United States Government Accountability Office

Report to Congressional Addressees

December 2022

CARES ACT

Structural Characteristics That Can Help Insulate HHS Agencies against Potential Political Interference

GAO-23-105415

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GAO Highlights

Highlights of GAO-23-105415, a report to congressional addressees

Why GAO Did This Study

HHS agencies—including CDC, FDA, NIH, and ASPR—have been at the forefront of the federal government's response to the COVID-19 pandemic since the President declared it a national emergency on March 13, 2020. Recent reports from GAO and others have identified shortcomings in this response, including allegations of political interference.

This report examines the key characteristics that can help insulate agencies from political interference and describes the structural characteristics that the selected HHS agencies have in place.

GAO identified characteristics of agency insulation from political interference by reviewing scholarly literature, policy reviews, and other sources, and interviewing political science experts. GAO obtained perspectives about scientific integrity and political interference at the selected agencies and ideas for structural reforms by interviewing former and current agency officials.

This report presents GAO's findings on structural characteristics at selected HHS agencies. GAO continues to examine selected HHS agencies' experiences with political interference and any steps that could be taken to strengthen protections against such interference.

GAO provided a draft of this report to HHS for review. The agency provided written and technical comments on the draft, both of which we incorporated as appropriate.

View GAO-23-105415. For more information, contact Sharon M. Silas at 202-512-7114 or SilasS@GAO.gov

What GAO Found

The *Sourcebook of United States Executive Agencies* describes over 60 structural characteristics or features related to an agency's organization or design. These features can affect an agency's degree of autonomy from political influences and help insulate it from political interference. These characteristics include: 10 that describe general information about an agency (e.g., whether it is established in statute); 35 that relate to an agency's leadership structure and personnel (e.g., the number of political appointees serving); eight that insulate agency policy (e.g., whether it has self-funding authority); and 11 other key structural features of an agency (e.g., whether it has advisory committees established).

Selected Department of Health and Human Services (HHS) agencies—Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), National Institutes of Health (NIH), and Administration for Strategic Preparedness and Response (ASPR)—have several of these structural characteristics in place. For example:

- All four selected agencies have active advisory committees that advise on key areas of scientific decision-making, which can help insulate them from political interference by allowing the participation of external experts in agency decision-making.
- Three selected agencies—FDA, NIH, and ASPR—have leaders who are selected by the President and confirmed by the Senate, which can help protect against political interference. For example, it may be more politically difficult to remove Senate-confirmed agency heads, particularly those confirmed with bipartisan support.

However, the selected HHS agencies do not have many of the structural characteristics that can help insulate them from political interference compared to independent agencies, such as the Federal Reserve, because they are located in an executive department. For example, the selected agencies have few, if any, characteristics that can limit the President's influence over agency leaders and policy, such as limits on the retention of agency leaders.

In addition, all four selected HHS agencies each have between two and five political appointees serving in key senior leadership and policy positions, which can increase presidential control over agencies. Moreover, the number of political appointees at CDC, FDA, and ASPR has increased at least twofold from 2016 through 2020.

Multiple senior agency officials highlighted how the government-wide coordination required in response to an emergency like the COVID-19 pandemic can create more opportunity for potential political interference. Experts and former agency heads have identified structural reforms that may improve insulation of selected HHS agencies against political interference in future public health emergencies. These structural reform ideas include converting FDA into an independent agency; making the CDC director a Senate-confirmed position; and reducing the number of political appointees at the selected agencies.

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Abbreviations

ASPR	Administration for Strategic Preparedness and Response
CDC	Centers for Disease Control and Prevention
COVID-19	Coronavirus Disease 2019
FDA	Food and Drug Administration
HHS	Department of Health and Human Services
NIH	National Institutes of Health
OMB	Office of Management and Budget

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Congressional Addressees

Department of Health and Human Services (HHS) agencies—including the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the National Institutes of Health (NIH), and the Administration for Strategic Preparedness and Response (ASPR)—have been at the forefront of the federal government's response to the COVID-19 pandemic since the President declared it a national emergency on March 13, 2020.[1] Recent reports from GAO and others have identified shortcomings in this response, including allegations of political interference, or political involvement that sought to undermine an agency's impartiality, nonpartisanship, and professional judgment.[2]

In January 2022, we added HHS's leadership and coordination of public health emergencies, such as the COVID-19 pandemic, to our High Risk List after our prior work identified persistent deficiencies in HHS's

[1]On July 22, 2022, the Secretary of Health and Human Services removed the Office of the Assistant Secretary for Preparedness and Response from the HHS Office of the Secretary and created a new operating division in the department, to be known as the Administration for Strategic Preparedness and Response (ASPR). In this report, we refer to ASPR under the new organizational name and structure, though our review was conducted primarily when the previous organizational structure was in place.

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

Midway through our review, in January 2022, the Scientific Integrity Fast-Track Action Committee (interagency task force) of the National Science and Technology Council published a report that defined "interference" to mean inappropriate, scientifically unjustified intervention in the conduct, management, communication, or use of science. The report 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). We did not use this definition for the purposes of our review.

preparedness and response efforts.[3] Additionally, in April 2022, we reported that agency respondents from CDC, FDA, and NIH told us that they observed instances of potential political interference that may have compromised the scientific integrity of certain aspects of the COVID-19 pandemic response.[4]

Federal agencies have certain policies, characteristics, and design features that can help insulate them from political interference. For example, since 2007, Congress and multiple administrations have taken actions to protect the integrity of federal science agencies by ensuring that they have policies and procedures in place that protect against the suppression or alteration of scientific findings for political purposes.[5]

Additionally, agencies have features that may affect their independence and accountability, according to various U.S. government reports and political science literature.[6] For example, according to the Administrative

[3]The High Risk List is a list of federal programs and operations that are vulnerable to fraud, waste, abuse, and mismanagement, or need transformation. See GAO, *COVID-19: Significant Improvements Are Needed for Overseeing Relief Funds and Leading Responses to Public Health Emergencies,* GAO-22-105291. (Washington, D.C.: Jan. 27, 2022).

[4]See GAO, *Scientific Integrity: HHS Agencies Need to Develop Procedures and Train Staff on Reporting and Addressing Political Interference,* GAO-22-104613. (Washington, D.C.: Apr. 20, 2022). For the purposes of GAO-22-104613 and this report, the term "scientific integrity" refers to the use of scientific evidence and data to make policy decisions that are based on established scientific methods and processes and are not inappropriately influenced by political considerations. When appropriate, these decisions are then shared openly with the public.

[5]For example, the America COMPETES Act of 2007 required the Director of the Office of Science and Technology Policy 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 conducted by their scientists. Pub. L. No. 110-69, § 1009, 121 Stat. 572, 581-82 (2007) (codified at 42 U.S.C. § 6620). Since 2009, multiple administrations have provided executive departments and agencies with a range of guidance for ensuring scientific integrity, such as principles for ensuring scientific integrity in agency culture, public communications, and professional development.

[6]See, for example, Marshall J. Breger and Gary J. Edles, *Independent Agencies in the United States: Law, Structure, and Politics* (New York: Oxford University Press, 2015); and K. Datla and R. L. Revesz, "Deconstructing Independent Agencies (and Executive Agencies), *Cornell Law Review*, vol. 98, no. 4 (2013): 769.

One expert we spoke with noted that no agency is fully insulated from political influence or unaccountable to the political system. Instead, agency insulation from political interference may be viewed as a continuum, depending on how much presidential or congressional influence is present within an agency.

Conference of the United States' *Sourcebook of United States Executive Agencies (Sourcebook)*, the structural characteristics of agencies related to their organization and design can affect the degree of agency autonomy from political influences, including both the legitimate exercise of the President's and Congress's constitutional duties and political interference. [7] Agency features that allow for presidential and congressional influence, such as appointments, removals, and appropriations, can also help provide for agency accountability to elected officials. Conversely, structural features that enhance agency autonomy from the President and Congress may also help insulate it from potential political interference.

You asked us to review structural protections against political interference at selected HHS agencies.[8] In addition, the CARES Act directs us to monitor and oversee the federal government's efforts to prepare for, respond to, and recover from the pandemic.[9] This report examines the key characteristics that can help insulate agencies from political interference and describes the structural characteristics that the selected

[7]J. Selin and D. Lewis, *Sourcebook of United States Executive Agencies* (Second Edition) (Washington, D.C.: Administrative Conference of the United States, October 2018). See https://www.acus.gov/research-projects/sourcebook-united-states-executive-agencies-second-edition. Accessed December 1, 2022. The Administrative Conference of the United States is an independent federal agency charged with convening expert representatives from the public and private sectors to promote efficiency, participation, and fairness in the promulgation of federal regulations and in the administration of federal programs.

The U.S. government is comprised of three coequal branches—legislative, executive, and judicial—that have constitutional duties to supervise and direct the operations of federal agencies. For example, Presidents execute federal laws by directing agency activities, and Congress oversees the execution of laws by creating and funding federal programs and agencies. See U.S. Const. art. I, §§ 8, 9; and art. II, § 3.

[8]GAO has ongoing work to examine selected HHS agencies' experiences with political interference under our CARES Act mandate. We will report on these findings in a future report.

[9]Pub. L. No. 116-136, § 19010, 134 Stat. 281, 579-81 (2020). In addition to our reports on individual programs, we have regularly issued government-wide reports on the federal response to the COVID-19 pandemic. For the latest report, see GAO, *COVID-19: Current and Future Federal Preparedness Requires Fixes to Improve Health Data and Address Improper Payments*, GAO-22-105397 (Washington, D.C.: Apr. 27, 2022). All of these reports are available on GAO's website at https://www.gao.gov/coronavirus.

HHS agencies have in place.[10] We focused on four agencies within HHS that have played key roles in the public health response to the COVID-19 pandemic: CDC, FDA, NIH, and ASPR.

To address this objective, we examined the *Sourcebook*, which provides a comprehensive list of structural characteristics and describes how they may affect political interference and agency responsiveness to political officials. We determined the extent to which the characteristics identified in the *Sourcebook* as helping to insulate agencies from political interference were in place at the selected agencies. To determine which characteristics were in place, we reviewed agency statutes and public laws; the House Committee on Oversight and Reform, *United States Government Policy and Supporting Positions* (Plum Book); the Federal Advisory Committee Act database; other U.S. government sources; and agency written responses. We also reviewed relevant federal guidance on scientific integrity as well as HHS's scientific integrity policy, and agency-specific scientific integrity policies and procedures.[11]

To obtain perspectives about scientific integrity and political interference at the selected agencies and ideas for structural reforms, we spoke individually with a bipartisan selection of 10 former agency heads—at least one from each of the selected agencies. We also spoke with current and former senior agency officials; when referring to these interviewees, we use the term "senior agency official." In addition, we conducted interviews with 16 employees, including managers and non-managers, from three of the four selected agencies—CDC, FDA, and NIH.[12] When reporting our results, we use the term "respondent" to refer to an employee we interviewed as part of our semi-structured interview

[10]In April 2022, we issued a related report on scientific integrity at FDA, CDC, NIH, and ASPR, which examined (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. See GAO-22-104613.

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

[12]ASPR was excluded from this methodology because at the time of this review, it followed HHS's *Policies and Principles for Assuring Scientific Integrity* and did not have its own scientific integrity policy. "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.

methodology.[13] For more information on our objective, scope, and methodology, see appendix I.

We conducted this performance audit from October 2020 to December 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 objective.

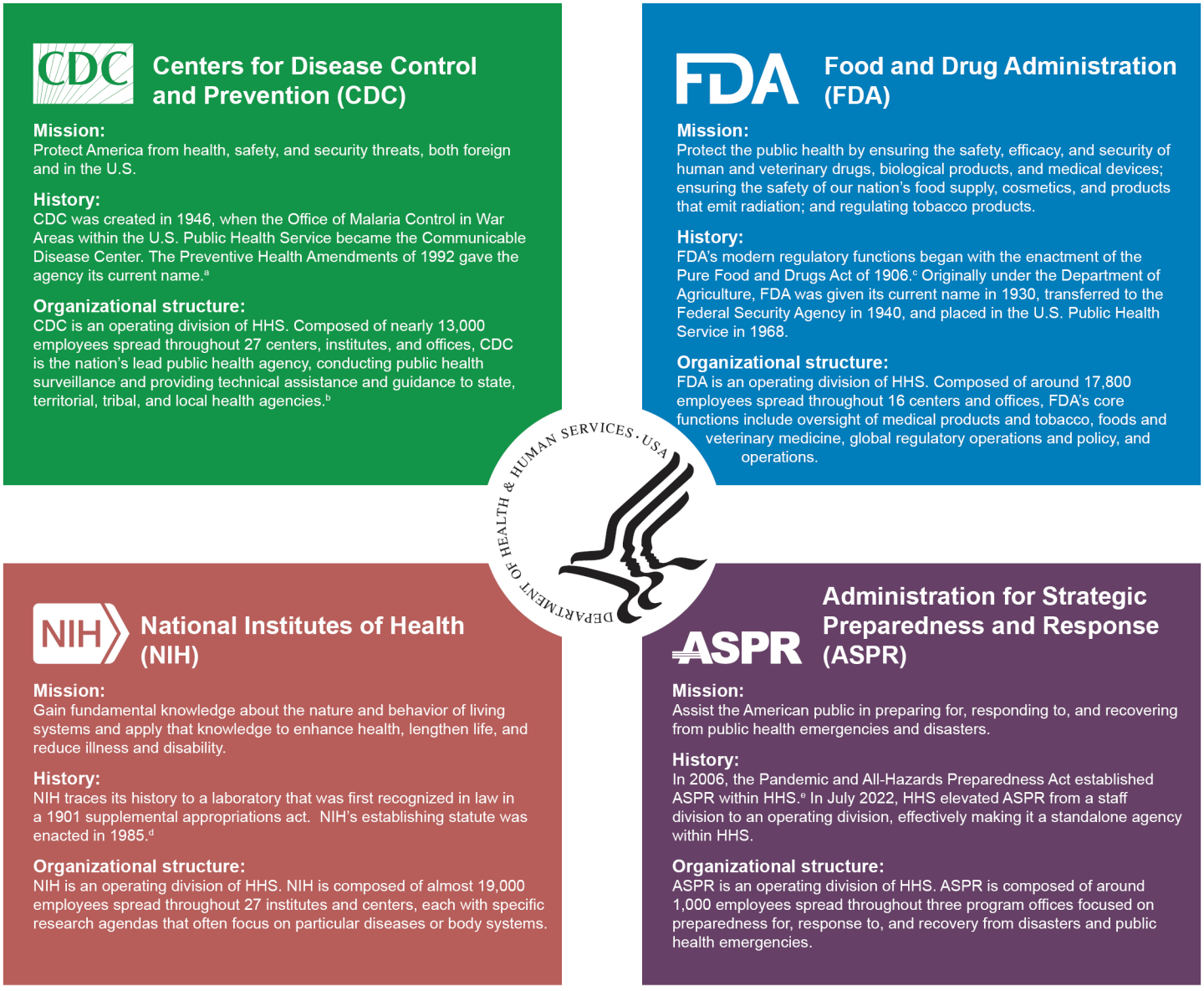
Background

HHS and Selected Agencies

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

[13]Our results from these interviews represent the views of those who provided information and are not generalizable to any other employees.

Figure 1: Mission, History, and Organizational Structure of Selected Department of Health and Human Services (HHS) Agencies



Source: GAO review of information from CDC, FDA, NIH, and ASPR officials. | GAO-23-105415

Notes:

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

[b]In August 2022, CDC announced a plan to reorganize the agency's structure to prioritize public health needs and efforts to curb continuing outbreaks. Among others things, preliminary actions include restructuring the agency's communications office, creating a new executive council, and establishing an office of intergovernmental affairs.

[c]See Pub. L. No. 59-384, 34 Stat. 768.

[d]See Health Research Extension Act of 1985, Pub. L. No. 99-158, 99 Stat. 820.

[e]See Pub. L. No. 109-417, § 102, 120 Stat. 2831, 2832-34 (2006).

COVID-19 Pandemic Response

HHS is the federal department responsible for leading and coordinating the federal public health and medical response to emergencies and disasters.[14] Throughout the COVID-19 pandemic response, HHS and its agencies have coordinated with federal, state, local, tribal, and territorial governments, as well as public and private partners, to: develop diagnostic tests; collect and report COVID-19 indicator data; and support the development, manufacturing, and distribution of vaccines and therapeutics to prevent and treat COVID-19. Selected HHS agencies have, in some cases, adopted certain operating postures and procedures to respond to the COVID-19 pandemic.[15]

- **CDC.** CDC employs a centralized Incident Management System within its Emergency Operations Center for the COVID-19 agency-wide response to allow for the coordination of resources, information, and experts.[16] The Incident Management System is comprised of task force teams focused on different areas of the response, such as epidemiology and surveillance, or data and analytics, according to CDC officials.
- **FDA.** FDA facilitates patient access to medical products—including drugs, biologics, and medical devices—used to prevent, treat, or

[14]HHS is the lead agency for the public health and medical services functions of the National Response Framework, a guide issued by the Department of Homeland Security that dictates how the nation responds to all types of disasters and emergencies. The Federal Emergency Management Agency leads the overall framework, thereby leading the federal response during such emergencies and disasters.

[15]Certain agencies, such as ASPR, did not change their standard operating procedures as part of their COVID-19 pandemic response.

[16]According to CDC, an Incident Management System is a temporary, formal organization structure that is activated to support a response, adjusted to meet rapidly changing demands of that response, and then disbanded at the end of the response.

diagnose COVID-19, such as through emergency use authorizations, in addition to the traditional approval process.[17]

- **NIH.** NIH supports the development of COVID-19 vaccines and treatments by creating and distributing testing products and supporting research, including executing and funding COVID-19-related clinical trials to assess the safety and efficacy of vaccines and therapeutics.
- **ASPR.** ASPR serves as the principal advisor to the Secretary of Health and Human Services on all matters related to the federal public health and medical response to public health emergencies, such as COVID-19. It also oversees the Strategic National Stockpile, which contains medical countermeasures—including drugs, vaccines, supplies, and other materials—to respond to a broad range of public health emergencies.

In addition to the efforts taken by HHS and its agencies, the COVID-19 pandemic response has required support from the existing federal public health emergency systems and structures, as well as from new entities and processes created within the Executive Office of the President. For example, the White House Coronavirus Task Force was established in January 2020 to coordinate a whole-of-government approach during the Trump administration. Since the Biden administration took office in January 2021, the White House COVID-19 Response Team has been responsible for coordinating across the federal government on the COVID-19 response and for communicating to the public and other stakeholders about these efforts. Additionally, the Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs developed expedited interagency review procedures for rulemaking and guidance related to the COVID-19 pandemic to ensure a coordinated federal response.[18]

[17]Typically, FDA must approve, license, or clear a new product before it can be marketed in the United States. See 21 U.S.C. § 355 (drugs); 21 U.S.C. § 360e(c) and 360(k) (devices); and 42 U.S.C. § 262 (biologics). However, during an emergency, FDA may temporarily allow the use of a product that has not been approved, licensed, or cleared by issuing an emergency use authorization, provided certain statutory criteria are met. See 21 U.S.C. § 360bbb-3.

[18]See Office of Management and Budget, *Promoting Public Trust in the Federal Government and Effective Policy Implementation through Interagency Review and Coordination of the American Rescue Plan Act*, M-21-24, (Apr. 26, 2021).

Scientific Integrity

In 2012, HHS issued a scientific integrity policy that 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.[19] As of September 2022, HHS was updating this policy in response to direction from the Executive Office of the President. Specifically, a 2021 presidential memorandum included requirements for heads of agencies to take certain actions to strengthen scientific integrity, including developing and publishing procedures for implementing the agency's scientific integrity policy, as appropriate and consistent with applicable law.[20] The 2021 presidential memorandum also directed the White House's Office of Science and Technology Policy 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, which was issued by the resulting task force in January 2022.[21] At the time of our review, agency implementation of the

OMB oversees the implementation of the President's policy, budget, management, and regulatory objectives. Among other functions, OMB is responsible for budget development and execution, coordination and review of all significant federal regulations from executive agencies, and clearance and coordination of legislative and other materials, such as agency testimony, legislative proposals, and other communications with Congress, across executive departments and agencies.

[19]See HHS, *Policies and Principles for Assuring Scientific Integrity* (March 2012). 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, which are being updated, as of September 2022, in response to direction from the Executive Office of the President. At the time of our review, ASPR relied on HHS's scientific integrity policy, though agency officials told us that it would consider developing an agency-specific scientific integrity policy as part of its transition to an operating division.

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

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

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 interagency task force will begin developing a framework to support regular assessment and iterative improvement of agency scientific integrity policies. Heads of agencies are to ensure that their scientific integrity policies reflect the findings of the report and the requirements outlined in the framework. At the time of our review, officials from the Office of Science and Technology Policy told us that the framework would be issued in fall 2022.

approaches outlined in the January 2021 memorandum and January 2022 report were ongoing, according to agency officials.

Structural Characteristics

According to the *Sourcebook*, certain structural characteristics can help insulate agencies from political interference from:

- the President (and the administration), such as limitations on the appointment and removal of agency leaders and number of political appointees at an agency; and
- Congress, such as agency authority to collect fees to finance its programs and activities.

The *Sourcebook* provides a comprehensive list of over 60 structural characteristics and describes how these characteristics may affect agency autonomy, or lack thereof, over personnel, policy, finances, and decision-making (see Table 1).[22]

[22]The *Sourcebook* describes these structural characteristics for over 270 federal agencies, including six components of the Executive Office of the President; 15 executive departments and 173 bureaus within those departments; and 78 agencies outside of the Executive Office of the President and executive departments and two bureaus within those agencies.

Table 1: Categories and Examples of Structural Characteristics from the *Sourcebook of United States Executive Agencies*, 2nd Edition

Category	Description
General Information[a]	This category has 10 characteristics that describe general information about an agency. These characteristics can affect an agency's independence or responsiveness to the President and Congress. Example characteristics include: • Agency location (executive department, etc.); • Date the agency was created; and • Whether the agency is established in statute.
Leadership Structure and Agency Personnel	This category has 35 characteristics related to agency leaders and personnel. These characteristics can affect a president's ability to influence who leads and operates the agency.[b] Example characteristics include: • Number of political appointees; • Limits on the appointment and removal of agency leaders; and • Limits on the selection and retention of agency leaders.
Features Insulating Agency Policy	This category has eight characteristics related to agency policy-making and resources. These characteristics can affect presidential and congressional influence over agency actions and priorities. Example characteristics include: • Office of Management and Budget review of agency budget, rules, and communications with Congress; • Agency self-funding authority (e.g. authority to collect fees in addition to regular appropriations); and • Statutory mandates for select agency reports to Congress.
Other Key Structural Features	This category has 11 characteristics related to an agency's administrative and decision-making processes. These characteristics can affect an agency's independence or responsiveness to the President and Congress. Example characteristics include: • Advisory committees; • Agency-wide management and transparency positions (Chief Information Officer, Inspector General, etc.); and • Adjudication authority (e.g. agency can conduct or hold hearings).

Source: J. Selin and D. Lewis, *Sourcebook of United States Executive Agencies* (Second Edition) (Washington, D.C.: Administrative Conference of the United States, October 2018). | GAO-23-105415

Notes:

[a]In the *Sourcebook of United States Executive Agencies*, what we are referring to as the General Information category is called "Housekeeping Variables."

[b]For the most part, structural characteristics in this category can help insulate an agency from political interference from the President. However, some characteristics in this category also have implications for congressional influence because they can affect the level of congressional input into the selection of agency leaders, such as whether an agency head is Senate-confirmed.

Selected HHS Agencies Have Several Characteristics That Can Help Insulate against Potential Political Interference; Structural Reforms May Improve Insulation

Selected HHS Agencies Have Several Structural Characteristics That Can Help Insulate against Potential Political Interference

Of the structural characteristics identified in the *Sourcebook* as helping insulate agencies from political interference, the selected HHS agencies had at least one in place in each of the General Information, Leadership Structure and Agency Personnel, and Other Key Structural Features categories.[23] We describe below several examples of structural characteristics that the selected agencies have or, in most cases, do not have in place and how these characteristics can relate to political interference.[24] We also describe other characteristics—such as agency policies and procedures that support a culture of scientific integrity—that senior agency officials and agency respondents we spoke with told us can help insulate agencies from political interference. See appendix II for the full list of structural characteristics for each agency.

General Information

Of the 10 structural characteristics in this category that describe general information about the selected agencies, it is most noteworthy that all of the selected agencies are located in an executive department. As a

[23]We group the structural characteristics into four categories identified from the *Sourcebook*: (1) General Information; (2) Leadership Structure and Agency Personnel; (3) Features Insulating Agency Policy; and (4) Other Key Structural Features.

[24]The total number of structural characteristics for the selected agencies is not indicative of greater insulation from political interference. For example, in some cases, the absence of certain characteristics or data associated with certain characteristics can help insulate agencies from political interference, such as the number of political appointees at an agency. In addition, some characteristics, such as the agency's location in the federal government, affect which other characteristics are relevant, and, as a result, no agency can have all possible characteristics. Finally, some characteristics can help insulate agencies from political interference from one political actor (e.g., Congress or the President) relative to another, such as whether an agency's leader is Senate-confirmed.

result, the selected agencies do not have many of the characteristics that can help insulate them from political interference from the President and Congress compared to independent agencies, such as the Federal Reserve. For example, the selected agencies do not have many of the characteristics that can limit the President's influence over agency leaders and policy, such as limits on the removal of agency leaders.

In contrast, the Federal Reserve has several structural characteristics that the *Sourcebook* identifies as increasing independence from executive control and insulation from political interference. For example, the Federal Reserve System is governed by a multi-member body (i.e., Board of Governors) rather than a single agency head, and its members are appointed to fixed, staggered terms (14 years).[25]

According to the *Sourcebook*, agencies located in executive departments, like HHS, generally have fewer characteristics that can help insulate them from political interference compared to independent agencies because, in many cases, Congress designed independent agencies to be expert and insulated from politics. In addition, being an agency located in a larger department, such as HHS, can also increase opportunities for political interference because the agency may normally receive direction from the department secretary (a political appointee) and may have to obtain department-level approval before making certain policy changes, based on our review of the *Sourcebook*, a political science article, and an interview with a former FDA commissioner.

Leadership Structure and Agency Personnel

Of the 35 structural characteristics in this category, NIH had three; CDC and FDA both had two; and ASPR had one.[26] Of note, three of the four selected agencies have a statutory mandate that the President, with the advice and consent of the Senate, appoints the agency leader. Specifically, FDA, NIH, and ASPR have leaders that are selected by the President and confirmed by the Senate, whereas the CDC director does not require Senate confirmation.[27] A former FDA commissioner told us

[25]See 12 U.S.C. § 242.

[26]We excluded 14 characteristics from our count. Specifically, we excluded eight characteristics related multimember commissions and board of directors because they were not applicable to the selected agencies. We also did not consider as part of our count six other characteristics because they described the number of employees and political appointees at the agency.

[27]See 21 U.S.C. § 393(d)(1) (FDA), 42 U.S.C. § 282(a) (NIH), and 42 U.S.C. § 300hh-10(a) (ASPR). In contrast to the other three agencies, CDC and the position of CDC director are not explicitly established in statute.

that, in their opinion, Senate-confirmed agency heads, like the FDA commissioner, are more protected from political interference. For example, it may be more politically difficult to remove Senate-confirmed agency heads, particularly those confirmed with bipartisan support.

In general, agency leadership is one area in which the selected agencies have few, if any, structural characteristics that can help insulate them from political interference. Specifically the selected agencies have few characteristics that place limits on the appointment, removal, selection, and retention of agency leaders. For example, the selected agencies do not have statutory mandates that fix the term, or length, of the appointment of agency leaders or require that they have specific qualifications, such as health care or scientific expertise. According to the *Sourcebook*, characteristics related to agency leadership can help insulate agencies from presidential interference because they can affect the degree of influence the President has over agency leaders.

Relatedly, the selected agencies each have between two and five political appointees serving in key senior leadership and policy positions, which can increase presidential control over agencies.[28] Specifically, political appointees—who generally serve at the pleasure of the President—can make and advocate for agency policy on behalf of an administration. According to the *Sourcebook,* agencies with more political appointees are more likely to be responsive to the White House and subject to partisan politics. From 1960 to 2008, the number and percentage of political appointees have almost doubled, driven, in part, by political actors seeking to gain greater control over federal policy-making, according to the *Sourcebook*. Of the selected agencies, ASPR has the largest number of political appointees with five, while CDC has the least with two (see Table 2). In addition, the numbers of political appointees increased from 2016 through 2020 at CDC, FDA, and ASPR, but has since declined at CDC and FDA as of 2022; the number of political appointees at NIH has varied over time (see fig. 2).

[28]There are four major categories of political appointees: presidential appointees with Senate confirmation; presidential appointees; non-career employees in the Senior Executive Service; and Schedule C employees. In 2019, GAO identified about 4,000 political appointee positions from these four major categories across the entire executive branch as of June 30, 2016. For more information on government-wide political appointees, see GAO, *Federal Ethics Programs: Government-wide Political Appointee Data and Some Ethics Oversight Procedures at Interior and SBA Could Be Improved*, GAO-19-249 (Washington, D.C.: Mar. 14, 2019).

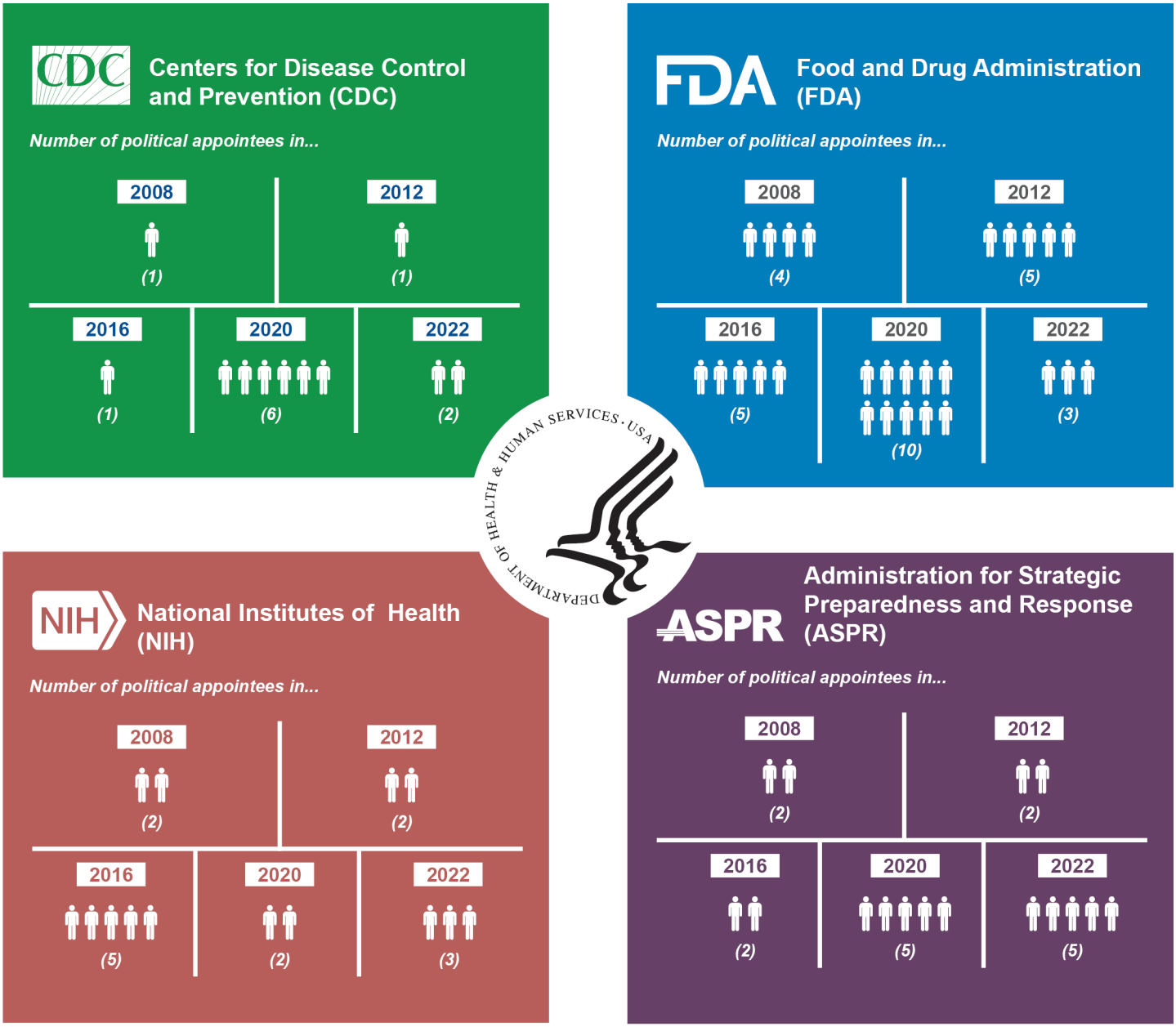
Table 2: Political Appointee Positions at Selected Department of Health and Human Services Agencies

Agency	Positions Held by Political Appointees	Total Number of Agency Employees
Centers for Disease Control and Prevention (CDC)	CDC Director Senior Counselor (as of August 2022)	**12,952** (as of August 2022)
Food and Drug Administration (FDA)	Commissioner of Food and Drugs (FDA Commissioner) Deputy Commissioner for Policy, Legislation, and International Affairs Associate Commissioner for External Affairs (as of September 2022)	**17,868** (as of September 2022)
National Institutes of Health (NIH)	NIH Director (vacant since December 2021) National Cancer Institute Director Senior Director (as of August 2022)	**18,927** (as of August 2022)
Administration for Strategic Preparedness and Response (ASPR)	Assistant Secretary for Preparedness and Response Chief of Staff Chief Strategy Officer Senior Policy Advisor for COVID Response (2 total) (as of September 2022)	**984** (as of September 2022)

Source: GAO analysis of data from CDC, FDA, NIH, and ASPR officials. | GAO-23-105415

Note: The political appointee positions identified for each agency include four types of appointments: presidential appointees with Senate confirmation; presidential appointees; non-career employees in the Senior Executive Service; and Schedule C employees. Vacant positions are included in the count.

Figure 2: Number of Political Appointees at Selected Department of Health and Human Services Agencies, September 2008-September 2022



Source: GAO analysis of 2022 data from CDC, FDA, NIH, and ASPR officials, and the 2008, 2012, 2016, and 2020 editions of the Senate Homeland Security and Governmental Affairs Committee and House Committee on Oversight and Reform, *United States Government Policy and Supporting Positions* (Plum Book). | GAO-23-105415

Note: The Senate Homeland Security and Governmental Affairs Committee and the House Committee on Oversight and Reform publish the Plum Book every 4 years. The Plum Book is

generally published in December after the presidential election and is based on agency data reported to the Office of Personnel Management as of the June prior to the election.

The total number of political appointees for each year is comprised of four types of appointments identified in the Plum Book: presidential appointees with Senate confirmation; presidential appointees; non-career employees in the Senior Executive Service; and Schedule C employees. Vacant positions are included in the count.

A former NIH director told us that an agency's political appointees play an important role by serving as coordinators between the agency and the administration, as well as the agency's touchpoint to Congress. However, the former director stated that the relatively small number of political appointees at NIH helps protect the agency from political interference. Additionally, the former director said that, over time, the executive branch has sought to gain more control over agencies, with the exception of NIH, through the use of political appointees. As such, the former NIH director believed that other agencies, such as FDA and CDC, have a harder time protecting against political interference, because they have more positions staffed by political appointees.

In contrast, the selected agencies have other structural characteristics in place related to agency personnel that can help insulate them from political interference. These include fixed terms for the appointment of agency officials other than the agency head or statutory authority to hire for select scientific or technical positions outside federal civil service requirements.[29] According to the *Sourcebook,* these characteristics can help insulate agencies from political interference from the President because they limit presidential influence over the removal and selection of agency leaders, including those responsible for leading scientific work. Additionally, differing authorities for agency personnel can make it more difficult for the President or Congress to direct agency policy.

For example, NIH institute and center directors, such as the director of the National Institute of Allergy and Infectious Diseases, are appointed to 5-year terms, although there are no limits on the number of reappointments an institute and center director may serve.[30] In addition,

[29]There are a number of statutory authorities to expedite the hiring process for federal employees or to achieve certain public policy goals. For example, provisions under Title 42 of the U.S. Code provide authority for HHS to hire individuals to fill mission critical positions in science and medicine. For additional information, see GAO, *Federal Hiring: OPM Needs to Improve Management and Oversight of Hiring Authorities*, GAO-16-521 (Washington, D.C.: Aug. 2, 2016).

[30]See 42 U.S.C. § 284(a)(2).

the Secretary of Health and Human Services may hire "outstanding and qualified" candidates to scientific and technical positions in FDA that support the development, review, and regulation of medical products without regard for certain civil service provisions.[31]

Features Insulating Agency Policy

Of the eight structural characteristics in this category, FDA had two; CDC and NIH both had one; and ASPR had none.[32] Of note, the selected agencies had none of the characteristics that the *Sourcebook* identifies as potentially helping to insulate policy-making from political interference by the President, such as those related to bypassing OMB review. For example, all of the selected agencies must submit their budgets, significant rules, and communications with Congress to HHS for department-level review, and then to OMB for review by the administration.[33] According to the *Sourcebook*, bypassing OMB review can help insulate agencies from political interference because it limits the President's control over agency resources, budget execution, and policy-making.

Other Key Structural Features

Of the 11 structural characteristics in this category, FDA and NIH had eight, CDC had seven, and ASPR had five. Of note, all the agencies had at least one structural characteristic related to advisory committees and rulemaking, which can help insulate them from political interference in agency decision-making. For example, advisory committees can help insulate agencies from political interference by allowing external actors, such as scientific experts and researchers, to advise on agency decision-making, based on our review of a political science article. However, CDC officials told us that, during an emergency response, when the need for rapid information is heightened, quickly convening external experts through a formal process may not be feasible.

[31]For example, the FDA commissioner has the authority to determine and set the pay rate of these positions, notwithstanding any requirements related to pay rates set by the Office of Personnel Management. See 21 U.S.C. § 379d-3a(b).

[32]We did not consider as part of our count two characteristics because they described the extent of certain aspects of congressional oversight for the selected agencies. Specifically, we excluded the number of statutorily mandated recurring agency reports to Congress and the number of committees specified by statute as overseeing the agency.

[33]See Office of Management and Budget, Circular No. A-11 Preparation, Submission, and Execution of the Budget (August 2021); Exec. Order No. 12866, Regulatory Planning and Review, 58 Fed. Reg. 51,735 (Oct. 4, 1993); and Office of Management and Budget, Circular No A-19 Legislative Coordination and Clearance (September 1979).

A former NIH director told us that advisory committees help protect against political interference, particularly with regard to controversial research topics, because federal law helps ensure that they are comprised of diverse members with fixed terms for their appointment.[34] These fixed terms help prevent administrations from changing the composition of committees in their favor.

All four agencies have active advisory committees that advise on key areas of agencies' scientific decision-making, such as grant funding and vaccine licensure.[35]

- NIH has the most number of active advisory committees (144), which provide peer review of research grant applications and advise on research programs and policy and program development for the agency's institutes and centers.
- FDA has 31 advisory committees, which provide independent expert advice on scientific, technical, and policy matters related to blood, vaccines, and other biologics; human drugs; tobacco products; and medical devices.
- CDC has 20 advisory committees, which provide advice and recommendations on a broad range of public health issues, such as occupational and environmental health, childhood and adult immunizations, and injury prevention and control.
- ASPR has four advisory committees, which coordinate federal efforts to prevent, prepare, respond, and recover from public health emergencies or medical disasters.

Other Characteristics

Separate from structural characteristics identified in the *Sourcebook,* agency policies and procedures that support a culture of scientific

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

[35]Advisory committees at the four agencies are either established in statute or based on agency- or department-specific general statutory authorities to create advisory committees. For example, see 42 U.S.C. § 217a.

integrity can also help insulate agencies from political interference.[36] According to the Scientific Integrity Fast-Track Action Committee report, a strong organizational culture of scientific integrity is a necessary foundation to protect agencies against inappropriate influence, including political interference.[37] Such an organizational culture fosters open discussion and transparent processes and promotes an awareness of, and compliance with, scientific integrity policies by agency officials at all levels.

Similarly, senior agency officials and agency respondents we spoke with identified agency scientific integrity-related processes and culture as helping insulate the selected agencies from political interference, and described the key role that agency leaders play in protecting scientific integrity at the selected agencies. Specifically:

- **Agency processes.** Senior agency officials discussed several types of agency scientific integrity-related processes that helped insulate agency staff and decision-making from political interference. For example,
  - A former FDA commissioner told us that FDA's regulatory and scientific processes help ensure the independence of the agency's career staff and help insulate the agency's decision-making from political pressure, particularly during emergencies, such as the COVID-19 pandemic.
  - A former NIH director said that, in their view, of all the HHS agencies, NIH is the most independent and protected from political interference because of its peer-review process, which prevents the agency's research funding from being allocated based on political considerations.
  - A senior CDC official told us that CDC's clearance process for guidance and other products helps prevent political interference

[36]In April 2022, we recommended that CDC, FDA, NIH, and HHS develop procedures for reporting and addressing allegations of political interference so that employees know how to report such allegations and the agencies have a clear, consistent process for investigating and addressing them. See GAO-22-104613.

[37]Scientific Integrity Fast-Track Action Committee of the National Science and Technology Council, *Protecting the integrity of Government Science*, (January 2022). The report identified several practices that can help support scientific integrity at agencies, including: (1) agency leadership and modeling of appropriate behaviors; (2) processes that protect the integrity of the research process, such as peer review; (3) mechanisms for communicating scientific information with integrity; (4) staff training on scientific integrity; and (5) policies and procedures to safeguard against scientific integrity violations.

and protects scientific integrity at the agency because of the large number of people at CDC involved in the review process.

- **Agency culture.** Current and former senior agency officials and agency respondents with whom we spoke described how the culture at their respective agencies helps support agency independence and scientific integrity. For example, a former FDA commissioner told us that the agency has a "longstanding" culture that promotes independence, including at the senior leadership level. A respondent from NIH said that NIH has a science-based and nonpartisan culture at every level of the agency, including at the director level, which helps uphold scientific integrity at the agency.
- **Agency leadership.** Senior agency officials and agency respondents told us that agency leadership also can play a key role in protecting agencies' scientific integrity and insulating career staff from political interference.
  - Senior agency officials from all four agencies told us that one of the primary responsibilities of agency heads is to ensure scientific integrity at their agency. For example, a former CDC director said the agency head must be the strongest advocate for practice- and evidence-based public health policies that are supported by science.
  - Multiple agency respondents said they believed agency leadership shields staff from political pressure so scientists can focus on making science-based decisions. For example, one respondent from FDA told us scientific integrity and insulation from political interference at FDA is contingent on having the "right" senior leaders in place, and FDA senior leaders insulated staff from political pressure the agency experience during the COVID-19 pandemic.

Structural Reforms May Improve Insulation of Selected HHS Agencies against Potential Political Interference in Future Public Health Emergencies

Multiple senior agency officials told us that whole-of-government responses to public health emergencies like the COVID-19 pandemic may create more opportunity for potential political interference. For example, current and former senior agency officials told us that the constantly evolving nature of the pandemic, and the critical public health threat it posed, prompted a whole-of-government response in which traditional agency roles and approaches to scientific decision-making were altered. In addition, multiple senior agency officials highlighted how the coordination and quick action required in an emergency response can result in more political involvement in scientific decision-making than is standard, thus creating more opportunity for political interference.

For example, a CDC senior official stated that the unprecedented involvement of political appointees from outside CDC in the *Morbidity and Mortality Weekly Report* review process in 2020 was intended to support a coordinated government pandemic response.[38] However, in some cases, this involvement resulted in officials from outside of CDC requesting that scientific findings be altered, which current and former CDC officials felt jeopardized the publication's scientific integrity and public trust in its content.[39]

Experts and former agency heads told us they believe certain structural reforms may help insulate HHS agencies from political interference going forward. Specifically, former agency heads suggested the following structural reform ideas:

- **FDA as an independent agency.** Two former FDA commissioners told us FDA should be separated from HHS because of its regulatory role. This echoes a proposal they developed in 2019, along with five other former commissioners, to transform FDA into an independent federal agency.[40] The proposal stated that greater FDA independence could help further the agency's ability to ensure predictable, science-based decision-making; promote the agency's capacity to act swiftly in an emergency; and enhance transparency and sustain public confidence. However, a former FDA commissioner we spoke with said that a potential downside to having FDA moved out of HHS would be that it would no longer be located in the same department with other

[38]According to the CDC, the *Morbidity and Mortality Weekly Report* series is the agency's primary vehicle for scientific publication of timely, reliable, authoritative, accurate, objective, and useful public health information and recommendations. Readership predominantly consists of physicians, nurses, public health practitioners, epidemiologists and other scientists, researchers, educators, and laboratorians.

[39]An October 2022 report from the Select Subcommittee on the Coronavirus Crisis found that in 2020, senior HHS officials attempted to alter or suppress at least 19 different CDC scientific reports, including those published in the *Morbidity and Mortality Weekly Report*. See Select Subcommittee on the Coronavirus Crisis, *"'It Was Compromised': The Trump Administration's Unprecedented Campaign to Control CDC and Politicize Public Health During the Coronavirus Crisis."* (Washington, D.C.: October 2022)

[40]In June 2016, six former FDA commissioners publicly announced their consensus view that FDA should be transformed into an independent federal agency. In January 2019, the Aspen Institute published *Context & Evidence: Why an Independent FDA?,* a white paper that summarized discussions with the former FDA commissioners (including a seventh, who joined the group in 2017) on this topic. The seven FDA commissioners were: Robert Califf, Margaret Hamburg, Andrew von Eschenbach, Mark McClellan, Jane Henney, David A. Kessler, and Frank Young.

public health agencies, such as NIH and CDC, with which it needs to coordinate closely. Additionally, HHS officials told us that separating FDA from HHS would disrupt many longstanding collaborations and agreements that support a wide range of coordinated federal efforts, and the department strongly disagrees with the suggestion.

- **Senate-confirmed CDC director.** As of December 2022, Congress was considering legislation that would require the CDC director be a Senate-confirmed position.[41] CDC officials told us that the agency does not believe this reform would be beneficial. Former CDC directors, however, have mixed opinions about whether it would be beneficial overall for the agency to have a Senate-confirmed director.[42] For example, during a university-sponsored panel discussion in April 2022, one former CDC director said that making the position Senate-confirmed would politicize and delay the process for selecting the CDC director. According to the former director, this would increase the risk that individuals would be nominated to the position for their industry or political connections rather than their technical and public health management expertise.
- **Term appointments.** A former CDC director with whom we spoke suggested having a term appointment for the CDC director to help insulate the position from political interference and ensure consistency of the agency's leadership across different administrations. A former FDA commissioner made a similar suggestion, recommending that the FDA commissioner be appointed to a 6-year term, so the position is not tied to the election cycle.
- **Fewer political appointees**. A former CDC director told us that, in their view, CDC should not have any political appointees other than the CDC director. The former director said that during the COVID-19 pandemic, political appointees at CDC undermined public trust in the agency through their attempts to influence CDC publications. A former FDA commissioner stated that, during their tenure at FDA, they sought to reduce the number of political appointees by filling critical

[41]See PREVENT Pandemics Act, S. 3799, 117th Cong. (2022). As of December 2022, this bill had been reported out of the Senate Committee on Health, Education, Labor and Pensions.

[42]For example, see Harvard T. H. Chan School of Public Health panel discussion, "CDC at the Crossroads," April 5, 2022. Accessed via https://www.hsph.harvard.edu/event/cdc-at-the-crossroads/, on April 27, 2022.

positions, such as the agency's general counsel, with career scientists and practitioners.[43]

In 2022, two of the selected HHS agencies began undertaking organizational reforms to improve their response to public health emergencies and strengthen public trust. Specifically, in July 2022, the Secretary of Health and Human Services removed ASPR from the Office of the Secretary and created a new operating division within HHS in an effort to better mobilize a coordinated national response to future disasters and emergencies. Additionally, in August 2022, the CDC director proposed a series of organizational changes aimed at making the agency more nimble and responsive during health emergencies, including creating an executive council to help set agency priorities.

According to current agency officials, these reforms are designed to improve the agencies' response capabilities, and are not specifically intended to address issues related to scientific integrity or strengthen protections against political interference. However, CDC officials told us that the implementation of some of the agency's planned reforms, such as moving the Office of Science, which includes the Office of Scientific Integrity, into the Office of the Director, could strengthen the agency's scientific integrity efforts. At the time of this review, officials from all of the selected HHS agencies told us that they were not considering reviewing and implementing any additional structural reforms that could improve agency insulation against potential political interference. According to the officials, they feel that their agencies' current plans, structure, and processes are sufficient.

GAO will continue to examine selected HHS agencies' experiences with political interference during the COVID-19 response and any steps that could be taken to strengthen protections against such interference under

[43]According to the Plum Book, agencies have some discretion as to the number of political appointee positions they have. For example, agencies may request the Office of Personnel Management to place a position in Schedule C. Schedule C positions authorized by the Office of Personnel Management are automatically revoked when the incumbent leaves the position. In addition, the proportion of non-career employees in the Senior Executive Service varies by agency, generally up to a limit of 25 percent of the agency's number of Senior Executive Service positions. The Office of Personnel Management approves each use of a non-career authority by an agency, and the authority reverts to the Office of Personnel Management when the non-career appointee leaves the position.

our CARES Act mandate. We will report on these findings in a future report.

Agency Comments and Our Evaluation

We provided a draft of this report to HHS for comment. HHS provided written comments on a draft of this report, which are reproduced in appendix III, and technical comments, both of which we incorporated as appropriate. In its response to our draft report, HHS stated that it is actively working to implement the January 27, 2021, presidential *Memorandum on Restoring Trust in Government through Scientific Integrity and Evidence-based Policymaking* through the formation of a working group that is updating HHS's scientific integrity policy. HHS noted that FDA, NIH, CDC, and ASPR are also actively engaged in updating the relevant agency-specific policies and procedures and that it believes that the "ongoing efforts to enhance scientific integrity will better protect against political interference in scientific activities, and have fewer negative unintended consequences, than several of the structural changes suggested by GAO." The proposed structural reforms that we discuss in our report are not recommendations from GAO, but instead, were suggestions from outside experts and former agency heads at FDA, NIH, CDC, and ASPR and may warrant further consideration.

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

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

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The Honorable Elizabeth Warren
United States Senate

The Honorable Paul D. Tonko
House of Representatives

Appendix I: Objective, Scope, and Methodology

This report examines the key characteristics that can help insulate agencies from political interference and describes the structural characteristics that the selected Department of Health and Human Services (HHS) agencies have in place.[1] For the purposes of this report, 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.[2] Our definition of political interference reflects that interference may also come from within an agency.

The term "scientific integrity" refers to the use of scientific evidence and data to make policy decisions that are based on established scientific methods and processes and are not inappropriately influenced by political considerations. When appropriate, these decisions are shared openly with the public. We developed this definition based on our review of the principles contained in the 2009 presidential memorandum on scientific

[1]In April 2022, we issued a related report on scientific integrity at the selected agencies, which examines (1) the extent to which the selected agencies received allegations or identified instances of political interference that compromised scientific decision making, and the procedures that are in place to address allegations; and (2) the steps the selected agencies have taken to train staff on their scientific integrity policies and procedures, including political inference. See GAO, *Scientific Integrity: HHS Agencies Need to Develop Procedures and Train Staff on Reporting and Addressing Political Interference,* GAO-22-104613. (Washington, D.C.: Apr. 20, 2022).

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

Midway through our review, in January 2022, the Scientific Integrity Fast-Track Action Committee (interagency task force) of the National Science and Technology Council published a report that defined "interference" to mean inappropriate, scientifically unjustified intervention in the conduct, management, communication, or use of science. The report 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). We did not use this definition for the purposes of our review.

integrity and the 2010 Office of Science and Technology Policy memorandum.[3]

For our review, we selected four agencies within HHS that have 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 Administration for Strategic Preparedness and Response (ASPR).[4] The news media reported allegations of scientific integrity violations or political interference in scientific decision-making related to the COVID-19 pandemic response at all four agencies.[5]

To identify the key characteristics that can insulate federal agencies from political interference, we reviewed scholarly literature, policy reviews and other sources, and interviewed two university-affiliated political science experts. Through these steps, we identified the *Sourcebook of United States Executive Agencies* (*Sourcebook*), which provides a comprehensive list of over 60 structural characteristics that describe the

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

[4] In July 2022, the Secretary of Health and Human Services removed ASPR from the HHS Office of the Secretary and created a new operating division in the department, to be known as the Administration for Strategic Preparedness and Response (ASPR). In this report, we refer to ASPR under the new organizational name and structure, though our review was conducted primarily when the previous organizational structure was in place.

[5]See, 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 Florko, “An ousted vaccine agency director offers an explosive, direct allegation: Trump is politicizing science,” *STAT*, April 22, 2020.

features and organization of federal agencies, including how these characteristics relate to agency insulation from political interference.[6]

To further assess the sufficiency of the *Sourcebook* for our review, we conducted a search in the bibliographic database Scopus of political science literature that, as of March 2021, cited the *Sourcebook*. Of the 40 articles that cited the *Sourcebook*, we reviewed 11 full articles for: (1) alternative perspectives or criticism of the *Sourcebook* or the structural characteristics identified in the report; (2) confirmation or supporting information on the *Sourcebook's* characteristics; and (3) additional typologies or characteristics that may insulate agencies from political interference. We determined that eight of the 11 articles were relevant to assessing the sufficiency of the *Sourcebook*, and of those eight reviewed, there were no articles that challenged the validity, criticized, or otherwise disputed the *Sourcebook.* Based on our review of the selected literature, we determined that the *Sourcebook* was sufficient for identifying characteristics that scholars have recognized as potentially insulating agencies from political interference.

To collect information on the structural characteristics in place at the four agencies, we primarily reviewed the sources of information identified in the *Sourcebook*.[7] Specifically, we reviewed the agencies' establishing

[6]J. Selin and D. Lewis, *Sourcebook of United States Executive Agencies* (Second Edition) (Washington, D.C.: Administrative Conference of the United States, October 2018). The *Sourcebook* describes these structural characteristics for over 270 federal agencies, including six components of the Executive Office of the President; 15 executive departments and 173 bureaus within those departments; and 78 agencies outside of the Executive Office of the President and executive departments and two bureaus within those agencies.

The *Sourcebook* was originally commissioned by the Administrative Conference of the United States in 2012. The Administrative Conference of the United States is an independent federal agency charged with convening expert representatives from the public and private sectors to promote efficiency, participation, and fairness in the promulgation of federal regulations and in the administration of federal programs.

[7]*Sourcebook* researchers collected data on the structural characteristics from the agency's establishing statute; other public laws; Office of Management and Budget circulars; the Senate Homeland Security and Government Affairs Committee, *United States Government Policy and Supporting Positions*, 2016, (Plum Book); federal workforce data from the Office of Personnel Management's FedScope website; the Federal Register; U.S. House of Representatives, Reports to be Made to Congress, H.R. Doc. No. 117-4 (2021); and Office of Personnel Management information on federal Administrative Law Judges.

statute; other public laws; Office of Management and Budget (OMB) circulars; the House Committee on Oversight and Reform, *United States Government Policy and Supporting Positions* (Plum Book); and the Federal Register. In addition to these sources, we also reviewed other agency statutes, agencies' websites, the Federal Advisory Committee Act database, and agency written responses to our requests for information on select characteristics. Since CDC is not explicitly established in statute, we reviewed statutes related to CDC's operating divisions and offices, as well as the agency's role in combatting public health threats and capabilities related to bioterrorism and public health emergencies.

To determine the reliability of political appointee data we obtained from the Plum Book, we reviewed a prior GAO report that evaluated the comprehensiveness and timeliness of several data sources that identified political appointees serving in the executive branch, including the Plum Book. The report found that political appointee data in the Plum Book are comprehensive, but not timely.[8] To address limitations on the timeliness of Plum Book data, we obtained the most current data on the number, types, and position titles of political appointees from the selected agencies. To determine the reliability of advisory committee data we obtained from the Federal Advisory Committee Act, we reviewed the websites of the selected agencies to verify the list and names of committees collected from the Federal Advisory Committee Act database. We found that information from the database on advisory committee name, establishment authority, and status—specifically, whether the committee was inactive—was complete and generally accurate. To address limitations on the accuracy of the Federal Advisory Committee

The *Sourcebook* discussed several limitations in the data collection methodology. First, the *Sourcebook* pulled information only from the establishing statute, and noted that it was possible that other statutory provisions outside of the establishing statute impose additional requirements on the agency or specify additional structural features of the agency. Additionally, the *Sourcebook* noted that not all structural features are detailed in statute. Agencies promulgate regulations to implement law and clarify areas where statutory law is unclear. Agencies also clarify this uncertainty in regulation, practice, or agency bylaws. Finally, in some cases, administrative common law adds content to what is not explicitly included in statute.

[8]GAO, *Federal Ethics Programs: Government-wide Political Appointee Data and Some Ethics Oversight Procedures at Interior and SBA Could Be Improved*, GAO-19-249 (Washington, D.C.: Mar. 14, 2019).

The Senate Homeland Security and Governmental Affairs Committee and the House Committee on Oversight and Reform publish the Plum Book every 4 years. The Plum Book is generally published in December after the presidential election and is based on agency data reported to the Office of Personnel Management as of the June prior to the election.

Act database information, we requested that the four agencies verify and update the name, establishment authority, and operating status (active or inactive) of the advisory committees we identified.

We met with former agency heads and external organizations to discuss their perspectives on scientific integrity-related topics, including political interference. We also asked their opinions about structural reforms related to the agencies' organization and design that could help to insulate them from such interference. We selected former agency heads from different Republican and Democratic administrations, including 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 Authority. We also met with other current senior agency officials to discuss their general views on issues related to scientific integrity and political interference within HHS.[9]

We also reviewed HHS's scientific integrity policy and agency-specific policies related to scientific integrity, communications, and clearance processes, and discussed the agency-specific policies with agency officials, asked clarifying questions, and reviewed their written responses.[10] Additionally, we 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.[11]

We also conducted semi-structured interviews with 16 employees, which included managers and non-managers at three of the four selected

[9]We spoke with agency officials serving in both the Trump and Biden administrations, as we conducted this audit from October 2020 to December 2022, across the change in administrations. When referring to these interviewees, we use the term "senior agency official."

[10]HHS, *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, (Feb. 2012). NIH, *NIH Policies and Procedures for Promoting Scientific Integrity*, (Nov. 2012).

[11]The Brennan Center for Justice is a nonpartisan law and policy institute.

The Union of Concerned Scientists is a national nonprofit organization that combines technical analysis and advocacy to create innovative, practical solutions for a healthy, safe, and sustainable future.

agencies—CDC, FDA, and NIH.[12] 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, and their familiarity or experience with instances of potential political interference.

We used a nongeneralizable stratified purposeful sampling approach to select participants. The strata or agency subcomponents were developed by identifying three subcomponents—such as centers, institutes, or offices—within each agency with a mission relevant to COVID-19 research and response.[13] Additionally, we selected some, but not all, of our subcomponents on the basis that they were affected by alleged political interference during the COVID-19 pandemic.[14]

We selected two participants (one manager and one non-manager) from each of our nine strata: (1) CDC's National Center for Immunization and 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)

[12]A semi-structured interview methodology generally involves asking a similar set of questions of multiple interviewees, which enable summaries of responses across interviewees. ASPR 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 like CDC, FDA, and NIH have. "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.

[13]Participation 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.

When reporting our results, we use "respondent" to refer to an employee we interviewed as part of our semi-structured interview methodology. When summarizing responses in our reporting, we use the term "multiple" for instances where at least two respondents are referenced in a statement.

[14]For 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.

NIH's National Heart, Lung, and Blood Institute; (8) NIH's National Institute of Allergy and Infectious Diseases; and (9) NIH's National Institute of Biomedical Imaging and Bioengineering.

To build our sampling frame for selection of the participants, 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.[15] 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 conducted this performance audit from October 2020 to December 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.

[15]An 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.

Appendix II: Structural Characteristics in Place at Selected Department of Health and Human Services (HHS) Agencies

The tables below describe the structural characteristics, or features related to agency organization or design, in place at four HHS agencies: Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), National Institutes of Health (NIH), and Administration for Strategic Preparedness and Response (ASPR).[1] We identified these structural characteristics from the *Sourcebook of United States Executive Agencies* (*Sourcebook*)—a report produced by the Administrative Conference of the United States, an independent U.S. government agency.[2] The *Sourcebook* describes the diversity of federal agencies and their structural characteristics, including how these characteristics can relate to political interference.[3] Structural characteristics can help insulate agencies from political interference from Congress, the President, or both because they affect, in part, the influence Congress and the President have over an agency's decision-making and its responsiveness to political officials and other stakeholders, such as industry.

We grouped the structural characteristics in the tables below into four categories identified from the *Sourcebook*: (1) General Information; (2) Leadership Structure and Agency Personnel; (3) Features Insulating

[1]In July 2022, the Secretary of Health and Human Services elevated the Office of the Assistant Secretary for Preparedness and Response from a staff division to a new operating division in HHS, to be known as the Administration for Strategic Preparedness and Response (ASPR). In this report, we refer to ASPR under the new organizational name and structure, though our review was conducted primarily when the previous organizational structure was in place.

[2]J. Selin and D. Lewis, *Sourcebook of United States Executive Agencies* (Second Edition) (Washington, D.C.: Administrative Conference of the United States, October 2018). The *Sourcebook* is the primary authoritative treatment of the structure and organization of the federal government, based on our review of political science literature and interviews with university-affiliated political science experts.

The Administrative Conference of the United States is an independent federal agency charged with convening expert representatives from the public and private sectors to promote efficiency, participation, and fairness in the promulgation of federal regulations and in the administration of federal programs.

[3]The *Sourcebook* describes these structural characteristics for over 270 federal agencies, including six components of the Executive Office of the President; 15 executive departments and 173 bureaus within those departments; and 78 agencies outside of the Executive Office of the President and executive departments and two bureaus within those agencies.

Agency Policy; and (4) Other Key Structural Features.[4] Specifically, we described whether the selected agencies have the characteristic in place (e.g., Yes, No) and provided additional information for selected characteristics, such as relevant statutes pertaining to the characteristic, as applicable.[5] See appendix I for more information about our scope and methodology for this review.

General Information

This category comprises 10 characteristics that describe general information about an agency. Characteristics in this category can affect an agency's independence or how responsive an agency is to the President and Congress. Of note, all of the selected agencies are located within an executive department and, as a result, have fewer characteristics that can help insulate them from political interference, particularly from the President, compared to independent agencies.

[4]In the *Sourcebook*, what we are referring to as the General Information category is called "Housekeeping Variables." For the most part, the names and descriptions of the characteristics in the tables also derive from the *Sourcebook*. However, we adapted the descriptions of some characteristics in the Other Key Structural Features category to describe more specifically how these characteristics are reflected at the selected agencies.

[5]We primarily reviewed the sources of information identified in the *Sourcebook* to collect information on the structural characteristics at the selected agencies. Specifically, we reviewed the agencies' establishing statute; other public laws; Office of Management and Budget (OMB) circulars; the House Committee on Oversight and Reform, *United States Government Policy and Supporting Positions* (Plum Book); and the Federal Register. In addition to these sources, we reviewed other agency statutes, agencies' websites, the Federal Advisory Committee Act database, and agency written responses to collect information on select characteristics.

The total number of structural characteristics for the selected agencies is not indicative of greater insulation from political interference. For example, in some cases, the absence of certain characteristics or data associated with certain characteristics can help insulate agencies from political interference, such as the number of political appointees at an agency. In addition, some characteristics, such as the agency's location in the federal government, affect which other characteristics are relevant, and, as a result, no agency can have all possible characteristics. Finally, some characteristics can help insulate agencies from political interference from one political actor (e.g., Congress or the President) relative to another, such as whether an agency's leader is Senate-confirmed.

Table 3: Structural Characteristics at Selected Department of Health and Human Services (HHS) Agencies – General Information

Characteristic and Description	Centers for Disease Control and Prevention (CDC)	Food and Drug Administration (FDA)	National Institutes of Health (NIH)	Administration for Strategic for Preparedness and Response (ASPR)
Name	Centers for Disease Control and Prevention	Food and Drug Administration	National Institutes of Health	Administration for Strategic Preparedness and Response
Statute Sections of the U.S. Code that establish the agency	None[a]	21 U.S.C. § 393	42 U.S.C. § 281	42 U.S.C. § 300hh-10
Date of Creation	**July 1, 1946[b]**	**June 30, 1906[c]**	**March 3, 1901[d]**	**December 19, 2006[e]**
Executive Office of the President Agency is a component of the Executive Office of the President	No	No	No	No
Exec. Dept. Agency is an executive department or a component of an executive department	Yes	Yes	Yes	Yes
Bureau Agency is a component of a larger department or agency	Yes	Yes	Yes	Yes
Corporation Agency is a wholly owned government corporation	No	No	No	No
CodeRef Agency is referenced anywhere in the U.S. Code	Yes	Yes	Yes	Yes
StatMandate Federal statute mandates the establishment of the agency	No[f]	Yes[g]	Yes[h]	Yes[i]
StatPermit Federal statute permits, but does not mandate, the establishment of the agency	No[f]	No (see above)	No (see above)	No (see above)

Source: GAO analysis of the U.S. Code and agency websites. | GAO-23-105415

Notes:

[a]There are numerous references to the CDC in federal statute, but the agency is not expressly established in law.

[b]CDC traces its history to 1946, when the Malaria Control in War Areas program within the U.S. Public Health Service transitioned into the Communicable Disease Center. The Preventive Health Amendments of 1992 changed the agency's name and all references in statute to the Centers for Disease Control and Prevention. See Pub. L. No. 102-531, § 312, 106 Stat. 3469, 3504-06.

[c]Although it was not known by its present name until 1930, FDA traces its modern regulatory functions to the enactment of the Pure Food and Drugs Act of 1906, Pub. L. No. 59-384, 34 Stat. 768.

[d]According to NIH, the founding legislation for the agency was a 1901 supplemental appropriations act that provided funds for a laboratory within the Marine Hospital Service, predecessor agency to the U.S. Public Health Service, to investigate infectious and contagious diseases and public health matters. NIH's establishing statute was enacted in 1985. See Health Research Extension Act of 1985, Pub. L. No. 99-158, 99 Stat. 820.

[e]Pandemic and All-Hazards Preparedness Act, Pub. L. No. 109-417, § 102, 120 Stat. 2831, 2832-34 (2006).

[f]Unlike the other selected HHS agencies, CDC is not explicitly established in statute, although the authority exists to do so. Many elements of CDC's operations are established in statute, such as CDC's role in defending against and combatting public health threats and capabilities related to bioterrorism and public health emergencies. See 42 U.S.C. § 247d-4. In addition, several of CDC's operating divisions and offices are explicitly authorized, such as the National Center for Health Statistics. See 42 U.S.C. § 242k.

[g]See 21 U.S.C. § 393.

[h]See 42 U.S.C. § 281.

[i]See 42 U.S.C. § 300hh-10.

Leadership Structure and Agency Personnel

This category comprises 35 characteristics that relate to various aspects of an agency's leadership and personnel.[6] Characteristics in this category and, in some cases, the absence or reduction of these characteristics, such as the number of political appointees, can help insulate agencies from political interference by the President because they can affect how much influence the President has over who leads and operates the agency.[7] Of the 35 characteristics in this category, NIH had three, CDC and FDA had two, and ASPR had one.[8] Of note, the selected agencies have almost none of the characteristics that can help insulate their leaders from political interference by the President, such as those that place limits on the appointment, removal, selection, and retention of agency leaders.

[6]We excluded eight of the 35 characteristics in this category from the tables because the selected agencies were not multimember commissions and did not have a board of directors.

[7]For the most part, structural characteristics in this category can help insulate an agency from political interference from the President. However, some characteristics in this category also have implications for congressional influence because they can affect the level of congressional input into the selection of agency leaders, such as whether an agency head is Senate-confirmed.

[8]We excluded 14 characteristics from our count. Specifically, we excluded the eight characteristics related to multimember commissions and board of directors because they were not applicable to the selected agencies. We also did not consider as part of our count six characteristics in Table 4 because they described the number of employees and political appointees at the selected agencies.

Table 4: Structural Characteristics at Selected Department of Health and Human Services (HHS) Agencies – Leadership Structure and Agency Head Selection and Retention

Characteristic and Description	Centers for Disease Control and Prevention (CDC)	Food and Drug Administration (FDA)	National Institutes of Health (NIH)	Administration for Strategic Preparedness and Response (ASPR)
Multimember Agency is a multimember commission, has a board of directors, or the like	No	No	No	No
Acting Service Rules[a] Statute specifies that in the event of absence, disability, or vacancy at the position of agency head, the President may designate an individual to fill the vacancy	No	No	No	No
PAS Head[b] Statute specifies that the President, with advice and consent of Senate, appoints the agency head and the agency head is not an official from another agency	No[c]	Yes[d]	Yes[e]	Yes[f]
President Selects Chair Statute specifies that the President designates the agency head but does not provide for Senate advice and consent	No	No	No	No
Sec/Com Selects Head For bureaus within larger agencies, statute specifies that the head of the larger organization designates the agency head	No	No	No	No
Outside Head Statute specifies that the head of the agency is an official who also serves in a position in the administration that is outside of the agency	No	No	No	No
Head Removal Statute specifies that the head may only be removed for inefficiency, neglect of duty, or malfeasance in office; or statute specifies a term of office for the head of the agency	No	No	No	No

Characteristic and Description	Centers for Disease Control and Prevention (CDC)	Food and Drug Administration (FDA)	National Institutes of Health (NIH)	Administration for Strategic Preparedness and Response (ASPR)
ChairServe President Statute specifies that head of agency serves at the pleasure of the President	No	No	No	No

Source: GAO analysis of the U.S. code. | GAO-23-105415

Notes:

[a]Or, statute designates a specific official within the agency who may perform the agency head's duties in case of absence, disability, or vacancy and does not allow for presidential designation.

[b]PAS is a presidential appointment with Senate confirmation. See House Committee on Oversight and Reform, *United States Government Policy and Supporting Positions (*Plum Book) (2020).

[c]The PREVENT Pandemics Act, a bill introduced in March 2022, would require the CDC director to be a Senate-confirmed position. S. 3799, 117th Cong. (2022). As of December 2022, this bill had been reported out of the Senate Committee on Health, Education, Labor and Pensions.

[d]See 21 U.S.C. § 393(d)(1).

[e]See 42 U.S.C. § 282(a).

[f]See 42 U.S.C. § 300hh-10(a).

Table 5: Structural Characteristics at Selected Department of Health and Human Services (HHS) Agencies – Limitations on Agency Appointments and Removals

Characteristic and Description	Centers for Disease Control and Prevention (CDC)	Food and Drug Administration (FDA)	National Institutes of Health (NIH)	Administration for Strategic Preparedness and Response (ASPR)
Citizen of US Statute mandates that board members or commissioners or the agency head must be citizens of the United States	No	No	No	No
Civilian Statute mandates that board members or commissioners or the agency head must be civilians	No	No	No	No
Geographic Statute places a geographic limitation on the nomination or selection of board members or commissioners or the agency head	No	No	No	No
Demographic Statute places a demographic limitation on the nomination or selection of board members or commissioners or the agency head	No	No	No	No
Expertise Statute places an expertise or experience limitation on the nomination or selection of members or commissioners or the agency head	No	No	No	No
Lower Level Expertise[a] Statute places an expertise or experience limitation on the nomination or selection of individuals below the level of agency head	No	No	No	No
Conflict of Interest[b] Agency statute places a conflict of interest limitation on the nomination or selection of members	No	No	No	No

Characteristic and Description	Centers for Disease Control and Prevention (CDC)	Food and Drug Administration (FDA)	National Institutes of Health (NIH)	Administration for Strategic Preparedness and Response (ASPR)
Congressional Input Statute provides some mechanism for congressional input in the nomination process aside from confirmation	No	No	No	No
Fixed Terms Statute specifies a fixed term for members, commissioners, or agency heads	No	No	No	No
Lower Level Fixed Terms[c] Statute specifies a fixed term for an employee of the agency other than members, commissioners, or agency heads	Yes[d]	No	Yes[e]	No[f]
For Cause Statute states that members of the commission or board or the agency head may only be removed by the President for "neglect of duty," "malfeasance in office," "inefficiency," or similar language	No	No	No	No
ServePresident Statute specifies that officials serve at the pleasure of the President	No	No	No	No

Source: GAO analysis of the U.S. code and agency written responses. | GAO-23-105415

Notes:

[a]In the *Sourcebook*, this characteristic is "LLExpertise." Expertise requirements for members of advisory commissions are excluded from this characteristic.

[b]For the purposes of our review, we interpreted this characteristic to refer to members of a board of directors, commissioners, or agency heads. Separate from any conflict of interest limitations that may be mandated by agency statute, the executive branch ethics program is aimed at preventing conflicts of interest on the part of executive branch employees, including agency heads. For example, political appointees and high-ranking government officials are required to complete a public financial disclosure report to help prevent and mitigate conflicts of interest. See GAO, *Federal Ethics Programs: Government-wide Political Appointee Data and Some Ethics Oversight Procedures at Interior and SBA Could Be Improved*, GAO-19-249 (Washington, D.C.: Mar. 14, 2019).

[c]In the *Sourcebook,* this characteristic is "LL Fixed Terms." Fixed terms for members of advisory commissions are excluded from this characteristic.

[d]For example, the director of CDC's National Institute for Occupational Safety and Health is appointed to a 6-year term, unless previously removed by the Secretary of Health and Human Services. See 29 U.S.C. § 671(b).

[e]For example, certain directors of NIH's institutes and centers are appointed to 5-year terms, but there is no limit on the number of terms a director may serve. See 42 U.S.C. § 284(a)(2).

[f]The Secretary of Health and Human Services may appoint highly qualified individuals to scientific or professional positions in ASPR's Biomedical Advanced Research and Development Authority for up to 6 years. See 42 U.S.C. § 247d-7e(c)(7)(A)(iii). However, this provision applies to the Biomedical Advanced Research and Development Authority specifically and not to ASPR more broadly.

Table 6: Structural Characteristics at Selected Department of Health and Human Services (HHS) Agencies – Political Appointees and Agency Personnel

Characteristic and Description	Centers for Disease Control and Prevention (CDC)	Food and Drug Administration (FDA)	National Institutes of Health (NIH)	Administration for Strategic Preparedness and Response (ASPR)
PAS[a] Number of positions in agency subject to presidential appointment with Senate confirmation	None	1[b] (as of September 2022)	1[c] (as of November 2022)	1[d] (as of September 2022)
NA[e] Number of Senior Executive Service general positions in agency filled by noncareer appointment	2[f] (as of August 2022)	2[g] (as of September 2022)	1[h] (as of November 2022)	2[i] (as of September 2022)
SchC[j] Number of positions in agency filled by Schedule C Excepted Appointment	None	None	None	2[k] (as of September 2022)
PA[l] Number of positions in agency subject to presidential appointment without Senate confirmation that are not noncareer SES positions or Schedule C positions	None	None	1[m] (as of November 2022)	None
XS[n] Number of policy and supporting positions in the agency subject to statutory excepted appointment that are not PAS, NA, SC, or PA positions	None	None	None	None
Agency-specific personnel 5 U.S.C. § 5012 excepts agency employees from the definition of "employee"; agency's statute permits the agency to use employment systems particular to that agency; or agency's statute allows a limited number of employees to fall outside of civil service provisions	Yes[o]	Yes[p]	Yes[q]	No[r]

Characteristic and Description	Centers for Disease Control and Prevention (CDC)	Food and Drug Administration (FDA)	National Institutes of Health (NIH)	Administration for Strategic Preparedness and Response (ASPR)
Employees Number of employees in the agency	12,952 (as of August 2022)	17,868 (as of September 2022)	18,927 (as of August 2022)	984 (as of September 2022)

Source: GAO analysis of the U.S. code and data from agency officials. | GAO-23-105415

Notes:

[a]PAS is a presidential appointment with Senate confirmation. See House Committee on Oversight and Reform, *United States Government Policy and Supporting Positions* (Plum Book) (2020).

[b]The political appointee in this category is the Commissioner of Food and Drugs (FDA commissioner).

[c]The political appointee in this category is the NIH director. NIH officials told us that, as of August 2022, this position has been vacant since December 2021.

[d]The political appointee in this category is the Assistant Secretary for Preparedness and Response.

[e]NA is a noncareer political appointment. Noncareer appointees may be appointed to any senior executive service general position. There is no requirement for competitive staffing for noncareer appointees, but the agency head must certify that the appointee meets the qualifications requirements for the position. See the 2020 Plum Book.

[f]The political appointees in this category are: the CDC director; and Senior Counselor.

[g]The political appointees in this category are: the Deputy Commissioner for Policy, Legislation, and International Affairs; and Associate Commissioner for External Affairs.

[h]The political appointees in this category is the Senior Director.

[i]The political appointees in this category are: the Chief of Staff; and Chief Strategy Officer.

[j]SchC is a Schedule C excepted political appointment. These positions are excepted from the competitive service because of their confidential or policy-determining character. See the 2020 Plum Book.

[k]The political appointees in this category are Senior Policy Advisors for the COVID Response.

[l]PA is a presidential appointment without Senate confirmation. See the 2020 Plum Book.

[m]The political appointee in this category is the National Cancer Institute director.

[n]XS is an appointment exempted by statute. See the 2020 Plum Book.

[o]For example, the Secretary of Health and Human Services may appoint a limited number of “highly qualified” individuals to scientific positions at CDC that have expertise in biosurveillance, as well as other related scientific or technical fields, without regard to certain civil service provisions. See 42 U.S.C. § 247d-4(f).

[p]For example, the Secretary of Health and Human Services may appoint “outstanding and qualified” candidates to scientific positions in FDA that support the development, review, and regulation of medical products, without regard to certain civil service provisions. See 21 U.S.C. § 379d-3a.

[q]For example, the Secretary of Health and Human Services may appoint a limited number of technical employees to positions in NIH to perform, administer, or support countermeasure research and development activities, without regard to certain civil service provisions. See 42 U.S.C. § 247d-6a(e)(1).

[r]The Secretary of Health and Human Services may appoint a limited number of “highly qualified” individuals to scientific positions in ASPR’s Biomedical Advanced Research and Development Authority, without regard to certain civil service provisions. See 42 U.S.C. § 247d-7e(c)(7). However, this provision applies to the Biomedical Advanced Research and Development Authority specifically and not to ASPR more broadly.

Features Insulating Agency Policy

This category comprises eight characteristics that relate to various aspects of agency policy-making and resources. Characteristics in this category can help insulate agencies from political interference by either the President or Congress, because they can affect how much influence and oversight the President and Congress have over agency actions and priorities. For example, those characteristics related to bypassing OMB review can help to insulate an agency from political interference by the President, while characteristics related to agency funding and congressional oversight can help to insulate an agency from political interference by Congress. Of the eight characteristics in this category, FDA had two, CDC and NIH had one, and ASPR had none.[9] Of note, the selected agencies had none of the characteristics that can help insulate their policy-making from political interference by the President.

[9]We did not consider as part of our count two characteristics from Table 6 because they described the extent of certain aspects of congressional oversight for the selected agencies; specifically the number of statutorily mandated recurring agency reports to Congress and the number of committees specified by statute as overseeing the agency.

Table 7: Structural Characteristics at Selected Department of Health and Human Services (HHS) Agencies – Features Insulating Agency Policy from the President

Characteristic and Description	Centers for Disease Control and Prevention (CDC)	Food and Drug Administration (FDA)	National Institutes of Health (NIH)	Administration for Strategic Preparedness and Response (ASPR)
Exempted OMB Budget Review[a] The President must submit the agency's budget requests to Congress without revision, with the President's budget proposals; or the agency submits its budget directly to Congress without Office of Management and Budget (OMB) review	No	No	No[b]	No
Exempted OMB Rule Review[c] The agency is exempted from submitting all regulatory actions to the administrator of OMB's Office of Information and Regulatory Affairs	No	No	No	No
Exempted OMB Communications Review[d] The agency asserts "informal" legislative bypass authority without any explicit authority, statutory or otherwise, even though OMB Circular A-19 covers the agency	No	No	No	No
Independent Litigating Agency authorizing statute includes provisions relating to independent litigating authority	No	No	No	No

Source: GAO analysis of the U.S. code, OMB circulars, and NIH's website. | GAO-23-105415

Notes:

[a]In the *Sourcebook*, this characteristic is "No OMB Budget Review."

[b]In addition to submitting its annual budget request as part of the President's budget, the National Cancer Act authorizes NIH's National Cancer Institute to submit an annual Professional Judgment Budget directly to the President and Congress that reflects the Institute's research priorities and identifies areas of potential investment in cancer research. See 42 U.S.C. § 285a-2(b)(9). Congress may review the National Cancer Institute's Professional Judgment Budget and the President's budget request to develop and pass appropriations to fund the Institute's operations.

[c]In the *Sourcebook*, this characteristic is "No OMB Rule Review."

[d]Or, statutory law exempts the agency from submitting its communications to OMB for coordination and clearance prior to transmittal to Congress. In the *Sourcebook*, this characteristic is "No OMB Communications Review."

Table 8: Structural Characteristics at Selected Department of Health and Human Services (HHS) Agencies – Features Insulating Agency Policy from Congress

Characteristic and Description	Centers for Disease Control and Prevention (CDC)	Food and Drug Administration (FDA)	National Institutes of Health (NIH)	Administration for Strategic Preparedness and Response (ASPR)
Independent Funding[a] Statute authorizes the agency to: (1) collect fees to cover a substantial portion of the agency's operating expenses; (2) collect fees for products and services; or (3) accept and use gifts, donations, or property. Or, statute establishes a working capital fund or other similar fund without fiscal year limitation	Yes[b]	Yes[c]	Yes[d]	No
No Approp Statute authorizes the agency to assess and collect fees or charges for the purpose of covering a substantial portion of the cost of operating expenses incurred by the agency	No	Yes[e]	No	No
Reporting Requirements Number of statutorily mandated recurring agency reports to Congress	16[f] (as of November 2022)	42[g] (as of October 2021)	10[h] (as of October 2021)	4[i] (as of October 2021)
Number Committees Number of committees specified by statute as overseeing the agency in any way, including, inter alia, receiving reports, hearing testimony, or exercising a legislative veto	5[j]	4[k]	8[l]	4[m]

Source: GAO analysis of the U.S. code, public laws, HHS budget data, and agency written responses. | GAO-23-105415

Notes:

[a]Or, statute authorizes the agency to participate in activities generally associated with the business of banking. According to the *Sourcebook*, the most important characteristic by which Congress controls agency actions and priorities is appropriations because an agency may only spend federal revenues or funds if Congress has appropriated them. However, in some cases, Congress has limited its influence over agency funding by allowing agencies more freedom to collect and spend revenues, such as the ability to charge and spend fees for specific purposes. These agency self-funding mechanisms are captured in this characteristic.

[b]Multiple statutes authorize CDC to collect user or administrative fees for a variety of activities, such as conducting sanitation inspections of cruise ships (42 U.S.C. § 269(a)). CDC is also authorized to accept and use any gift, donation, or devise of real or personal property from the National Foundation for the Centers for Disease Control and Prevention to facilitate the agency's work. See 42 U.S.C. § 280e-11(h)(1). CDC also administers a working capital fund to improve the provision of supplies and service. See Consolidated Appropriations Act, 2012, Pub. L. No. 112–74, div. F, title II, 125 Stat. 786, 1070 (2011).

[c]Multiple statutes authorize FDA to assess and collect user fees for a variety of activities, such as those related to prescription drugs (21 U.S.C. § 379h), and tobacco products (21 U.S.C. § 387s). User fees collected by FDA must be appropriated to the agency through the annual appropriations process, and FDA's major user fee programs must be reauthorized every 5 years. FDA is also authorized to accept gifts or donations of services or property to carry out certain requirements (21 U.S.C. § 379b(c)). FDA also administers a working capital fund to provide services for agency programs (21 U.S.C. § 399i).

[d]Multiple statutes authorize NIH to collect fees for a variety of activities, such as for the library services provided by the National Library of Medicine (42 U.S.C § 286(d)(2)). In addition, NIH's institute and center directors are also authorized to accept gifts for their respective activities (42 U.S.C. § 284(b)(1)(I)).

[e]According to FDA officials, FDA's operating costs for fiscal year 2021 totaled $3.01 billion, of which $1.33 billion (or 44 percent) were covered by user fees.

[f]CDC is statutorily required to provide 16 reports to Congress on topics such as sudden unexpected infant/childhood death (42 U.S.C. § 300c-14).

[g]FDA is statutorily required to provide 42 reports to Congress on topics such as drug shortages (21 U.S.C. § 356c-1(a)) and prescription drug activities (21 U.S.C. § 379h-2(a)).

[h]NIH is statutorily required to provide 10 reports to Congress on topics such as on the use of breast cancer research funds (39 U.S.C. § 414).

[i]ASPR is statutorily required to provide four reports to Congress on topics such as the Strategic National Stockpile (42 U.S.C. § 247d-6b(a)(2)).

[j]These committees are: the Senate Committee on Appropriations; Senate Committee on Health, Education, Labor and Pensions; House Committee on Appropriations; House Committee on Energy and Commerce; and House Select Subcommittee on the Coronavirus Crisis.

[k]These committees are: the Senate Committee on Appropriations; Senate Committee on Health, Education, Labor and Pensions; House Committee on Appropriations; and House Committee on Energy and Commerce.

[l]These committees are: the Senate Committee on Health, Education, Labor and Pensions; Senate Committee on Appropriations; Senate Homeland Security and Governmental Affairs; Senate Small Business and Entrepreneurship Committee; House Committee on Energy and Commerce; House Committee on Appropriations; House Committee on Oversight and Reform; and House Small Business Committee.

[m]These committees are: the Senate Committee on Appropriations; Senate Committee on Health, Education, Labor and Pensions; House Committee on Appropriations; and House Committee on Energy and Commerce.

Other Key Structural Features

This category comprises 11 characteristics related to agency administrative and decision-making processes. Characteristics in this category can affect how responsive the agency is to the President or Congress. Of the 11 characteristics in this category, FDA and NIH had eight, CDC had seven, and ASPR had five. Of note, all the agencies had at least one structural characteristic related to advisory committees and rulemaking, which can help insulate them from political interference in agency decision-making.

Table 9: Structural Characteristics at Selected Department of Health and Human Services (HHS) Agencies – Government-Wide Management and Transparency Laws

Characteristic and Description	Centers for Disease Control and Prevention (CDC)	Food and Drug Administration (FDA)	National Institutes of Health (NIH)	Administration for Strategic Preparedness and Response (ASPR)
CIO[a] The agency is statutorily mandated to have a Chief Information Officer (CIO), or is a subpart of an agency statutorily mandated to have a Chief Information Officer	Yes[b]	Yes[b]	Yes[b]	Yes[b]
IG[c] The agency is statutorily mandated to have an Inspector General (IG), or is a subpart of an agency statutorily mandated to have an Inspector General	Yes[d]	Yes[d]	Yes[d]	Yes[d]
CFO[e] The agency is statutorily mandated to have a Chief Financial Officer (CFO), or is a subpart of an agency statutorily mandated to have a Chief Financial Officer	Yes[f]	Yes[f]	Yes[f]	Yes[f]
Sunshine The agency is subject to the Government in the Sunshine Act of 1976	No	No	No	No

Source: GAO analysis of the U.S. code and agency websites. | GAO-23-105415

Notes:

[a]In the *Sourcebook*, the description of this characteristic is: the agency is statutorily mandated to have a Chief Information Officer.

[b]HHS's Office of the Chief Information Officer leads the development and implementation of enterprise information technology across the department, and certain functions and authorities have been delegated to chief information officers at CDC, FDA, and NIH.

[c]In the *Sourcebook*, the description of this characteristic is: the agency is an "establishment" or "designated federal entity" as defined by the Inspector General Act of 1978 and Office of Management and Budget's (OMB) published list of designated federal entities, and has an Office of Inspector General that is headed by an Inspector General who is appointed by the President with the advice and consent of the Senate or who is appointed by the agency; or the agency is a "federal entity" as defined by the Inspector General Act of 1978 and OMB's published list of federal entities and has an audit office that is required to report an annual audit and investigative activities to each house of Congress and the Director of OMB.

[d]HHS's Office of Inspector General has broad oversight over HHS programs, including those at ASPR, CDC, FDA, and NIH.

[e]In the *Sourcebook*, the description of this characteristic is: the Chief Financial Officers Act mandates that the agency have a Chief Financial Officer appointed by the President and confirmed by the

Senate or appointed by the head of the agency and is a career executive from either the competitive service or the Senior Executive Service.

[f]HHS's Office of the Assistant Secretary of Financial Resources provides advice and guidance on all aspects of HHS's budget and financial management, and grants and acquisition management, and directs and implements these activities across the department. In addition, certain functions and authorities have been delegated to chief financial officers at CDC, FDA, and NIH.

Table 10: Structural Characteristics at Selected Department of Health and Human Services (HHS) Agencies – Advisory Committees, Rulemaking, and Adjudication

Characteristic and Description	Centers for Disease Control and Prevention (CDC)	Food and Drug Administration (FDA)	National Institutes of Health (NIH)	Administration for Strategic Preparedness and Response (ASPR)
Advisory Committees[a] Statute establishes an advisory committee attached to the agency or any of its subparts	Yes[b]	Yes[c]	Yes[d]	Yes[e]
Establish Advisory Committees[a] Statute specifies that one or more advisory committees may be established to advise the agency, or any of its subparts, in any way	Yes[f]	Yes[g]	Yes[h]	No
Outside Approval Statute specifies that one or more agency actions require outside approval before being taken	No[i]	No	Yes[j]	No
Rulemaking Statute authorizes agency to promulgate rules and/or regulations	Yes	Yes	Yes	Yes[k]
Significant Rule Based on the Federal Register, agency has promulgated a rule in the last 15 years that the Unified Agenda of Regulatory and Deregulatory Actions classified as significant under Executive Order 12,866	Yes	Yes	Yes	No
Adjudication Statute gives agency, or any subpart of the agency, the authority to conduct or hold hearings or adjudication, take testimony, receive evidence, employ administrative law judges, or other similar adjudicatory functions	No	Yes[l]	No	No

Characteristic and Description	Centers for Disease Control and Prevention (CDC)	Food and Drug Administration (FDA)	National Institutes of Health (NIH)	Administration for Strategic Preparedness and Response (ASPR)
Administrative Law Judges Agency employs administrative law judges	No	No[m]	No	No

Source: GAO analysis of the U.S. code, Federal Advisory Committee Act database, Federal Register, and agency websites and written responses. | GAO-23-105415

Notes:

[a]The *Sourcebook* describes these characteristics as relating to "advisory commissions" rather than "advisory committees."

[b]CDC has 10 statutorily-established advisory committees, one of which is administratively inactive.

[c]FDA has eight active, statutorily-established advisory committees and boards.

[d]According to NIH, the agency has 47 statutorily-established program advisory committees and national advisory councils and boards, 11 of which are administratively inactive and one of which was terminated as of March 2021.

[e]ASPR has four active, statutorily-established advisory committees and boards.

[f]CDC has 11 active advisory committees and boards established based on HHS's general statutory authority to create advisory councils or committees under 42 U.S.C. § 217a.

[g]FDA has 23 active advisory committees and boards established based on the agency's general statutory authority to create technical and scientific review groups under 21 U.S.C. § 394.

[h]NIH has 109 active program advisory committees, national advisory councils and boards, boards of scientific counselors, integrated/initial review groups, and special emphasis panels based on NIH and HHS's general and NIH's institute-specific authorities to create technical and scientific peer review groups, scientific program advisory committees, and advisory councils or committees. See 42 U.S.C. §§ 282(b)(16), 283k(b), 284(c)(3), 285a-2(b)(7), and 217a.

[i]According to CDC, the authorities that have been delegated to CDC and under which the agency operates, in general, do not expressly require approval from outside sources, though some include an expectation to seek recommendations prior to taking action. See, e.g., 42 U.S.C. § 241(a)(3).

[j]For example, NIH grant proposals require the approval of a technical or scientific peer board attached to the agency before they can be funded. See 42 U.S.C. § 289a-1(a)(2).

[k]According to ASPR, while ASPR and its Biomedical Advanced Research and Development Authority have authority to issue rules, their statutory authorities generally do not require rulemaking.

[l]FDA is authorized to hold formal and informal evidentiary hearings for certain regulatory decisions or actions, such as to dispute FDA's decision not to approve a new drug application (21 U.S.C. § 355(c) and (d)) and to withdraw accelerated approval of a drug product (21 U.S.C. § 356(c)(3)). In addition, the Federal Food, Drug and Cosmetic Act provides a list of prohibited acts that could result in certain penalties. See 21 U.S.C. §§ 331 and 333.

[m]According to FDA, it relies on the staff of administrative law judges in HHS's Departmental Appeals Board when the law requires an administrative law judge to preside over a hearing. In cases when an administrative law judge is not required, FDA's Office of the Commissioner will sometimes appoint a presiding officer from within FDA to preside over a hearing, as appropriate.

Appendix III: 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

November 29, 2022

Sharon M. Silas
Director, Health Care
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Ms. Silas:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, **"CARES ACT: Structural Characteristics That Can Help Insulate HHS Agencies Against Potential Political Interference" (GAO-23-105415).**

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

GENERAL COMMENTS FROM THE DEPARTMENT OF HEALTH & HUMAN SERVICES ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED — CARES ACT: STRUCTURAL CHARACTERISTICS THAT CAN HELP INSULATE HHS AGENCIES AGAINST POTENTIAL POLITICAL INTERFERENCE (GAO-23-105415)

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 Department is committed to providing the best, most current data and scientific understanding available to protect the health, safety, and well-being of our communities. Science plays a vital role in HHS's mission and is central 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 the public health response to the COVID-19 pandemic and other public health threats. The Department's Strategic Plan FY 2022-2026 centers this work with Strategic Goal 4, which asserts HHS's dedication to restoring trust and accelerating advancements in science and research.

As we continue to respond to the COVID-19 pandemic, HHS leadership ensures that all public health decisions are based on the highest-quality scientific information. This commitment has been critical to efforts to deliver COVID-19 vaccines, therapeutics, and tests to the public in record time. The Department also continues to evaluate guidance and recommendations to reflect new evidence as science and data on SARS-CoV-2 and COVID-19 continue to evolve.

HHS employees, including those across the research enterprise and the scientific workforce, work tirelessly to respond to the many health issues facing the nation, including the COVID-19 pandemic. They work with our state, Tribal, local, and territorial partners, research institutions, industry, and community organizations, among others to ensure science is translated into action that protects individuals, communities, and populations.

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 appreciates GAO's consideration of the characteristics that may influence the potential for political interference in scientific activities at ASPR, CDC, FDA, and NIH. We believe that our ongoing efforts to enhance scientific integrity will better protect against political interference in scientific activities, and have fewer negative unintended consequences, than several of the structural changes suggested by GAO.

HHS is actively working to implement the January 27, 2021, Presidential Memorandum on Restoring Trust in Government through Scientific Integrity and Evidence-based Policymaking. 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 Scientific Integrity Policy to comply with the requirements of the Presidential Memorandum. FDA, NIH, CDC, and ASPR are also actively engaged in updating the relevant policies and procedures at their own OpDivs. HHS expects that updated scientific integrity policies will be complete and submitted to the White House Office of Science and Technology Policy (OSTP) in compliance with the Presidential Memorandum. These policies will explicitly bar political interference in scientific activities, as defined by the Scientific Integrity Fact-Track

Action Committee report, and provide procedures and processes for reporting allegations of political interference.

Appendix IV: GAO Contact and Staff Acknowledgments

GAO contact

Sharon M. Silas at (202) 512-7114 or SilasS@gao.gov

Staff Acknowledgments

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

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