).

⁵For example, a September 2020 KFF Health Tracking Poll found that about four in 10 adults said that both FDA and CDC are paying “too much attention” to politics when it comes to reviewing and approving treatments for COVID-19 or issuing guidelines and recommendations. See KFF, “KFF Health Tracking Poll – September 2020: Top Issues in 2020 Election, The Role of Misinformation, and Views on A Potential Coronavirus Vaccine.” <https://www.kff.org/coronavirus-covid-19/report/kff-health-tracking-poll-september-2020/> (accessed June 12, 2023).

have played key roles in the public health response to the COVID-19 pandemic: CDC, FDA, NIH, and ASPR. This report describes actions experts believe these selected HHS agencies can take to protect against political interference. This report is also part of our body of work conducted in response to the CARES Act.⁶

To address this objective, in May 2023, we convened a roundtable of 11 experts to discuss actions selected HHS agencies could take to protect against potential political interference. Specifically, we contracted with the National Academies to help us identify individuals with expertise in this topic area.⁷ The experts we selected represented a range of perspectives and experiences, including those with experience working in the federal government; various academic areas, including political science and oversight and regulatory functions of government; and the non-profit sector. The experts who participated in the roundtable and their institutional affiliations at the time of our roundtable are listed in appendix I.

The selected experts discussed how to define and recognize political interference, and identified actions the selected HHS agencies could take to protect against political interference. To help facilitate this discussion, we selected six instances of potential political interference identified as part of prior GAO work that we used as case studies for the experts to review.⁸ All six case studies occurred during the COVID-19 pandemic

⁶The CARES Act included a provision for us to monitor and oversee the federal government's efforts to prepare for, respond to, and recover from the COVID-19 pandemic. Pub. L. No. 116-136, § 19010(b), 134 Stat. 281, 580 (2020). The American Rescue Plan Act of 2021 also included a provision for us to conduct oversight of the COVID-19 response. Pub. L. No. 117-2, § 4002, 135 Stat. 4, 78. All of GAO's reports related to the COVID-19 pandemic are available on GAO's website at <https://www.gao.gov/coronavirus>.

⁷This roundtable was planned and convened with the assistance of the National Academies to better ensure that a breadth of expertise was brought to bear in its composition; however, all final decisions regarding meeting substance and expert participation were made by GAO.

⁸The six case studies are related to allegations that: (1) FDA was pressured to issue an EUA for hydroxychloroquine and chloroquine for treatment of COVID-19, (2) the development of CDC's school reopening guidance inappropriately involved teachers unions, (3) the White House directed NIH to cancel certain grant funding, (4) the CDC Director was pressured to overrule the agency's advisory committee when recommending booster shots, (5) political appointees within HHS sought to edit CDC's *Morbidity and Mortality Weekly Report (MMWR)*, and (6) political pressure influenced CDC in its decision to lift the mask mandate for fully vaccinated individuals.

response; involved events at CDC, FDA, NIH, or ASPR; and had bipartisan identification as a significant instance of potential political interference. To gather information about these case studies, we spoke with former agency officials and other stakeholders and reviewed applicable policies, procedures, and internal documents. (See appendix I for more information on our selection of these case studies.)

We analyzed the roundtable transcripts to identify common themes discussed by and key statements of experts regarding potential actions HHS agencies could take to protect against political interference. The actions identified by experts are not listed in any specific rank or order in this report, and their inclusion should not be interpreted as GAO endorsing any of them.⁹ Implementing any one action or a combination of actions might require additional efforts to address program design or legal issues. We did not assess how effective the actions listed in this report might be, or the extent to which legislative or policy changes and federal financial support would be needed to implement them. However, we report considerations experts noted concerning the potential effectiveness of specific actions.

In addition to convening the roundtable, we reviewed relevant federal guidance related to political interference and scientific integrity. For example, we reviewed a federal framework for scientific integrity policy and practice issued by the Office of Science and Technology Policy (OSTP) in January 2023.¹⁰ We also interviewed officials and reviewed written responses from selected HHS agencies about actions they have taken or are planning to take to address potential political interference.

⁹The comments of the experts represented the views of the experts themselves and not the organizations with which they are affiliated, and are not generalizable to the views of others in the field.

¹⁰Scientific Integrity Framework Interagency Working Group of the National Science and Technology Council, *A Framework for Federal Scientific Integrity Policy and Practice*, January 12, 2023. The Office of Science and Technology Policy (OSTP) was established by the National Science and Technology Policy, Organization, and Priorities Act of 1976 to provide the President and others within the Executive Office of the President with advice on the scientific, engineering, and technological aspects of the economy, among other topics. OSTP leads interagency science and technology policy coordination efforts and serves as a source of scientific and technological analysis and judgment for the President with respect to major policies, plans, and programs of the federal government, among other things. The Director of OSTP serves as a member of the National Science and Technology Council, which was established by executive order in 1993 to coordinate the science and technology policy-making process across the federal government.

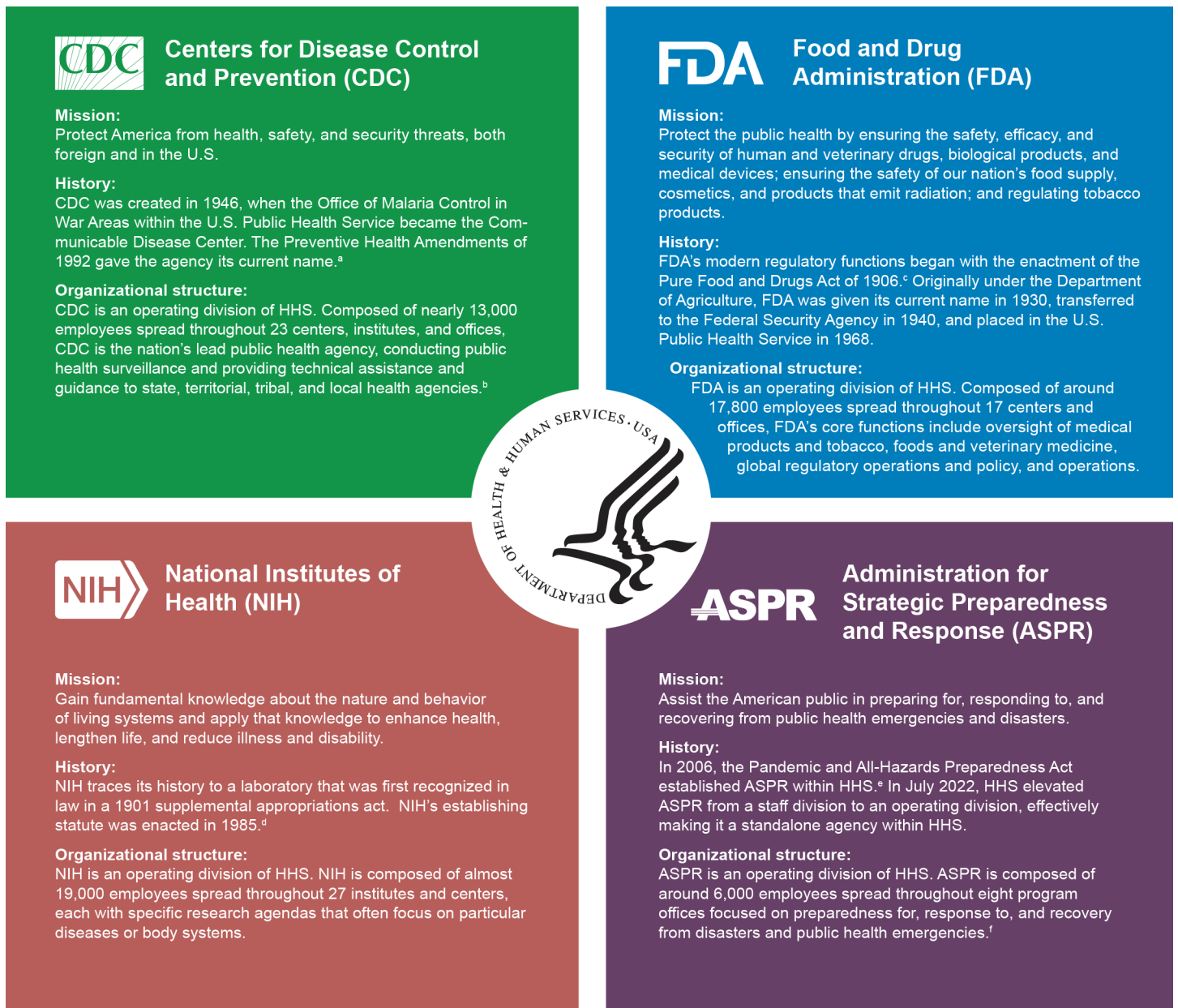
We conducted this performance audit from January 2023 to September 2023 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

HHS and Selected Agencies

HHS's mission is to enhance the health and well-being of all Americans by supporting sound, sustained advances in the sciences underlying medicine, public health, and social services. Within HHS, the four selected agencies—CDC, FDA, NIH, and ASPR—have distinct missions, histories, and organizational structures (see fig. 1).

Figure 1: Missions and Organizational Structures of Selected Department of Health and Human Services (HHS) Agencies



Source: GAO review of information from CDC, FDA, NIH, and ASPR officials; CDC, FDA, NIH, ASPR, HHS (seals, logos). | GAO-23-106529

^aSee Pub. L. No. 102-531, § 312, 106 Stat. 3469, 3504-06. Ten HHS offices and agencies, including ASPR, CDC, FDA, and NIH, are designated components of the U.S. Public Health Service.

^bIn August 2022, CDC announced a plan to reorganize the agency's structure to prioritize public health needs and efforts to curb continuing outbreaks. Among other things, preliminary actions

include restructuring the agency's communications office, creating a new executive council, and establishing an office of intergovernmental affairs.

^cSee Pub. L. No. 59-384, 34 Stat. 768.

^dSee Health Research Extension Act of 1985, Pub. L. No. 99-158, 99 Stat. 820.

^eSee Pub. L. No. 109-417, § 102, 120 Stat. 2831, 2832-34 (2006).

^fHHS officials told us that ASPR had 1,879 full-time employees and 4,231 intermittent employees serving as ASPR responders, as of June 2023.

Political Interference

As we previously noted, the term “political interference” refers to political influence that seeks to undermine impartiality, nonpartisanship, and professional judgment.¹¹ While the term political interference is broad in nature, this report focuses on potential political interference in scientific decision-making at the selected HHS agencies. The term “scientific integrity” refers to the use of scientific evidence and data to make policy decisions that are based on established scientific methods and processes, are not inappropriately influenced by political considerations, and are shared openly and transparently with the public, when appropriate.

A January 2022 report by the National Science and Technology Council concluded that, “while Federal science is fundamentally sound, it remains subject to political and other forms of interference that can undermine Federal decision-making and erode public trust in science.”¹² Since 2007, Congress and multiple administrations have taken actions to protect the integrity of federal science agencies by ensuring that they have policies and procedures in place to protect against the suppression or alteration of scientific findings for political purposes.

Additionally, structural characteristics of agencies related to their organization and design can affect the degree of agency autonomy from political influence, including both the appropriate exercise of the President’s and Congress’s constitutional duties and inappropriate political interference, according to the *Sourcebook of United States*

¹¹In June 2023, HHS officials told us that they use the following definition of political interference—inappropriately shaping or interfering in the conduct, management, communication, or use of science for political advantage or such that it undermines impartiality, nonpartisanship, or professional judgment. The definition we used for purposes of reporting differs because we adopted National Academy’s definition in the absence of a standardized definition at HHS when we began our review.

¹²See Scientific Integrity Fast-Track Action Committee of the National Science and Technology Council, *Protecting the Integrity of Government Science* (January 2022).

Executive Agencies (Sourcebook).¹³ Agency features that allow for presidential and congressional influence, such as appointments, removals, and appropriations, can help provide for agency accountability to elected officials. Conversely, structural features that enhance agency autonomy from the President and Congress may help insulate it from potential political interference.

Various U.S. government reports and political science articles have explored topics related to agency independence and accountability; for example, the *Sourcebook* provides a comprehensive list of over 60 structural characteristics that describe the features and organization of federal agencies.¹⁴ A 2021 presidential memorandum included requirements for federal agencies to take certain actions to strengthen scientific integrity, including developing and publishing procedures for implementing scientific integrity policies.¹⁵

In response to the presidential memorandum, OSTP issued a framework in January 2023 to support regular assessment and iterative improvement of agency scientific integrity policies and practices. The framework identifies critical policy features that will guide OSTP's assessment of agency policies. Critical policy features outlined in the framework include that agency policies should have the federal definition of scientific integrity, describe the process for reporting allegations of potential political interference, and be prominently and publicly available on the

¹³The *Sourcebook* is a report produced by the Administrative Conference of the United States, an independent U.S. government agency. See J. Selin and D. Lewis, *Sourcebook of United States Executive Agencies* (Second Edition) (Washington, D.C.: Administrative Conference of the United States, October 2018).

¹⁴J. Selin and D. Lewis, *Sourcebook of United States Executive Agencies* (Second Edition). We previously reported on these structural characteristics at selected HHS agencies. See GAO, *CARES Act: Structural Characteristics That Can Help Insulate HHS Agencies against Potential Political Interference*, [GAO-23-105415](#). (Washington, D.C.: Dec. 15, 2022).

¹⁵The White House, *Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking* (January 27, 2021).

agency's website.¹⁶ This framework includes a model scientific integrity policy that agencies can use as they work to develop and improve their own scientific integrity policies, practices, and culture. The model policy also includes measures to prevent and address political interference in the conduct, management, communication, or use of science, and notes that such measures should be at the forefront of agency practices.

Potential Instances of Political Interference at Selected HHS Agencies

Since the beginning of the COVID-19 pandemic response, there have been allegations of political interference at the HHS agencies in our review. We selected examples of these allegations that served as case studies for the expert panel. We did not ask the expert panelists to determine whether political interference occurred in any of these case studies. We provided these to the expert panelists for purposes of facilitating discussion. The case studies were:

- **FDA issuance of an EUA for hydroxychloroquine and chloroquine.** Allegations that FDA was pressured to issue an EUA for hydroxychloroquine and chloroquine to treat COVID-19.¹⁷ In March 2020, the President stated that trials of these drugs to treat COVID-19 were producing encouraging results and would be available to Americans almost immediately. About a week later, the Biomedical Advanced Research and Development Authority (BARDA) sponsored an EUA request to use these drugs to treat COVID-19.¹⁸ FDA issued an EUA 2 days later. Some stakeholders—including several former FDA officials—expressed concern regarding FDA's EUA, stating that data regarding the safety and effectiveness of these drugs for the treatment of COVID-19 were largely anecdotal at the time the EUA

¹⁶According to the framework, scientific integrity is the adherence to professional practices, ethical behavior, and the principles of honesty and objectivity when conducting, managing, using the results of, and communicating about science and scientific activities. Inclusivity, transparency, and protection from inappropriate influence are hallmarks of scientific integrity. Scientific Integrity Framework Interagency Working Group of the National Science and Technology Council, *A Framework for Federal Scientific Integrity Policy and Practice*, January 12, 2023. The definition we developed for purposes of reporting differs because we developed ours in the absence of a standardized federal definition. Also in response to the 2021 presidential memorandum, OSTP published a report in January 2022 that identified good agency practices on scientific integrity. Scientific Integrity Fast-Track Action Committee, *Protecting the Integrity of Government Science*.

¹⁷Hydroxychloroquine and chloroquine have been approved for other uses, such as the treatment of malaria, but not for the treatment of COVID-19.

¹⁸BARDA, a component of ASPR, funds and helps oversee the advanced research and development of certain medical countermeasures.

was issued. The EUA was later revoked after data from a large randomized controlled trial showed no evidence of benefit for mortality or other outcomes.¹⁹

- **CDC school re-opening guidance.** Allegations that the development of CDC’s school reopening guidance inappropriately involved teachers unions in February 2021. Officials from the White House and CDC met with teachers unions to discuss school re-opening. One of the unions provided suggested language for the guidance after the meeting. CDC’s published guidance included the suggested language. In February 2022, the incident manager of CDC’s COVID-19 response later testified that receiving and incorporating language written by stakeholders is “uncommon,” although receiving input on potential guidance from stakeholders is normal. In March 2022, the CDC Director testified that coordination with the teachers unions on this guidance was appropriate and that CDC sought input on the guidance from more than 50 stakeholders.
- **NIH grant termination.** Allegations that the White House directed NIH to terminate a grant for a project studying how coronaviruses spread from bats to people. NIH later reinstated but immediately suspended the grant until the grantee could meet additional award conditions related to biosafety, monitoring, and other concerns.²⁰ A senior NIH official testified in June 2020 that NIH terminated the grant because it was told to do so and later confirmed to the media that the White House gave this direction to NIH. HHS’s Office of Inspector General issued a report in January 2023 that found NIH did not follow proper procedures in terminating the grant.²¹
- **CDC recommendations on COVID-19 booster shots.** Allegations that the White House pressured the CDC Director to adopt different recommendations than CDC’s advisory committee when the administration announced its plan to make COVID-19 vaccine booster

¹⁹FDA may revoke an EUA if the circumstances giving rise to the emergency declaration no longer exist, the criteria for issuance of the EUA are no longer met, or other circumstances make revocation appropriate to protect public health or safety. 21 U.S.C. § 360bbb-3(g)(2).

²⁰In May 2023, NIH reinstated the grant, placing several stipulations on the scope of the research and on the organization’s accounting practices.

²¹Department of Health and Human Services, Office of Inspector General, *The National Institutes of Health and EcoHealth Alliance Did Not Effectively Monitor Awards and Subawards, Resulting in Missed Opportunities to Oversee Research and Other Deficiencies*, A-05-21-00025 (January 2023).

shots available prior to FDA and CDC review. In September 2021, news articles discussed concerns of health experts and scientists over the role that politics may have played in the administration's decisions regarding booster shots. Members of CDC's advisory committee expressed concerns that the data did not necessarily support a booster for the general population.

- **CDC Morbidity and Mortality Weekly Report (MMWR).** Allegations that political appointees within HHS sought to edit draft *MMWR* article summaries and titles.²² In May 2020, CDC changed its longstanding practice of not sharing certain information about upcoming *MMWR* articles with individuals outside CDC, according to agency officials. Specifically, CDC changed its practice of not sharing any information about upcoming *MMWR* articles outside of CDC besides publication titles because of the whole-of-government pandemic response, according to these agency officials. As a result, *MMWR* summaries (high-level article synopses) and proofs (full-text article drafts) were shared with a number of individuals, including political appointees outside of CDC, according to the agency. From May 2020 through the end of the calendar year, a political appointee located outside CDC requested that edits be made to upcoming *MMWR* articles.

In November 2020, three former *MMWR* editors-in-chief published an op-ed in the *Journal of the American Medical Association* expressing concerns about the editorial independence of the CDC publication. In December 2020, the House Select Subcommittee on the Coronavirus Crisis held a hearing to further investigate the matter and released emails that it received from HHS that documented that a political appointee had contacted the *MMWR* editor-in-chief on multiple occasions to discuss specific articles prior to publication, based on the appointee's review of summaries. CDC resumed its former practice of not sharing *MMWR* information prior to publication, other than publication titles, outside the agency on January 20, 2021, according to agency officials.

- **CDC updates to mask guidance.** Allegations that political pressure influenced the agency in its decision to lift the mask mandate for fully vaccinated individuals in May 2021; this decision was subsequently reversed in July 2021. CDC faced criticism after updating its mask guidance in May 2021 and July 2021, according to media reporting.

²²According to CDC, the *MMWR* is the agency's "primary vehicle for scientific publication of timely, reliable, authoritative, accurate, objective, and useful public health information and recommendations."

For example, multiple media reports cited criticism from experts and political officials on CDC's decision to update the agency's mask guidance in July 2021 without simultaneously providing the scientific data to support the change. In addition, a member of Congress wrote a letter to the Secretary of Health and Human Services expressing concerns about political interference related to its constantly changing mask guidance and asked for additional information on who was involved in the decisions.

Experts Identified Safeguards in Three Areas That Could Help Protect Against Political Interference at Selected HHS Agencies

Experts in our roundtable identified safeguards to help protect against potential political interference at selected HHS agencies. These safeguards fell into three interrelated areas: agency processes, training on agency scientific integrity processes, and institutional structures. Selected HHS agencies have taken, or are in the process of taking, steps related to some of the safeguards identified by experts, such as developing training on scientific integrity policies.

Agency Processes

Experts told us that specific agency processes should include certain safeguards, including clear scientific integrity policies; transparency; and clear documentation of the decision-making process.

Expert Perspective on Scientific Integrity Policies

Establishing scientific integrity policies "can fortify decision makers and give them something to point to against political influence."

Source: Statement from GAO's roundtable of 11 experts. | GAO-23-106529

- **Scientific integrity policies.** Experts told us that establishing scientific integrity policies is an important safeguard to protect against potential political interference as it supports a culture of scientific integrity.²³ According to experts, selected HHS agencies should consider several things when establishing or updating such policies, including ensuring that the policy includes (1) a well-documented decision-making process for non-emergency and emergency situations, (2) clear delineation of roles and responsibilities for both internal and external stakeholders when making scientific decisions, and (3) a transparent process by which officials can report and address allegations of political interference.

²³According to *A Framework for Federal Scientific Integrity Policy and Practice*, a culture of scientific integrity means "both creating an empowering environment that is conducive to innovation and progress and also protecting scientists and the process of science" wherein "scientific findings and products must not be suppressed, delayed, or altered for political purposes and must not be subjected to inappropriate influence," among other tenets.

HHS issued a scientific integrity policy in 2012 that included principles designed to ensure the integrity of scientific and scholarly activities that the department conducts and supports, and the science it uses to inform management and public policy decisions. In April 2023, HHS officials told us HHS's Office of the Assistant Secretary for Planning and Evaluation is drafting updates to this scientific integrity policy, as required by the January 2021 presidential memorandum. In July 2023, HHS made a draft of the updated HHS scientific integrity policy available for public comment.²⁴ According to HHS officials, the updated policy will include specific provisions prohibiting political interference, ensuring independent review of scientific activities, prohibiting the suppression or delay of scientific findings for non-scientific reasons, and protecting against retaliation, among other things. We were also told that the updated policy will establish clear procedures for reporting and handling allegations of political interference.

This is consistent with our recommendations in April 2022 that HHS and agency heads should ensure that procedures for reporting and addressing potential political interference in scientific decision-making are developed and documented, including adding a definition of political interference to these policy documents. HHS concurred with these recommendations. As of April 2023, these recommendations had not been implemented.²⁵ Final publication of HHS's scientific integrity policy is expected in February 2024, according to HHS officials. HHS agencies may develop their own complementary policies but are not required to do so. CDC, FDA, and NIH developed their own individual scientific integrity policies and procedures and, according to HHS officials, are in the process of updating them. According to officials, ASPR relies on HHS's scientific integrity policy.

- **Transparency.** Experts told us that transparency in the decision-making process should include noting the policy or process that guided the decision, the evidence underlying the decision, and the role of internal and external stakeholders when making a science-based decision. Experts noted transparency is particularly important for instances in which an agency changes its normal processes, such

²⁴The version of the updated policy made available for public comment can be found at <https://www.federalregister.gov/public-inspection/2023-15408/draft-scientific-integrity-policy> (accessed Aug. 28, 2023).

²⁵See [GAO-22-104613](#).

as during an emergency, or a political appointee or elected official intervenes in an established process. For example, experts said that agencies should share publicly those instances in which a political official intervenes to stop, delay, or alter a normal process. According to experts, in some of these instances political interference may not have occurred, but a lack of transparency may have created the perception that it did. Therefore, greater transparency can also help address perceived instances of political interference. (See text box for case study examples of how transparency may be a safeguard against potential political interference.)

Case Study Examples:

Food and Drug Administration (FDA) Emergency Use Authorization (EUA) of Hydroxychloroquine and Chloroquine

Experts told us that the EUA process is a technical, science-based process. They noted that it would have been a usual part of this process for the administration to ask FDA to review the science and come to a science-based decision. However, in this instance, it appeared that the administration did not request a review but instead announced availability of the treatment before any review was conducted. To ensure political accountability, experts said it would be important to have transparency in any political decision that preempted or overrode the technical, scientific process. Experts noted that in the case of an emergency, there can be some appropriate deviations from the normal process; however, one expert said that the executive branch should be transparent about any decisions to supersede a technical or scientific process in future emergencies.

CDC School Reopening Guidance

Experts told us it is appropriate for CDC to engage with a variety of stakeholders, including teachers unions, when developing guidance. They said getting such input can help ensure the guidance reflects the needs and concerns of those most affected. However, experts noted some concerns with the process for developing this particular guidance. For example, one expert noted that while there is a desire for CDC to get input from many stakeholders, the lack of transparency when developing this guidance was an issue. Another expert told us CDC should have been more inclusive of other stakeholder groups and should have been open about the stakeholders from which it sought input. By doing so, people would see more balance in the various stakeholders involved rather than only seeing involvement by teachers unions, according to this expert.

Source: GAO roundtable discussion with 11 experts. | GAO-23-106529

Experts told us that increased transparency can come with costs. For example, one expert noted that increased transparency is important but there is an added administrative burden that can both slow down and complicate the decision-making process. Therefore, according to this expert, it would be important to be mindful that any steps added to ensure transparency do not cause undue burden. Another expert noted that transparency may make agency officials less willing to say what they really think should their opinion be unpopular or controversial.

OSTP has also identified transparency as a hallmark of scientific integrity.²⁶ In particular, OSTP's framework encourages federal agencies to ensure the quality, accuracy, and transparency of scientific information used to support policy and decision-making. Similarly, we previously

²⁶Office of Science and Technology Policy, *A Framework for Federal Scientific Integrity Policy and Practice*.

reported that transparency is a component of an organizational culture supportive of scientific integrity, which is a necessary foundation to protect agencies against inappropriate influence, according to the January 2022 report by the National Science and Technology Council.²⁷ HHS officials told us that transparency is a key component of OSTP's definition of scientific integrity and will be part of the department's updated scientific integrity policy. According to officials, to the extent possible, information on scientific decisions will be made publicly available.

Expert Perspective on Documenting Decisions

"All these difficult issues do not go away when you impose any kind of general requirement on real people. But if you give people the opportunity, or even the expectation, that they document how they are making their decisions, I think maybe that might help."

Source: Statement from GAO's roundtable of 11 experts. | GAO-23-106529

- **Documenting decision-making processes.** Experts told us that agencies need to document the decision-making processes—including what procedures guide those decisions. One expert noted it is particularly important that the process and any key decisions be documented in cases where an agency deviates from normal process, such as during an emergency. Documenting the process also promotes transparency, which, as noted above, can protect against potential political interference. One expert added that, although documenting decisions is burdensome, it strengthens the scientific process and transparency, and improves the decision-making process overall. (See text box for case study example of how documenting decision-making processes may be a safeguard against potential political interference.)

Case Study Example: Centers for Disease Control and Prevention's (CDC) *Morbidity and Mortality Weekly Report (MMWR)*

Former CDC officials told us that, prior to the COVID-19 pandemic, draft *MMWR* article summaries (high-level article synopses) and proofs (full-text article drafts) had never been shared outside CDC, a longstanding, though undocumented, tradition intended to preserve the publication's editorial independence and scientific integrity. In May 2020, CDC changed its practice of not sharing any information about upcoming *MMWR* articles outside of CDC besides publication titles because of the whole-of-government pandemic response, according to agency officials. As a result, *MMWR* summaries and proofs were shared with a number of individuals, including political appointees outside of CDC, according to the agency.

When CDC changed its practice in May 2020, it opened the process up to political influence, according to experts. They told us that documenting those informal review practices could safeguard against potential political interference because CDC officials would be able to point to agreed-upon practices if outside officials attempt to influence the publication in the future. Experts also noted that documenting the *MMWR* review policies could also help promote greater transparency, another safeguard against potential political interference.

Source: GAO roundtable discussion with 11 experts. | GAO-23-106529

²⁷See [GAO-23-105415](#).

Expert Perspective on Processes for Differing Scientific Opinions

One expert said that the use of processes for handling “differing scientific opinions” would have been a powerful process safeguard in the case study on FDA’s emergency use authorization for hydroxychloroquine and chloroquine. This expert suggested that the use of such a process could have included summarizing the scientific evidence and presenting a different conclusion for decision-maker consideration.

Source: Statement from GAO’s roundtable of 11 experts. | GAO-23-106529

Experts told us that developing a mechanism for federal agencies to formally document differences in scientific opinion could help enhance transparency in decision-making within HHS agencies. According to OSTP’s framework, each agency should develop a mechanism for employees engaged in the science informing agency policy decisions to express any disagreement with scientific data, interpretations, or conclusions in writing. Under the framework, differing scientific opinions should be documented as part of the peer review or as part of agency documents considered as part of the decision-making process. According to the framework, the use of such a process can increase early scientific integrity consultations, helping to ensure accountability in the process.

HHS officials told us that its updated scientific integrity policy will address the decision-making process and describe steps officials may use to document differing scientific opinions when it is finalized in February 2024. According to officials, some agencies, including FDA and CDC, also have existing dispute resolution policies and may continue to use them when the updated scientific integrity policy is finalized.

Expert Perspective on the Human Element of Decision-Making

In discussing a case study, one expert noted the importance of the human element when making decisions and responding to potential pressure, even when there are policies and procedures in place to protect against such pressure.

“I think this is a really powerful reminder that at the end of every one of these decisions is a human being subject to human pressures of one kind or another. And if you were continually threatened...both privately and then [in] public and the media, for most people, it just becomes too much. And I don’t think that we can discount the human condition here...I think whatever kinds of solutions we want to propose need to buffer people against that to the extent possible recognizing we’re never going to fully succeed.”

Source: Statement from GAO’s roundtable of 11 experts. | GAO-23-106529

While experts noted establishing agency processes is an important safeguard, they also told us no agency is fully insulated from political influence and there is an appropriate role for political appointees and elected officials in agency processes. For example, experts told us it is appropriate for a political appointee or elected official to encourage an agency to expedite or prioritize a project. One expert noted it would also be appropriate for political appointees or elected officials to evaluate risks or trade-offs in decision-making. However, experts said it would be inappropriate for a political appointee or elected official to exert influence in a manner that interferes with the scientific integrity of the process or seeks to distort or misuse the science behind a decision.

Training on Scientific Integrity Processes

Experts told us training agency staff, including political appointees and career officials, on scientific integrity processes could serve as a safeguard against potential political interference. According to experts, agency officials are unclear about what would constitute political interference and how to report it. Experts said this uncertainty could be greater during an emergency when certain actions that would normally be unusual may be more appropriate, such as not waiting for all scientific evidence before making a decision. Additional training when officials onboard, or during their tenure, could increase agency officials' comprehension of political appointees' appropriate role in an agency, including instances in which there may be different roles during emergency situations, and reduce political interference.

In our prior work, we found that CDC, FDA, NIH, and ASPR train staff on some scientific-integrity-related topics, but only NIH includes information on political interference in scientific decision-making as part of this training. We recommended in April 2022 that employees and contractors performing scientific activities in HHS agencies receive training on how to report allegations of political interference in scientific decision-making.²⁸ HHS concurred with this recommendation. As of April 2023, this recommendation has not been implemented.

HHS officials told us the agency will develop scientific integrity training after it finalizes its scientific integrity policy in February 2024. According to HHS officials, this training will be for all HHS staff, including employees, political appointees, contractors, and others covered by the policy. The training will describe HHS's policies and procedures related to scientific integrity, including how to recognize, avoid, and report potential political interference. In addition, officials said the training will differentiate between scientifically trained political appointees engaging in the legitimate conduct, management, communication, and use of science, and political appointees inappropriately breaching scientific integrity because of political motivations.

Institutional Structures

Experts told us establishing safeguards to strengthen agencies' institutional structures could help selected HHS agencies protect against potential political interference. In particular, experts told us using advisory committees, limiting the number of political appointees, and designating a

²⁸See [GAO-22-104613](#).

scientific integrity liaison or ombudsman could serve as safeguards supporting an agency's structure.

- **Advisory Committees.** Experts told us advisory committees can provide independent advice or recommendations on scientific matters, including recommendations that may differ from an agency's decision, which can help minimize political influence on scientific decisions. Experts' comments on advisory committees are consistent with the model policy in OSTP's framework, which states advisory committees are an important tool for ensuring the credibility, quality, and transparency of agency science.²⁹ Similarly, advisory committees can help insulate an agency from political interference by allowing external actors, such as scientific experts and researchers, to advise on agency decision-making based on our review of a political science article.³⁰ As we previously reported, all four of the selected HHS agencies have active advisory committees that advise on key areas of agencies' scientific decision-making.³¹ According to HHS officials, its revised scientific integrity policy will affirm HHS's adherence to the Federal Advisory Committee Act in the recruitment and selection of committee members based on expertise and knowledge when it is finalized in February 2024.³² (See text box for case study example of how advisory committees may be a safeguard against potential political interference.)

²⁹Office of Science and Technology Policy, *A Framework for Federal Scientific Integrity Policy and Practice*.

³⁰Jennifer L. Selin, "What Makes an Agency Independent?," *American Journal of Political Science*, vol. 59, no. 4 (October 2015).

³¹[GAO-23-105415](#).

³²The Federal Advisory Committee Act helps assure that federal advisory committees: (1) provide advice that is relevant, objective, and open to the public; (2) act promptly to complete their work; and (3) comply with reasonable cost controls and record keeping requirements. The act requires that committee memberships be "fairly balanced in terms of the points of view represented and the functions to be performed." See Pub. L. No. 92-463, 86 Stat. 770 (1972) (codified, as amended, at 5 U.S.C. app.).

Case Study Example: Centers for Disease Control and Prevention (CDC) Recommendations on COVID-19 Booster Shots

In 2021, leaders from the Department of Health and Human Services (HHS) announced that COVID-19 booster shots would soon be available to all fully vaccinated adults, prior to CDC's advisory committee meeting on booster recommendations. CDC's guidance on booster shots differed, in part, from the CDC advisory committee's recommendations. While the CDC director is not required to accept the advisory committee's recommendations, according to CDC officials, experts told us that greater transparency in this process, including why the administration's announcement preceded the advisory committee's review, could have helped to avoid actual or perceived political interference. For example, experts said CDC could have explained what other factors or data led CDC to issue guidance that differed, in part, from its advisory committee's recommendation.

Source: GAO roundtable discussion with 11 experts. | GAO-23-106529

Expert Perspective on Reducing the Number of Political Appointees

"If there is a different kind of appointment authority that leads to more professional expertise, longer tenure, more of a sense of professional commitments, that is probably better as a firewall against interference in science."

Source: Statement from GAO's roundtable of 11 experts. | GAO-23-106529

- **Political Appointees.** Experts told us that the number of political appointees in an agency may make the agency more vulnerable to political pressure; therefore, limiting the number of appointees could make it more difficult for political appointees to influence the work of the agencies. One expert noted that there are many agencies across the government that are led by career officials and not political appointees, which could make it easier to withstand political pressure.

We previously reported that the selected HHS agencies each had between two and five political appointees serving in key senior leadership positions as of August or September 2022, which can increase political influence over agencies.³³ Politically appointed positions at selected agencies include the CDC Director, the FDA Commissioner, the NIH Director, and the Assistant Secretary for Preparedness and Response. In addition, the number of political appointees increased from 2016 through 2020 at CDC, FDA, and ASPR, but has since declined at CDC and FDA as of 2022. Political appointees—who generally serve at the pleasure of the President—can make and advocate for agency policy on behalf of an administration. Therefore agencies with more political appointees are more likely to be subject to partisan politics and responsive to the White House.

- **Agency Scientific Integrity Liaison or Ombudsman.** Experts said that designating an agency scientific integrity liaison or ombudsman who is dedicated to ensuring scientific integrity on an ongoing basis could help agency officials better understand the scientific integrity process, including how to report potential political interference. According to experts, this would be in keeping with the January 2021

³³See [GAO-23-105415](#). There are four major categories of political appointees: presidential appointees with Senate confirmation; presidential appointees; non-career employees in the Senior Executive Service; and Schedule C employees.

Expert Perspective on Scientific Integrity Officers

“As others have argued, the benefits of having a scientific integrity officer there, someone dedicated to trying to make sure this work is ongoing...save[s] so much in so many different ways. People would understand what the process is. People would understand what their protections are. And it can prevent these different types of integrity violations and political interference that we have been mentioning here, which has enormous consequences on literally the entire culture of the agency.”

Source: Statement from GAO’s roundtable of 11 experts. | GAO-23-106529

presidential memorandum that requires all agencies to designate a scientific integrity official. This official would be responsible for leading training and outreach initiatives related to scientific integrity policy and would serve as a neutral point of contact for receiving questions about or allegations of compromised scientific integrity.³⁴

One expert told us that while such a role is important, there can be staffing issues as those positions are often neglected. Further, the expert also told us the effect of an ombudsman could be limited given other priorities agencies may have. According to HHS, the department designated an interim scientific integrity official within the Office of the Assistant Secretary for Planning and Evaluation, an office that advises HHS on policy development in health and science, among other things. According to HHS officials, as of June 2023, HHS is in the process of recruiting for this position. Officials noted that the duties of this position will be included in HHS’s updated scientific integrity policy when it is published in February 2024.

Expert Perspective on Overall Caution of Professionalization and Structural Changes

“We don’t want to be strict in processes professionalization and structure changes [so] that we make it impossible for well-intentioned policy change to take place in the government with these agencies that we are talking about.”

Source: Statement from GAO’s roundtable of 11 experts. | GAO-23-106529

Experts highlighted that a multi-layered approach to protect against potential political interference—a “web” of safeguards—might yield the best results. Experts also told us that procedural safeguards may be better in protecting against political interference than safeguards that require individual action. As we previously noted, we have made recommendations related to several of the safeguards identified by experts, including that HHS and agency heads should ensure that (1) procedures for reporting and addressing potential political interference in scientific decision-making are developed and documented, including adding a definition of political interference to these policy documents and (2) employees and contractors performing scientific activities in HHS agencies receive training on how to report allegations of political interference in scientific decision-making.

Agency Comments

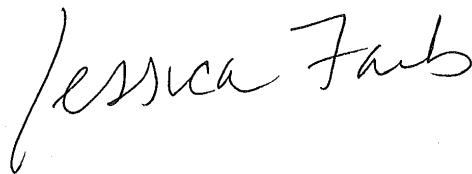
We provided a draft of this report to HHS for comment. HHS provided written comments on a draft of this report, which are reproduced in appendix II, and technical comments, both of which we incorporated as appropriate. In its response to our draft report, HHS outlined actions the agency has taken to implement the 2021 presidential *Memorandum on Restoring Trust in Government through Scientific Integrity and Evidence-*

³⁴The White House, *Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking* (January 27, 2021).

based Policymaking, which include making a draft of the HHS scientific integrity policy available for public comment in July 2023, launching a scientific integrity website, and developing a portal for reporting allegations regarding scientific integrity in HHS's work. HHS noted that the department was not in the position to confirm or deny the accuracy of the content of the case studies presented to expert panelists at the roundtable. To develop the case studies we provided to the panelists as examples of allegations of potential political interference, we reviewed agency policies and procedures, prior GAO reports, relevant reports from Congress and other stakeholders, and internal documents. We also spoke with former government officials and relevant stakeholders.

We are sending copies of this report to the appropriate congressional committees, the Secretary of Health and Human Services, and other interested parties. In addition, the report will be available at no charge on GAO's website at <http://www.gao.gov>.

If you or your staff have any questions about this report, please contact me at (202) 512-7114 or at FarbJ@gao.gov. Contact points for our Office of Congressional Relations and Office of Public Affairs can be found on the last page of this report. Other major contributors to this report are listed in appendix III.



Jessica Farb
Managing Director, Health Care

List of Requesters

The Honorable Patty Murray
Chair
Committee on Appropriations
United States Senate

The Honorable Bernard Sanders
Chair
Committee on Health, Education, Labor, and Pensions
United States Senate

The Honorable Gary C. Peters
Chairman
Committee on Homeland Security and Governmental Affairs
United States Senate

The Honorable Elizabeth Warren
United States Senate

The Honorable James E. Clyburn
House of Representatives

The Honorable Paul D. Tonko
House of Representatives

Appendix I: Objective, Scope, and Methodology

This report describes actions that experts believe selected Department of Health and Human Services (HHS) agencies could take to protect against potential political interference, or political influence that seeks to undermine an agency's impartiality, nonpartisanship, and professional judgment.¹ This appendix provides additional information on our expert roundtable discussion, expert selection process, and selected case studies provided to experts during the roundtable.

Expert Roundtable Discussion

To address our research objective, in May 2023, with the assistance of the National Academies of Sciences, Engineering, and Medicine (National Academies), we convened a 2-day virtual roundtable of 11 experts to discuss (1) how to define and recognize political interference and (2) actions selected HHS agencies can take to protect against political interference.² To facilitate this discussion, we provided experts with information on six instances of potential political interference that were identified by GAO and others. All six case studies occurred during the COVID-19 pandemic response; involved events at the Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), National Institutes of Health (NIH), or Administration for Strategic Preparedness and Response (ASPR); and had bipartisan identification as a significant instance of potential political interference. We did not ask the expert panelists to determine whether political interference occurred in any of these examples.

We analyzed the roundtable transcripts to identify common themes discussed by and key statements of experts regarding potential actions HHS agencies could take to protect against political interference. We did not poll expert participants or take votes on approaches discussed during the roundtable. Consequently, we do not provide counts or otherwise quantify the number of experts agreeing to an approach. Further,

¹For the purposes of this report, we adapted a definition of "political interference" from a 2017 report by the National Academies of Sciences, Engineering, and Medicine (National Academies), which states that undue external influences are those from outside an agency that seek to undermine its impartiality, nonpartisanship, and professional judgment. See National Academies of Sciences, Engineering, and Medicine, *Principles and Practices for a Federal Statistical Agency: Sixth Edition*. (Washington, D.C.: 2017). According to the National Academies, it provides independent, objective analysis and advice to the nation, including the federal government, and conducts other activities to solve complex problems and inform public policy decisions.

²This roundtable was planned and convened with the assistance of the National Academies to better ensure that a breadth of expertise was brought to bear in its composition; however, all final decisions regarding meeting substance and expert participation were made by GAO.

because experts were generating and discussing ideas as part of a free-flowing group discussion, the number of times a concept was or was not repeated does not necessarily indicate the level of consensus on that concept. Throughout the report, we use the term “experts” to refer to more than one expert.

The options for specific actions we present in this report were identified by the experts. We did not analyze or evaluate the options and their inclusion in this report should not be interpreted as GAO or any federal agency or department endorsing any of them. The options are not listed in any specific rank or order. We did not assess how effective the options may be, or the extent to which program design modifications, legal changes, and federal financial support would be needed to implement any given action or combination of actions. However, we report considerations experts noted concerning the potential effectiveness of specific actions. To the extent HHS has any ongoing activities related to these actions, we included such information.

Expert Selection

The 11 experts selected for our 2-day virtual roundtable represented a broad spectrum of views and expertise and a variety of professional and academic fields. For example, they were former federal agency officials; academic researchers, including in the field of political science; and leaders of non-profit organizations.³ We selected the experts based on their experience and knowledge that could be relevant to discussions of potential political interference and recommendations from the National Academies. Specifically, we sought the participation of those with current or prior experience in the following categories: (1) academic researchers working in this field, including political scientists, (2) former federal agency officials who had experience at the selected HHS agencies, and (3) relevant experts from non-profit organizations. When selecting experts, we considered (1) type and depth of experience, (2) published work and its relevance to our research objective, (3) and present and past employment history. Table 1 lists the 11 selected experts and their affiliations at the time of the roundtable.

³The comments of the experts represented the views of the experts themselves and not the organizations with which they are affiliated, and are not generalizable to the views of others in the field.

Table 1: Alphabetical List of Expert Participants in GAO Expert Panel to Identify Actions Selected Department of Health and Human Services Agencies Could Take to Protect Against Potential Political Interference, Held May 1-2, 2023, and Institutional Affiliation at the Time of Roundtable

1	Lisa Bressman, JD	Vanderbilt University
2	Daniel Carpenter, PhD	Harvard University
3	Anita Desikan, MPH	Center for Science and Democracy at the Union of Concerned Scientists
4	Steven K. Galson, MD, MPH	Boston Consulting Group
5	Ali S. Khan, MD, MPH, MBA	University of Nebraska
6	Martha Kinsella, JD	Brennan Center for Justice
7	Lauren Kurtz, JD	Climate Science Legal Defense Fund
8	David E. Lewis, PhD	Vanderbilt University
9	Nicole Lurie, MD, MSPH	Coalition for Epidemic Preparedness Initiatives
10	William Schultz, JD	Zukerman Spaeder
11	Daniel Sosin, MD, MPH, FACP	New Mexico Department of Health

Source: GAO. | GAO-23-106529

To help identify any potential biases or conflicts of interest, we asked each expert who participated in the roundtable to disclose whether they had investments, sources of earned income, organizational positions, relationships, or other circumstances that could affect, or could be viewed to affect, their views on actions to protect against potential political interference. None of the experts reported potential conflicts that would affect their ability to participate in the roundtable.

Selected Case Studies

We selected six instances of potential political interference that we identified as part of prior work and presented them to the expert panelists as case studies. As part of our prior work, we spoke with a bipartisan selection of eight former agency heads and other stakeholders to obtain their opinions on which events occurring at CDC, FDA, NIH, and ASPR during the COVID-19 response were significant instances of potential political interference. In addition to these interviews, we reviewed relevant government inquiries and reports on related topics.⁴ Based on these discussions, we produced a list of 44 events to consider selecting as case studies.

In fall 2021, we conducted a second round of case study selection to consider additional instances of potential political interference of which we

⁴Government inquiries refer to congressional reports, statements from the administration, and other official government documents.

were made aware from May 2021 through November 2021. In the second round of selection, we assembled a list of relevant instances of potential political interference from hotline reports we received, semi-structured interviews we conducted, stakeholder reports, and government inquiries.⁵ From those sources, we produced a list of five events to consider in our second round of case study selection. To determine which of the five identified events had bipartisan identification as a significant instance of potential political interference, we contacted the eight former agency heads with whom we spoke earlier in the engagement for their opinions. Five of the eight officials responded with feedback.

In February 2023, we used the lists from both rounds of case study selection to judgmentally select six case studies from this list of events that: (1) had bipartisan identification as a significant instance of potential political interference as determined by assessments made by at least one Republican and one Democratic former political appointee whom we interviewed or public statements made by a current member of Congress; (2) involved potential deviations from agency policies or procedures; and (3) provided variation in terms of the agency involved and topic matter in question. See table 2 for the six selected case studies of potential political interference.

⁵The confidential hotline—consisting of an email account and voicemail inbox—was created to collect agency employees’ opinions and perspectives related to issues of scientific integrity and political interference at the selected agencies. The confidential hotline was available to selected subcomponents at CDC, FDA, NIH, and ASPR over a 2-month period. We conducted the semi-structured interviews with 16 employees, including managers and non-managers, from three of the four selected agencies—CDC, FDA, and NIH. Specifically, we collected information on employee perspectives on their agency’s implementation of its scientific integrity policy, their agency’s ability to protect against political interferences, and their familiarity or experience with instances of potential political interference.

Appendix I: Objective, Scope, and Methodology

Table 2: Six Instances of Potential Political Interference at Selected Department of Health and Human Services Agencies Provided to Participants in GAO Expert Panel, Held May 1-2, 2023

No.	Potential Political Interference Described in the Case Study
1	Allegations that the Food and Drug Administration (FDA) was pressured to issue an emergency use authorization for hydroxychloroquine and chloroquine for treatment of COVID-19.
2	Allegations that the development of the Centers for Disease Control and Prevention's (CDC) school reopening guidance inappropriately involved teachers unions.
3	Allegations that the White House directed the National Institutes of Health (NIH) to terminate a grant for a project studying how coronaviruses spread from bats to people.
4	Allegations that the White House pressured the CDC Director to adopt different recommendations on COVID-19 booster shots than the recommendations made by CDC's advisory committee.
5	Allegations that political appointees within the Department of Health and Human Services sought to edit CDC's <i>Morbidity and Mortality Weekly Report</i> article summaries and titles.
6	Allegations that political pressure influenced CDC in its decision to lift the mask mandate for fully vaccinated individuals.

Source: GAO. | GAO-23-106529

To develop the case studies, we reviewed agency policies and procedures, prior GAO reports, relevant reports from Congress and other stakeholders, and internal documents.

Appendix II: Comments from the Department of Health and Human Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

August 10, 2023

Jessica Farb
Managing Director, Health Care
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Ms. Farb:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, **"CARES ACT: Experts Identified Safeguards to Help Selected HHS Agencies Protect Against Potential Political Interference"** (GAO-23-106529).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

Melanie Anne Egorin

Melanie Anne Egorin, PhD
Assistant Secretary for Legislation

Attachment

**Appendix II: Comments from the Department
of Health and Human Services**

GENERAL COMMENTS FROM THE DEPARTMENT OF HEALTH & HUMAN SERVICES ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED – CARES ACT: EXPERTS IDENTIFIED SAFEGUARDS TO HELP SELECTED HHS AGENCIES PROTECT AGAINST POTENTIAL POLITICAL INTERFERENCE (GAO-23-106529)

General Comment

The U.S. Department of Health & Human Services (HHS) appreciates the opportunity from the Government Accountability Office (GAO) to review and comment on this draft report.

Throughout this engagement, the Department has maintained that HHS is not in a position to confirm or deny the accuracy of much of the content contained in GAO's six case studies as depicted by GAO. Thus, the six case studies that GAO chose to present to the National Academies of Sciences, Engineering, and Medicine are regarded by HHS as hypothetical scenarios used for discussion purposes only.

HHS is continuing to take various actions to implement the 2021 Presidential Memorandum on Restoring Trust in Government through Scientific Integrity and Evidence-based Policymaking. These actions include:

- HHS drafted an updated HHS Scientific Integrity Policy, which we anticipate will be finalized and published by early next year. The draft HHS Scientific Integrity Policy explicitly prohibits political interference in scientific activities and provides procedures and processes for reporting allegations of political interference, among other violations of scientific integrity.
- On July 20, 2023, HHS made the draft HHS Scientific Integrity Policy available for public comment - <https://www.federalregister.gov/public-inspection/2023-15408/draft-scientific-integrity-policy>.
- Also on July 20, 2023, the new HHS scientific integrity website was launched - <https://www.hhs.gov/programs/research/scientificintegrity>.
- HHS is working on a portal for reporting allegations regarding scientific integrity in HHS' work.
- HHS is developing scientific integrity training for employees, contractors, and other covered entities, which will be made available after publication of the final HHS Scientific Integrity Policy.

HHS will continue to update GAO on its efforts.

Appendix III: GAO Contact and Staff Acknowledgments

GAO Contact

Jessica Farb at (202) 512-7114 or FarbJ@gao.gov

Staff Acknowledgments

In addition to the contact named above, Ray Sendejas (Assistant Director), Amy Leone (Analyst-in-Charge), Sam Amrhein, Margot Bolon, Jenny Chanley, Amanda Cherrin, Kaitlin Farquharson, Sandra George, Douglas G. Hunker, Eric Peterson, Corinne Quinones, Lisa Rogers, Ethiene Salgado-Rodriguez, Rebecca Sero, Sharon Silas, and Walter Vance made key contributions to this report. Anna Beischer, Adam Brooks, Joycelyn Cudjoe, Cynthia Khan, Amelia Koby, Rob Marek, Priyanka Panjwani, Amy Pereira, Caylin Rathburn-Smith, Roxanna Sun, and Candice Wright also made important contributions.

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