



Testimony

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on the Coronavirus Crisis,
Committee on Oversight and Reform,
House of Representatives

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SCIENTIFIC INTEGRITY

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

Statement of Gene L. Dodaro,
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Chairman Clyburn, Ranking Member Scalise, and Members of the Subcommittee:

I am pleased to be here today to discuss our April 2022 report on scientific integrity procedures and training at selected Department of Health and Human Services' (HHS) agencies.¹ To maintain public trust and credibility, safeguarding our nation's public health agencies' scientific decision-making from political interference is critically important. This is particularly true during a public health emergency such as the COVID-19 pandemic.

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.

In 2019, we issued a report that broadly examined scientific integrity policies at nine agencies across the government.² We made 10 recommendations to six agencies. They addressed specific issues related to educating staff, providing oversight, monitoring and evaluating scientific integrity policy implementation, and developing procedures to identify and address policy violations.³ The six agencies agreed with our recommendations. They are at various stages of implementing them, but much work remains to be done to assure the public of the integrity of federally funded science that informs policy decisions.

Last week, we issued our first of two planned reports on scientific integrity at four agencies and offices within HHS. They 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 four agencies are the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the National

¹GAO, *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).

²GAO, *Scientific Integrity Policies: Additional Actions Could Strengthen Integrity of Federal Research*, [GAO-19-265](#) (Washington D.C.: April 2019).

³For example, we recommended that agencies educate and communicate their scientific integrity policies to staff and to develop documented procedures for identifying and addressing alleged violations of these policies. See [GAO-19-265](#) for more detail.

Institutes of Health (NIH), and the Office of the Assistant Secretary for Preparedness and Response (ASPR).⁴

My comments today will summarize the key findings from this report.⁵ Specifically, I will discuss:

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. training provided by the selected agencies on scientific integrity policies and procedures, including those related to potential political interference.

For the purposes of our report, we use the term “scientific integrity” to refer 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 existing scientific integrity guidance for agencies. 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.⁶ While the term political interference is broad in nature, our report focuses on

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 testimony, HHS’s operating and staff divisions are referred to as agencies.

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

⁶See 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).

political interference in scientific decision-making at the selected HHS agencies. Political interference in scientific decision-making is one way that scientific integrity can be compromised.

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

In 2021, a presidential memorandum reaffirmed and built upon earlier scientific integrity guidance, and, among other things, specified that scientific findings should never be distorted or influenced by political considerations.⁸ The 2021 presidential memorandum also included a requirement for the Office of Science and Technology Policy (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. The task force issued its report in January 2022, and heads of agencies are to ensure that their scientific integrity policies reflect the report's findings.⁹ 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 iterative improvement of agency scientific integrity policies.

For our report, 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,

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).

⁸The White House, *Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking* (January 27, 2021).

⁹Scientific Integrity Fast-Track Action Committee of the National Science and Technology Council, *Protecting the integrity of Government Science*, (January 2022).

and discussed these with agency officials.¹⁰ We also conducted interviews with a total of 16 employees, which included both managers and non-managers, at three of the four selected agencies—CDC, FDA, and NIH. In addition, we 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. More detailed information on our objectives, scope, and methodology for that work can be found in the issued report.

We conducted the work on which this statement is based 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.

HHS Scientific Integrity Procedures Did Not Specifically Address Political Interference, Which May Have Led to Underreporting

In our April 2022 report, we found that 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 offered various explanations for how their agencies would handle allegations:

- **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 told us that their scientific dispute resolution procedure would address any underlying scientific disagreements, and potential

¹⁰HHS issued a scientific integrity policy in 2012 that addresses the guidance specified in OSTP's 2010 scientific integrity memorandum. 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. 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. See HHS, *Policies and Principles for Assuring Scientific Integrity* (March 2012) and OSTP, *Scientific Integrity, Memorandum for the Heads of Executive Departments and Agencies* (Dec. 17, 2010).

political interference in scientific decision-making would be referred to the HHS Office of Inspector General (OIG).¹¹

- **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. This office 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 include a procedure for reporting allegations of political interference in scientific decision-making to the Division of Program Integrity.
- **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.¹²

Also agency officials did not identify any formally reported internal allegations of political interference in scientific decision-making from 2010 to 2021. However, respondents from CDC, FDA, and NIH told us they observed but did not report such issues.¹³ These respondents told us they did not report their observations to any agency or external officials for various reasons. These include fearing retaliation, being unsure how to report issues, and believing agency leaders were already aware of the potential political interference they observed.

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

¹¹Scientific 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

¹²In addition to internal agency scientific integrity procedures, HHS agency employees may also be able to file external complaints through various means, such as to HHS OIG or, in certain circumstances, the Office of Special Counsel (OSC).

¹³In this testimony, we use "respondents" to refer to at least one employee we interviewed as part of our semi-structured interview and confidential hotline methodologies from each agency referenced in the statement. We did not independently verify the events described by these respondents, and we are not making any determinations regarding whether political interference occurred.

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.

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 likely 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 what the addition of well-defined internal reporting procedures would provide.

We recommended that CDC, FDA, NIH, and HHS 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. HHS concurred with our recommendations. In addition, HHS stated that it formed a working group 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.

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

In our April 2022 report, we found that 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 training. In particular:

- **NIH** training materials state that employees can contact NIH's Division of Program Integrity to report allegations if they have concerns about possible political interference in scientific decision-making. However, 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.
- **CDC** trains staff on some aspects of its scientific integrity policy, including public health ethics.
- **FDA** trains staff annually on ethics, and its centers train staff on its process for resolving scientific disputes.
- **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.

Agency officials at CDC, FDA, and ASPR told us that their agencies' scientific-integrity-related trainings do not address political interference or include information on how to report allegations of political interference in scientific decision-making for various reasons:

- **CDC** has not defined political interference and does not have a formal process to address allegations of political interference.
- **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.
- **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.

We recommended that CDC, FDA, and HHS ensure that employees and contractors performing scientific activities are trained on how to report allegations of political interference in scientific decision-making. HHS concurred with our recommendations.

Chairman Clyburn, Ranking Member Scalise, and Members of the Subcommittee, this concludes my prepared statement. I would be pleased to respond to any questions that you may have at this time.

GAO Contact and Staff Acknowledgments

If you or your staff have any questions about this statement, please contact Candice N. Wright, Director, Science, Technology Assessment, and Analytics 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 statement. GAO staff who made key contributions to this testimony are Rob Marek (Assistant Director), Douglas G. Hunker (Analyst-in-Charge), Anna Beischer, Jenny Chanley, Louise Fickel, Amy Pereira, and Corinne Quinones. Additional staff who made contributions to our April 2022 report are identified in that report.

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