



April 2022

SCIENTIFIC INTEGRITY

HHS Agencies Need to Develop Procedures and Train Staff on Reporting and Addressing Political Interference

Why GAO Did This Study

Since 2007, Congress and multiple administrations have taken actions to help ensure that federal science agencies have scientific integrity policies and procedures in place that, among other things, protect against the suppression or alteration of scientific findings for political purposes. GAO defined scientific integrity as 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 with the public when appropriate. GAO was asked to review scientific integrity policies and procedures, and how allegations of political interference in scientific decision-making are addressed at CDC, FDA, NIH, and ASPR.

This report examines the procedures in place to address such allegations and the extent to which agencies received them. It also examines training provided by selected agencies on scientific integrity policies and procedures, including those related to political interference. GAO analyzed the agencies' scientific integrity policies, procedures, and trainings; interviewed agency officials, and employees, which includes managers and non-managers; and deployed a confidential hotline.

What GAO Recommends

GAO is making seven recommendations to CDC, FDA, NIH, and HHS, including that they develop procedures for reporting and addressing allegations of political interference and train staff on how to report such allegations. HHS concurred with the recommendations.

View [GAO-22-104613](#). For more information, contact Candice Wright at 202-512-6888 or WrightC@GAO.gov

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HHS Agencies Need to Develop Procedures and Train Staff on Reporting and Addressing Political Interference

What GAO Found

The four agencies GAO reviewed do not have procedures that define political interference in scientific decision-making or describe how it should be reported and addressed. These agencies within the Department of Health and Human Services (HHS) are: the Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), the National Institutes of Health (NIH), and the Office of the Assistant Secretary for Preparedness and Response (ASPR).

The absence of specific procedures may explain why the four selected agencies did not identify any formally reported internal allegations of potential political interference in scientific decision-making from 2010 through 2021. Through semi-structured interviews and a confidential hotline, employees at CDC, FDA, and NIH told GAO they observed incidents that they perceived to be political interference but did not report them for various reasons. These reasons included fearing retaliation, being unsure how to report issues, and believing agency leaders were already aware. HHS could strengthen its desired goal of sustaining a culture of scientific integrity by developing procedures for reporting and addressing political interference in scientific decision-making. Such procedures would ensure that employees know how to report allegations, and that HHS's agencies have a clear, consistent process for investigating and addressing such allegations. To help reduce employees' fear of retaliation and encourage appropriate reporting, agencies could include information on whistleblower protections, and clarify any reporting requirements for employees who believe they observed potential political interference in scientific decision-making.

All four selected agencies—CDC, FDA, NIH, and ASPR—train staff on some scientific integrity-related topics, such as public health ethics, but only NIH includes information on political interference in scientific decision-making as part of its scientific integrity training (see figure). Training agency employees and contractors performing scientific activities would help agencies ensure that employees and contractors understand how to report allegations of political interference.

Elements of Scientific-Integrity-Related Procedures and Training at Selected HHS Agencies

	Centers for Disease Control and Prevention	Food and Drug Administration	National Institutes of Health	Office of the Assistant Secretary for Preparedness and Response ^a
Scientific integrity policy	✓	✓	✓	✓
Policy defines political interference in scientific decision-making	—	—	—	—
Specific procedures to report and address political interference in scientific decision-making	—	—	—	—
Training on political interference in scientific decision-making	—	—	✓	—

Source: GAO analysis of information from selected Department of Health and Human Services (HHS) agencies. | GAO-22-104613

^aThe Office of the Assistant Secretary for Preparedness and Response follows HHS's *Policies and Principles for Assuring Scientific Integrity*.

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Abbreviations

ASPR	Office of the Assistant Secretary for Preparedness and Response
CDC	Centers for Disease Control and Prevention
FDA	Food and Drug Administration
HHS	Department of Health and Human Services
NIH	National Institutes of Health
OGE	Office of Government Ethics
OIG	Office of Inspector General
OSC	Office of Special Counsel
OSTP	Office of Science and Technology Policy

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April 20, 2022

Congressional Addressees

Since 2007, Congress and multiple administrations have taken actions to help ensure that federal science agencies have policies and procedures in place that, among other things, protect against the suppression or alteration of scientific findings for political purposes. Political interference in scientific decision-making violates agencies' policies that are designed to preserve the integrity of scientific information used to guide policy decisions.

The CARES Act includes a provision for GAO to report on its ongoing oversight efforts related to COVID-19.¹ In addition, we were asked to review scientific integrity policies and procedures and how political interference in scientific decision-making is addressed at selected Department of Health and Human Services (HHS) agencies. We focused on four agencies within HHS that have had key roles in conducting and supporting scientific research, communicating information to the public, evaluating the safety and effectiveness of medical products, and leading other aspects of the public health response to the COVID-19 pandemic: the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the National Institutes of Health (NIH), and the Office of the Assistant Secretary for Preparedness and Response (ASPR).²

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, are not inappropriately influenced by political considerations, and are shared

¹Pub. L. No. 116-136, § 19010, 134 Stat. 281, 579-81 (2020). We regularly issue government-wide reports on the federal response to the COVID-19 pandemic. For the latest report, see GAO, *COVID-19: Significant Improvements Are Needed for Overseeing Relief Funds and Leading Responses to Public Health Emergencies* (Washington, D.C.: Jan. 27, 2022). Our next government-wide report will be issued in April 2022 and will be available on GAO's website at <https://www.gao.gov/coronavirus>.

²HHS's operating divisions—including CDC, FDA, and NIH—are responsible for administering a wide variety of health and human services, including research. HHS's staff divisions—including ASPR—are responsible for providing leadership, direction, and policy and management guidance to HHS. For the purposes of this report, HHS's operating and staff divisions are referred to as agencies.

openly and transparently with the public, when appropriate.³ The term “political interference” refers to political influences that seek to undermine impartiality, nonpartisanship, and professional judgment.⁴ While the term political interference is broad in nature, this report focuses on political interference in scientific decision-making at the selected HHS agencies.

This report examines (1) the procedures in place at the selected agencies to address allegations of political interference in scientific decision-making and the extent to which agencies received such allegations and (2) available training provided by the selected agencies on scientific integrity policies and procedures, including those related to political interference.⁵

To address these objectives, we reviewed relevant federal guidance on scientific integrity as well as HHS’s scientific integrity policy, agency-specific scientific integrity policies and procedures, and agency training materials, and discussed these with agency officials. We requested data from each selected agency from the period 2010-2021 on internal allegations of political interference. The agencies told us they did not receive such allegations during that time period and did not provide any data. We spoke with knowledgeable agency officials about the lack of allegations. In addition, we conducted interviews with a total of 16 employees, which included both managers and non-managers, at three of

³We developed this definition 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).

⁴We adapted this definition from a 2017 report by the National Academies of Sciences, Engineering, and Medicine, 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). Near the end of our review, in January 2022, the Scientific Integrity Fast-Track Action Committee (interagency task force) of the National Science and Technology Council defined “interference” to mean inappropriate, scientifically unjustified intervention in the conduct, management, communication, or use of science. The interagency task force further defined “political interference” to mean interference conducted by political officials or motivated by political considerations. Scientific Integrity Fast-Track Action Committee of the National Science and Technology Council, *Protecting the integrity of Government Science*, (January 2022).

⁵We plan to issue an additional report that will examine the key characteristics that can insulate agencies from political interference, and how, if at all, the selected HHS agencies have experienced potential political interference while carrying out their missions.

the four selected agencies—CDC, FDA, and NIH.⁶ We also developed a confidential hotline—consisting of both an email account and voicemail inbox—where employees at selected centers, institutes, and offices at the four agencies could report information on scientific integrity and potential political interference. When reporting our results, we use “respondent” to refer to an employee we interviewed as part of our semi-structured interview and confidential hotline methodologies. For more information on our objectives, scope, and methodology, see appendix I.

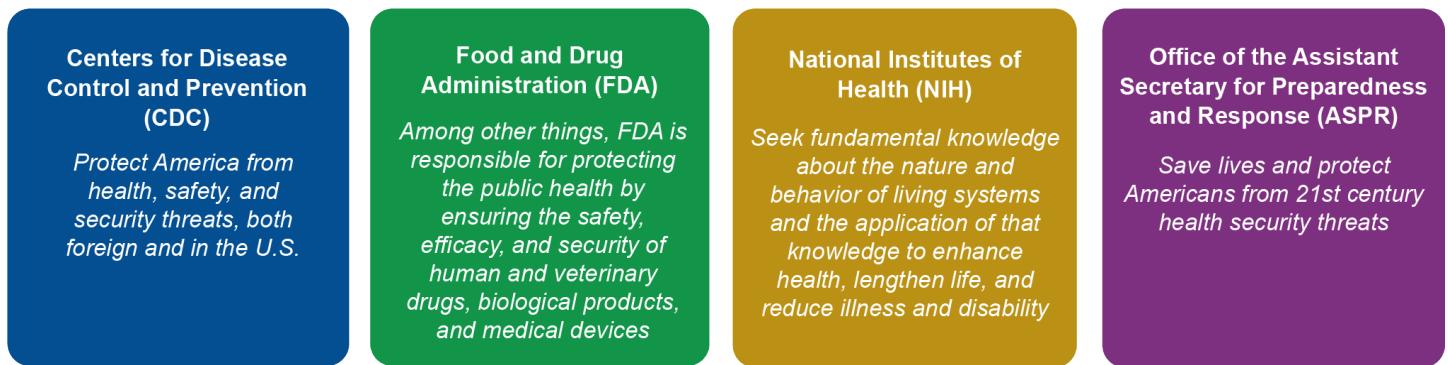
We conducted this performance audit from October 2020 to April 2022 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions 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’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 that led various aspects of the public health response to the COVID-19 pandemic have distinct missions (see fig. 1).

⁶ASPR was excluded from this methodology because it follows HHS’s Policies and Principles for Assuring Scientific Integrity and does not have its own scientific integrity policy. We gave employees at ASPR’s Biomedical Advanced Research and Development Agency the opportunity to provide us with comments through the confidential hotline. “Managers” include senior management at the subcomponent, typically a branch chief or director. “Non-managers” include all personnel in a subcomponent that are directly involved in carrying out the scientific mission of the subcomponent, including employees with supervisory experience and employees with non-supervisory experience.

Figure 1: Public Health Missions of Selected Agencies at the Department of Health and Human Services



Source: GAO review of CDC, FDA, NIH, and ASPR information. | GAO-22-104613

Since the onset of the COVID-19 pandemic, there have been various allegations of political interference affecting scientific decisions at several HHS offices and agencies. For example, in May 2020, a senior official from ASPR claimed HHS retaliated against him for disclosing, among other things, concerns about inappropriate political interference to make chloroquine and hydroxychloroquine available to the public as treatments for COVID-19.⁷ Additionally, in July 2021, for example, several members of Congress criticized CDC for allegedly revising its face mask guidance for political purposes.⁸

Statutes and Federal Guidance on Scientific Integrity

The America COMPETES Act of 2007 required the Director of the Office of Science and Technology Policy (OSTP) to ensure that all civilian federal agencies that conduct scientific research develop policies and procedures for the public release of data and results of research

⁷See the Office of Special Counsel (OSC), *OSC Announces Settlement Agreement Between HHS and Former BARDA Director Dr. Rick Bright After his Reassignment*, (August 2021).

⁸For example, see Letter from the Honorable Virginia Foxx to the Honorable Xavier Becerra (July 29, 2021) and Press Release from Marco Rubio, U.S. Senator, Florida, *Rubio Introduces Bill to Audit CDC Mask Guidance Decision-making and Messaging Process* (July 29, 2021). CDC regularly issues guidance on its public website on a variety of COVID-19-related topics, such as testing and COVID-19 prevention in K-12 schools. According to CDC's scientific integrity policy, the agency emphasizes using scientific evidence for developing policies, guidelines, and recommendations.

conducted by their scientists.⁹ Those policies and procedures were required to (1) address what is and what is not permitted, (2) be applied uniformly, and (3) be widely communicated and readily accessible to all employees of each agency and the public. To implement requirements in the America COMPETES Act, OSTP developed principles to provide guidance to agencies on establishing and implementing policies regarding the communication of scientific information to the media and the open exchange of research data by federal scientists.¹⁰

Since 2009, multiple administrations have provided executive departments and agencies with a range of guidance for ensuring scientific integrity:

- **2009 presidential memorandum.** This memorandum stated that the public must be able to trust in the science and scientific process informing public policy decisions and, among other things, provided that political officials should not suppress or alter scientific or technological findings and conclusions.¹¹ To this end, the memorandum directs the Director of OSTP to develop recommendations for presidential action designed to guarantee scientific integrity based on a number of principles, including a principle that each agency should have procedures to identify and address instances where the scientific process or the integrity of scientific and technological information has been compromised.
- **2010 OSTP memorandum.** In December 2010, OSTP issued a memorandum to provide further guidance to executive departments and agencies to implement the administration's policies on scientific integrity. OSTP's guidance identified four broad pillars of scientific

⁹Pub. L. No. 110-69, § 1009, 121 Stat. 572, 581-82 (2007) (codified at 42 U.S.C. § 6620). The act also required the Director of OSTP, in consultation with the Director of the Office of Management and Budget and the heads of all federal civilian agencies that conduct scientific research, to develop and issue an overarching set of principles to ensure the communication and open exchange of data and results of research conducted by a scientist employed by a federal civilian agency and to prevent the intentional or unintentional suppression or distortion of such research findings. The policies and procedures were to be consistent with these principles.

¹⁰OSTP, *Principles for the Release of Scientific Research Results*, Memorandum (Washington, D.C.: May 28, 2008).

¹¹The White House, Office of the Press Secretary, *Scientific Integrity, Memorandum for the Heads of Executive Departments and Agencies* (Washington, D.C.: March 9, 2009).

integrity, and each pillar has several principles that provide guidance toward meeting the pillar (see fig. 2).¹²

Figure 2: Pillars of Scientific Integrity as Defined by the Office of Science and Technology Policy (OSTP)



Sources: GAO (analysis), OSTP (information), PaulBradbury/koto/pressmaster/merrvas/Khwanchai/stock.adobe.com (images). | GAO-22-104613

¹²OSTP, Scientific Integrity, *Memorandum for the Heads of Executive Departments and Agencies* (Dec. 17, 2010).

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- **2021 presidential memorandum.** This memorandum reaffirms and builds upon the 2009 and 2010 memorandums and, among other things, specifies that scientific findings should never be distorted or influenced by political considerations.¹³ The memorandum also includes requirements for heads of agencies to take certain actions, including the following:
 - Develop and publish procedures, as appropriate and consistent with applicable law, for implementing the agency’s scientific integrity policy. This action includes establishing and publishing a process for reporting, investigating, and appealing allegations of deviations from the agency’s policy, and resolving any disputes or disagreements about scientific methods and conclusions; and
 - Educate all agency employees and contractors who perform scientific activities for the agency, including new hires, on their rights and responsibilities related to scientific integrity. This action includes providing routine training on the scientific integrity policies for all agency employees.

The 2021 presidential memorandum also directed OSTP to convene an interagency task force to conduct a review of the effectiveness of agency scientific integrity policies and publish a report on its findings. Heads of agencies are to ensure that their scientific integrity policies reflect the findings of the interagency task force’s report.¹⁴ The task force is formally called the Scientific Integrity Fast-Track Action Committee of the National Science and Technology Council and includes members from HHS, CDC, FDA, NIH, and ASPR. It first met in May 2021 and issued its report in January 2022.¹⁵ Among other things, the report identified additional scientific integrity principles, such as considering violations of scientific integrity to be similar in importance to violations of government ethics, with comparable consequences. The report stated that the task force will begin developing a framework to support regular assessment and

¹³The White House, *Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking* (January 27, 2021).

¹⁴Heads of agencies with an existing scientific integrity policy are to submit updated policies and heads of agencies without an existing scientific integrity policy are to submit draft scientific integrity policies to the Director of OSTP within 180 days of the publication of the task force’s report.

¹⁵Scientific Integrity Fast-Track Action Committee of the National Science and Technology Council, *Protecting the integrity of Government Science*, (January 2022).

iterative improvement of agency scientific integrity policies.¹⁶ At the time of our review, agency implementation of the January 2021 memorandum and responses to the interagency task force’s report were ongoing, and agency implementation plans were not yet finalized, according to agency officials.

HHS Scientific Integrity Policies

HHS issued a scientific integrity policy in 2012 that addresses the four pillars of scientific integrity specified in OSTP’s 2010 memorandum.¹⁷ The policy describes 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. For example, HHS’s policy states that the department will sustain a culture of scientific integrity, which aligns with one of the principles outlined in OSTP’s 2010 memorandum. The policy also allows HHS agencies to develop their own complementary policies but does not require them to do so. CDC, FDA, and NIH developed agency-specific scientific integrity policies, while ASPR relies on HHS’s scientific integrity policy.

Agency Scientific Integrity Procedures Do Not Specifically Address Political Interference, Which May Have Led to Underreporting

CDC, FDA, and NIH procedures for reporting and addressing internal allegations of scientific integrity policy violations do not define political interference in scientific decision-making or describe how to report or address it, which may have resulted in underreporting of such issues. ASPR relies on HHS’s scientific integrity policy, which does not include any such procedures. The four selected agencies did not identify any formally reported internal allegations of potential political interference in scientific decision-making between the years 2010 through 2021, but respondents we interviewed at CDC, FDA, and NIH told us they observed but did not report such issues.¹⁸

¹⁶The 2021 presidential memorandum directs the interagency task force to develop a framework to inform and support the regular assessment and iterative improvement of agency scientific integrity policies and practices.

¹⁷See HHS, *Policies and Principles for Assuring Scientific Integrity* (March 2012).

¹⁸By “respondents,” we mean the employees we interviewed as part of our semi-structured interview and confidential hotline methodologies.

Agency Scientific Integrity Policies and Procedures Do Not Define Political Interference or Describe How It Should Be Reported and Addressed

CDC, FDA, and NIH scientific integrity policies and procedures for reporting and addressing internal allegations of scientific integrity policy violations do not define political interference in scientific decision-making or describe how it should be reported and addressed. ASPR does not have procedures for reporting and addressing internal allegations of scientific integrity policy violations. HHS and the selected agencies' scientific integrity policies only contain the following information related to political interference in scientific decision-making:

- **CDC.** Scientific findings and results should be disseminated without being influenced by policy or political issues.
- **FDA.** Shielding the agency's science and its scientific staff from political influence is characterized as a key scientific integrity principle.
- **ASPR.** ASPR follows HHS's scientific integrity policy, which states that political officials should not suppress or alter, nor appear to suppress or alter, scientific or technological findings.

NIH's scientific integrity policy does not include information related to political interference in scientific decision-making. One NIH official, however, stated that any scientific decisions that relied on anything other than evidence-based research would be inappropriate and would constitute interference with the scientific process.

None of the agencies in our review—CDC, FDA, NIH, and ASPR—have procedures specific to reporting and addressing potential political interference in scientific decision-making. Instead, agency officials explained that potential political interference in scientific decision-making may be reported and addressed internally on a case-by-case basis or through existing internal scientific integrity procedures intended for other purposes. In particular:

- **CDC** officials said that potential political interference in scientific decision-making would be handled on a case-by-case basis, typically by being elevated to senior CDC leadership.
- **FDA** officials said that the agency does not have procedures specific to reporting and addressing potential political interference in scientific decision-making. FDA officials told us such issues would be routed through the agency's scientific dispute resolution procedure. However, this procedure does not reference political interference in scientific

decision-making.¹⁹ According to FDA officials, the scientific dispute resolution procedure would address any underlying scientific disagreements, and potential political interference in scientific decision-making would be referred to the HHS Office of Inspector General (OIG).²⁰

- **NIH** officials stated that potential political interference in scientific decision-making could be reported to NIH's Division of Program Integrity in the Office of Management Assessment, which is responsible for receiving allegations and investigating employee misconduct. However, NIH officials also told us the Division of Program Integrity does not have a definition of political interference in scientific decision-making and does not track political interference in scientific decision-making separately from other types of misconduct allegations, such as misuse of grant or contract funds. Additionally, NIH's scientific integrity policy does not identify reporting allegations of political interference in scientific decision-making to the Division of Program Integrity as the intended procedure for handling such issues.
- **ASPR** officials stated that ASPR follows HHS's scientific integrity policy. However, HHS does not have documented procedures for reporting and addressing political interference in scientific decision-making.

In addition to internal agency scientific integrity procedures, HHS agency employees may also file external complaints through various means, such as:

- **HHS OIG.** HHS OIG officials told us that employees could report potential political interference in scientific decision-making by filing a complaint with HHS OIG. An HHS OIG official stated that HHS OIG believes allegations of political interference in scientific decision-making are rare in the context of the tens of thousands of allegations that HHS OIG receives each year, and most of the allegations of political interference come from external stakeholders, such as members of Congress. For example, an HHS OIG official stated that, over the past two years, HHS OIG received seven requests from

¹⁹Scientific disputes are disputes involving the interpretation of science and decisions taken upon that interpretation. FDA's scientific dispute resolution procedure is one of FDA's mechanisms for preserving and protecting the agency's scientific integrity.

²⁰HHS OIG conducts investigations relating to fraud, waste, abuse, or other misconduct in connection with the programs and operations of HHS.

Congress to examine issues that may relate to potential political interference in scientific decision-making. In addition to these requests from Congress, HHS OIG officials told us that, based on the institutional memory of current HHS OIG staff, they estimate that HHS OIG received fewer than ten other allegations related to potential political interference in scientific decision-making from other sources, including from HHS employees.²¹ HHS OIG officials said they received some of these other allegations more recently (6 to 18 months ago), while they received others approximately 30 years ago.

- **Office of Special Counsel (OSC).** OSC investigates whistleblower complaints and reprisals for whistleblowing in the federal government, including complaints involving potential political interference in scientific decision-making under certain circumstances.²² For example, a senior ASPR official filed a whistleblower retaliation complaint with OSC in May 2020. According to OSC, this senior official alleged HHS retaliated against the official for disclosing, among other things, concerns about inappropriate political interference to make chloroquine and hydroxychloroquine available to the public as treatments for COVID-19.

Respondents from CDC, FDA, and NIH Observed but Did Not Report Potential Political Interference in Scientific Decision-Making

Agency officials did not identify any formally reported internal allegations of political interference in scientific decision-making from 2010 to 2021, but respondents from CDC, FDA, and NIH we interviewed told us they observed but did not report such issues.²³ The respondents did not report their observations to any agency or external officials for various reasons, including:

²¹HHS OIG officials further stated that HHS OIG does not track whether allegations involve potential political interference in scientific decision-making.

²²OSC is an independent federal investigative and prosecutorial agency whose primary mission is to safeguard the merit system in federal employment by protecting employees and applicants for federal employment from prohibited personnel practices, including reprisal for whistleblowing. OSC also reviews disclosures of wrongdoing within the federal government made by current and former federal employees, and applicants for federal employment in the executive branch that the individual reasonably believes evidences (1) a violations of law, rule, or regulation; (2) gross mismanagement; (3) a gross waste of funds; (4) an abuse of authority; (5) a substantial and specific danger to public health or safety; or (6) censorship related to research, analysis, or technical information. When OSC receives a disclosure of wrongdoing, OSC reviews the information, and may, depending on its review of the information, refer information to the agency head for investigation. If referred to the agency head, the agency must investigate the allegations and submit a report to OSC on the agency's findings.

²³We did not independently verify the events described by these respondents, and we are not making any determinations regarding whether political interference occurred.

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- **Fearing retaliation.** Respondents from CDC and FDA told us they did not report potential political interference in scientific decision-making because they feared retaliation.
 - **Being unsure how to report issues.** Respondents from CDC and FDA stated they were not sure how to report the potential political interference in scientific decision-making they observed. For example, a CDC respondent told us they were not aware of any existing internal procedures that could be used to report potential political interference in scientific decision-making.
 - **Believing agency leaders were already aware.** Respondents from CDC, FDA, and NIH stated they did not report potential political interference in scientific decision-making because they thought leadership was already aware of the issue.

A few respondents from CDC and FDA stated they felt that the potential political interference they observed resulted in the alteration or suppression of scientific findings. Some of these respondents believed that this potential political interference may have resulted in the politically motivated alteration of public health guidance or delayed publication of COVID-19-related scientific findings.

The 2009 presidential memorandum on scientific integrity includes a principle that agencies should have procedures to identify and address instances in which the scientific process or the integrity of scientific and technological information may be compromised.²⁴ Political interference in scientific decision-making is one way that such information may become compromised. Further, according to the *Standards for Internal Control in the Federal Government*, agency management should clearly document internal controls in management directives, administrative policies, or operating manuals.²⁵ In the context of this report, this would include documenting procedures for reporting and addressing potential political interference in scientific decision-making.

²⁴The White House, *Memorandum for the Heads of Executive Departments and Agencies, Scientific Integrity* (March 2009). The 2009 presidential memorandum directs the Director of OSTP to develop recommendations for presidential action designed to guarantee scientific integrity throughout the executive branch, based on a number of principles, including that agencies should have procedures to identify and address instances in which the scientific process or the integrity of scientific and technological information may be compromised.

²⁵GAO, *Standards for Internal Control in the Federal Government*, [GAO-14-704G](#) (Washington, D.C.: September 2014).

None of the agencies in our review—CDC, FDA, NIH, and ASPR—have developed procedures specific to reporting and addressing potential political interference in scientific decision-making. Officials at CDC and FDA told us that there was not a specific reason why CDC and FDA lack such procedures and that the agencies did not intentionally omit this information from their existing policies and procedures. Officials from CDC and FDA acknowledged the need to strengthen agency procedures for reporting and addressing potential political interference in scientific decision-making. FDA officials told us the agency is planning to develop new procedures for reporting and addressing political interference in scientific decision-making.

NIH officials stated their existing procedures do not address political interference in scientific decision-making because NIH has not experienced political interference. However, one respondent from NIH we interviewed described observing an instance of potential political interference in scientific decision-making but did not report it for a number of reasons, including believing that agency leadership was already aware of the issue.

ASPR officials told us the agency does not have procedures for reporting and addressing political interference in scientific decision-making because it follows the HHS scientific integrity policy. However, HHS officials told us that the department does not have procedures for reporting and addressing potential political interference in scientific decision-making because it relies on its staff and operating divisions to report and address such issues.

Agencies' reliance on reporting and addressing potential political interference internally on a case-by-case basis or through existing internal scientific integrity procedures intended for other purposes may have led to an underreporting of political interference in scientific decision-making. This practice also provides less assurance that the agency scientific integrity policies are protecting against losses of scientific integrity than well-defined internal reporting procedures would provide. Without procedures for reporting and addressing potential political interference in scientific decision-making, including a definition of political interference in scientific decision-making, the selected agencies will not be able to ensure that (1) employees and contractors have a clear understanding of how to identify and report potential instances of political interference in scientific decision-making, (2) potential instances of political interference in scientific decision-making are investigated consistently, or (3)

confirmed instances are appropriately addressed.²⁶ In addition, to help reduce employees' fear of retaliation and encourage appropriate reporting, agencies could include in their procedures information on applicable whistleblower protections, and clarify any reporting requirements for employees who believe they observed potential political interference in scientific decision-making.²⁷

By developing such procedures, the agencies would also be better positioned to address the 2021 presidential memorandum, which directs agency heads to establish and publish, as appropriate and consistent with applicable law, procedures for reporting and addressing alleged violations of the agency's scientific integrity policy.²⁸

Agencies' Trainings Cover Aspects of Scientific Integrity, but Only NIH's Training Addresses Political Interference

All four selected agencies—CDC, FDA, NIH, and ASPR—train staff on some scientific-integrity-related topics. However, only NIH includes information on political interference in scientific decision-making as part of its scientific integrity training. While the NIH training materials do not define political interference, they state that employees can report allegations if they have concerns about possible political interference in scientific decision-making. However, this information is not specified in NIH's scientific integrity policy. More specifically for each agency:

- **NIH** developed training for staff on its scientific integrity policy, which addresses political interference in scientific decision-making.

²⁶We have previously reported that documenting procedures for addressing scientific integrity policy violations will help ensure that all staff have a clear understanding of how to report allegations and that investigations will be conducted consistently. See GAO, *Scientific Integrity Policies: Additional Actions Could Strengthen Integrity of Federal Research*, [GAO-19-265](#) (Washington, D.C.: April 2019).

²⁷Statutory provisions provide federal employee whistleblowers with protections, including from adverse personnel actions taken in response to a disclosure protected by law, as well as remedies for such prohibited personnel actions. See 5 U.S.C. § 2302 (a)(2), (b)(8), (b)(9)(A)(i), 5 U.S.C. § 2302 note. Whistleblowers have many options on where to go to disclose wrongdoing, including but not limited to an Inspector General, OSC, a supervisor or someone higher up in management, or a member of Congress or congressional committee. However, to be protected from adverse personnel actions, disclosures involving information that is classified or otherwise protected from public release must be limited to confidential channels, such as Inspectors General, OSC, or Congress.

²⁸The White House, *Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking* (January 2021). Agency implementation of the 2021 presidential memorandum was ongoing during our review. Additionally, the interagency task force's 2022 report states that agencies need robust procedures for detecting, adjudicating, and remedying alleged violations of scientific integrity.

Specifically, certain new employees, such as intramural trainees, learn within the first year of arrival that they can contact NIH's Division of Program Integrity if they perceive that a decision is influenced by political interference. According to NIH officials, employees can report any allegation of misconduct to the Division of Program Integrity, including potential political interference in scientific decision-making. However, as discussed earlier in this report, the Division of Program Integrity does not define or track political interference in scientific decision-making, and NIH's scientific integrity policy does not identify reporting allegations to the Division of Program Integrity as the intended procedure for addressing political interference. Multiple NIH respondents from our interviews said they would reference the training materials if they were to encounter potential political interference.²⁹

- **CDC** trains staff on some aspects of its scientific integrity policy, including public health ethics, but the training does not address political interference or include information on how to report such allegations. CDC's scientific integrity training is required once every 3 years for staff involved in scientific research and non-research activities.
- **FDA** trains staff annually on ethics, and its centers train staff on the scientific dispute resolution process during center-specific new employee orientations.³⁰ However, these trainings do not address political interference or include information on how to report allegations of potential political interference in scientific decision-making.
- **ASPR** trains staff on some topics included in the HHS scientific integrity policy, such as peer review and its processes for reviewing and approving information released to the public through annual seminars. However, ASPR does not provide training on how to report allegations of political interference in scientific decision-making.

Agency officials at CDC, FDA, and ASPR told us that their agencies' scientific-integrity-related trainings do not address political interference or

²⁹By "multiple" we mean at least two respondents from each agency referenced in the statement.

³⁰FDA has six product-based centers, among them the Center for Drug Evaluation and Research, which regulates over-the-counter and prescription drugs, including some biological therapeutics and generic drugs.

include information on how to report allegations of political interference in scientific decision-making for the following reasons:

- **CDC** has not defined political interference and does not have a formal process to address allegations of political interference. Multiple CDC respondents recommended that CDC implement additional training on scientific integrity, including training on how to report allegations of political interference. CDC officials agreed that including information on political interference could help strengthen the agency's scientific integrity training. In December 2021, CDC officials stated that the agency plans to align its scientific integrity trainings with any recommendations made by OSTP's interagency task force.³¹
- **FDA** officials told us that FDA does not train staff on how to report potential political interference because FDA did not receive any formally reported instances of potential political interference in the period between 2010 through 2021. One FDA respondent recommended that FDA implement training on political interference in scientific decision-making. The then Acting FDA Commissioner acknowledged that training on political interference in scientific decision-making could help support scientific integrity at FDA.
- **ASPR** is a staff division that relies on HHS to develop scientific integrity training, according to ASPR officials. However, according to HHS officials, the department does not provide department-wide scientific integrity training. Accordingly, there is no training—either at the department level or within ASPR—for reporting and addressing political interference in scientific decision-making that ASPR provides to its employees.

Standards for Internal Control in the Federal Government states that management should internally communicate quality information to allow staff to perform key roles in achieving objectives and addressing risks.³² For example, training is one way the four agencies can communicate their scientific integrity policies and related procedures to staff and contractors. Respondents from CDC and FDA told us they were not sure how to report

³¹The interagency task force's 2022 report identified good practices for agencies to consider to improve training in scientific integrity, including mandated and repeated scientific integrity training for everyone at an agency who plays a role in scientific decision-making. According to the report, the interagency task force will also develop a framework to support regular assessment and iterative improvement of agency scientific integrity policies.

³²[GAO-14-704G](#).

the potential political interference in scientific decision-making they observed.

Providing agency employees and contractors involved in scientific decision-making with training on how to perform their key roles, including how to recognize and report political interference allegations, would better position the four agencies to ensure that employees and contractors understand how to report such issues. The agencies would also be better positioned to address the 2021 presidential memorandum, which states that agencies must routinely educate their employees and contractors on their rights and responsibilities related to scientific integrity.³³

Conclusions

Ensuring sound scientific decision-making is vital to supporting sustained advances in the nation's public health security, especially during a global health emergency. HHS agencies that have led the public health response to the COVID-19 pandemic regularly make scientific decisions that have broad public health consequences. To maintain public trust and credibility, these agencies need to ensure that these decisions are evidence-based and free from political interference.

The agencies included in our review have taken some steps toward ensuring scientific integrity and insulating their staff and decision-making from political interference, such as developing policies and training staff on some scientific integrity-related topics. However, none of the four agencies included in this report has well-defined procedures for reporting or addressing political interference in scientific decision-making. Developing such procedures could strengthen HHS's desired goal of sustaining a culture of scientific integrity by ensuring that employees know how to report allegations, and that agencies have a clear, consistent process for investigating and addressing such allegations.

Providing clear employee training on political interference and how to address it could also better promote scientific integrity. For example, NIH training for new employees refers to an agency division where employees can report potential political interference. However, that division does not define or track political interference. Training offered by the other three agencies—CDC, FDA, and ASPR—does not address political

³³During our review, agency implementation of the January 2021 presidential memorandum was ongoing. Additionally, the interagency task force's 2022 report states that scientific integrity training reinforces agency culture by helping employees understand relevant policies, providing a common language for communicating about scientific integrity, and delineating specific roles and responsibilities.

interference in scientific decision-making at all. Ensuring that agency employees and contractors involved in scientific activities are trained on policies related to potential political interference in scientific decision-making, including how to report allegations, could help to ensure that agencies have the information, understanding, and procedures they need to help maintain their scientific integrity objectives.

Recommendations for Executive Action

We are making seven recommendations to CDC, FDA, NIH, and HHS. Specifically:

The CDC Director 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. (Recommendation 1)

The CDC Director should ensure that CDC employees and contractors performing scientific activities are trained on how to report allegations of political interference in scientific decision-making. (Recommendation 2)

The FDA Commissioner 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. (Recommendation 3)

The FDA Commissioner should ensure that FDA employees and contractors performing scientific activities are trained on how to report allegations of political interference in scientific decision-making. (Recommendation 4)

The NIH Director 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, and that its scientific integrity trainings on these procedures are updated. (Recommendation 5)

The Secretary of Health and Human Services should ensure that procedures for reporting and addressing potential political interference in scientific decision-making are documented, including adding a definition of political interference, and that the procedures are communicated to the Assistant Secretary for Preparedness and Response. (Recommendation 6)

The Secretary of Health and Human Services, in coordination with the Assistant Secretary for Preparedness and Response, should ensure that ASPR employees and contractors performing scientific activities are trained on how to report allegations of political interference in scientific decision-making. (Recommendation 7)

Agency Comments

We provided a draft of this report to HHS, CDC, FDA, NIH, and ASPR for review and comment. In its written comments, reproduced in appendix II, HHS concurred with our recommendations. In response to the 2021 presidential memorandum, HHS stated that it formed a working group—which includes members from relevant HHS agencies—to develop updates to HHS’s scientific integrity policy. HHS stated it intends to complete and submit its updated policy to OSTP by July 2022.³⁴ HHS also provided technical comments, which we incorporated as appropriate.

We are sending copies of this report to the Secretary of Health and Human Services, the CDC Director, the FDA Commissioner, the NIH Director, and the Assistant Secretary for Preparedness and Response. In addition, the report is available at no charge on the GAO website at <https://www.gao.gov>.

If you or your staff have any questions about this report, please contact me at (202) 512-6888 or WrightC@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix III.



Candice N. Wright
Director
Science, Technology Assessment, and Analytics

³⁴The 2021 presidential memorandum directs heads of agencies to submit either updated policies for those agencies with an existing scientific integrity policy, or draft scientific integrity policies for those agencies without an existing policy to the Director of OSTP within 180 days of the publication of the task force’s report.

List of Addressees

The Honorable Patrick Leahy
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The Honorable Richard Shelby
Vice Chairman
Committee on Appropriations
United States Senate

The Honorable Ron Wyden
Chairman
The Honorable Mike Crapo
Ranking Member
Committee on Finance
United States Senate

The Honorable Patty Murray
Chair
The Honorable Richard Burr
Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate

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United States Senate

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Committee on Ways and Means
House of Representatives

The Honorable James E. Clyburn
Chairman
Select Subcommittee on the Coronavirus Crisis
Committee on Oversight and Reform
House of Representatives

The Honorable Elizabeth Warren
United States Senate

The Honorable Paul D. Tonko
House of Representatives

Appendix I: Scope and Methodology

This report examines (1) the procedures in place at the selected Department of Health and Human Services (HHS) agencies to address allegations of political interference in scientific decision-making and the extent to which agencies received such allegations and (2) available training provided by selected agencies on scientific integrity policies and procedures, including those related to political interference.¹

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, are not inappropriately influenced by political considerations, and are shared openly and transparently with the public, when appropriate. We developed this definition based on our review of the principles contained in the 2009 presidential memorandum on scientific integrity and the 2010 Office of Science and Technology Policy (OSTP) memorandum.² The term “political interference” refers to political influences that seek to undermine impartiality, nonpartisanship, and professional judgment. We adapted this definition from a 2017 report by the National Academies of Sciences, Engineering, and Medicine, which states that undue external influences are those from outside the agency that seek to undermine its impartiality, nonpartisanship, and professional judgment.³ Our definition of political interference reflects that interference may also come from within an agency. While the term political interference is broad in nature, our report focuses on political interference in scientific decision-making at the selected HHS agencies.

For both objectives, we selected for our review four agencies with key roles in conducting and supporting scientific research, communicating information to the public, and leading other aspects of the public health response to the COVID-19 pandemic: the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the National Institutes of Health (NIH), and the Office of the Assistant

¹We plan to issue an additional report that will examine the key characteristics that can insulate agencies from political interference, and how, if at all, the selected HHS agencies have experienced potential political interference while carrying out their missions.

²The White House, Office of the Press Secretary, Scientific Integrity, *Memorandum for the Heads of Executive Departments and Agencies* (Washington, D.C.: Mar. 9, 2009), and Office of Science and Technology Policy, Scientific Integrity, *Memorandum for the Heads of Executive Departments and Agencies* (Dec. 17, 2010).

³See National Academies of Sciences, Engineering, and Medicine, *Principles and Practices for a Federal Statistical Agency: Sixth Edition*. (Washington, D.C.: 2017).

Secretary for Preparedness and Response (ASPR).⁴ The news media reported allegations of scientific integrity violations or allegations of political interference in scientific decision-making related to the COVID-19 pandemic response at all four agencies.⁵ Our selection includes all three of the agencies within HHS that have developed their own scientific integrity policies.

To enrich our understanding of these topics, we met with former agency heads and external organizations to discuss their perceptions of scientific-integrity-related topics, including political interference, at the selected agencies. Our selection of former agency heads from different administrations included two former CDC directors, three former FDA commissioners, the then-current FDA Acting Commissioner, two former NIH directors, one former Assistant Secretary for Preparedness and Response, and one former director of the Biomedical Advanced Research and Development Agency. We also met with representatives from the Brennan Center for Justice and the Union of Concerned Scientists and reviewed reports on scientific integrity that those organizations issued. Additionally, we met with Office of Science and Technology Policy (OSTP) officials to discuss their interagency review on scientific integrity and reviewed the associated report.⁶

We reviewed HHS's scientific integrity policy and agency-specific scientific integrity policies.⁷ We compared these policies with the 2009

⁴HHS's operating divisions—including CDC, FDA, and NIH—are responsible for administering a wide variety of health and human services, including research. HHS's staff divisions—including ASPR—are responsible for providing leadership, direction, and policy and management guidance to HHS. For the purposes of this report, HHS's operating and staff divisions are referred to as agencies.

⁵See, for example: Rich Mendez, "Trump officials bragged about pressuring CDC to alter Covid reports, emails reveal," *CNBC*, April 9, 2021; Katie Thomas and Sheri Fink, "F.D.A. 'Grossly Misrepresented' Blood Plasma Data, Scientists Say," *The New York Times*, August 24, 2020; Jon Cohen and Meredith Wadman, "NIH's axing of bat coronavirus grant a 'horrible precedent' and might break rules, critics say," *Science*, April 30, 2020; Nicholas Florco, "An ousted vaccine agency director offers an explosive, direct allegation: Trump is politicizing science," *STAT*, April 22, 2020.

⁶Scientific Integrity Fast-Track Action Committee of the National Science and Technology Council, *Protecting the integrity of Government Science*, (January 2022).

⁷HHS, *Policies and Principles for Assuring Scientific Integrity*, (March 2012). CDC, *CDC Guidance on Scientific Integrity*, (April 2016). FDA, *Scientific Integrity at FDA*, Staff Manual Guide 9001.1, (February 2012). NIH, *NIH Policies and Procedures for Promoting Scientific Integrity*, (November 2012).

presidential and 2010 OSTP memorandums on scientific integrity. Specifically, we identified six principles from the 2009 memorandum and 17 principles from the 2010 memorandum and compared these principles with HHS's scientific integrity policy and agency-specific scientific integrity policies. We discussed the agency-specific scientific integrity policies with agency officials, asked clarifying questions, and reviewed their written responses.

We conducted semi-structured interviews with 16 employees, which included managers and non-managers at three of the four selected agencies—CDC, FDA, and NIH.⁸ 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 interference, their familiarity or experience with potential scientific integrity policy violations, and their familiarity or experience with their agency's scientific integrity trainings. We used a nongeneralizable stratified purposeful sampling approach to select participants. We selected two participants (one manager and one non-manager) from each of our nine strata, which we developed by identifying three subcomponents—such as centers, institutes, or offices—within each agency with a mission relevant to COVID-19 research and response.⁹

Additionally, we selected some but not all of our subcomponents because they were allegedly affected by political interference during the COVID-19 pandemic.¹⁰ The nine selected subcomponents are: (1) CDC's National

⁸ASPR was excluded from this methodology because it follows HHS's Policies and Principles for Assuring Scientific Integrity and does not have its own scientific integrity policy principles and procedures. A semi-structured interview methodology generally involves asking a similar subset of questions of multiple interviewees, which enable summaries of responses across interviewees. "Managers" include senior management at the subcomponent, typically a branch chief or director. "Non-managers" include all personnel in a subcomponent that are directly involved in carrying out the scientific mission of the subcomponent, including employees with supervisory experience and employees with non-supervisory experience.

⁹Participation in the semi-structured interviews was voluntary. Some employees at CDC, FDA, and NIH declined to participate in the interviews. In such cases, we selected a new potential participant. We intended to conduct a total of 18 interviews, however, none of the employees we contacted from FDA's Center for Biologics Evaluation and Research accepted our invitation to participate in a semi-structured interview, bringing our total to 16 interviews.

¹⁰For the purposes of developing our strata, we determined that a subcomponent was affected by alleged political interference if there were external reports from, among others, media organizations, former HHS officials, or public interest organizations alleging political interference in scientific decision-making.

Center for Infectious Respiratory Diseases; (2) CDC's Center for Surveillance, Epidemiology, and Laboratory Services; (3) CDC's Maritime Unit; (4) FDA's Center for Biologics Evaluation and Research; (5) FDA's Center for Drug Evaluation and Research; (6) FDA's Center for Devices and Radiological Health; (7) NIH's National Heart, Lung, and Blood Institute; (8) NIH's National Institute for Allergies and Infectious Diseases; and (9) NIH's National Institute for Biomedical Imaging and Bioengineering.

To build our sampling frame for selection, we used publicly available lists of agency employees, which included managers and non-managers. For one of our strata, we built our sampling frame using a list of employees, which included managers and non-managers provided to us by CDC officials. We then worked with each agency to schedule semi-structured interviews with each of the 16 participants who accepted our invitation to be interviewed. At the request of HHS, we conducted the semi-structured interviews with an agency liaison present unless the participant requested that the liaison not attend.¹¹ These agency liaisons did not actively participate in any substantive part of the discussions. Our results from these interviews represent the views of the employees who participated and are not generalizable to any other employees, even within our selected strata.

We also developed a confidential hotline—consisting of both an email account and voicemail inbox—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 provided information on how to contact us through the confidential hotline to the selected agencies, who then distributed it to three subcomponents per agency at CDC, FDA, and NIH, as well as one subcomponent at ASPR—the Biomedical and Advanced Research and Development Authority. We selected these subcomponents based on their missions' relevance to COVID-19 research and response, proximity

¹¹An FDA official from FDA's Office of the Chief Counsel also attended multiple FDA interviews at the request of the interview participants. This official did not actively participate in any substantive part of the discussions.

to alleged political interference in scientific decision-making, and consultations with agency officials.¹²

Additionally, we provided information on how to contact us through the confidential hotline to each of the 16 semi-structured interview participants to give them the opportunity to provide us with additional information. We then reviewed the submissions and followed up with selected employees, as appropriate. We did not follow up on all such submissions, but we prioritized submissions deemed most pertinent to our review. When reporting our results, we use “respondent” to refer to an employee we interviewed as part of our semi-structured interview and confidential hotline methodologies. By “multiple” we mean at least two respondents from each agency referenced in the statement.

To determine the extent to which the selected agencies received allegations or identified instances of political interference that compromised scientific decision-making, we conducted interviews with agency officials and collected information on allegations of political interference in scientific decision-making. Specifically, we interviewed agency officials with knowledge of the selected agencies’ procedures for reporting, addressing, and tracking potential political interference in scientific decision-making, as well as officials from HHS’s Office of Inspector General (OIG). We also obtained written responses to questions from the Office of Government Ethics (OGE) and the Office of Special Counsel (OSC).¹³ Additionally, through our semi-structured interview and hotline methodologies, we collected employee perspectives on their agencies’ implementation of scientific integrity policies and their experiences with instances of potential political interference.

We requested agency data from our selected agencies from 2010-2021 on internal allegations of political interference in scientific decision-making but did not receive data because the agencies told us they did not receive any such allegations during that time period. We spoke with knowledgeable agency officials about the lack of allegations. Additionally,

¹²The same CDC, FDA, and NIH subcomponents were selected for both the semi-structured interview and hotline methodologies.

¹³OGE leads and oversees the executive branch ethics program which works to prevent financial conflicts of interest to help ensure government decisions are made free from personal financial bias. OSC is an independent federal investigative and prosecutorial agency whose primary mission is to safeguard the merit system by protecting federal employees and applicants from prohibited personnel practices, especially reprisal for whistleblowing.

we requested data on the number of allegations of political interference in scientific decision-making at HHS for the period 2010 through 2021 from OGE, HHS OIG, and OSC. OGE did not identify any relevant allegations. HHS OIG and OSC identified related allegations.

To determine the procedures the selected agencies established for addressing alleged violations of their scientific integrity policies, including those involving political interference, we reviewed written policies and procedures for each agency. We specifically reviewed procedures for addressing research misconduct, scientific disputes, and employee misconduct. FDA relies on its centers to develop their own complementary scientific dispute resolution procedures.¹⁴ We reviewed a selection of these center scientific dispute resolution procedures from the same centers selected for our semi-structured interviews: the Center for Biologics Evaluation and Research, the Center for Drug Evaluation and Research, and the Center for Devices and Radiological Health. We compared these procedures to federal guidance and federal standards for internal control. Specifically, we compared the agencies' procedures to the 2009 presidential memorandum on scientific integrity, which includes a principle that agencies should have in place procedures to identify and address instances in which the scientific process or the integrity of scientific and technological information may be compromised.¹⁵

We also compared the agencies' procedures against the *Standards for Internal Control in the Federal Government*, which states that management should design control activities to achieve objectives and respond to risks, which include clearly documenting internal controls in management directives, administrative policies, or operating manuals.¹⁶ Additionally, we interviewed agency officials with knowledge of the selected agencies' procedures for addressing alleged violations, and we collected employee perspectives on the strengths and weaknesses of

¹⁴FDA has six product-based centers, among them the Center for Drug Evaluation and Research, which regulates over-the-counter and prescription drugs, including some biological therapeutics and generic drugs.

¹⁵The White House, Office of the Press Secretary, *Scientific Integrity, Memorandum for the Heads of Executive Departments and Agencies* (Washington, D.C.: Mar. 9, 2009). The 2009 presidential memorandum directs the Director of OSTP to develop recommendations for presidential action designed to guarantee scientific integrity throughout the executive branch, based on a number of principles, including that agencies should have procedures to identify and address instances in which the scientific process or the integrity of scientific and technological information may be compromised.

¹⁶[GAO-14-704G](#).

agency procedures through the semi-structured interview and hotline methodologies.

To determine the steps the selected agencies have taken to train staff on their scientific integrity policies and procedures, including political interference, we requested and reviewed scientific integrity training documentation for each agency. We specifically reviewed trainings for educating staff on the agency's scientific integrity policy and how to report potential political interference. FDA allows its centers to develop their own scientific integrity trainings, in addition to agency-level training. We reviewed center-level trainings from the centers we selected for our semi-structured interviews, including FDA's Center for Biologics Evaluation and Research, Center for Drug Evaluation and Research, and Center for Devices and Radiological Health. We compared these scientific integrity trainings against the *Standards for Internal Control in the Federal Government*, which states that management should internally communicate the necessary quality information to achieve the entity's objectives.¹⁷ Additionally, we collected employee perspectives on the scientific integrity training they received at each agency through the semi-structured interviews.

We conducted this performance audit from October 2020 to April 2022 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.

¹⁷[GAO-14-704G](#).

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

March 24, 2022

Candice N. Wright
Director, Science, Technology Assessments, and Analytics
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Ms. Wright:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, "***Scientific Integrity: HHS Agencies Need to Develop Procedures and Train Staff on Reporting and Addressing Political Interference***" (Job code 104613/GAO-22-104613).

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 — SCIENTIFIC INTEGRITY: HHS AGENCIES NEED TO DEVELOP
PROCEDURES AND TRAIN STAFF ON REPORTING AND ADDRESSING POLITICAL
INTERFERENCE (GAO-22-104613)**

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

The development and use of scientific information are essential to the success of the HHS mission. HHS is taking a coordinated approach to enhance scientific integrity so that the ways that science is conducted, managed, communicated, and used is free from political interference.

HHS concurs with GAO's recommendations that it should ensure that procedures for reporting and addressing potential political interference in scientific decision-making are developed and documented. Further, HHS concurs with GAO's recommendations that employees and relevant contractors be trained on how to report allegations of inappropriate political interference in scientific decision-making. It is important to differentiate scientifically trained political officials engaging in the legitimate conduct, management, communication, and use of science from political officials inappropriately breaching scientific integrity because of political motivations. Science plays a vital role in HHS's mission and is critical to decision-making, informing the ways in which HHS conducts and supports scientific research, communicates scientific information to the public, evaluates the safety and efficacy of medical products, and leads aspects of the public health response to the COVID-19 pandemic and other public health threats. It is of the utmost importance to HHS that the scientific information considered in HHS decision-making is robust, of the highest quality, trustworthy, and the result of as rigorous a set of scientific processes as can be achieved.

HHS Operating Divisions (OpDivs) and Staff Divisions (StaffDivs) support a culture of scientific integrity. HHS ensures objectivity, clarity, reproducibility, and utility of scientific activities and assessments. HHS pursues this effort through a federated approach, with an HHS-wide statement of Policies and Principles for Assuring Scientific Integrity (the Policy) as well as policies and procedures that are specific to relevant OpDivs. Bias, fabrication, falsification, plagiarism, outside interference, censorship, and inadequate procedural and information security are problematic irrespective of motivation, whether political or not.

Building on this foundation, HHS is actively working to implement the January 27, 2021, Presidential Memorandum on Restoring Trust in Government through Scientific Integrity and Evidence-based Policymaking. Pursuant to that memorandum, the National Science and Technology Council Scientific Integrity Fast-Track Action Committee (FTAC), which included several representatives from HHS, released a report entitled *Protecting the Integrity of Government Science* in January 2022. This report reviewed agency scientific integrity policies; considered whether they prevent political interference in the conduct, management, communication, and use of science; and identified effective practices for improving implementation of these policies. In response to the Presidential Memorandum, HHS formed a working group including representatives from relevant OpDivs and StaffDivs. This working group is developing updates to the HHS Policy to comply with the requirements of the

Page 1 of 2

**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 — SCIENTIFIC INTEGRITY: HHS AGENCIES NEED TO DEVELOP
PROCEDURES AND TRAIN STAFF ON REPORTING AND ADDRESSING POLITICAL
INTERFERENCE (GAO-22-104613)**

Presidential Memorandum. Many of these working group members are also actively engaged in updating the relevant policies and procedures at their own OpDivs. HHS expects that an updated Policy will be complete and submitted to the White House Office of Science and Technology Policy (OSTP) by the deadline in July, in compliance with the Presidential Memorandum. HHS continues to be engaged with the interagency Task Force as it develops a framework for implementing the FTAC's recommendations. HHS's updates to its Department-wide Policy will comply with requirements included in both the January 2022 FTAC report and the forthcoming framework report. Further, HHS intends to evaluate the implications of implementing GAO's recommendations on our stakeholder communities. Therefore, HHS will provide an action plan to address the seven recommendations in our 180-day letter response to Congress.

Appendix III: GAO Contact and Staff Acknowledgements

GAO contact

Candice N. Wright at (202) 512-6888 or WrightC@gao.gov

Staff Acknowledgements

In addition to the contact named above, Rob Marek (Assistant Director), Douglas G. Hunker (Analyst-in-Charge), Anna Beischer, Adam Brooks, Jenny Chanley, Amanda Cherrin, Joycelyn Cudjoe, Kaitlin Farquharson, Louise Fickel, Cynthia Khan, Amelia Koby, Priyanka Panjwani, Amy Pereira, Eric Peterson, Corinne Quinones, Caylin Rathburn-Smith, Ray Sendejas, and Sharon Silas made key contributions to this report.

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