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## Strengthening Science in Government: Advancing Science in the Public's Interest

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The Scientists in Government Project • March 2010

# Strengthening Science in Government: Advancing Science in the Public's Interest

The Project on Scientific Knowledge and Public Policy  
at The George Washington University  
School of Public Health and Health Services



THE GEORGE WASHINGTON UNIVERSITY  
SCHOOL OF PUBLIC HEALTH  
AND HEALTH SERVICES

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\* DM contributed to this research project until November 2009, when he was confirmed as Assistant Secretary of Labor for Occupational Safety and Health.

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# Acronyms

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**ARS** – Agricultural Research Service

**ATSDR** – Agency for Toxic Substances and Disease Registry

**CDC** – Centers for Disease Control and Prevention

**CDER** – Center for Drug Evaluation and Research

**CPSC** – US Consumer Product Safety Commission

**DOD** – US Department of Defense

**DOI** – US Department of the Interior

**EPA** – US Environmental Protection Agency

**FDA** – US Food and Drug Administration

**FSIS** – Food Safety and Inspection Service

**HHS** – US Department of Health and Human Services

**HUD** – US Department of Housing and Urban Development

**IHS** – Indian Health Service

**NCTR** – National Center for Toxicological Research

**NIH** – National Institutes of Health

**NIOSH** – National Institute for Occupational Safety and Health

**NIST** – National Institute of Standards and Technology

**OMB** – Office of Management and Budget

**OPM** – Office of Personnel Management

**OSHA** – Occupational Safety and Health Administration

**OSTP** – Office of Science and Technology Policy

**PHS** – US Public Health Service Commissioned Corps

**SAMHSA** – Substance Abuse and Mental Health Services Administration

**USDA** – US Department of Agriculture

**USGS** – US Geological Survey

**VHA** – Veterans Health Administration

The search for truth, Albert Einstein has said, also implies a duty:  
“One must not conceal any part of what one has recognized to be true.”<sup>1</sup>

## Executive Summary

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### Introduction

**T**he statement above serves not only as a guiding principle of good science, but as a framework for effective, science-based policy-making. The best public policies are built on a foundation of rigorous data and analyses, widely shared among scientists and the public. The fundamental obligations of a science-based society—advancing the public health, protecting the workforce, safeguarding the environment, developing appropriate energy technologies, defending the nation, and much more—depend on a full and open exchange of ideas, methods, findings, and interpretations.

New scientific knowledge constantly builds on existing scientific knowledge. When information is readily shared, new findings can be analyzed and new hypotheses vetted in an ongoing process that continually generates opportunities for further study and analysis. Science flourishes when scientific ideas are given a fair hearing by colleagues, debated on their merits, tested through replication and further research, and revised in light of new understanding.

In all that, there is a direct public benefit. Safety and effectiveness studies are essential to drug approval decisions, laboratory and animal studies provide standard-setting data for chemical exposures in the workplace, and understanding the cycle of carbon emissions helps shape the response to global climate change. Strong science drives

sound decision-making and the public policies that strengthen our nation.

Beyond the merits of advancing science, the open exchange of ideas is also cherished because it is concordant with the ideals of a democratic society. Freedom of information is a core belief in the American system.

Despite these laudable goals, there is no such thing as “pure” science, no isolated chamber where scientists can expect to carry out their research, announce their findings, and assume they will be the sole consideration in addressing a real-world challenge.

An analysis of the approach to science taken by the five White House administrations that preceded that of President Barack Obama explains, “It is naïve to believe that scientific findings are the sole determinant of policy ... Much of the funding, direction and use of American science is determined by the federal government and the political biases of the dominant party invariably influence the decisions that get made.”<sup>2</sup>

Policy decisions may be based on science, but they are not purely scientific. Preferences and political considerations shape decisions about regulation, research priorities, service delivery, and program development and evaluation. Nonetheless, the integrity of the science and the validity of the data that informs these decisions must be preserved.



## PRESSURES ON SCIENTISTS

The pressures and constraints facing scientists within government differ considerably from those present in academic settings. For the most part, the nation's universities have embraced the concept of scientific freedom, granting their faculty the unfettered right to publish their findings.

Corporate control of scientific studies is a continuing issue of concern in academia, however, especially over the past decade as reports surfaced that research sponsors blocked the publication of findings detrimental to their commercial interests on a number of occasions.<sup>3</sup> Such was the level of distress that the editors of thirteen of the world's leading biomedical journals, including *The New England Journal of Medicine* and *The Journal of the American Medical Association*, declared in 2001 that they would not publish studies where research sponsors had the ability to control presentation of the results.<sup>4</sup>

Many universities have developed similar guidelines to protect the independence of research, requiring faculty members to retain full rights to disclose the information they gather, even if a commercial sponsor has funded the work.

Scientists in government are less subject to overt commercial pressures because they are on the public payroll, but the principles and practice of open science have often butted against other agendas. Industry interests, interest-group pressures, political ideology, and bureaucratic procedures all have considerable influence on the work they do.

The unique challenge of government scientists is to balance their work as researchers, regulators, and applied scientists with their role as employees of structured, hierarchical organizations. In particular, they may be expected to represent and advocate for official agency positions, regardless of their personal perspective on an issue. Conversely, they may be barred from presenting conclusions or analyses that are inconsistent with an agency's stance, even if they are speaking as private citizens.

Government scientists are typically subject to some level of approval prior to launching a research project, and their work often goes through several additional layers of review

once it is complete and results are ready to be disseminated through articles and presentations. Procedures differ from agency to agency, and there are often notable differences between the approach spelled out in formal guidance documents, if they exist, and what actually happens on the ground.

Many factors may shape research priorities and the review process, including the topic, the agency, the managerial style of those in charge, and the sensitivities of the moment. Clearance procedures are generally more complex when the work has significant policy and/or economic implications, and political appointees often have an influential voice in the review and approval process, whether or not they have scientific expertise. The Union of Concerned Scientists reported in 2008, "New and excessive analytical requirements have provided opportunities for industry groups to highlight uncertainty in agency science, and have prevented federal agencies from responding promptly to urgent threats to public health and safety."<sup>5</sup>

Across most agencies, the many steps involved in clearance often result in long delays before significant scientific findings are widely shared. Along the way, interactions between scientists and the media may be tightly controlled, and in some instances the free exchange of data and results with colleagues may be curtailed.

The lack of uniformity across agencies, and even among offices and centers within a single agency, is striking and highlights the need to explore and clarify the nature of the rights and responsibilities accorded government scientists. In the absence of clear policies, or in the presence of policies that place significant restrictions on scientific freedom, these employees may be constrained in their ability to meet their obligations to the scientific community, and to the public at large.

In the first decade of the 21st century, public concern about political interference with science mounted. Events such as the Food and Drug Administration's long delay in approving emergency contraception for over-the-counter sale,<sup>6</sup> the use of ideological criteria to select members of federal scientific advisory committees,<sup>7</sup> and the suppression and distortion of scientific findings on climate change called into question the integrity of government science.<sup>8</sup>

Under both the Bush and Obama administrations, the White House Office of Science and Technology Policy (OSTP) has taken steps to advance the openness and integrity of scientific agencies. In May 2008, as directed by the America COMPETES Act, OSTP released a set of principles directing federal agencies to pursue “robust and open communication of scientific information.”<sup>22</sup> In March 2009, in response to a Memorandum on Scientific Integrity from President Obama, OSTP began developing a plan to “ensure the highest level of integrity in all

aspects of the executive branch’s involvement with scientific and technological processes” (see box below).<sup>23</sup>

Several independent, non-partisan organizations have also focused in recent years on scientific integrity, conflicts of interest, and the politicization of science. These organizations include the American Association for the Advancement of Science, the Government Accountability Project, the Institute of Medicine, the Science and Engineering Workforce Project, and the Union of Concerned Scientists.

### President Obama’s Memorandum on Scientific Integrity

In March 2009, the Obama Administration issued a Memorandum on Scientific Integrity that appeared to acknowledge many of the concerns that have been expressed in recent years about the limitations of information dissemination and the bias towards political considerations over scientific rigor. Specifically, the memo declared:

The public must be able to trust the science and scientific process informing public policy decisions. Political officials should not suppress or alter scientific or technological findings and conclusions. If scientific and technological information is developed and used by the Federal Government, it should ordinarily be made available to the public. To the extent permitted by law, there should be transparency in the preparation, identification, and use of scientific and technological information in policymaking. The selection of scientists and technology professionals for positions in the executive branch should be based on their scientific and technological knowledge, credentials, experience, and integrity.<sup>23</sup>

To build on those objectives, the memo called for the Office of Science and Technology Policy (OSTP) to develop a plan to ensure integrity in all aspects of government science, based on the following principles:

- (a) The selection and retention of candidates for science and technology positions in the executive branch should be based on the candidate’s knowledge, credentials, experience, and integrity;
- (b) Each agency should have appropriate rules and procedures to ensure the integrity of the scientific process within the agency;
- (c) When scientific or technological information is considered in policy decisions, the information should be subject to well-established scientific processes, including peer review where appropriate, and each agency should appropriately and accurately reflect that information in complying with and applying relevant statutory standards;
- (d) Except for information that is properly restricted from disclosure under procedures established in accordance with statute, regulation, Executive Order, or Presidential Memorandum, each agency should make available to the public the scientific or technological findings or conclusions considered or relied on in policy decisions;
- (e) Each agency should have in place procedures to identify and address instances in which the scientific process or the integrity of scientific and technological information may be compromised; and
- (f) Each agency should adopt such additional procedures, including any appropriate whistleblower protections, as are necessary to ensure the integrity of scientific and technological information and processes on which the agency relies in its decisionmaking or otherwise uses or prepares.<sup>23</sup>

OSTP called for public comments to inform its work, and the Project on Scientific Knowledge and Public Policy submitted recommendations based on the preliminary results of this research.<sup>24</sup> OSTP did not issue a plan in mid-2009 as anticipated, but was expected to do so in 2010.

## SCIENTISTS IN GOVERNMENT PROJECT: SHAPING THE DEBATE

The federal government must ensure that its scientists are able to function effectively, both so that agencies can produce top-quality science to answer important questions and so that they can attract and retain scientific talent. Agencies must also demonstrate to the public that their scientists are working in the public's interests and that agency management is facilitating (rather than suppressing or interfering with) the production and dissemination of knowledge. The public's confidence in government science—and in the government as a whole—is at stake.

The Scientists in Government project was launched as part of a larger effort to ensure that government uses the best science to protect and promote the health and well-being of Americans. It operates under the umbrella of the Project on Scientific Knowledge and Public Policy (SKAPP) at The George Washington University School of Public Health and Health Services.

With support from the Open Society Institute, the Scientists in Government Project seeks to provoke and influence the public discussion about federal scientists' rights and responsibilities. This report presents the results of a qualitative research study that included interviews with

current and former federal scientists at health and environmental agencies, a review of publicly available online agency policies regarding agency research, and a literature review. Qualitative research is “a broad approach to the study of social phenomena ... [drawing] on multiple methods of inquiry,” such as structured interviews and analysis of documents and materials.<sup>25</sup>

This study considers the barriers and opportunities for scientists as they set their research agendas, endeavor to speak freely with one another, disseminate their conclusions and the data that support them, and provide a firm grounding for science-based policies and practices. It also examines the internal and external influences on the research activities of government scientists, and includes recommendations to enhance transparency, minimize interference, and ensure timely access to findings.

The scientists who participated in this research spoke eloquently about their frustrations with a political and bureaucratic climate that sometimes impedes their best work, and offered insights about the policies and practices that can be strengthened or changed to improve their situations. Their voices are a reminder that an open exchange of information is essential to the conduct of good science, the advancement of knowledge, and ultimately the strengthening of the nation's health.

### Research Questions

In exploring the role and functioning of government scientists through qualitative interviews and a review of publicly available online agency policies, Scientists in Government researchers sought answers to the following questions:

- To what extent do agencies foster environments that support scientific work in fulfillment of agency missions?
- What policies exist regarding research, publication, and communication by scientists working at science-based agencies within the federal government?
- How well do agencies facilitate the processes of conducting scientific work and disseminating results?
- What is the nature of agency review of scientific publications?
- Do government scientists retain their autonomy to publish and communicate their scientific findings and conclusions?
- What is the nature of influence affecting federal scientists and their work? How do agencies address this influence?
- Do accessible and useful feedback and dispute-resolution mechanisms exist for federal scientists?

## Findings and Recommendations

The following sections describe some key findings from interviews with scientists and a review of several agencies' written policies. Each recommendation section includes an overarching principle as well as specific recommendations to address the issues raised.

The recommendations address the issues around which scientists expressed the most need for change. Addressing scientists' concerns can improve morale at federal agencies, which will in turn improve scientists' productivity and lead to better government. The recommendations below are often restatements of suggestions made by multiple scientists about how to ensure that their work proceeds efficiently and can be translated quickly into public benefits.

While the majority of the recommendations apply to agencies, White House offices and the Office of Personnel Management (OPM) also have a role to play in ensuring that recommended policies are adopted. This leads to the first overarching recommendation pertaining to all other recommendations in this report.

### OVERARCHING RECOMMENDATION: ENSURING POLICY CONSISTENCY AND CLEAR COMMUNICATION

The White House OSTP and Office of Management and Budget (OMB) should ensure that agencies adopt the policies described in this report's recommendations, and that the policies are generally consistent across agencies and appropriate within each agency's mission and scope. These policies should be clearly and actively communicated to agency leadership, scientific managers, and the federal scientific workforce.

When OPM policies (for instance, those regarding hiring and promotion) conflict with the recommendations in this report, OPM should revise its policies to allow agencies to follow the recommendations.

### MORALE

Scientists' morale affects their agencies' productivity, as well as recruitment and retention. Many of the scientists interviewed characterized their own morale, and often that of their colleagues, as being low or eroding.

## Research Participants' Agency Affiliations

Interviews were conducted with individuals who work for, or had previously worked for, the following agencies (some interviewees had work experience at more than one agency):

### Agencies of the Department of Health and Human Services:

- Centers for Disease Control and Prevention (CDC), including the National Institute for Occupational Safety and Health (NIOSH) and the Agency for Toxic Substances and Disease Registry (ATSDR)
- Food and Drug Administration (FDA), including the Center for Drug Evaluation and Research (CDER) and the National Center for Toxicological Research (NCTR)
- National Institutes of Health (NIH)
- Indian Health Service (IHS)
- Substance Abuse and Mental Health Services Administration (SAMHSA)

### Other agencies:

- US Consumer Product Safety Commission (CPSC)
- US Department of Agriculture (USDA)
- US Department of Commerce, including the National Institute of Standards and Technology (NIST)
- US Department of Defense (DoD)
- US Department of Housing and Urban Development (HUD)
- US Department of Labor, including the Occupational Safety and Health Administration (OSHA)
- US Department of Veterans Affairs, including the Veterans Health Administration (VHA)
- US Environmental Protection Agency (EPA)

Their comments demonstrate the need to improve several aspects of work at science-based federal agencies.

Scientists cited their strong desire to work for the public good as a factor that drew them to government employment. When scientists feel that agencies are failing to advance their missions as effectively as they should, morale suffers.

During interviews, scientists described the following issues as affecting morale at their agencies:

- **Changing Priorities:** Because each change in administration brings new personnel and priorities to federal agencies, scientists often face abrupt changes in research directions. Although such changes are understandable, the effects on scientists can be harsh. A National Institute for Occupational Safety and Health (NIOSH) scientist described spending seven years working on a high-profile topic, only to be told when a new administration entered that the project was no longer a priority and funding for it was no longer available. Others reported working as much as 10 or 15 years on projects, only to have them halted before the research was completed.
- **Bureaucratic Processes:** Many scientists felt they were spending too much time on internal processes—such as getting research proposals approved or seeking clearance to publish articles—and were left with too little time for actually conducting scientific work. Some scientists said they also had to spend an inordinate amount of time dealing with office politics.
- **Inadequate Resources:** Because federal employee salaries and annual pay increases are set by the federal government and have been rising steadily, many agencies find that an increasing share of their program and research budgets must go to personnel costs. This leaves scientists competing for a shrinking pool of money to fund research, and they may have to produce lengthy proposals in order to get relatively small amounts of research funding. Some agencies try to stretch their dollars by using fewer staff people to accomplish the same amount of work or by outsourcing

administrative functions, but these steps can also have the result of taking scientists' time away from their primary responsibilities.

- **Principles Under Threat:** Of all the concerns raised in the interviews, one of the most destructive to morale was an agency's perceived relinquishment of principles. Several scientists described situations in which they or their colleagues had taken a principled stand—e.g., advocating for a particular research agenda or project, or arguing against hiring an unqualified job candidate—only to experience negative consequences. Agencies often face outside pressure to change the course of their work. If managers stand up for scientific integrity in such cases, scientists can feel supported; however, if managers in turn pressure scientists to abandon a line of research or downplay certain results due to potential controversy, the scientists can fear that the agency has lost its integrity or is failing to live up to the mission that attracted them to the job in the first place.

Some scientists expressed concern that eroding morale is harming agencies' abilities to recruit and retain top scientific talent. In some cases, scientists feared that while many of their agencies' best scientists were leaving, others who were not serving the agency well and should retire were staying.

Among the scientists who described problems with low morale, some had already retired or changed jobs. Among those still at an agency, some stated that they remained in their jobs because of practical considerations, such as impending retirements or children in need of college tuition. Others noted that despite problems, they appreciated the opportunity to do important work on interesting topics that would not be available to them in academia or the private sector.

Not all scientists spoke about these problems at their agencies; some praised their managers and expressed appreciation for the research opportunities they enjoy. Also, some who described bureaucratic or budgetary frustrations considered these to be acceptable trade-offs given the stability, career development opportunities, and other benefits that government careers provide.

Several interviewees recommended that scientists considering federal-agency positions understand and accept the constraints that will necessarily accompany government employment. They suggested that agency scientists cultivate patience and thick skins.

## MANAGEMENT

One of the prominent themes that emerged from interviews was the importance of effective managers. While some scientists praised their managers, most felt that those above them were not doing all they could to ensure productivity and top-quality scientific achievements.

Many of the scientists interviewed expressed strong views about the qualifications and roles of those whose jobs involve managing scientists. Scientists from several agencies stated that managers should have enough of a background in science to understand what the scientists they supervise are doing and why. Managers should also be able to explain work conducted by scientists to non-scientists, including other agency officials and the lawmakers who determine agency budgets and shape research priorities.

**“We need supervisors who have the courage to speak up for the science.”**

– CDC branch chief

It appears that managers need a combination of political skills and toughness to perform what many scientists see as a crucial role: standing up for science and buffering scientists from political pressures. Some scientists expressed disappointment and frustration with managers who they felt were too quick to yield to pressure to avoid or minimize controversial topics or findings. Others expressed appreciation for managers who resisted such pressure and defended scientific integrity.

Managers may also need to resist pressure from agency leadership to create additional administrative tasks for scientist that will detract from their scientific work without adding commensurate value to the agency.

One theme that arose during the interviews was that scientists do not necessarily make good managers. Some scientists may seek promotion to a managerial position for which they feel little inclination because it is the only way they can continue up the career ladder to higher pay and greater responsibility. A few scientists suggested that scientists should have career advancement options that do not include managerial duties.

One issue that managers may need to address is the tension that can arise between federal civil service employees and members of the Public Health Service (PHS) Commissioned Corps. In the interviews, several scientists—civil servants and PHS members alike—noted that tensions can arise around the different promotion and advancement requirements the two types of employees face, and these tensions can harm morale.

## RECOMMENDATIONS: MANAGEMENT

**PRINCIPLE:** Agencies should hire and promote managers who have the training and skills necessary to facilitate scientists’ ability to conduct and disseminate research.

**Recommendation:** Agencies should recruit and train managers who will buffer scientists against undue influence and ensure that the agency pursues its scientific mission.

**Recommendation:** Agencies should hire managers who have enough scientific training to translate between scientists and upper management and policymakers.

**Recommendation:** Agencies should provide management training to those who will be managing scientists.

**Recommendation:** Agencies should not require scientists to become managers in order to advance in their professional careers.

**Recommendation:** Agencies should evaluate and address perceived and real inconsistencies in the treatment of scientists on different career pathways (e.g., PHS vs. civil servants).

**Recommendation:** Agencies should minimize administrative duties that detract from scientists’ ability to conduct their work.



“We are all scientists and we want to give our input, and we feel neglected or dismissed if we are not asked our opinion.”

– NIOSH medical officer

## FEEDBACK MECHANISMS

Managers at all levels could benefit from hearing scientists’ concerns and suggestions, but interviews suggested many agencies’ current mechanisms for collecting feedback are insufficient.

Many scientists felt that their observations and suggestions could be useful in improving agency policies and practices, but were frustrated by a lack of opportunities to provide feedback in a meaningful way. A few scientists provided examples of existing feedback mechanisms they considered to be effective, but many others stated that the mechanisms either did not exist or were not useful, either because scientists would not use them for fear of retribution or because those who could benefit from the feedback would ignore the results.

Scientists from several agencies stressed that feedback mechanisms must allow for anonymity, since many employees fear that stating criticisms openly could provoke retaliation. Several scientists feared that criticizing agency management could lead to losing funding or other project support, being transferred to a less desirable location or position, and facing even more obstacles to getting research done. Some scientists had either experienced such retaliation or witnessed a colleague experiencing it.

The Whistleblower Protection Act is designed to protect those “evidencing illegal or improper government activities”; however, a few scientists reported either acting as whistleblowers or witnessing a colleague’s whistleblowing, and they stated that these protections were inadequate to prevent retaliation.

## RECOMMENDATIONS: FEEDBACK MECHANISMS

**PRINCIPLE:** Agencies should encourage honest feedback from scientists, and use it to inform decisions about policies and practices.

**Recommendation:** Provide a formal and anonymous means by which scientists can provide feedback to relevant colleagues, including upper management, without fear of retaliation.

**Recommendation:** Provide regular and follow-up training to ensure that all managers and supervisors are properly trained to understand employees’ rights and to comply with the procedures that protect whistleblowers.

## APPROVING PROPOSED RESEARCH

Science-based agencies have a limited amount of funding to devote to specific research projects, so they often develop processes by which scientists essentially apply to their own agencies for intramural funding. Publicly available online policies governing the selection or approval of such intramural research projects are markedly less formal than those in place for extramural research (in which outside entities apply to an agency for research funding).

At the intramural level, the most consistent policy statement across agencies is that proposed, and sometimes ongoing, intramural research studies will be reviewed by experts. The Centers for Disease Control and Prevention (CDC) and NIOSH’s Mining Program specifically note that those reviews are undertaken by “external” experts. NIOSH’s Mining Program specifies that the reviewers must be “technical experts in their fields,”<sup>64</sup> while CDC refers to “subject matter experts”;<sup>65</sup> both agencies’ policies state that these external reviewers should be free from conflicts of interest. At the National Institutes of Health (NIH), research program priorities are shaped, in part, through “professional hiring and promotion decisions” and resource allocation decisions.<sup>66</sup>

At the research planning stage, none of the publicly available online policies reviewed for this study describe additional procedures for evaluating confidential or sensitive topics.

The relatively brief descriptions contained in publicly available online agency policies related to intramural research contrast with the complicated review processes described by scientists at NIOSH, other CDC agencies, and elsewhere. In particular, interviewees note that the lag between a proposed idea and approval to move forward is often long. Agencies may require detailed applications and extensive review processes even when the amount of funding being sought is small. Several NIOSH interviewees raised concerns about this issue, and their experience is described in the box on the next page.

Federal scientists conducting surveys must also receive clearance from OMB. The Paperwork Reduction Act, first passed in 1980 and amended in 1995, established a procedure for federal agencies to follow before initiating a collection of information (e.g., a survey) from 10 or more people. The agency must provide a 60-day notice of its proposed information collection in the Federal Register and solicit comments to “evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency” and to “minimize the burden of the collection of information on those who are to respond.”<sup>67</sup> Although OMB has made some improvements to the process by which it evaluates requests to collect information, some scientists still considered the process to be excessively burdensome.

## **RECOMMENDATIONS: APPROVING PROPOSED RESEARCH**

**PRINCIPLE:** Agencies should limit the time and effort required by scientists proposing research to what is necessary to ensure that the agency is supporting high-quality research.

**Recommendation:** Agencies should streamline intramural proposal processes to the extent possible.

**Recommendation:** Agencies should make the time and effort required to propose research commensurate with the amount of funding being sought.

**Recommendation:** OMB should streamline the process for approving information collections subject to its oversight, and facilitate the process for the scientists involved.

## **DISSEMINATING SCIENTIFIC WORK**

In general, scientists throughout the federal science infrastructure feel a strong obligation to disseminate their findings to other scientists, and to the general public, in a timely manner. A number of government employees commented that they work for the public, and the public has a right to see their results, “since it is their tax dollars that are paying for the research in the first place.”

Likewise, federal agencies typically consider it part of their mission to disseminate scientific information to the public, and encourage their employees to do so. In agency policies publicly available online, some agencies state that all information products must be cleared before being published or released. Others allow their centers to set their own requirements, and do not specify that all information products must be reviewed.

### **Clearance**

Most federal scientists must submit scientific materials for clearance before disseminating them or submitting to a journal. This process may involve review by several people at different levels within the agency.

Agencies generally require internal review in addition to peer review required by the journals to which scientists submit manuscripts. The review will usually address the science, and it may also determine whether the information product has policy implications and demonstrates a high standard of editorial quality. Policies at the Department of the Interior (DOI) and DOI’s United States Geological Survey (USGS) require that products be well constructed or well written in order to be cleared.

At many agencies, the nature of the information product will influence the nature of the review process. The review process for research with policy implications typically involves more layers and takes longer to complete—something that scientists say can restrict the publication of research that challenges the status quo. Under the Information Quality Act of 2001, higher standards are in place for “influential” scientific information as defined by the OMB.

Scientists described clearance processes that often included review by multiple individuals and entailed



## NIOSH Scientists Describe Their Agency's Research Approval Process

At NIOSH, research projects must be determined to fit within the agency's National Occupational Research Agenda (NORA), which includes 21 priority research areas.

During interviews, NIOSH scientists described a lengthy process for seeking NORA funding. Researchers now submit a one-page letter of intent that includes a list of collaborators, a budget, preliminary data, and the NORA sector goals it is designed to meet. If the idea is of interest, researchers are asked for a full proposal that uses a format and instructions similar to that of a full extramural NIH proposal; it may be 100-200 pages in length. Far more proposals are invited than are ultimately funded – one interviewee recalled that in one funding round, 18 of the original 100 letters of intent were funded. Reflecting the commitment to move research into practice, a relatively recent requirement is to provide in the proposal a description of how study results will be used.

The proposal then moves through a lengthy approval process that begins with an internal review that typically involves the team leader, branch chief, and a number of people in the researcher's division, including the associate director of science. It is also reviewed by the Institutional Review Board, and by a person at CDC who is intimately familiar with OMB regulations.

According to scientists, the proposal may also go to OMB, which can request changes and require that the scientist revise and resubmit the proposal. Following OMB review, it may have to be returned to the IRB for approval of a revised research strategy before data collection can begin.

Scientists reported that full approval can take up to 2-1/2 years, which can be problematic. One scientist commented, "The relevance and collaborators can change during this time."

A NIOSH research chemist called the process "extremely onerous," especially for projects that do not have a lot of money at stake (there is no distinction in the process by funding level). "It takes up huge blocks of time ... I put together a 50-page proposal, single-spaced, for a project that was giving me \$15,000 a year ... Does that make sense?"

The process can also create "a negative work environment," noted the research chemist. "If you spend a lot of time competing for funding and you never get any, what work are you then hired to do?"

On the other hand, some scientists said they appreciated the NORA process because once they are funded, they are not likely to be asked for further information from their supervisors. Whether this outcome occurs seems to depend on the individual's managers and the division in which the scientist is located.

multiple requests for revisions or responses from authors. A number of scientists stated that they could understand the need for the process and had benefited from reviewers' feedback. Others found the benefits of the process to be outweighed by problems.

Scientists expressed frustration about a lack of clarity and consistency regarding the clearance process. Some were concerned about a lack of consensus about what constitutes policy; a number felt their agencies only wanted results that supported their predetermined

policies. This seemed to be a problem for scientists at the Food and Drug Administration (FDA) in particular.

Several interviewees suggested that an individual's experience with the clearance process depends in part on his or her rank.

The issue of reviewers' qualifications also arose in several interviews. Scientists repeatedly stressed that a scientific review should be conducted by scientists. They also noted that the requirement to respond to all reviewers' comments can place significant demands on

scientists' time, although not all comments are necessarily useful or relevant.

Scientists mentioned a number of incidents in which the clearance process appears to have been used to delay or prevent the publication of research because of industry concerns or agency fears about the publication igniting controversy.

### **Delays**

Many scientists expressed frustration about the time-consuming nature of their agencies' clearance processes. Some stated that lengthy, complicated processes discourage some of their colleagues from publishing. Others reported that agency scientists will remove their names from papers co-authored with others outside the agency in order to spare their colleagues the agency's lengthy review process.

Scientists report a range of typical approval times. In some agencies, scientists say it might take three to four weeks; for others, three to four months is typical. Delays of a year or even two were also reported. In some instances, delays reflect the complexities of research or proprietary and confidentiality concerns, but comments from scientists suggest that research with significant policy implications is particularly likely to be delayed.

At NIOSH, scientists say papers are subject to a "tripartite review" by the affected industry, labor, and government agencies (in addition to internal staff), which can take an additional 3-6 months.

Some agencies' policies acknowledge potential problems with lengthy clearance processes and urge those responsible for developing and implementing the processes to make review times as short as possible. Some agencies have policies specifying the time frame in which the clearance is to be completed, although they differ considerably in the extent to which they cover all of the required clearance steps.

CDC's policy calls for clearance standards that "balance the concerns of quality and timeliness," and a timeline that should generally not exceed one month (unless the author is asked to make revisions).<sup>74</sup> In practice, scientists report that delays in the clearance process are common.

Concerns about information products becoming bogged down in lengthy clearance processes prompted Congress to specify a firm timeline for clearance of FDA publications in the FDA Amendments Act of 2007. The legislation requires an FDA policy that gives reviewing officials 30 days to provide written clearance. If the deadline is not met, authors can submit the article for publication with the appropriate disclaimer.

### **Disclaimers**

The use of disclaimers on information products can provide an opportunity for scientists to disseminate their work without going through an agency approval process. It is common for agencies to require that employees publishing or presenting scientific work relevant to their jobs but not cleared by the agency include a statement indicating the work is the product of an individual scientist and does not represent the views of the agency.

The use of disclaimers can be problematic, however, if they are required even when the research has been reviewed and cleared by agency officials. Interviewees reported that NIOSH and the Environmental Protection Agency (EPA) National Center for Environmental Assessment require that all publications and presentations include a disclaimer. This seemed counterintuitive to many scientists, who wondered why an agency would fund the research and then not attach its name to the findings.

The NIH policy states that the clearance process normally eliminates the need for a disclaimer, but one may still be required to make clear that the work does not necessarily represent the NIH view.

The issue of scientific publications produced on scientists' personal time also arose during the interviews. Even though such publications usually include a disclaimer stating that the work represents only the view of the author and not that of the agency where the author is employed, a few agencies still require scientists to submit these publications for agency clearance.

## **RECOMMENDATIONS:**

### **DISSEMINATING SCIENTIFIC WORK**

**PRINCIPLE:** Agencies should disseminate scientific work in a timely fashion, and the clearance process should not

be a tool for slowing down the dissemination of scientific information that may be deemed unfavorable.

**Recommendation:** All agencies should have clear policies on review and clearance, and apply them consistently and in a timely fashion.

**Recommendation:** Agencies assigning reviewers to review the content of scientific output should ensure that the reviewers have expertise in a relevant field.

**Recommendation:** Agencies should encourage expeditious and focused reviews.

**Recommendation:** Agencies should have processes for expedited clearance of time-sensitive materials.

**Recommendation:** Agencies should allow scientific work conducted on agency time but not approved by the agency within a reasonable timeframe to be published with a disclaimer that it represents only the views of the author(s) rather than the agency.

**Recommendation:** Agencies should allow scientists to disseminate scientific work done on their own time, provided they attach any necessary disclaimers, without receiving agency approval. Scientists should not face retribution if they exercise this right.

## COMMUNICATING WITH THE PUBLIC

The primary method by which scientists communicate their findings to the public is through the media, and the policies governing scientists' interactions with reporters have come under scrutiny in recent years. In 2008, OSTP instructed agencies to develop and update policies regarding employee interactions with the public and press. The policies should be designed to ensure that "employees may freely and openly discuss with the

public, subject to classification restrictions and consistent with existing laws and regulations, scientific and technical ideas, approaches, findings, and conclusions based on their official work."<sup>22</sup>

Agency policies publicly available online are not entirely supportive of such free and open discussion. The policies tend to require, or strongly encourage, employees to seek prior approval before being interviewed. However, many agencies appear to offer little or no guidance on the subject, and the perception among scientists at most agencies is that some sort of preapproval is required to speak with the media.

In interviews, a picture emerged of a common agency practice requiring that all media inquiries be routed through a central office. This prevents scientists from speaking directly to reporters until the media office determines which agency employee should respond.

In some scientists' view, this practice is a necessary step to ensuring that the agency speaks to the public with a single voice. Others questioned the appropriateness of having a manager or political appointee answer questions about scientific work they may not fully understand, and some expressed frustration that they may devote a great deal of time to a project but not be the one speaking about it.

Some scientists appreciate having a media office to handle press calls when they do not view themselves as having the necessary skills to respond. Scientists noted the complexity of interacting with the media, and those working on potentially controversial topics were particularly concerned about saying the wrong thing in a media interaction. According to the scientists, some agencies offered strong media training but others did not.

"We are still arguing about disclaimers ... If they're saying we don't speak for the agency, why can't we just say anything we want? Instead, it still has to be cleared."

– CDC branch chief

“I would prefer to provide the information to the media ... Otherwise information gets lost in translation.”

– VHA health systems specialist

In addition to deciding who should respond to press inquiries, some agency media officials also make a practice of being on the line or in the room with any scientist being interviewed. Although not all of the scientists who described this practice found it to be intrusive, some see it as potentially having a chilling effect on what scientists say.

### **RECOMMENDATIONS: COMMUNICATING WITH THE PUBLIC**

**PRINCIPLE:** As directed by the OSTP principles, agencies should develop policies that “provide for the widest practicable and appropriate dissemination of factual information concerning agency scientific activities and their results” and ensure free and open discussion.

**Recommendation:** Agencies should have clear policies on scientists’ communication with the media and the public, and ensure that they are understood and consistently enforced.

**Recommendation:** Agencies’ default policy should be to allow scientists to handle media inquiries directly and interact with reporters without the presence of media office representatives; under certain circumstances (e.g., when the topic is a policy rather than technical issue) it may be necessary for the media office to play a more central role.

**Recommendation:** Agencies should not require scientists to speak with the media; those who wish to do so should be offered media training or be allowed to shift inquiries to the media office.

### **PROFESSIONAL DEVELOPMENT**

Interactions with colleagues from scientists’ disciplines are crucial for professional development. For many scientists, attendance at professional meetings is the most important way for them to build professional

relationships, receive feedback on projects, and learn about new developments in their fields. Nonetheless, many scientists felt their agencies did not fully appreciate the benefits of attending scientific meetings.

While some agencies actively encourage their scientists to attend outside meetings and conferences, others are reluctant to do so. Scientists reported that in recent years, funding restrictions have reduced the number of meetings they can attend. Most scientists interviewed indicated they could attend one or two professional meetings or conferences a year; however, a few scientists mentioned that they had not attended a meeting in recent years and did not know when their next chance would arise.

CDC and NIOSH scientists explained that restrictions have recently been placed on the number of employees of their agencies who could attend any single conference. This caused particular frustration in the case of the industrial hygienists’ annual conference. One scientist reported that approximately 90 NIOSH employees had customarily attended this event (since NIOSH employs more industrial hygienists than any other federal agency), but a CDC official had decided that only 12 should attend.

Participation is sometimes contingent on presentation of a paper at the meeting the scientist wishes to attend. Scientists working on multi-year projects, or those whose agencies have lengthy clearance processes for presentations, may find this a difficult requirement to meet. NIOSH scientists indicated that conference participation is not supported until a scientist is ready to submit a manuscript to a journal for publication.

Scientists at higher levels within some agencies seem to have an easier time securing money and time for travel, which can frustrate their lower-ranking counterparts. Lower-ranking scientists commented that those who were allowed to attend the most meetings tended to be those who were the most trustworthy in the eyes of the agency.

Several scientists reported that they will pay for their own attendance at professional events if their agencies will not cover the costs, and may even use vacation time to attend conferences and meetings.

### **RECOMMENDATIONS: PROFESSIONAL DEVELOPMENT**

**PRINCIPLE:** Scientists should be encouraged to maintain their professional standing and pursue professional development through engagement with their scientific colleagues, to the extent possible given their agencies' resources.

“There should be a commitment to professional development ... there should be resources to do that. Managers should recognize that is part of their job, to get those resources.”

– HUD manager

**Recommendation:** Agencies should ensure that requirements determining which scientists are eligible for support to attend professional meetings and conferences are flexible, appropriate, and applied consistently.

**Recommendation:** Agencies should allow all scientists for whom attendance at a particular meeting is appropriate to attend without imposing arbitrary limits on the total number of employee attendees.

### **INTER-AGENCY DATA SHARING AND COMMUNICATION**

Some scientists also noted the importance of interacting with colleagues from other federal agencies on topics of common interest. Accessing data from other agencies can be difficult due to both technological and bureaucratic hurdles; incompatible data systems and restrictive Memoranda of Understanding (MOUs) between agencies were two of the problems raised.

A few scientists also stated that they were discouraged from contacting colleagues at other agencies directly

about issues that both agencies study. One FDA scientist stated that contacts with colleagues at other agencies to discuss scientific topics are prohibited.

### **RECOMMENDATIONS: INTER-AGENCY DATA SHARING AND COMMUNICATION**

**PRINCIPLE:** Scientists should be able to communicate and share data freely and efficiently across federal agencies.

**Recommendation:** Agencies should develop and communicate clear policies on data sharing.

**Recommendation:** Agencies should end explicit or perceived prohibitions on inter-agency communications.

**Recommendation:** Agencies should examine the need for establishing MOUs with other agencies before data sharing occurs; when MOUs are deemed necessary, they should be developed quickly and in a straightforward manner.

**Recommendation:** Agencies should identify ease of data sharing as a priority when making decisions about data systems.

### **INFLUENCE**

Federal-agency science is subject to influence from the public, private, and political arenas, particularly with regards to which topics are researched and how scientific information is disseminated. Most scientists found these influences burdensome, especially when they were asked to redirect their work based on what one scientist referred to as “political whims.” At the same time, some interviewees noted that such influences are inescapable for scientists employed by the federal government, and that a certain amount of input from stakeholders is appropriate and may be beneficial.

Many governmental processes are designed to allow for input from groups who are affected by government action or inaction on a particular issue. Scientists noted that it is often appropriate for private- and public-sector groups to communicate with federal agencies to share their experiences and expertise on particular issues that an agency may be studying. They differentiated between such appropriate activities and what they considered to be undue

influence—for instance, asking an agency to deviate from standard scientific procedures. Most scientists expressed concerns about undue influence compromising scientific integrity in some specific instances at their agencies, and a few considered it a systemic problem.

### **Political Influence**

Many interviewees cited examples of Congress exercising influence over agencies' work. Often, members of Congress will direct an agency to study a health issue that is of concern to a member's constituents—even if that requirement comes without additional funding and may draw resources from work that scientists see as more important for the public's health. Fears of Congressional disapproval, which may lead to reduced funding or greater restrictions for an agency, can also discourage agencies from addressing controversial topics or releasing complete research results.

Influence from government players can also operate subtly. Changes in agency leadership often spell new scientific priorities and management styles, which can subject scientific work to new research directions and requirements. Several scientists expressed concerns about additional layers of bureaucracy that they must navigate, and about additional reviews from lawyers and policy specialists that scientists find unhelpful to advancing agencies' scientific goals.

Several scientists also brought up the difficulty of getting their work cleared by OMB, which often raises questions about particular elements of scientific information products; one scientist reported that OMB had insisted that a large amount of exposure information be deleted from a report, and the agency felt it had no choice but to comply. Since agencies must continue working with the same OMB staff members, they have an incentive to maintain harmonious relationships and may tailor their work based on expectations of what that office will object to.

### **Private- and Public-sector Influence**

During interviews, scientists provided numerous examples of cases in which they felt that members of Congress and agency leadership were exerting influence on scientists because these officials were themselves

influenced by the private sector. In general, scientists expressed more concern about private-sector influence than public-sector influence, but not all of the scientists interviewed felt that industry groups exerted inappropriate or outsized influence.

Multiple scientists gave examples of particular reports or data that they were instructed not to release because the information was unfavorable to an industry. A few scientists stated that when they or a colleague released such unfavorable information despite warnings, harmful career repercussions followed. A scientist from US Department of Agriculture (USDA) and another from FDA felt that private-sector influence was so pervasive that their agencies were now doing more to serve regulated industries than the public.

**“I used to think that politics had nothing to do with what we do here, when I was very new ... [But] politics are more important than I thought ... They influence what the agency chooses to pursue to research.”**

– NIOSH team leader

Scientists did not seem to fear that public-sector groups exert undue influence over agency decisions about disseminating scientific work, although a few interviewees expressed frustration about what they saw as unfounded criticism from advocacy groups about agency science being slanted in favor of industry. Scientists noted that pressure from advocacy groups—particularly those focused on specific diseases—can influence research priorities. Such influence may not be problematic if it keeps an important health issue on Congressional or agency priority lists.

Groups' ability to influence agency science can fluctuate over time. Scientists who worked with tribal groups noted that American Indians have historically had little say in research conducted in and around their tribes, but new mechanisms for soliciting tribal input are helping to address this shortfall. By contrast, NIOSH scientists reported



decreased participation from affected workers in agency research about workplace hazards.

### **RECOMMENDATIONS: INFLUENCE**

**PRINCIPLE:** Agencies should protect scientific work from inappropriate influence.

**Recommendation:** Agencies should adopt policies and training programs for both managers and scientists that affirm agency commitment to scientific integrity and help employees distinguish between appropriate and inappropriate influence on scientific work.

**Recommendation:** Agencies should have policies in place to ensure transparency regarding input from political actors as well as private- and public-sector stakeholders.

### **FOLLOW-UP SURVEY**

To investigate effects that a new administration might be having on scientists' views of the topics covered during the interviews, we conducted an online follow-up survey during July and August 2009, approximately six months after the Obama administration began. The research team used the online survey service Zoomerang<sup>28</sup> to disseminate, collect, and analyze the anonymous survey.

Of the 30 scientists who responded, 18 are currently employed by the federal government at one of the following agencies: Veterans Health Administration (VHA), Indian Health Service (IHS), CDC (including NIOSH), USDA, or EPA.

**“The primary concern at USDA is industry, not public health.”**

– USDA division director

A majority of respondents reported that there had been no change in the areas of access to data, research review processes, publication/review clearance processes, scientists' communication with the media and the public, and scientists' ability to attend meetings and conferences.

In three other areas, responses indicated that some scientists perceive improvements. Although 50% of respondents believed there to be no change in the agency providing a supportive workplace, 20% of the respondents did report a change for the better. To the question about scientists' ability and willingness to provide feedback, 33% reported improvement. And, according to 30% of respondents, the overall work environment has changed for the better.

Despite indications that some scientists perceive improvements at their agencies, comments reflected a belief that change comes slowly, if at all, to federal agencies. Some scientists felt that entrenched managers and civil-service leadership would hamper improvements, and several noted that funding concerns have not abated and may worsen further.

“[I don’t anticipate much change] because the bureaucratic system in place during the previous administration is now ensconced in our agency.”

– Scientist responding to follow-up survey

## Conclusion

The roles and responsibilities of scientists who work for the federal government in science-based agencies cannot be simplified into a sound bite or single issue. This study and the recommendations that have emerged from it call for ensuring a balance that will protect the fundamental principles of scientific method, integrity, freedom of inquiry, and dissemination of results as well as one that will achieve the missions and goals of the scientific agencies as established by our elected representatives.

The commitment and pride of scientists who work in federal agencies is remarkable. Their dedication to the public mission of our health and environmental agencies was demonstrated repeatedly throughout this study. Individual scientists within federal agencies, their managers, agency leaders, the relevant offices at the White House, and Congress all play critical roles in creating a work environment that promotes the morale and productivity of the scientific workforce that ultimately benefits the public.

The principles that are outlined in this report start with valuing the scientific workforce and establishing policies that are consistent across the federal government while being tailored appropriately for the mission and scope of each agency. Transparency, consistency, and accountability must be key elements in these policies.

The OSTP, along with the OMB, should bring agencies’ leadership together to establish common policy approaches. Specific policies should address

- Improving management training and overall management approaches for scientific projects and staff, including promoting opportunities for honest feedback without fear of retaliation;

- Minimizing the bureaucratic maze needed to initiate new research and to allow for publication or other dissemination of research results, with or without disclaimers;
- Providing the opportunity for scientists to communicate with the public, while also providing any support or training that scientists need to improve their skills in public communication;
- Promoting engagement with federal scientists at other agencies and with the larger scientific community, including sharing of data and professional opportunities; and
- Minimizing the impact of inappropriate influence from non-scientific directions, while recognizing the appropriate roles of elected officials and the public in shaping the missions, scientific work, and policies of the agencies.

Concerns about scientific integrity and the politicization of science have been raised across several administrations, and peaked during the first decade of the 21st century over issues ranging from climate-change research and reproductive-health issues to regulatory standards. It is notable that in follow-up research conducted after the 2009 inauguration, several scientists who participated in this research did not anticipate that the change in administration would significantly alter their agencies’ approach to science. Change in large agencies with hierarchical structures is difficult and takes time. This presents a challenge to both the new leadership and the existing career scientists to initiate and maintain new strategies and approaches for improving and sustaining the scientific workforce.



## Methodology

The Scientists in Government Project, launched by the Project on Scientific Knowledge and Public Policy (SKAPP) with support from the Open Society Institute, seeks to contribute to the public discussion about federal scientists' rights and responsibilities. This report presents the results of a qualitative research study that included:

- Structured, in-depth interviews with current and former federal-agency scientists, which were transcribed and coded using themes derived from Grounded Theory;
- a review of publicly available online agency policies regarding agency research; and
- a literature review.

The report considers the barriers and opportunities for scientists as they set their research agendas, endeavor to speak freely with one another, disseminate their conclusions and the data that support them, and provide a firm grounding for science-based policies and practices. It also examines the internal and external influences on the research activities of government scientists, and concludes with recommendations to enhance transparency, minimize interference, and ensure timely access to findings.

An advisory committee composed of five scientists experienced in working with federal-agency scientists provided advice and input to assist with the development of an interview guide and research-participant recruitment. Two informational interviews with experts in the field validated the interview guide. A literature review provided a foundation and rationale for the interviewing process.

The research team recruited interview participants who held advanced degrees and had at least five years of experience working in a scientific capacity for a federal agency that focuses on health or the environment. The criterion of working for a health or environment agency was broadened to include persons who may not have been working specifically at this type of agency, but whose work was related to health or the environment.

From May 2008 through January 2009, 37 structured, in-depth, confidential interviews were conducted by a researcher trained in qualitative research methods with individuals who work for, or had previously worked for, the following agencies (some interviewees had work experience at more than one agency):

### Agencies of the Department of Health and Human Services:

- Centers for Disease Control and Prevention (CDC), including the National Institute for Occupational Safety and Health (NIOSH) and the Agency for Toxic Substances and Disease Registry (ATSDR)
- Food and Drug Administration (FDA), including the Center for Drug Evaluation and Research (CDER) and the National Center for Toxicological Research (NCTR)
- National Institutes of Health (NIH)
- Indian Health Service (IHS)
- Substance Abuse and Mental Health Services Administration (SAMHSA)

### Other agencies:

- US Consumer Product Safety Commission (CPSC)
- US Department of Agriculture (USDA)
- US Department of Commerce, including the National Institute of Standards and Technology (NIST)
- US Department of Defense (DoD)
- US Department of Housing and Urban Development (HUD)
- US Department of Labor (DOL), including the Occupational Safety and Health Administration (OSHA)
- US Department of Veterans Affairs, including the Veterans Health Administration (VHA)
- US Environmental Protection Agency (EPA)

The term "agency" when used in this report refers not only to agencies but to departments (e.g., the US

Department of Agriculture) and to offices, institutions, or bureaus (e.g., the National Institute for Occupational Safety and Health)—in short, to any organization that derives its authority from federal law.

To investigate effects that a new administration might be having on scientists' views of the topics covered during the interviews, an online follow-up survey was conducted (using the online survey tool Zoomerang)<sup>28</sup> during July and August 2009, approximately six months after the Obama administration began.

The 37 participants had experience working for 13 different agencies, for a total of 55 agency work experiences (see Table ES-1). It is noteworthy that 12 of the participants have experience working for NIOSH, which is part of CDC. In addition, five participants were members of the Public Health Service (PHS) Commissioned Corps; members of the PHS work for a variety of agencies within the Department of Health and Human Services (HHS) while serving in the Commissioned Corps.

Information about participants' sex, race, and age was compared to corresponding information from the US Office of Personnel Management (OPM) Demographic Report of 2006<sup>62</sup> regarding government employees in the "professional" category, whose description matched the study's recruitment criteria most closely. Compared to government employees in the "professional" category, the group of study participants included more males, more employees older than age 45, and fewer employees who identify as belonging to a minority group.

Because the OPM report does not calculate average length of government service for the professional category alone, we used the average number of years of service for all federal employees, which is 14.6 years. Our participants had a longer average length of service, 16.9 years.

The team then searched online for policies from health- and environment-focused agencies regarding procedures

for research, publication, and communication with the media and the public by scientists employed at federal agencies. We found relevant policies regarding at least one of these activities from the following agencies and centers:

- Agricultural Research Service (an agency of the US Department of Agriculture)
- Center for Drug Evaluation and Research (a center of the Food and Drug Administration)
- Centers for Disease Control and Prevention
- Environmental Protection Agency
- Food Safety and Inspection Service (an agency of the US Department of Agriculture)
- National Institute for Occupational Safety and Health (an institute of the Centers for Disease Control and Prevention)
- National Institutes of Health
- US Department of Agriculture
- US Department of Interior
- US Geological Survey (a bureau of the Department of Interior)

Qualitative research is "a broad approach to the study of social phenomena ... [drawing on] multiple methods of inquiry," including structured interviews and analysis of documents and materials. Qualitative research also has limitations.<sup>25</sup> One of these is funding, which determines the amount of time a researcher can devote to a project. Ultimately, qualitative researchers aim to reach the point of data saturation; however, a researcher is never absolutely certain that it has been attained. Qualitative research does not employ nor aspire to have a representative sample; rather, validity and reliability are achieved by rigorous application of field methods and analysis, especially recruitment for the characteristics being researched.

**Table ES-1: Number of Interviewees with Experience at Various Federal Agencies**

Agency	Number of Participants
US Department of Health & Human Services (HHS) .....	34
Centers for Disease Control & Prevention (CDC), including the Agency for Toxic Substances & Disease Registry (ATSDR) and National Institute for Occupational Safety & Health (NIOSH) .....	20
Food & Drug Administration (FDA), including the Center for Drug Evaluation & Research (CDER) and the National Center for Toxicological Research (NCTR) .....	6
Indian Health Service (IHS) .....	3
National Institutes of Health (NIH) .....	4
Substance Abuse & Mental Health Services Administration (SAMHSA) .....	1
US Consumer Product Safety Commission (CPSC) .....	1
US Department of Agriculture (USDA) .....	3
US Department of Commerce, including the National Institute of Standards & Technology (NIST) .....	1
US Department of Defense (DoD) .....	4
US Department of Housing & Urban Development (HUD) .....	1
US Department of Labor, including the Occupational Safety & Health Administration (OSHA) .....	1
US Department of Veterans Affairs, including the Veterans Health Administration (VHA) .....	2
US Environmental Protection Agency (EPA) .....	8

# Introduction

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The search for truth, Albert Einstein has said, also implies a duty: “One must not conceal any part of what one has recognized to be true.”<sup>1</sup>

This statement serves not only as a guiding principle of good science, but as a framework for effective, science-based policy-making. The best public policies are built on a foundation of rigorous data and analyses, widely shared among scientists and the public. The fundamental obligations of a science-based society—advancing the public health, protecting the workforce, safeguarding the environment, developing appropriate energy technologies, defending the nation, and much more—depend on a full and open exchange of ideas, methods, findings, and interpretations.

New scientific knowledge constantly builds on existing scientific knowledge. When information is readily shared, new findings can be analyzed and new hypotheses vetted in an ongoing process that continually generates opportunities for further study and analysis. Science flourishes when scientific ideas are given a fair hearing by colleagues, debated on their merits, tested through replication and further research, and revised in light of new understanding.

In all that, there is a direct public benefit. Safety and effectiveness studies are essential to drug approval decisions, laboratory and animal studies provide standard-setting data for chemical exposures in the workplace, and understanding the cycle of carbon emissions helps shape the response to global climate change. Strong science drives sound decision-making and the public policies that strengthen our nation.

Beyond the merits of advancing science, the open exchange of ideas is also cherished because it is concordant with the ideals of a democratic society. Freedom of information is a core belief in the American system.

Despite these laudable goals, there is no such thing as “pure” science, no isolated chamber where scientists can expect to carry out their research, announce their findings, and assume they will be the sole consideration in addressing a real-world challenge.

An analysis of the approach to science taken by the five White House administrations that preceded that of President Barack Obama explains, “It is naïve to believe that scientific findings are the sole determinant of policy ... Much of the funding, direction and use of American science is determined by the federal government and the political biases of the dominant party invariably influence the decisions that get made.”<sup>2</sup>

Policy decisions may be based on science, but they are not purely scientific. Preferences and political considerations shape decisions about regulation, research priorities, service delivery, and program development and evaluation. Nonetheless, the integrity of the science and the validity of the data that inform these decisions must be preserved.

## Pressures on Scientists

The pressures and constraints facing scientists within government differ considerably from those present in academic settings. For the most part, the nation’s universities have embraced the concept of scientific freedom, granting their faculty the unfettered right to publish their findings.

Corporate control of scientific studies is a continuing issue of concern in academia, however, especially over the past decade as reports surfaced that research sponsors blocked the publication of findings detrimental to their commercial interests on a number of occasions.<sup>3</sup> Such was the level of distress that the editors of thirteen of the world’s leading biomedical journals, including *The New England Journal of Medicine* and *The Journal of the American Medical Association*, declared in 2001 that they would not publish studies where research sponsors had the ability to control presentation of the results.<sup>4</sup>

Many universities have developed similar guidelines to protect the independence of research, requiring faculty members to retain full rights to disclose the information they gather, even if a commercial sponsor has funded the work.

Scientists in government are less subject to overt commercial pressures because they are on the public payroll, but the principles and practice of open science have often butted against other agendas. Industry interests, interest-group pressures, political ideology, and bureaucratic procedures all have considerable influence on the work they do.

### **GOVERNMENT SCIENTISTS' UNIQUE ROLE**

The unique challenge of government scientists is to balance their work as researchers, regulators, and applied scientists with their role as employees of structured, hierarchical organizations. In particular, they may be expected to represent and advocate for official agency positions, regardless of their personal perspectives on issues. Conversely, they may be barred from presenting conclusions or analyses that are inconsistent with an agency's stance, even if they are speaking as private citizens.

Government scientists are typically subject to some level of approval prior to launching a research project, and their work often goes through several additional layers of review once it is complete and results are ready to be disseminated through articles and presentations. Procedures differ from agency to agency, and there are often notable differences between the approach spelled out in formal guidance documents, if they exist, and what actually happens on the ground.

Many factors may shape research priorities and the review process, including the topic, the agency, the managerial style of those in charge, and the sensitivities of the moment. Clearance procedures are generally more complex when the work has significant policy and/or economic implications, and political appointees often have an influential voice in the review and approval process, whether or not they have scientific expertise. The Union of Concerned Scientists reported in 2008, "New and excessive analytical requirements have provided opportunities for industry groups to highlight uncertainty in agency science, and have prevented federal agencies from responding promptly to urgent threats to public health and safety."<sup>5</sup>

Across most agencies, the many steps involved in clearance often result in long delays before significant scientific findings are widely shared. Along the way, interactions

between scientists and the media may be tightly controlled, and in some instances the free exchange of data and results with colleagues may be curtailed.

The lack of uniformity across agencies, and even among offices and centers within a single agency, is striking and highlights the need to explore and clarify the nature of the rights and responsibilities accorded government scientists. In the absence of clear policies, or in the presence of policies that place significant restrictions on scientific freedom, these employees may be constrained in their ability to meet their obligations to the scientific community and to the public at large.

In the first decade of the 21st century, public concern about political interference with science mounted. Events such as the Food and Drug Administration's (FDA's) long delay in approving emergency contraception for over-the-counter sale,<sup>6</sup> the use of ideological criteria to select members of federal scientific advisory committees,<sup>7</sup> and the suppression and distortion of scientific findings on climate change<sup>8</sup> called into question the integrity of government science.

### **Scientists in Government Project: Shaping the Debate**

**T**he federal government must ensure that its scientists are able to function effectively, both so that agencies can produce top-quality science to answer important questions and so that they can attract and retain scientific talent. Agencies must also demonstrate to the public that their scientists are working in the public's interests and that agency management is facilitating (rather than suppressing or interfering with) the production and dissemination of knowledge. The public's confidence in government science—and in the government as a whole—is at stake.

The Scientists in Government project was launched as part of a larger effort to ensure that government uses the best science to protect and promote the health and well-being of Americans. It operates under the umbrella of the Project on Scientific Knowledge and Public Policy (SKAPP) at the George Washington University School of Public Health and Health Services.

With support from the Open Society Institute, the Scientists in Government Project seeks to provoke and influence the public discussion about federal scientists' rights and responsibilities. This report presents the results of a qualitative research study that included interviews with current and former federal scientists at health and environmental agencies, a review of publicly available online agency policies regarding agency research, and a literature review. Qualitative research is "a broad approach to the study of social phenomena ... [drawing] on multiple methods of inquiry," such as structured interviews and analysis of documents and materials.<sup>9</sup>

This study considers the barriers and opportunities for scientists as they set their research agendas, endeavor to speak freely with one another, disseminate their conclusions and the data that support them, and provide a firm grounding for science-based policies and practices. It also examines the internal and external influences on the research activities of government scientists, and includes recommendations to enhance transparency, minimize interference, and ensure timely access to findings.

The scientists who participated in this research spoke eloquently about their frustrations with a political and bureaucratic climate that sometimes impedes their best work, and offered insights about the policies and practices that can be strengthened or changed to improve their situations. Their voices are a reminder that an open exchange of information is essential to the conduct of good science, the advancement of knowledge, and ultimately the strengthening of the nation's health.

## Non-Partisan Efforts to Protect and Advance Government Science

A number of other independent, non-partisan organizations have also focused in recent years on scientific integrity, conflicts of interest, and the politicization of science. Among activities of interest:

- The **American Association for the Advancement of Science**, through its Program on Scientific Freedom, Responsibility & Law, examines the ethical, legal, and social issues associated with the conduct of research and advances in science and technology.<sup>10</sup> AAAS is a

member of Professionals for the Public Interest, a coalition formed to defend members against external pressures that challenge the integrity of their work.<sup>11</sup>

- The **Government Accountability Project** produced "ABCs of Drug Safety: Accountability, Balance and Citizen Empowerment,"<sup>12</sup> focused on the approval process for new drugs and conflicts of interest at the FDA. It has also investigated external pressures on climate scientists, collaborating with the Union of Concerned Scientists on a report about political interference in climate science and producing its own report, "Redacting the Science of Climate Change: An Investigative and Synthesis Report."<sup>13</sup>
- The **Institute of Medicine** has undertaken research based on the premise that "reliance on science that is free of political interference provides the foundation for public trust in government decision making."<sup>14</sup> Its reports include an independent evaluation of the Food and Drug Administration, with recommendations in the areas of organizational culture, scientific expertise, and advisory committees.<sup>15</sup>
- The **Science and Engineering Workforce Project**, a project of Harvard University's Labor and Worklife Program and the National Bureau of Economic Research, supported by the Alfred P. Sloan Foundation, produces publications and events focusing on the state of the science and engineering workforce.<sup>16</sup>
- The **Union of Concerned Scientists** has conducted a series of surveys with government-agency scientists, and has documented a wide array of what it calls "abuses of science."<sup>17</sup> Publications include "Voices of Federal Scientists: Americans' Health and Safety Depends on Independent Science,"<sup>18</sup> "Atmosphere of Pressure: Political Interference in Federal Climate Science,"<sup>19</sup> "The A to Z Guide to Political Interference in Science,"<sup>20</sup> and "Federal Science and the Public Good."<sup>21</sup>

## Recent Executive-branch Actions

Under both the Bush and Obama administrations, the White House Office of Science and Technology Policy (OSTP) has taken steps to advance the openness and integrity of scientific agencies. In May 2008,



OSTP released a set of principles for federal agencies' communication of scientific research results, as required by the 2007 America COMPETES Act. The document states:

Robust and open communication of scientific information is critical not only for advancing science, but also for ensuring that society is informed and provided with objective and factual information to make sound decisions. Accordingly, the Federal government is committed to a culture of scientific openness that fosters and protects the open exchange of ideas, data and information to the scientific community, policymakers, and the public.<sup>22</sup>

OSTP Director John Marburger sent the principles to agency heads along with a memo directing them to develop and update "clear guidelines regarding processes for sharing research data and results generated by Federal scientists."<sup>22</sup>

In March 2009, the Obama administration issued a Memorandum on Scientific Integrity that appeared to acknowledge many of the concerns that have been expressed in recent years about the limitations of information dissemination and the bias towards political

considerations over scientific rigor.<sup>23</sup> Specifically, the memorandum declared:

The public must be able to trust the science and scientific process informing public policy decisions. Political officials should not suppress or alter scientific or technological findings and conclusions. If scientific and technological information is developed and used by the Federal Government, it should ordinarily be made available to the public. To the extent permitted by law, there should be transparency in the preparation, identification, and use of scientific and technological information in policymaking. The selection of scientists and technology professionals for positions in the executive branch should be based on their scientific and technological knowledge, credentials, experience, and integrity.<sup>23</sup>

To build on those objectives, the memorandum called for OSTP to develop a plan to ensure integrity in all aspects of government science. OSTP called for public comments to inform its work, and the Project on Scientific Knowledge and Public Policy submitted recommendations based on the preliminary results of this research.<sup>24</sup> OSTP did not issue a plan in mid-2009 as anticipated, but is expected to do so in 2010.

## Research Questions

In exploring the role and functioning of government scientists through qualitative interviews and a review of publicly available online agency policies, Scientists in Government researchers sought answers to the following questions:

- To what extent do agencies foster environments that support scientific work in fulfillment of agency missions?
- What policies exist regarding research, publication, and communication by scientists working at science-based agencies within the federal government?
- How well do agencies facilitate the processes of conducting scientific work and disseminating results?
- What is the nature of agency review of scientific publications?
- Do government scientists retain their autonomy to publish and communicate their scientific findings and conclusions?
- What is the nature of influence affecting federal scientists and their work? How do agencies address this influence?
- Do accessible and useful feedback and dispute-resolution mechanisms exist for federal scientists?

# Methodology

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The study methodology is a qualitatively-based design using semi-structured, key-informant interviews. All interviews were conducted by a qualitative Research Associate (RA1). A second Research Associate (RA2) was present at each interview along with the RA1. The Principal Investigator (PI) provided oversight of the methodology to ensure its accuracy. The RA1 was trained in qualitative methodologies and has utilized these skills in domestic and international settings while adhering to all Institutional Review Board (IRB) standards.

Literature and policy reviews were conducted. Reports, journal articles, newspaper articles, and various other types of publications were collected and analyzed to help provide a foundation and rationale on which the interviews were based. An advisory committee composed of five experts with extensive experience working with government scientists provided insights and guidance to the project.

## Interview Guide

An interview guide (see Appendix A) was developed and revised using feedback from the advisory committee members and two informational interviews conducted with leaders in the field of science and government. The RA1 used these interviews to discuss the proposed research and the questions being developed for the semi-structured, key-informant interviews. Feedback and advice from these interviews assisted with the development of the interview guide.

Three pilot interviews were conducted using this interview guide in May 2008. Additional feedback from these interviews helped refine the interview guide and provided the interviewer with a better understanding of what was feasible and necessary to ask during each interview.

## Participant Recruitment

Hundreds of potential subjects were asked to participate in the study with the expectation that approximately 50 would be willing and able to participate. Within the project's available budget and

timeframe, 37 participants were secured for interviews. Five sampling strategies from qualitative inquiry were used to recruit interview participants. These strategies were Snowball or Chain, Criterion, Opportunistic, Combination or Mixed, and Convenience.<sup>25</sup>

Interview recruitment began once IRB approval was received in May 2008, and continued through November 2008. (See Appendix B for IRB approval information.) Pilot interviews were conducted in May 2008, and the remaining interviews began in June 2008 and continued through January 2009.

The research team recruited participants who held advanced degrees and had at least five years of experience working in a scientific capacity for a federal agency that focuses on health or the environment. The criterion of working for a health or environment agency was broadened to include persons whose agencies may not have this focus, but whose work was related to health or the environment. For example, a participant from the Department of Housing and Urban Development (HUD) worked on lead and asbestos exposures in federal housing. Therefore, it was a health and environment topic that was being addressed even though the agency's mission is not primarily health or the environment. All participants met all of these criteria, with the exception of three who had worked fewer than five years for the government. There were no inclusion or exclusion criteria based upon gender, race/ethnicity, age, risk factors, or prevalence/incidence.

Recruitment information was disseminated on numerous listservs (American Public Health Association, environmental and occupational health, federal, universities, local, etc.), and research team members distributed recruitment flyers at several conferences (e.g., American Public Health Association annual meeting and the Center for Science in the Public Interest's conference on scientific integrity.) Members of the research team also participated in meetings to inform colleagues of the work and to recruit participants, including meeting with the Department of Professional Employees at AFL-CIO and presenting at the "Representing Professionals in Science, Engineering,



and Technology” conference at Harvard University Law School.<sup>26</sup> After conducting 25 interviews, the assistance of participants was solicited to recruit additional participants, and this yielded an additional 12 interviews.

Subjects were given the option to sign a consent form or not, since such records could compromise confidentiality; instead, interview participation was considered consent. All research documents and audio tapes containing identifiable information (e.g., agency name or subject title) were kept in a secure location only accessible to the research team, and will be destroyed.

## Interview Participants

From May 2008 through January 2009, 37 in-depth, semi-structured, key-informant interviews were conducted with individuals who worked for, or had previously worked for, 13 different federal agencies. Several interviewees had work experience at multiple agencies, which resulted in a total of 55 agency work experiences. Participants described experiences at the following agencies:

### **Agencies of the Department of Health and Human Services:**

- Centers for Disease Control and Prevention (CDC), including the National Institute for Occupational Safety and Health (NIOSH) and the Agency for Toxic Substances and Disease Registry (ATSDR)
- Food and Drug Administration (FDA), including the Center for Drug Evaluation and Research (CDER) and the National Center for Toxicological Research (NCTR)
- National Institutes of Health (NIH)
- Indian Health Service (IHS)
- Substance Abuse and Mental Health Services Administration (SAMHSA)

### **Other agencies:**

- US Consumer Product Safety Commission (CPSC)
- US Department of Agriculture (USDA)

- US Department of Commerce, including the National Institute of Standards and Technology (NIST)
- US Department of Defense (DOD)
- US Department of Housing and Urban Development (HUD)
- US Department of Labor, including the Occupational Safety and Health Administration (OSHA)
- US Department of Veterans Affairs, including the Veterans Health Administration (VHA)
- US Environmental Protection Agency (EPA)

Several of these participants were members of the Public Health Service (PHS) Commissioned Corps, and were also able to comment on their experience of working for federal agencies while serving as PHS members.

## Interview Data Analysis

Data was collected via audio tapes of interviews and via handwritten/typed notes taken during the interviews by RA2. After each interview was conducted, field notes were typed and reviewed to identify any items in need of clarification. The audio tapes were transcribed, and the transcribers signed confidentiality statements and adhered to all IRB regulations. Audio tapes, transcripts, and notes were used during the issue-focused,<sup>27</sup> open-coding analysis, which provided a means by which to organize and interpret collected data.

The analysis of the qualitative data involved creating data categories based on general themes and subcategories, also known as ‘codes,’ into which each piece of data was assigned. In order to reduce the possibility of bias when conducting the qualitative data analysis, the research team worked together to code two interviews. Using the principle of Grounded Theory, under which the data drives the analysis, the team read through the interviews and identified the themes, or codes, that emerged. Then, to determine the validity of the themes identified by the entire team, two of the team members conducted analysis separately and then compared their coded data

to determine whether two different researchers would come to the same conclusions regarding code assignment. Based on this process, the team members determined that the themes were accurate. Once this process was completed, RA1 conducted the analysis of the interviews, applying agreed-upon codes to every statement made in the interviews, then sorting the statements into theme-based documents, and finally synthesizing the data to be used in writing the report.

Qualitative research is “a broad approach to the study of social phenomena ... [drawing on] multiple methods of inquiry,” including structured interviews and analysis of documents and materials.<sup>9</sup> Qualitative research also has limitations. One of these is funding, which determines the amount of time a researcher can devote to a project. Ultimately, qualitative researchers aim to reach the point of data saturation; however, a researcher is never absolutely certain that it has been attained. Qualitative research does not employ nor aspire to have a representative sample; rather, validity and reliability are achieved by rigorous application of field methods and analysis, especially recruitment for the characteristics being researched.

### **Additional Research: Policy Review**

To supplement the data collected through interviews, the research team also reviewed policies regarding the practice of science from science-based federal agencies that focus on health or the environment. The team began by contacting health- and environment-focused agencies to request policies regarding the work of agency scientists, and received a few responses referencing online agency resources. In one case, a response from the Department of Labor indicated that policies from the Mine Safety and Health Administration (MSHA) were posted on the agency’s intranet, but not on the website accessible to the public.

The team then searched online for policies from health- and environment-focused agencies regarding procedures for research, publication, and communication with

the media and the public by scientists employed at federal agencies. Relevant policies were found regarding at least one of these activities from the following agencies and centers:

- Center for Drug Evaluation and Research (a center of the US Food and Drug Administration)
- Centers for Disease Control and Prevention, including the National Institute for Occupational Safety and Health
- National Institutes of Health
- US Department of Agriculture, including Agricultural Research Service and Food Safety and Inspection Service
- US Department of the Interior, including the US Geological Survey
- US Environmental Protection Agency

### **Follow-up Survey**

To investigate effects that a new administration might be having on scientists’ views of the topics covered during the interviews, an online follow-up survey was conducted during July and August 2009, approximately six months after the Obama administration began.

The questions addressed workplace supportiveness, access to data, research review process, publication/review clearance process, access to media, access to meetings/conferences, ability and willingness to provide feedback, and overall work environment.

The research team utilized an online survey service called Zoomerang<sup>28</sup> to disseminate, collect, and analyze the anonymous survey. Only the RA1 had access to the survey online, and results, once downloaded, became available only to the research team. These results will also be destroyed.

# Agency Background

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The term “agency” when used in this report refers not only to agencies but to departments (e.g., the US Department of Agriculture) and to offices, institutions, or bureaus (e.g., the National Institute for Occupational Safety and Health)—in short, to any organization that derives its authority from federal law. The agencies whose names appear in bold type below, in alphabetical order, are those that are included in this report. An agency may be included because one of its current or former scientists participated in an interview, or because its policies were reviewed as part of the research.

**US Consumer Product Safety Commission (CPSC)** monitors and researches hazards presented by consumer products; it uses both mandatory and voluntary standards to reduce the risk of injury and death from consumer products, and may obtain the recall of products when necessary. It is an independent regulatory agency headed by three commissioners who are nominated by the President and confirmed by the Senate to seven-year terms.<sup>29</sup>

**US Department of Agriculture (USDA)** addresses agriculture and food issues; its key activities include expanding markets for agricultural products and enhancing food safety.<sup>30</sup> Its centers and services include:

- **Agricultural Research Service (ARS)** conducts research in four areas: Nutrition, Food Safety/Quality; Animal Production and Protection; Natural Resources and Sustainable Agricultural Systems; and Crop Production and Protection.<sup>31</sup>
- **Food Safety and Inspection Service (FSIS)** is the regulatory agency responsible for the safety of commercial meat, poultry, and egg products; FSIS is required to conduct carcass-by-carcass inspections at all federally inspected slaughter facilities and verify that these facilities follow food safety regulations.<sup>32</sup>
- **Forest Service** manages public lands in national forests and grasslands;<sup>33</sup> its research program focuses on informing policy decisions in the areas of Resource

Use Sciences, Quantitative Sciences, Forest Management Sciences, and Environmental Sciences.<sup>34</sup>

US Department of Commerce works to advance economic growth and job opportunities; it has responsibilities in the areas of trade, technology, and environmental stewardship, among others.<sup>35</sup> Its **National Institute of Standards and Technology (NIST)** provides technology, measurements, and standards to “help U.S. industry invent and manufacture superior products reliably, provide critical services, ensure a fair marketplace for consumers and businesses, and promote acceptance of US products in foreign markets.”<sup>36</sup>

**US Department of Defense (DOD)** is responsible for the US military. Medical personnel serving in the military conduct research as well as providing care, and DOD sponsors extramural research.

**US Department of Health and Human Services** “is the United States government’s principal agency for protecting the health of all Americans and providing essential human services, especially for those who are least able to help themselves.”<sup>37</sup> The agencies and offices within it include the following:

- **Centers for Disease Control and Prevention (CDC)** is “dedicated to protecting health and promoting quality of life through the prevention and control of disease, injury, and disability.”<sup>38</sup> Among its functions are disease surveillance and collection of statistics used by health researchers. The agencies within it include:
  - **Agency for Toxic Substances and Disease Registry (ATSDR)** functions include providing information on toxic substances and conducting public health assessments of Superfund sites.<sup>39</sup>
  - **National Institute for Occupational Safety and Health (NIOSH)** conducts research and makes recommendations to prevent injuries and illnesses at workplaces. Upon request, it will conduct Health Hazard Evaluations of specific worksites.<sup>40</sup>

- **Food and Drug Administration (FDA)** is a regulatory agency that ensures “the safety of all food except for meat, poultry and some egg products” and “the safety and effectiveness of all drugs, biological products, medical devices, and animal drugs and feed.”<sup>41</sup> The agency’s drug-related regulatory responsibilities, including the evaluation of new drugs, are carried out by the **Center for Drug Evaluation and Research (CDER)**.<sup>42</sup> The **National Center for Toxicological Research (NCTR)**—in participation with researchers from elsewhere in the FDA, other government agencies, academia, and industry—provides innovative technology, methods development, vital scientific training, and technical expertise.<sup>43</sup>
- **Indian Health Service (IHS)** provides health services to American Indians and Alaska Natives.<sup>44</sup>
- **National Institutes of Health (NIH)** “is the primary federal agency for conducting and supporting medical research.”<sup>45</sup> It is composed of multiple Institutes and Centers that conduct intramural research and also sponsor extramural research.
- The Office of Public Health and Science houses 12 offices focusing on different aspects of public health, including the Office of the Surgeon General. The Surgeon General heads the **Commissioned Corps of the US Public Health Service (PHS)**,<sup>46</sup> which is “dedicated to delivering the Nation’s public health promotion and disease prevention programs and advancing public health science.”<sup>47</sup> The Commissioned Corps is one of the country’s seven uniformed services; its members are eligible to be employed by any HHS agency, and they receive benefits that often differ from those offered by the civil service.
- **Substance Abuse and Mental Health Services Administration (SAMHSA)** funds and administers “grant programs and contracts that support state and community efforts to expand and enhance prevention and early intervention programs and to improve the quality, availability and range of substance abuse treatment, mental health and recovery support services.”<sup>48</sup>

**US Department of Housing and Urban Development (HUD)** works to “increase homeownership, support community development and increase access to affordable housing free from discrimination.”<sup>49</sup> HUD programs and projects must comply with environmental review requirements.<sup>50</sup>

**US Department of the Interior (DOI)** manages a variety of surface lands (including national parks) and water resources (including dams and reservoirs), works to preserve species of fish and wildlife, and conducts research that helps land and resource managers with decision-making.<sup>51</sup> Its bureaus include the **US Geological Survey (USGS)**, which “collects, monitors, analyzes, and provides scientific understanding about natural resource conditions, issues, and problems.”<sup>52</sup>

US Department of Labor (DOL) administers federal laws on several issues affecting workers, including the work environment, the minimum wage, work hours, and freedom from employment discrimination.<sup>53</sup> DOL’s **Occupational Safety and Health Administration (OSHA)** is the regulatory agency that sets and enforces workplace health and safety standards under the Occupational Safety and Health Act.<sup>54</sup>

US Department of Veterans Affairs (VA) provides veterans and their eligible family members with healthcare and other benefits.<sup>55</sup> The **Veterans Health Administration (VHA)** is home to a healthcare system that consists of 153 medical centers, numerous community-based outpatient clinics, and other facilities;<sup>56</sup> it also conducts and funds research at many of these facilities.

**US Environmental Protection Agency (EPA)** is an independent regulatory agency that implements environmental laws, including the Clean Air Act and Clean Water Act, and researches environmental problems.<sup>57</sup> It includes several headquarters offices, 10 regional offices, and multiple labs.<sup>58</sup>

## Other Key Executive-branch Offices

In addition to the federal agencies listed above, two White House offices emerge from this research as having important effects on the work of scientists at federal agencies. The White House Office of Management and Budget (OMB) assists the President in overseeing the

federal budget, and as part of this role it “evaluates the effectiveness of agency programs, policies, and procedures, assesses competing funding demands among agencies, and sets funding priorities.”<sup>59</sup> The White House Office of Science and Technology Policy (OSTP) advises members of the Executive Branch on “the effects of science and technology on domestic and international affairs” and is authorized to “lead interagency efforts to develop and implement sound science and technology policies.”<sup>60</sup>

The Office of Personnel Management (OPM) also plays an important role in establishing personnel policies (hiring, promotion, etc.) and job descriptions that affect the roles of federal scientists.

## Political Appointees and Career Civil Servants

It is useful to note that the vast majority of the employees at the agencies listed above are civil servants, who begin and advance through their careers in a manner standardized across the federal government. By contrast, political appointees are selected by an individual administration for top positions at an agency, where they rarely remain for more than a few years. In *Getting to Know You: Rules of Engagement for Political Appointees and Career Executives*, Ferrara and Ross summarize the differences between the two types of employees in a table that highlights potential sources of friction (Table 1).<sup>61</sup>

**Table 1: Political Appointees and Career Civil Servants**

Factor	Political appointees	Careerists
Role perception	<ul style="list-style-type: none"> <li>• “Determine the nation’s business”</li> <li>• Focused on achieving policy outcomes</li> </ul>	<ul style="list-style-type: none"> <li>• “Determine the nation’s business”</li> <li>• Focused on ensuring a fair, open, and sound decision process</li> </ul>
Partisanship	<ul style="list-style-type: none"> <li>• Affiliated with a political party</li> <li>• Serve a particular president</li> </ul>	<ul style="list-style-type: none"> <li>• Nonpartisan on the job</li> <li>• Serve various presidents</li> </ul>
Professional experience	<ul style="list-style-type: none"> <li>• Often a mix of government, academic, and private sector</li> </ul>	<ul style="list-style-type: none"> <li>• Government has been their main career</li> </ul>
Tenure of service	<ul style="list-style-type: none"> <li>• Come in and go out</li> <li>• Average about two years in their positions, about four years in their agency, and about nine years of government service</li> </ul>	<ul style="list-style-type: none"> <li>• Senior executives average four years in their positions, 19 years in their agency, and more than 25 years of government service</li> <li>• In for the long term</li> </ul>
Time perspective	<ul style="list-style-type: none"> <li>• Tend to have a shorter-term outlook</li> </ul>	<ul style="list-style-type: none"> <li>• Tend to have a longer-term outlook</li> </ul>

*Source: Ferrara & Ross, 2005*

# Research Participant Characteristics

Based on discussions with advisory committee members and key informants, recruitment of study participants focused primarily on environment- and health-based agencies, but participants from other agencies were not excluded. The 37 participants had experience working for 13 different agencies (see Table 2); several interviewees had experience at multiple agencies, which resulted in a total of 55 agency work experiences.

It is noteworthy that 12 of the participants had experience working for the National Institute for Occupational Safety and Health (NIOSH), which is part of the Centers for Disease Control and Prevention. In addition, five participants were members of the Public Health Service (PHS) Commissioned Corps; members of the PHS work for a variety of agencies within the Department of Health and Human Services (HHS) while serving in the PHS.

**Table 2: Number of Interviewees with Experience at Various Federal Agencies**

Agency	Number of Participants
US Department of Health & Human Services (HHS) .....	34
Centers for Disease Control & Prevention (CDC), including the Agency for Toxic Substances & Disease Registry (ATSDR) and National Institute for Occupational Safety & Health (NIOSH) .....	20
Food & Drug Administration (FDA), including the Center for Drug Evaluation & Research (CDER) and the National Center for Toxicological Research (NCTR) .....	6
Indian Health Service (IHS) .....	3
National Institutes of Health (NIH) .....	4
Substance Abuse & Mental Health Services Administration (SAMHSA) .....	1
US Consumer Product Safety Commission (CPSC) .....	1
US Department of Agriculture (USDA) .....	3
US Department of Commerce, including the National Institute of Standards & Technology (NIST) .....	1
US Department of Defense (DoD) .....	4
US Department of Housing & Urban Development (HUD) .....	1
US Department of Labor, including the Occupational Safety & Health Administration (OSHA) .....	1
US Department of Veterans Affairs, including the Veterans Health Administration (VHA) .....	2
US Environmental Protection Agency (EPA) .....	8

Participants were asked to provide the position titles of all of the scientific positions they held at federal agencies. They provided the following titles:

Activity Chief  
 Associate Director for [Topic Area]  
 Associate Director of Health  
 Behavioral Scientist  
 Branch Chief  
 Clinical Associate  
 Commander  
 Director of [Topic Area] Health Program  
 Director of Policy  
 Division Director  
 Environmental Analyst  
 Environmental Engineer  
 Epidemiologist  
 Health Scientist  
 Health Scientist Administrator  
 Health Statistician  
 Health Systems Specialist  
 Industrial Hygienist  
 Institutional Environmental Health Officer  
 Mathematical Statistician  
 Medical Director  
 Medical Epidemiologist  
 Medical Officer  
 Project Officer  
 Research Biologist  
 Research Chemist  
 Research Scientist

Senior Advisor  
 Senior Economist  
 Senior Epidemiologist  
 Senior Research Health Scientist  
 Senior Research Scientist  
 Service Unit Sanitarian  
 Statistician  
 Survey Statistician  
 Team Leader  
 Veterinary Medical Officer

Information about participants' sex, race, and age was compared to corresponding information from the OPM's Demographic Report of 2006<sup>62</sup> regarding government employees in the "professional" category, whose description matched the study's recruitment criteria most closely. OPM defines professional occupations as follows:

Occupations that require knowledge in a field of science or learning typically acquired through education or training pertinent to the specialized field, as distinguished from general education. The work in a professional occupation requires the exercise of discretion, judgment, and personal responsibility for the application of an organized body of knowledge that is constantly studied to make discoveries and interpretations, and to improve the data, materials, and methods."<sup>62</sup>

Comparisons between the sex, race, and age of research participants and professional federal workers are detailed in Tables 3–5.

**Table 3: Sex of Interview Participants and Professional Federal Workers**

Sex	No. of Participants	% of Participants	% from 2006 OPM Report
Male	22	59.5%	56.9%
Female	15	40.5%	43.1%
TOTAL	37	100%	100%



**Table 4: Race of Interview Participants and Professional Federal Workers**

Race	Participants	% of Participants	% from 2006 OPM Report
<b>Non-Minority</b>	37	100%	75.5%
<b>Black</b>	0	0%	9.4%
<b>Hispanic</b>	0	0%	4.9%
<b>Asian/Pacific Islander</b>	0	0%	8.8%
<b>American Indian/Alaskan Native</b>	0	0%	1.4%
<b>TOTAL</b>	37	100%	100%

Study participants were asked which of four age ranges they fell into. OPM uses different age ranges, and it reports age distribution for the entire federal civilian non-postal executive-branch workforce, rather than just for workers falling into the professional category. Table 5 describes the age distributions of the participant pool and the federal civilian non-postal executive-branch workforce.

**Table 5: Age of Interview Participants and Federal Workers**

Age Range for Participants	No. of Participants	% of Participants	Age Range from 2006 OPM Report	% from 2006 OPM Report
< 35 years	0	0%	< 31 years	11%
36-45 years	2	0.5%	31-40 years	18.8%
46-55 years	15	40.5%	41-44 years	11.8%
> 55 years	20	54.0%	45-49 years	16.8%
<b>TOTAL</b>	37	100%	50-54 years	18.1%
			> 55 years	23.5%
			<b>TOTAL</b>	100%



Because the OPM report does not calculate average length of government service for the professional category alone, the average number of years of service for all federal civilian non-postal executive-branch employees, which is 14.6 years,<sup>62</sup> was used. The interview participants had a longer average length of service, 16.9 years. Table 6 describes the years of service of research participants.

<b>Table 6: Interview Participants' Length of Government Service</b>		
<b>Years of Service</b>	<b>No. of Participants</b>	<b>% of Participants</b>
<b>0-5 years</b>	3	8%
<b>6-10 years</b>	10	27%
<b>11-15 years</b>	2	5%
<b>16-20 years</b>	7	19%
<b>20+ years</b>	15	41%
TOTAL	37	100%

Table 7 describes the advanced degrees held by participants (several held more than one). OPM reports that 43% of federal civilian non-postal executive-branch employees hold at least a bachelor's degree;<sup>63</sup> this compares to 100% of research participants who have more than a bachelor's degree, but that outcome is to be expected since having an advanced degree was one of the study recruitment criteria.

<b>Table 7: Advanced Academic Degrees Held by Participants</b>		
<b>Advanced Academic Degrees</b>	<b>No. of Participants</b>	<b>% of Participants</b>
<b>MA</b>	3	4.7%
<b>MF</b>	1	1.6%
<b>MPH</b>	14	22%
<b>MS</b>	10	15.6%
<b>MD</b>	13	20%
<b>PhD</b>	20	31.3%
<b>DVM</b>	1	1.6%
<b>ScD</b>	2	3.2%

# Findings

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The following sections describe findings from interviews with scientists and a review of several agencies' written policies. Key findings include the following:

- **Morale**—Low and eroding morale is a problem across multiple agencies. Scientists identified several factors that harm morale, including abrupt changes in agency priorities, lengthy and burdensome bureaucratic processes for research and publication approval, inadequate resources, and relinquishment of agency principles.
- **Management**—The role of managers in charge of scientists should include buffering those scientists from political pressures that could compromise scientific integrity. Some scientists also suggested that although having a scientific background is important for managing scientists, not all scientists make good managers.
- **Feedback mechanisms**—Agencies need functional feedback mechanisms that encourage scientists to provide anonymous feedback that will be given consideration by managers and agency leadership.
- **Approving proposed research**—The process of applying for intramural research funding can require too much time and effort relative to the amount of funding being sought.
- **Disseminating scientific information**—The process of getting information products cleared for dissemination can be more lengthy and cumbersome than necessary to ensure the products' quality. Concerns exist about agency officials using the clearance process to delay or prevent the publication of information products that may call into question previous agency actions or affect the reputation of an industry or consumer product.
- **Communicating with the public**—The extent to which scientists are able to interact freely with the media and the public varies between agencies, and scientists

have differing views about the extent to which media offices should act as gatekeepers between reporters and scientists.

- **Interacting with colleagues**—Attending professional meetings is crucial to scientists' career development, but agency restrictions on employees' meeting attendance have multiplied in recent years and made such attendance increasingly difficult.
- **Influence**—Policies and practices designed to protect scientific integrity from inappropriate influence are not uniformly successful. Scientists expressed concern about agencies steering research away from potentially controversial topics, to the detriment of agency missions.

All of these issues affect the morale of scientists at federal agencies. The following section contains findings from scientist interviews describing the issues that scientists found most critical for maintaining agency morale. Later sections discuss these and other findings in greater detail.

## Morale

Scientists' morale affects their agencies' productivity, as well as recruitment and retention. Many of the scientists interviewed characterized their own morale, and often that of their colleagues, as being low or eroding. Their comments demonstrate the need to improve several aspects of work at science-based federal agencies.

Several scientists cited a desire to work for the public good as a factor that drew them to government employment. When scientists feel that their agencies are failing to advance their missions as effectively as they should, their morale suffers.

Factors that scientists mentioned as harming morale included frequent changes in agency priorities, often with limited input from the scientists who will conduct the research; onerous bureaucratic processes; insufficient resources; and a sense that an agency has relinquished its principles.

## CHANGING PRIORITIES

Because each change in administration brings new personnel and priorities to federal agencies, scientists often face abrupt changes in research directions. Although such changes are understandable, the effects on scientists can be harsh. One scientist described spending seven years working on a high-profile topic, only to be told when a new administration came in that the project was no longer a priority and funding for it was no longer available. Others reported working as much as 10 or 15 years on projects, only to have them halted before the research was completed. One mentioned coming upon a colleague crying in the bathroom, devastated by the order for a project's abrupt termination.

Some scientists expressed a desire to have more input into important decisions that affect their work. A CDC branch chief noted that when scientists promote agendas that do not coincide with upper management's plans, management may dismiss them as scientists' attempts to bolster their own CVs.

## BUREAUCRATIC PROCESSES

Scientists from several different agencies voiced concerns about lengthy and burdensome processes for getting research projects or publications approved. "I can't think of a bigger discouragement" to doing research or publishing than "to spend a year writing a report and then having it show up under somebody's desk," commented a statistician from CPSC.

Some scientists also felt that they had to spend an inordinate amount of time dealing with office politics. An FDA senior manager commented, "You have to work like a demon and convince people on the inside that there is a better way to do things ... That takes years and years of learning how to do that, and frankly by the time that I got to that point ... I was just too frustrated."

Overall, many scientists felt they were spending too much time on internal processes and too little actually conducting science.

## INADEQUATE RESOURCES

Because federal employee salaries and annual pay increases are set by the federal government and have been rising steadily, many agencies find that an increasing share of their budgets must go to personnel costs. This leaves scientists competing for a shrinking pool of money to fund research. Scientists from multiple agencies voiced frustrations about resource constraints:

- People are often asked to take on additional tasks—even those outside the scope of their job descriptions—without receiving additional funding or resources, even if it will hinder their performance on other job duties. This is particularly frustrating when scientists do not see the additional tasks as being valuable or necessary for the agency's work.
- A NIOSH epidemiologist reported that some of the agency's departments must devote nearly 90% of their budgets to personnel costs—which means that some scientists are writing grant proposals in order to cover overhead costs such as paper and toner cartridges.
- Some agencies have reduced administrative staff and/or outsourced administrative functions like photocopying and making travel arrangements, but this often leads to scientists taking on more of those tasks or facing additional delays in having them performed.

## PRINCIPLES UNDER THREAT

Of all the concerns raised in the interviews, one of the most destructive to morale was an agency's perceived relinquishment of principles. Examples offered by scientists included:

- Several scientists described situations in which they or their colleagues had taken a principled stand—e.g., advocating for a particular research agenda or project, or arguing against hiring an unqualified job candidate—only to experience negative consequences. Some also felt that their agencies as a whole were simply not doing the job they were

supposed to be doing. “Whenever I have stuck to principle it has been a nasty price to pay,” said a VHA health systems specialist.

- Agencies often face outside pressure to change the course of their work, and management’s response to such pressure can determine the extent to which morale suffers. An OSHA manager commented that scientists may feel as if they are “fighting a noble battle with support of their management,” or they can feel “abused and disrespected by upper management.” The latter situation is much more harmful to morale.
- A veterinary medical officer at the USDA stated that although the agency claims to be working in the public’s interest, “we are a fraud.”

Not all scientists spoke about these problems at their agencies; some praised their managers and expressed appreciation for the ability to research topics that would be difficult to investigate in other jobs. Also, some who described bureaucratic or budgetary frustrations considered these to be acceptable trade-offs given the stability, career development opportunities, and other benefits that government jobs promise.

Several interviewees recommended that scientists considering federal-agency employment understand and accept the constraints that will necessarily accompany a government job. These include extensive bureaucratic processes and a requirement to pursue research directions chosen by management. One scientist suggested that agency scientists cultivate patience and thick skins.

## RECRUITMENT AND RETENTION

Among the scientists who described low morale at federal agencies, several had already retired or changed jobs. Some scientists expressed concerns about the departure of talented scientists from agency positions and the difficulty of recruiting other top scientists to replace them. One NIOSH scientist could think of eight scientists who had left within the last two years, explaining, “They felt they weren’t being treated as full scientists.”

During the interviews, some scientists expressed concerns that while many of their agencies’ best scientists

were leaving, others who should have been retiring were staying. This has become a particular concern as many older workers have suffered significant losses in their retirement portfolios and decided to keep working longer than they had initially planned. While many older workers make valuable contributions, agencies may be reluctant to invest in training those who they expect to be retiring in the near future. “Sometimes people stay just out of inertia or laziness,” commented an OSHA manager, although “I think that is the minority.”

Some agencies have responded to budget concerns by hiring fellows—whose time at the agency is limited—rather than permanent employees. These positions may not be as attractive to top candidates as permanent positions would be, so recruitment becomes more challenging.

Scientists who described bleak conditions at their agencies were asked why they stayed, and several cited practical considerations, including impending retirement, a need to get children through college, being geographically limited by a partner’s career, or lacking the up-to-date credentials for securing another job. One VHA scientist stated that his mother is a veteran who would like to be interred at Arlington, and the scientist thinks that staying in his job will help that to happen—but he will likely leave shortly after his mother’s death.

Practical considerations are not the only reason why scientists continue working in frustrating circumstances, however; many also see unique opportunities and rewards in government service. An OSHA manager commented, “There is a lot of commitment and dedication to public service. There are people who believe deeply in the mission of their agency or the potential value of the science they do. They operate at a great sense of public service and idealism ... by and large the scientists who are working for these agencies are very dedicated, committed people.”

When asked why scientists remain at federal agencies despite significant challenges, an FDA senior manager replied, “The reason they do it is because they are getting to work on some of the most fascinating topics in the world ... what keeps you going is what you are doing is very important.”

Scientists who participated in this research volunteered in order to contribute to an effort aimed at improving the situations that currently threaten scientists' morale at federal agencies. The following sections describe findings from this research in greater detail. They discuss statements from both interviews and agencies' written policies; in-depth examples from individual agencies are provided where relevant, along with summarized results from multiple agencies.

## Management

One of the prominent themes that emerged from interviews was the importance of effective managers. While some scientists praised their managers, most felt that those above them were not doing all they could to ensure productivity and top-quality scientific achievements.

Many of the scientists interviewed expressed strong views about the qualifications and roles of those whose jobs involve managing scientists. Scientists from several agencies—including CDC, EPA, HUD, NIH, NIOSH, and OSHA—stated that managers should have enough of a background in science to understand what the scientists they supervise are doing and why. Having a manager with an insufficient understanding of science can frustrate scientists; an EPA/NIOSH epidemiologist stated, “You end up spending all of your time explaining not only to your boss who can't seem to remember why what you do is important, but to everyone [your boss reports to].”

In addition to understanding the work of the scientists they supervise, managers should also be able to explain that work to non-scientists, including other agency officials and the lawmakers who determine agency budgets and shape research priorities. Some scientists suggested that the most effective managers are those who can combine scientific knowledge with political skills; one senior scientist with experience at CDC and NIOSH suggested managers need to understand how Congress, Congressional committees, and cabinet departments work, “and they have to be pragmatic about it.”

An FDA senior manager recommended that managers learn about bureaucratic infighting and “how to ‘do’

meetings,” noting that “decisions are not made in meetings, they are made in hallways before meetings.”

It appears that managers need a combination of political skills and toughness to perform what many scientists see as a crucial role: standing up for science and buffering scientists from political pressures. Some scientists expressed disappointment and frustration with managers who they felt were too quick to yield to pressure to avoid or minimize controversial topics or findings. Others expressed appreciation for managers who resisted such pressure and defended scientific integrity. Comments on this issue included the following:

- A CDC branch chief stated, “[What] I wish some of my bosses could do was to speak the truth to their bosses. A lot of people are frightened of their next position. For example, instead of supporting the scientific work, they went along with the suppression of the data ... We need supervisors who have the courage to speak up for the science.”
- According to a NIOSH epidemiologist, “You’ve got to be very tough ... we see a dark correlation between good outcomes for scientists and the amount of push-back that our managers give. So, being smart, being nimble enough to work well with your supervisors and yet able to withstand pressure appropriately is absolutely critical.”
- An epidemiologist with experience at EPA and NIOSH commented, “I have a supportive environment because I feel like the only thing saving me is my immediate management and my division level management, and it’s been great resistance to that kind of pressure.”
- A senior manager from FDA explained, “There’s a lot of political skills that you have to have, when you get to a senior level, in order to protect the people under you ... Most people don’t realize that there is probably not a nastier work environment on earth than being in a bureaucracy, it is incredible ... You have to be willing to be stabbed in the back a thousand times.”

In addition to these qualities, which are important for managers of scientists operating in a political environment, scientists noted the importance of managerial

skills that are useful in a variety of settings: listening skills, openness to questions and ideas from others, and ability to mentor the employees they supervise.

When asked whether managers can acquire these and other managerial skills through training, many scientists thought that training for managers would be useful. At the same time, several interviewees suggested that some people are not well suited to becoming managers of scientists and should not be hired into those positions.

One theme that arose during the interviews was that scientists do not necessarily make good managers. Some scientists may seek promotion to a managerial position for which they feel little inclination because it is the only way they can continue up the career ladder to higher pay and greater responsibility. A few scientists suggested that scientists should have career advancement options that do not include managerial duties.

Management of scientists by non-career employees can also cause friction. One NIOSH epidemiologist reported an agency-wide push to fill division director positions with people who are hired from outside the government on what is understood to be a temporary basis. This epidemiologist raised the concern that these hires will be subject to political pressure, and that the practice is “a way of getting potentially unqualified people, who might come in from industry, who won’t come for federal salary to be a career employee, but want to come for a few years and manage or wreck a group and then leave.”

## **PUBLIC HEALTH SERVICE (PHS) AND CIVIL SERVICE**

One issue that managers may need to address is the tension that can arise between civil servants and members of the Public Health Service (PHS) Commissioned Corps. In the interviews, several scientists—civil servants and PHS members alike—noted that tensions can arise around the different requirements that the two types of employees face and can harm morale.

According to the scientists who spoke about these tensions, problems have arisen during the past several years as PHS members have been deployed more regularly for emergency response. During these deployments, civil

servants may resent taking on their PHS colleagues’ duties. The PHS members may also fear that non-PHS managers will view deployments unfavorably when making promotion decisions.

One scientist also reported that PHS members are now required to wear their uniforms to work (something that had been strongly recommended in 2003 and become compulsory in 2008), creating a more visible differentiation between the two types of employees.

Scientists pointed out several benefits and drawbacks to each type of career path. The main difficulty of PHS service is the requirement of working for 20 years in order to receive retirement benefits. PHS members receive unlimited sick leave and enjoy higher salaries and more vacation time than their civil-service counterparts do, although members of the civil service have the benefit of being eligible for annual bonuses. It is easier for PHS members to move between agencies, and the “points” they receive for deployment count towards promotion, in some cases taking the place of points that civil servants would earn by publishing. One scientist also suggested that supervisors may promote PHS members more often, because they have different options for advancing in rank and pay scale than civil servants do.

One NIOSH senior epidemiologist and PHS member commented, “The Commissioned Corps has privileges and civil servants have rights.” This scientist was concerned that PHS members with complaints about workplace issues had nowhere to turn for assistance; this scientist noted that although the civil servants’ unions do not seem to be used often to settle complaints, it is an option for those employees.

## **Feedback Mechanisms**

**M**anagers at all levels could benefit from hearing scientists’ concerns and suggestions, but interviews suggested many agencies’ current mechanisms for collecting feedback are insufficient.

Many scientists felt that their observations and suggestions could be useful in improving agency policies and practices, but were frustrated by a lack of opportunities to provide feedback in a meaningful way. “We are all



scientists and we want to give our input, and we feel neglected or dismissed if we are not asked our opinion,” one NIOSH medical officer said.

When asked how scientists could provide feedback on policies or practices they wanted to improve, some scientists provided examples of existing mechanisms. A VHA manager mentioned an annual survey on employee satisfaction; a DOD scientist noted that scientists had been involved in a review process that revamped documents, tools, and training; and an EPA scientist reported that the agency’s twice-yearly formal review process—at which scientists are asked what should be done differently and if anything additional is needed—has been effective for scientists on some issues.

Other scientists indicated that mechanisms for giving feedback exist, but may be ineffective because management will ignore scientists’ input or because scientists will be reluctant to use them.

- One NIOSH scientist noted that employees contributed input to a Total Quality Management overhaul in the 1990s, but upper management seemed to have made its decisions without taking employee suggestions into account.
- CDC scientists noted that requests for feedback are sometimes put out, but no results seem to come from feedback that is provided.
- A HUD manager expressed doubt that scientists from that agency would approach internal management or the Inspector General to complain about a process.
- An EPA scientist suggested that employees could bring concerns to the branch chief or to the Inspector General, but that these mechanisms are used infrequently. Another scientist suggested that going to the Inspector General would be a career-ending maneuver.

Other scientists did not see any evidence of feedback mechanisms existing at all. When asked about venues for feedback, an FDA senior manager responded, “Their venue was ‘accept it and be quiet about it, that’s it.’” Some CDC scientists stated that they lack a mechanism to provide

feedback on ways to improve things, because the agency’s top-down management style does not allow for it.

Scientists from several agencies stressed that feedback mechanisms must allow for anonymity, since many employees fear that stating criticisms openly could provoke retaliation. Despite whistleblower laws, several scientists feared that criticizing agency management could lead to them losing funding or other project support, being transferred to a less desirable location or position, and facing even more obstacles to getting research done.

A NIOSH epidemiologist suggested that retribution for speaking out could include “cutting your funding, putting you in a closet somewhere and giving you no personnel to help you accomplish your research, coming down very hard on your reviews, forcing you to go through endless rounds of review on everything you do.” A NIOSH senior scientist put it even more bluntly: “You get siloed, you get farmed out, you can get put somewhere and don’t get to do anything meaningful.”

One USDA scientist stated that she had been forced out of her position because she had questioned the decision to hire a supervisor who was less qualified than other candidates—and less qualified than the people that individual was responsible for supervising.

## Setting Priorities and Approving Research

Scientists hired by a federal agency have a general sense of what kind of research they can expect to conduct, but decisions about specific research projects will depend on agency funding and priorities, which change from year to year and with political administrations.

Because they are funded by taxpayers, agencies must prioritize research that will best serve the public. Individual agencies have developed processes to identify and support high-quality research projects that will help the agencies fulfill their Congressionally mandated missions. As a result, scientists employed by federal agencies often find themselves proposing research projects

that must compete with others for a share of limited agency funding.

A review of online agency policies for setting priorities and approving research found that policies regarding intramural research (i.e., research conducted by agency employees) were generally less detailed than those regarding extramural research (i.e., research conducted by outside scientists who apply to agencies for funding).

For example, EPA and NIOSH describe their evaluation criteria in detail on each extramural research grant announcement, and NIH and CDC have developed documents providing an overview of their evaluation approach to extramural research proposals.

At the intramural level, the most consistent policy statement across agencies is that proposed, and sometimes ongoing, intramural research studies will be reviewed by experts. NIOSH's Mining Program and CDC specifically note that those reviews are undertaken by "external" experts. NIOSH's Mining Program specifies that the reviewers must be "technical experts in their fields,"<sup>64</sup> while CDC refers to "subject matter experts";<sup>65</sup> both agencies' policies state that these external reviewers should be free from conflicts of interest. At NIH, research program priorities are shaped, in part, through "professional hiring and promotion decisions" and resource allocation decisions.<sup>66</sup> At the research planning stage, none of the policies describe additional procedures for evaluating confidential or sensitive topics.

The relatively brief descriptions contained in online agency policies related to intramural research contrast with the complicated review processes described by scientists at NIOSH, other CDC agencies, and elsewhere. In particular, interviewees note that the lag between a proposed idea and approval to move forward is often long.

Conflicts can also arise regarding which scientists should conduct specific studies. Some scientists reported in the interviews that they had been told they were not the "right" people to undertake certain types of research, even if they considered it to fit within their job descriptions and capabilities.

## IRB APPROVAL AND OMB CLEARANCE

Like their colleagues in academia, federal scientists must receive IRB approval for human subjects research. Unlike their colleagues in other settings, federal scientists must also receive clearance from the OMB before conducting surveys. The Paperwork Reduction Act, first passed in 1980 and amended in 1995, established a procedure for federal agencies to follow before initiating a collection of information (e.g., a survey) from 10 or more people. The agency must provide a 60-day notice of its proposed information collection in the Federal Register and solicit comments to "evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency" and to "minimize the burden of the collection of information on those who are to respond." The agency must also certify that the collection of information meets ten specific criteria, including that it "reduces to the extent practicable and appropriate the burden" on the people providing the information and "has been developed by an office that has planned and allocated resources for the efficient and effective management and use of the information to be collected."<sup>67</sup> This certification and the proposed collection of information, along with copies of pertinent statutory authority and other related materials, then go to the OMB for approval.

The Director of the OMB's Office of Information and Regulatory Affairs must allow at least 30 days for public comment prior to deciding whether to approve or disapprove the proposed collection of information. Notification of the decision must be provided within 60 days after receipt of the proposed collection; if that notification does not occur, approval may be inferred, but the agency may collect the information for no more than one year. (When the Director issues an approval, it may allow for collection of information for a period of up to three years.) Independent regulatory agencies "administered by two or more members of a commission, board, or similar body" may void the Director's disapproval by a majority vote.<sup>67</sup>

In a 2007 article in the journal *Health Affairs*, Berk, Schur, and Feldman state that in practice, this review process "often involves layers of review that rarely result in much

change to surveys yet may adversely affect the timeliness of the data collected.<sup>68</sup> They note that pre-testing of survey questions is often limited to only nine cases to avoid the OMB review requirement, and this low threshold hinders the assessment of design features.

## RESEARCH APPROVAL PROCESSES

During interviews, the procedures that scientists described for approving research processes varied by agency—but nearly every scientist felt that funding was insufficient to meet agency needs.

Because the interviews included several participants from NIOSH as well as other parts of the CDC, these agencies' practices are described in detail below.

### *Research Approval at NIOSH\**

The framework for occupational safety and health research at NIOSH is the National Occupational Research Agenda (NORA), which was unveiled in 1996 and extended in 2006, and is slated to run through 2016. Approximately 500 organizations and individuals outside NIOSH provided input into the development of the agenda, which includes 21 priority research areas.<sup>69</sup>

The priority-setting process is informed by:

- The number of workers at risk for a particular injury or illness.
- The seriousness of the hazard or issue.
- The probability that new information and approaches will make a difference.<sup>70</sup>

NIOSH has formed eight NORA Sector Councils focused on specific industries (such as construction, manufacturing, mining, and healthcare and social assistance). Representatives from academia, industry, labor, and government serve on these councils to draft goals, measures, and implementation plans.<sup>71</sup> NORA also has 15 cross-sector programs and seven coordinated emphasis areas.<sup>69</sup>

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\* While NIOSH is part of the CDC, information about the agency is reported separately because one-third of the interviewees for this project were current or former NIOSH employees.

According to interviews with scientists, researchers now submit a one-page letter of intent that includes a list of collaborators, a budget, preliminary data, and the NORA sector goals it is designed to meet. If the idea is of interest, researchers are asked for a full proposal that uses a format and instructions similar to a full NIH proposal and that can be 100-200 pages in length. Far more proposals are invited than are ultimately funded—one scientist stated that in one funding round, 18 of the original 100 letters of intent were funded. (Scientists gave different figures for proposal length and the percentage funded, which may be due to different processes in different branches or divisions or for different NORA sectors.) Reflecting the commitment to move research into practice, a relatively recent requirement in the proposal is a description of how study results will be used.

According to the scientists' description of the process, the proposal then moves through a lengthy approval process that begins with an internal review that typically involves a team leader, branch chief, and a number of people in the researcher's division, including the associate director of science. It may also be reviewed by the IRB and by a person at CDC who is intimately familiar with OMB regulations.

According to scientists, the proposal may also go to OMB, which can request changes and require that the scientist revise and resubmit the proposal. Following OMB review, it may have to be returned to the IRB for approval of a revised research strategy before data collection can begin.

Scientists reported that full approval can take up to 2-1/2 years, which can be problematic. One scientist commented, "The relevance and collaborators can change during this time."

A NIOSH research chemist called the process "extremely onerous," especially for projects that do not have a lot of money at stake (there is no distinction in the process by funding level). "It takes up huge blocks of time ... I put together a 50-page proposal, single-spaced, for a project that was giving me \$15,000 a year ... Does that make sense?" In this particular department, discretionary funding reportedly dropped from \$250,000 in 2002 to \$5,000 in 2008. Scientists were told that "things are bad all over and there is nothing that can be done."

The process can also create “a negative work environment,” noted the chemist. “If you spend a lot of time competing for funding and you never get any, what work are you then hired to do?” A medical officer at NIOSH spoke of an overarching result of limited funds: “We try to do things as best as we can, with what we have ... I feel a little hesitant to do a really huge [study] ... because we are all going to be using that one pot of money and I don’t want to blow the whole wad on my project.”

Scientists reported that before NIOSH adopted the NORA process, they only needed to convince their superiors that the research had merit for the division in order to secure project funding. One scientist stated that it is still possible to receive research money through a division’s discretionary funds instead of using the NORA process. To secure discretionary funds, scientists propose research ideas through their management chains, and division leaders determine allocations. However, discretionary budgets have been reduced, so these opportunities are still limited.

Scientists spoke of a drain of scientists from NIOSH due to a change in management style that has reduced scientists’ ability to participate in setting research priorities. According to a senior scientist, “All research areas are dictated from management and you must be limited to doing research in these specific areas ... As a consequence, eight people have left within the last two years alone. They felt they weren’t being treated as full scientists.”

NIOSH’s work has the potential to identify a need for private industries to spend more money on worker-health protections, which can make it a target for politicians seeking to reduce businesses’ costs. A NIOSH team leader spoke about how the agency became a political target in the past and now tries to avoid repeating that experience:

In 1995, there was a bill introduced in Congress to eliminate NIOSH, and the justification for it, among the people who introduced it was, we don’t need what this agency does ... The agency is now very careful to not get into something that is overly controversial, because we were one vote away from being totally eliminated ... I feel the area of occupational health is inherently more controversial than some other aspects of public health because you are impinging on industry.

Other NIOSH interviewees also stated that the memory of this Congressional attack on NIOSH remains strong and continues to inform agency decisions about research.

President George W. Bush’s Presidential Management Agenda emphasized performance and showing impact.<sup>72</sup> Scientists noted that this forced many agencies to switch from disease and health research to outcome research. An industrial hygienist stated, “We’ve not been able to get anywhere with projects ... that have to do with exposures, disease, or surveillance ... only those injury-related” are awarded funds.

A NIOSH scientist noted that the agency is now focused on safety research because it is easier to show impact on areas for which surveillance data is available, such as lost work days and fatalities. By contrast, cancer related to workplace exposures is challenging to study, and may go unresearched despite its importance. The scientist described NIOSH’s approach as “lamp-post research,” in which the agency studies what it already knows. (The term, the scientist explained, comes from a joke about the man who searched for his glasses under a lamp post—not because that was where he had lost them, but because that was where he could look for them most easily.)

### **Research Approval at CDC**

CDC policies state that major intramural studies conducted at CDC centers, institutes, and offices are to be reviewed by external experts “for scientific and technical quality” at inception and once every five years.<sup>65</sup>

Interviews suggest the process is more complex than the policies indicate. For research to move forward, scientists say, an investigator must write a proposal that is approved by the team lead, by branch chiefs, and ultimately by the center’s associate director and the division director. If the goal is to publish in a high-profile journal, such as *Journal of the American Medical Association* or the *New England Journal of Medicine*, it must go through additional clearance, including a review by the center’s associate director of science. Decisions as to whether the research should proceed, and be conducted by the person who has proposed it, are sometimes made by individuals who are not necessarily researchers themselves.

Scientists reported that CDC used to allow each program to set its own strategic plan, which would include research priorities. More formal review processes now exist for both extra- and intramural research programs.

Some researchers believe that winning reviewer approval to move forward requires them to lay out all of their potential findings up front, yet procedures state that information-gathering should not proceed until research is approved. According to one branch chief: “The easiest way to do this, and everyone’s figured it out by now, is to do the entire analysis and basically write the paper. At that point, it’s much easier to say what you are going to do. But it’s completely counterproductive because the idea is that you are not supposed to be working on things that haven’t been approved.”

### ***Other Agencies’ Research Approval Policies***

Scientists from other agencies described different processes in the interviews. In general, proposed research was considered in light of research priorities and strategies set at a high level. Examples include:

- A scientist from FDA’s NCTR explained that every research project begins with a concept paper that is vetted throughout the agency and ultimately approved by the NCTR director. Approved concepts are then developed into a full proposal, which is considered by a nine-member Science Advisory Board and by peer reviewers.
- According to a DOD scientist, priorities were set by scientific and medical people at the level of Assistant Secretary of Defense or the Navy Surgeon General. “Whether or not I agreed with them, they were the right people to be setting the ... priorities, and generally I did agree with them except, of course, when it didn’t go my way ... You have to trust that the chain of command has priorities and pressure they know about and we don’t.”
- A CPSC statistician reported that an idea must be in line with the current policymaker’s strategy in order to receive approval. “I’ve had ideas shot down verbally. I’ve never put something in writing and had it denied in the pre-approval stage.”

Scientists from all agencies expressed frustration, some more than others, about the time-consuming processes of research proposal approval. Some scientists did express concern about agencies setting research priorities or approving projects based on a desire to avoid controversial topics.

## **Scientific Dispute Resolution**

**D**uring interviews, scientists were asked about how their agencies resolve situations in which two scientists, or a scientist and a supervisor, disagree about a scientific aspect of their work. Such disputes might include disagreements about how to collect or analyze data or differing interpretations of study results.

Such scientific disputes may be beneficial if they result in a productive dialogue and lead to improvements in research. Scientists’ comments suggest that some agencies attempt to work through such disputes and seek agreement between the parties involved, while others let the most senior employee “win” the dispute.

- A DOD scientist described the following process when data-interpretation questions arose: “Other scientists would then be brought in from the outside to assist in evaluating the data and try to understand the differences. If there was a significant disagreement, additional parties would be brought in until the situation was resolved. Often times it had to do with statistical analysis and we would call university statisticians for input.”
- A NIOSH scientist reported that decisions were “not necessarily hierarchical ... You have to have supporting evidence and justification for your argument, and science generally wins the debate.”
- Speaking of a situation involving a fundamental disagreement with a supervisor’s decision, a CDC medical epidemiologist stated, “I would go to somebody who was an expert in the area and ask them” to help clarify the situation.
- A CPSC statistician suggested, “If the situation at hand is kept at the same level (e.g., all statisticians), then it



is more likely that a consensus will be sought. No one person can be an expert on everything.”

- According to a CDC branch chief, “The highest ... managerial position wins ... the supervisory person wins, no matter ... even if what they are saying is ridiculous ... you can’t do anything about it.”

Procedures for resolving scientific disputes seemed to vary depending on managers’ styles as well as agency policies. Although some scientists expressed dissatisfaction with procedures in which seniority decided a dispute’s outcome, others found it appropriate. “Management has the right to make decisions that you don’t agree with,” one NIOSH scientist said. A manager with experience at NIH and FDA deemed it appropriate for scientific disputes to be resolved at the level of one or two supervisors: “You should not have to go up to the Commissioner for problems like this ... that is a general pattern of problem solving in the bureaucracy as a whole.”

Personality issues can also influence how disputes in a particular office play out. One scientist described “turf wars” and commented, “Sometimes the problem is a personality conflict or long-standing perceptions about who does what, what certain disciplines can and cannot do.” Several scientists noted that egos and personalities often get in the way of discussions about scientific issues.

Often, disagreement still exists among scientists even after a dispute is resolved; in such situations, scientists reported it is not uncommon for an author to remove his or her name from a manuscript.

In some cases, scientists reported that they might attempt to work through disagreements one-on-one, and amiably agree to disagree if they could not settle on an outcome that satisfied both parties. One scientist noted that under these circumstances, a scientist should “just document your position so that it doesn’t come into question at a later date.” If a supervisor disagrees with a scientist’s interpretation of results, the scientist might still be able to publish his or her interpretation provided it includes a disclaimer stating that it represents the scientist’s individual views and not those of the agency.

As an example of how agencies fail to settle scientific disputes effectively, multiple scientists brought up the case of Dr. David Lewis. Dr. Lewis was a microbiologist working at an EPA laboratory, and his findings from research on sewage sludge led him to think that EPA’s sewage sludge regulation was insufficiently protective. In testimony before the House of Representatives Committee on Natural Resources, Subcommittee on Energy and Mineral Resources, Dr. Lewis stated that he had been forced out of his EPA job for “publishing research unresponsive of EPA policies.”<sup>73</sup> The scientists who described this case considered it a demonstration of an agency’s inability to deal appropriately with a scientific dispute—and suggested that the story makes other scientists think twice before pursuing a line of scientific work that could lead to a disagreement about current agency policy.

Several scientists with experience working at NIOSH spoke about how that agency addresses scientific disputes. Each NIOSH division has an Associate Director for Science (ADS), a scientist who has the responsibility for adjudicating on scientific issues. Despite having a scientist tasked with dispute resolution, some scientists voiced concerns about the resolution of these disagreements.

Several NIOSH scientists felt that the majority of disputes were not resolved on scientific merits, but, as one scientist put it, “the most unpleasant person wins.” One scientist suggested that the scientists filling the ADS positions lack the skills to stand up to difficult personalities, and this occurs because of the agency’s “poor habit of taking good scientists and making them managers who don’t get much training. Some of them shy away from conflict.”

A NIOSH senior scientist also noted that important details about scientific disagreements can be lost as information travels through layers of management to the ADS. This scientist suggested that the agency “bring in an outside person who is not allied with one group or the other ... bring everyone together ... instead of the scientist explaining something very complex to the first manager up who dumbs it down a little bit for the next manager up, and so on throughout the various levels ... I think it might be better to have an ombudsman.”

If scientists from multiple NIOSH divisions are involved in a scientific dispute, the division directors and ADSs receive written summaries from the scientists involved and hold a meeting at which they determine how the issue will be resolved. They then bring the involved parties together to hear the decision and finalize details about moving forward. Although scientists did not express concerns about whether this process arrives at appropriate outcomes, some felt that it takes too much time from senior staff and delays work.

## Disseminating Scientific Work

In addition to getting approval to conduct research, agency scientists must seek agency approval to publish an information product (e.g., a report or scholarly article) describing research findings. This clearance process can strengthen publications and ensure that agencies present unified messages, but it can also frustrate scientists.

In general, scientists throughout the federal science infrastructure feel a strong obligation to disseminate their findings to other scientists, and to the general public, in a timely manner. A number of government employees commented that they work for the public, they are paid by the public, and the public has a right to know “since it is their tax dollars that are paying for the research in the first place.”

In particular, many value publishing in peer-reviewed literature because it opens up a data-driven discussion in which anyone can participate. “If the information gets into the literature, it can be accessed by a larger body,” said one interviewee. It is also the case that information—data, findings, etc.—generally cannot be discussed with anyone outside of the agency without approval. Therefore, it is imperative that the science be approved to allow for open discussion.

Likewise, federal agencies typically consider it part of their mission to disseminate scientific information to the public, and encourage their employees to do so. “NIH is pushing people to make data available to the general public, whether through publication or other forms of dissemination,” said one scientist. “Some people look for creative

ways to get information into the public domain.” Posting data, manuscripts, and reports on a website, as CPSC does, is another significant mechanism for dissemination.

Plans for dissemination begin early at some agencies. At DOD, for example, planning begins when research is initially proposed and emphasizes peer-reviewed journals. “We discouraged publication in what I would call ‘throwaway’ journals that had commercial interests or did not represent mainstream science,” explained a DOD medical scientist. The agency has a supportive process in place to assist junior scientists throughout the research and dissemination process—developing protocols, conducting research, writing up findings, and submitting to journals. Senior researchers also work with junior colleagues to revise their submissions if they are turned down, this scientist explained.

## AGENCY APPROACHES TO CLEARANCE

Online policies describe what needs to be reviewed, and by whom, with varying degrees of specificity. Some federal agencies state that all information products must be cleared before being submitted for publication or released. Others allow their centers to set their own requirements, and do not specify that all information products must be reviewed. Some agencies also require scientists to seek approval for disseminating work done on their own time, especially if the author’s affiliation is identified.

At many agencies, the nature of the information product will influence the nature of the review process. For example, CDC policy states that the number and qualifications of persons responsible for clearance should be commensurate with these characteristics of the product: “visibility or breadth of dissemination; topic’s level of sensitivity; originality of findings; scientific or technical complexity; potential to impact CDC recommendations, policies, or programs; or urgency of need for dissemination.”<sup>74</sup>

The review process for research that has policy implications typically involves more layers and takes longer to complete, and it sometimes raises sensitive questions about a political agenda. On the other hand, mechanisms are in place for expedited clearance if information needs to be released promptly or if it is not deemed very



sensitive; as an NIH scientist noted, “literature reviews are subject to less scrutiny and more likely to be published quickly.”

Many review policies call for an assessment of the quality of the information product—both in terms of its scientific rigor and its editorial presentation—prior to the article being submitted to a journal peer review process. For example, USGS requires three types of review prior to bureau approval:

- Peer review, “which ensures the scientific quality of USGS information.”
- Policy review, “which ensures that all policies relevant to USGS Fundamental Science Practices are met and identifies policy-sensitive issues.”
- Editorial review, “which ensures appropriate Bureau standards and quality assurance for accuracy and clarity of expression are met.”<sup>75</sup>

## SCIENTISTS’ VIEWS OF CLEARANCE PROCESSES

Across the federal government, there are often significant differences between an agency’s written policies, which are in general relatively brief, and the multi-step clearance process that scientists say actually occurs. Interviews suggest that the review process sometimes hinders, rather than supports, scientists’ dissemination efforts. Several scientists used the word “onerous” in their comments and said clearance procedures sometimes became burdensome enough to discourage them from publishing. Common concerns included long delays and inconsistent and time-consuming requirements that sometimes involve reviewers who lack expertise in the relevant scientific field.

Where research or information products have policy implications, agency guidelines often call for closer review and assurances that the product reflects current policies accurately. In practice, say scientists, this often restricts the publication of research that challenges the status quo.

The complexity of the clearance process is illustrated by a scientist’s description of the steps involved in clearing a Congressionally mandated FDA report about mercury in food, which was designed to answer scientific

questions, including “Were the analytic methods used in the ‘70s adequate for identifying mercury exposure in the range of current interest?” Required reviews involved a peer review panel, a technical review process, and input from OMB and FDA’s Science Advisory Board, and took two years to be completed—and that, said the scientist, was an “expedited” timeframe because of a Congressional mandate.

Even when research is ultimately released and in theory publicly available, it can be difficult to locate, say some scientists. “Many reports are not put on agency websites and are not disseminated by other means,” said one scientist. “There should be greater efforts to publish government reports in the peer-reviewed literature.” In some cases, documents are actually posted on websites, but these sites may be poorly organized or difficult to search.

It is important to note, however, that comments about the review process were not uniformly negative—some scientists spoke positively about the effects of review on the quality of their papers.

## ONE AGENCY EXAMPLE OF CLEARANCE PROCESS

The contrast that sometimes exists between official clearance policies and the review process in the “real world” can be illustrated by an overview of CDC’s approach.

CDC requires the Office of the Director of each center to “develop and document clearance procedures for their respective units” and to identify appropriate staff to manage the clearance process. Clearance standards “should be appropriate for the type of information product under review, and should balance the concerns of quality and timeliness.” Agency policy calls for a timeline that should generally not exceed one month, although that can be extended if the author is asked to make revisions. CDC centers are also required to have an expedited clearance process during public health emergencies or for information products requiring immediate release.<sup>74</sup>

Each center is to develop and maintain a matrix on the CDC Intranet that:

- Identifies the information products produced by the center.

- Notes whether clearance is required for that information product and which officials, if any, must clear that type of product.
- Specifies the level of review required.
- Displays timelines for clearance officials.<sup>74</sup>

Each CDC center or office is supposed to “monitor and evaluate its clearance process to ensure timeliness and improve the process,” and to develop a mechanism for resolving any disputes that arise. If a dispute cannot be resolved at the center level, it should be taken to the agency’s Office of the Chief Science Officer for final arbitration.<sup>74</sup> (Further discussion of scientific dispute resolution appears in the previous section of this report.)

According to interviews with CDC scientists, a paper must be submitted for clearance first to the CDC branch chief, then to the associate director for science, and finally, if it deals with a sensitive topic, to the center associate director. Each reviewer has 10 business days to respond to the request for clearance but can at any point send the paper back to the scientist with comments or requests for clarification, which restarts the 10-day clock.

Scientists reported that if anyone in the review process is away from the office, the clearance request is delayed. Further delays may occur because an earlier reviewer can send back comments at a later stage in the process, forcing the scientist to revise the work, and restarting all clearance steps. As a result, the one-month deadline for clearing research papers is often missed, according to CDC scientists. “That timeframe doesn’t really mean much,” commented one.

Although one interviewee suggested that as a scientist becomes familiar with the process over the years, “the layers of review become fairly easy to navigate,” many others questioned the process:

- A CDC branch chief called it “a very onerous review process” that is “essentially a form of hindrance ... I don’t think there’s any benefit of having all these people look at this. It’s just a huge waste of time.”
- “There doesn’t seem to be a clear objective to the process,” commented one scientist. “Perhaps it is

because no one wants to take on full responsibility for anything. There is a level of fear that comes with that kind of power.”

- “There is an overemphasis on minor matters which are usually less about the science itself and more about the presentation and how it is written,” said a CDC division director.
- One scientist commented, “At CDC everyone considers themselves a subject-matter expert and therefore feel that they are entitled to make comments, recommendations, etc. on papers. Everyone has something to say.”
- “The process is over-extended and after a certain point there is not much more to gain,” one scientist said.

There is somewhat more enthusiasm for the expedited clearance process. “If there is a time-sensitive piece, such as a letter to the editor, the people in the process can sometimes be understanding of that and will push the piece through faster,” said one scientist.

Efforts under the previous CDC director to standardize the research review process and bring it more in line with the NIH review process fell short, according to one interviewee. The standardization attempt was likely difficult because the NIH model is largely conducted by academic institutions, whereas CDC’s research may also be conducted by state and local health departments and non-profit organizations.

One scientist noted that if one CDC scientist’s work includes a critique (explicit or implicit) of another CDC scientist’s work, the scientist whose work is being criticized must still receive clearance before responding. For instance, that scientist may write a letter to the editor of the journal that published the other scientist’s work, and receive clearance for the letter before submitting it to the journal.

## **OTHER FEDERAL-AGENCY CLEARANCE PROCESSES**

At other agencies, the following requirements are in place for clearing information products prior to dissemination. Unless otherwise indicated, they address the clearance process for submission to external journal publications.

- **CPSC:** The agency requires clearance for any “release of information initiated by the Commission, including information disseminated on the agency’s web site.” Articles submitted for publication to outside journals must also be cleared if the article concerns the agency or its activities in any way, and identifies the author’s affiliation. Clearance is required by each assistant or associate executive director whose area of responsibility is involved. (Publications or presentations that do not relate to CPSC policies, objectives, or operations are not subject to clearance procedures but “are still subject to regulation on employee standards of conduct.”)<sup>76</sup>

CPSC allows for emergency clearance when extenuating circumstances make it difficult to complete normal clearance procedures in a timely manner. Those measures require the direct written approval of the Office of the Executive Director, the Office of General Counsel, and the Office of Information of Public Affairs and do not replace the normal clearance measures. “Immediately after written clearance by each of these offices, the originator will submit a copy of the published writing for appropriate full clearance procedure,” states the policy.<sup>76</sup>

- **DOI:** DOI requires electronic or print publications to be “cleared through the appropriate bureau publication approval process,” but states that the Office of Communications (OCO) has overall responsibility for ensuring adherence to the agency’s policy. The policy specifies that “all materials that include any message from the Secretary must be reviewed and approved by OCO” and that “all articles for publication, letters to the editor, and editorial replies written by employees of the Department in their official capacities are subject to prior review by OCO. Bureau public affairs offices will determine when review is required.”<sup>77</sup>
- **DOI/USGS** requires that all information products “must be reviewed and approved for official release and dissemination, whether they are published by the USGS or an outside entity, if the work has been funded, whole or in part, by the USGS or if USGS affiliation is identified with the authorship.”<sup>75</sup> A peer review, a policy review, and an editorial review are required.

- **EPA:** The lengthy list of products specifically identified as subject to review includes materials with policy implications targeted to specific audiences (such as industry groups, community organizations, educators, consumers, and public officials), conference materials, fact sheets, reports, speeches, and “technical documents with broad and direct policy, political, social or ethical implications, or those used to introduce a new Agency policy or requirement.” In general, other types of technical material are not subject to review.<sup>78</sup>

EPA reminds authors that drafting materials for publication “will often require frequent coordination among originators, product review officers, content coordinators and designated reviewers.”<sup>78</sup>

- **FDA:** Although the agency does not appear to have a policy available online that describes agency-wide clearance requirements, the FDA Amendments Act (HR 3580) directs the FDA to establish a policy on review and clearance of scientific articles published by FDA employees. The legislation specifies that if an employee is directed by the policy to submit an article for review and clearance before seeking to publish it or present it at a conference, the employee must do so at least 30 days in advance.<sup>79</sup>
- **FDA/CDER:** Within CDER there is a requirement that “all communication materials concerning FDA programs, policies or activities” be cleared. When the topic affects only one division, division directors and office directors are the clearing officials, although office directors may designate the division director as the sole clearing official for certain communications. When material describes policy affecting more than one division, the chair of the relevant Coordinating Committee is generally the clearing official.<sup>80</sup>

The clearing official may request greater detail on some or all parts of the submission. Authors may appeal the decision of the clearing official to the Coordinating Committee chair for discipline-specific requests, or to the clearing official’s supervisor for non-discipline specific requests.<sup>80</sup>

- **NIH:** Each publication or audiovisual product prepared at an NIH institute or center must be approved by the

director of the originating component or by the director's designee. Official publications must also be approved by the editorial and public affairs offices—specifically, the Office of Communications and Public Liaison (OCPL) in the Office of the Director, and the Office of the Assistant Secretary for Public Affairs in DHHS. (This does not apply to articles written by NIH authors for publication in outside journals.)<sup>81</sup>

Any employee whose draft or presentation is denied clearance may request that the deputy director for intramural research review that decision.<sup>82</sup>

NIH dictates that the OCPL associate and deputy associate directors formally review the agency's clearance policies on an annual basis, and make appropriate changes as needed, based in part on user input submitted via emails, telephone calls, meetings, and memoranda. Specific contact information is provided to encourage feedback.<sup>81</sup>

An expedited clearance process exists when NIH provides "breaking news" to the public on research findings with immediate health implications prior to peer review and publication. Typically, this will be a clinical trial result that could influence the practice of medicine. A system of internal review is in place "to ensure that information disseminated to the public summarizes the facts as NIH currently knows them, and that appropriate disclaimers are attached, if necessary."<sup>82</sup>

During interviews, scientists provided additional details about clearance processes, including the following:

- **DOD:** In a process described by a scientist as "looser ... with fewer requirements than a university," the DOD process involves reviews by the IRB and the Office of Research.
- **VHA:** Any research that does not go through an IRB should be reviewed by a supervisor. Research that is to be published should be reviewed at the highest administrative level before its release.
- **IHS:** Any report containing information about a Native American tribe cannot be published without the

consent of that tribe, a requirement that recognizes tribal sovereignty as well as prior abuses.

Multiple NIOSH scientists provided a detailed picture of the review process at that agency. Although the process differs from division to division, it typically involves an internal branch review (including the team leader and branch chief) and two or more external reviewers, who are often academic subject-matter experts. "It's best to send it to those who you consider your 'enemies,' such as pro-industry people, as part of the external review, as well as to academics, who can anticipate potential criticisms," said a senior scientist.

Scientists must respond to reviewer comments, and then return the information product to the team leader and branch chief for approval. (If the piece has policy implications, additional review beyond these levels may be necessary.)

If the authors include scientists from multiple NIOSH divisions, each division must give its approval. If authors from other agencies are also involved, the information product must undergo cross-clearance, in which each agency applies its own review process.

Scientists noted that some NIOSH information products also require approval from the OMB, which sends each document to a variety of stakeholders and gives them an opportunity to comment on anything contained in the information product. Some scientists spoke of instances in which industry lawyers have generated hundreds of questions about information products; since scientists must respond to each external comment in writing, these long lists of questions resulted in months-long response processes.

Information products may also be sent to other agencies for review. NIOSH scientists who produce analytical methods for workplace sampling and analysis<sup>83</sup> reported that the review process for these methods has also become more complex; additional layers of internal and external review have been added, including opportunities for CDC, HHS, and often OMB to provide input.

## REVIEW FOR QUALITY AND EDITORIAL STANDARDS

The official policies and guidelines of many agencies include overarching statements about maintaining quality standards. For example:

- **CDC** “is committed to ensuring that all information products authored by CDC staff members or published by CDC and released for public use are of the highest quality and are scientifically sound, technically accurate, and useful to the intended audience.”<sup>74</sup>
- **EPA** guidelines state that “all Agency communications products, from concept to publication, are subject to rigorous review to ensure the highest possible quality.” Agency administrators are expected to develop a system of accountability to ensure that a proposed product “is necessary, accurate, consistent with Agency policy and that it properly addresses its audience.”<sup>78</sup>

EPA also offers these guidelines to authors: Drafts must “effectively convey appropriate messages to the target audience(s) ... Use an engaging and positive tone ... If the document describes an environmental problem or issue: describe what EPA has done, is doing and will do about it [and] clearly explain how the public can help alleviate the problem or resolve the issue ... Present current and accurate statistics and explain statistical models when used.”<sup>78</sup>

- **NIH** “expects publications or presentations by NIH employees to meet high standards of quality, make a substantial contribution to the field, and contain sufficient information for the informed audience to assess its validity.”<sup>82</sup>

Manuscripts that fail to meet an agency’s quality standards may not be cleared. A team leader gave one example: NIOSH can refuse to allow a Health Hazard Evaluation paper to be published; the agency “could potentially say ‘we don’t think this is of sufficient quality,’ and it cannot be submitted to a journal.” The team leader indicated that while this has occurred, it is not common.

Some official policies specifically address tone, clarity, and the caliber of the editorial presentation. For example, DOI requires that publications be “constructed well enough to

warrant publication as official expression,”<sup>84</sup> and USGS criteria for approval include “products are well written and effectively presented, and the tone is appropriate for ease of understanding by the intended audience.”<sup>75</sup> At USDA’s Agricultural Research Service (ARS), the research leader’s review is in part “to determine that it is in the best form possible to enhance communication of the research results.”<sup>85</sup>

By contrast, CDC’s policy states that clearance officials are not responsible for providing editing comments (such as comments on grammar and sentence structure), since those issues should be handled at other stages of the process: “Review by a writer/editor may occur during the pre-clearance preparation and review phase, or during or after the clearance phase at the discretion of the Center.”<sup>74</sup>

Likewise, at FDA, CDER policy discourages the clearing official from spending extensive time rewriting or commenting on a manuscript, though approval may hinge on overall quality of the content and writing. “If it is not of high journalistic quality, it should be returned to the originator.” The policy also states, “the Clearing Official may refuse to clear the material if it is not of high journalistic quality.”<sup>80</sup>

## ADDITIONAL REQUIREMENTS FOR “INFLUENTIAL SCIENTIFIC INFORMATION”

A significant new layer of requirements on the dissemination of government science was imposed by the OMB on all federal agencies under the Information Quality Act of 2001 (also known as the Data Quality Act). The overarching requirement is that information be of high quality, as defined by its utility, objectivity, and integrity.<sup>86</sup> OMB’s quality guidelines do not apply to opinions or research being published in academic journals, but those publications should include disclaimers stating that their views do not necessarily reflect the views of their agencies.<sup>87</sup>

Within this framework, agencies are required to issue their own information quality guidelines and establish administrative mechanisms that allow individuals to seek and obtain corrections for information that does not comply with the guidelines. Agencies must also report to the OMB director on their compliance with the guidelines and resolution of complaints.<sup>87</sup>



OMB outlined a peer review mechanism in its 2004 "Final Information Quality Bulletin for Peer Review," which "establishes that important scientific information shall be peer reviewed by qualified specialists before it is disseminated by the federal government."<sup>88</sup>

Higher standards are in place for "influential" scientific, financial, or statistical information, defined as information that will have a "clear and substantial impact on important public policies or important private sector decisions," and for a newly defined subset of that category, "highly influential scientific assessments." A scientific assessment will be considered highly influential if the OMB Office of Information and Regulatory Affairs determines that its "dissemination could have a potential impact of more than \$500 million in any one year on either the public or private sector or that the dissemination is novel, controversial, or precedent-setting, or has significant interagency interest."<sup>88</sup>

Where influential information is involved:

- Agencies must select peer reviewers based on expertise and balance, and must carefully examine their conflicts of interest and independence.
- In developing an adequate peer-review mechanism, agencies must consider "the novelty and complexity of the science to be reviewed, the relevance of the information to decision making, the extent of prior peer reviews, and the expected benefits and costs of additional review."
- The peer reviewers shall prepare a report describing their findings and conclusions, post that report online, make it available to the public for comment, and sponsor a public meeting where the relevant scientific issues can be discussed.
- The agency should consider all the comments made by peer reviewers, incorporate them where relevant and valid, and prepare a written response to the peer review report in which it explains where it agrees and disagrees, how it will respond, and how its actions will satisfy the key concerns in the report.<sup>88</sup>

When the OMB regulations were first developed, many agencies were concerned that they introduced additional, time-consuming layers of review. In addition to the bureaucratic requirements, these regulations were potentially a means to challenge or delay findings that had regulatory implications.

As required by the legislation, agencies have issued guidelines regarding the quality of information that they disseminate; these guidelines are readily available online. The individual agency guidelines describe the mechanisms each agency uses to ensure the quality of its information and the process by which affected persons can request correction of disseminated information that does not comply with information-quality guidelines. Several agencies provide details about how the OMB guidelines apply to their agencies by giving examples of specific types of information that meet definitions of influential information or scientific assessments, or by explaining how their agencies adapt the Safe Drinking Water Act quality principles for their specific types of information. (In 1996 amendments to the Safe Drinking Water Act, Congress specified standards of quality for the use of science in agency decision-making and for the dissemination of public information about risks of adverse health effects.) Some of the agency guidelines refer to existing policies or manuals on publication or peer review, which contain additional details about quality-assurance processes.

## **SCIENTISTS' CONCERNS ABOUT CLEARANCE PROCESSES**

In speaking about their agencies' clearance processes, scientists voiced several concerns, which included a lack of clarity and consistency in how policies are presented and applied. Scientists' experiences demonstrated a gap between official policies and scientists' experiences with clearance processes.

The overall sense of the review process prior to dissemination is that it takes too long, involves too many layers, and sometimes allows reviewers to "just make changes just for the sake of feeling they've made their mark on the document, even though there was no substantive

positive change,” stated a medical officer with experience at multiple agencies.

Some government scientists do report more positive experiences with the clearance process, but many say it is “challenging,” “unnecessary,” “burdensome,” and/or “demoralizing.” Regardless of the official policies in place, review and clearance requirements seem to be enforced differently within the same agency, and sometimes within the same department. Two scientists working side by side could have very different experiences, fostering perceptions of lack of continuity, confusion, and sometimes favoritism.

“I find the process burdensome, and it seems kind of arbitrary because there is not a firm, consistent approach across divisions,” said a NIOSH/EPA epidemiologist. An EPA statistician had a similar assessment. “The biggest problem from where I sit is that it is not clear what the process is ... We are not sure what the procedures are.”

To some degree, this may reflect differences in subject matter or the level of potential controversy contained within the research. Nonetheless, as one interviewee commented, “There should still be some sense of continuity for the sake of morale, and the reputation of the department and the agency.” A senior manager with experience at FDA and NIH gave a succinct recommendation: “Whatever the process is, it should be absolutely clearly known.”

One common frustration about the clearance process was the sheer number of people involved. Some scientists feel they spend too much of their time dealing with the multiple layers of review, and that meaningful communication between the different people involved is difficult. They fear that the end result will be less time for generating data and accomplishing agency goals.

- A senior manager from FDA commented, “It would be helpful if people knew exactly how we get things published ... I think that if you wrote it down on paper it might actually change it and make it better ... and people would see how incredibly burdensome it is.”
- An EPA scientist said, “I think all the layers are now making it harder and harder to communicate effectively.

Each one adds its own requirements that take time away from actually generating the data.”

- A NIOSH research chemist recommended, “Get rid of all these unnecessary layers of review. There is no reason that you have to have so many senior scientists in Atlanta and Washington reviewing everything we do that is supposed to be published as a NIOSH document or published on the NIOSH website, it is absurd ... All these people do is get in the way of getting things done, but is that the goal? It seems to me that [it is a way of] making it impossible for government to get anything done.”

Several interviewees suggested that how one experiences the clearance process depends in part on one’s rank. At NIH, for example, one interviewee pointed out that a bench scientist and a high-level manager will likely understand the necessity and benefits of review very differently.

Likewise, the experience levels of those conducting research are likely to influence their perspectives. One medical officer suggested that the review process was useful early in a person’s career, when it could be educational, “but as you get more advanced, I think it’s cumbersome, really lengthy.”

A NIOSH medical officer suggested that MDs and PhDs “should be able to review their own material. Agency review feels a little demeaning at times.” DOD supervisors apparently came to the same conclusion, according to one interview, because after being notified that a manuscript was ready for publication, they would “many times, depending on the scientist’s rank, simply wave it by.”

Some scientists reported that their agencies require that information products be sent to external reviewers for comment prior to dissemination. In cases where the product was a manuscript destined to go through a scientific journal’s peer-review process, scientists often felt the agency’s requirement for external review was unnecessarily duplicative.

“I personally don’t think there is a lot of added value to having government agency review on top of the peer



review process in journals,” said a HUD manager. “My experience with publications in scientific journals is that the peer review process is generally pretty rigorous . . . it is not easy to get published, and that is a good sign. For agencies to also add their own peer review on top of that seems to me to be unnecessary and also creates the possibility of political interference and holding up of key studies.”

Another concern about the many layers of review is the potential for breaches of confidentiality. A number of scientists stated that comments from their reviewers made it clear they had spoken with people who had seen an earlier version of their manuscript. There were also incidents in which people outside the approved review process were gaining access to unpublished work. One scientist gave an example: The spouse of one of the reviewers, who was employed at another federal agency, commented in a public setting about research that had not yet been cleared for publication.

At NIOSH, external reviews were a particular trouble spot. “It gets to be quite burdensome if you are a prolific writer,” said an epidemiologist. “I had seven papers last year, and I feel as if I am burdening my academic colleagues,” who are repeatedly asked to serve as external reviewers. One NIOSH scientist reported having 13 unions, eight companies, and half-a-dozen academics review a paper, and receiving 149 comments from just one company.

In some instances, the complexity or timeframe of the review process discourages researchers sufficiently for them to set their work aside. “Sometimes, people get so dispirited when they get comments from peer reviewers that they give up on the manuscript or just procrastinate,” said a NIOSH team leader. In particular, the complexity of revisions in analytic method review has resulted in some NIOSH scientists refusing to pursue publication, according to one interviewee.

## TIMELINES

Agencies are not blind to the problem of lengthy review processes that delay dissemination of important information to the public. In their written policies, some agencies call for time limits on clearance processes. However,

scientists’ comments suggest that actual reviews often fall far short of these goals.

Policies regarding clearance timelines may only apply to a portion of the entire clearance process that any single information product must undergo. The CDER timeline appears to cover the bulk of the process, while DOI and NIH provide timelines only for the agency-level approval that follows approval at the bureau level (for DOI) or the institute or center level (at NIH). Likewise, EPA products are reviewed at two levels (by a product review officer and the Office of Public Affairs (OPA)), but timelines are provided only for the OPA comments. These agencies’ policies include the following:

- **CDC:** The CDC calls for consistent clearance procedures to ensure that the highest-quality reviews are performed in a reasonable amount of time. The deadlines established for routine review and approval will vary by the length and complexity of the information product and by the other responsibilities of the clearing official (for example, a branch chief may take longer than a center director). However, the full clearance process is generally expected to take one month or less (although the need for author revisions may extend the deadlines).<sup>74</sup>

The CDC recommends that centers “give serious consideration to shortening the overall timeline as much as possible,” especially for the shortest, simplest information products and for those prepared in response to a public health emergency, a news event, or other time-sensitive issues. To ensure that routine clearance occurs efficiently, the policy also recommends establishing procedures for missed deadlines, designating alternative staff if a clearing official is not available, and each office should “monitor and evaluate its clearance process to ensure timeliness.”<sup>74</sup>

- **FDA/CDER:** CDER instructs authors to submit materials and a clearance request form to the appropriate clearing official at least two weeks before the scheduled presentation or publisher’s deadline for submission.<sup>80</sup> Although the clearance timelines at FDA are not currently specified, the FDA Amendments Act of 2007 requires a policy that gives reviewing officials 30 days

to provide written clearance (or “written clearance on the condition of specified changes having been made”). In the absence of clearance, authors may “submit the article for publication or presentation with an appropriate disclaimer.”<sup>79</sup>

- **DOI:** Assistant secretaries are to notify the Executive Secretariat two weeks before the anticipated release of a major report, and to indicate whether it is likely to require departmental review. If it does, it must be submitted to the Executive Secretariat at least a week before the release date, accompanied by transmittal letters and a draft press release, if required. The document may be the subject of briefing meetings with the secretary, or others as appropriate.<sup>90</sup>
- **EPA:** After preparing a draft, the author enters it into the agency’s communications-product database, where it must be approved first by the product review officer (no timeline is stated). It goes then to the Office of Public Affairs, which provides comments within 10 working days. Authors are required to modify their work in response to those comments. No timeline is given for the subsequent rounds of editing and commenting that may precede final approval.<sup>78</sup>
- **NIH:** Once an information product is approved within the institute or center, it is sent to the Office of Communications and Public Liaison in the Office of the Director, which forwards it to the Office of the Assistant Secretary for Public Affairs in DHHS. The manuscript is to be reviewed and returned to the author within seven to ten days, with any requested changes clearly marked.<sup>81</sup>

Regardless of official policy, the timeframe for review and clearance actually varies considerably by agency, the subject matter, and even the personnel who are in the office at the time, interview subjects explained. In some agencies, scientists say it might typically take three to four weeks, while in others, three to four months is often more typical. In some instances, delays of a year or even two have been reported. Frustrations about delayed reviews are common across agencies. For example:

- **CPSC:** A statistician reported that the agency review process involved a review by an immediate supervisor

for scientific integrity and editing, followed by five or six additional levels of review until it reaches the executive director. This scientist noted, “There did not seem to be a timeframe in which any one person in the chain of review had to respond and pass forward the report; things could just sit and sit.”

- **NIH:** Agency scientists say a multi-tiered review process can take up to six months to complete. “If you are finally given the chance to do a project and it takes six months just to get through all the committees, that is rather discouraging,” said a senior advisor.
- **NIOSH:** A medical officer involved with health hazard evaluations of workplaces commented, “There has been some trouble getting the information out in a timely manner. Reviewers go on vacation, so things get backed up, or they have different points of view about how things should be written, so there is a delay in hashing this out.” On the other hand, the situation has improved somewhat in recent years: “The agency used to have one person review at a time, but now there can be multiple reviews occurring at the same time.”

The review process may be less onerous to a scientist who has learned how to navigate it successfully. A senior epidemiologist stated, “You learn, as a supervisor, to change what you have to change to get things through ... If there is something that is really, really worth fighting for, you have to know when to pick your battles and try to do it in a way that is going to succeed.”

## SCIENTIFIC INFORMATION INVOLVING POLICY OR SENSITIVE SUBJECTS

Delays are more likely when an information product has policy implications or addresses a sensitive topic. Research that has policy implications warrants particularly careful review at many agencies, with reviewers focusing on whether agency policies are represented accurately and whether the new research supports or contradicts existing policy. Official statements related to research with policy implications include the following:

- **ARS:** The area director provides the research leader with a current list of sensitive subjects, and the research leader then “reviews manuscripts for sensitive

subjects” and ensures that if a manuscript addresses one of these subjects it is designated as “sensitive” on the agency’s “Request to Submit Manuscript for Publication” form.<sup>85</sup>

- **CDC:** The number and qualifications of clearance officials are influenced by the “topic’s level of sensitivity” and “potential to impact CDC recommendations, policies, or programs.” However, CDC policies state that “clearance is not a forum for extensive peer review or for policy debate. Such discussions belong in the pre-clearance phase.”<sup>74</sup>
- **CDER:** The CDER clearing official may refuse to clear material that “does not accurately reflect current policies.”<sup>80</sup>
- **DOI:** Approving officials must determine that “the paper is descriptive of a policy position fully adopted by the Department and that it is not merely the expression of an individual’s or group’s projected or desired program that does not reflect the official Department stance.”<sup>84</sup>
- **USGS** requires that authors whose products are of a sensitive nature—which include those with current or future policy implications—consult appropriate bureau and departmental officials. USGS specifically mentions land and resource management decisions or those “that involve matters of national interest, security or potential commercial gain” as potentially sensitive.<sup>75</sup>
- **EPA:** Agency guidelines state that officials must establish procedures to ensure that proposed products are “consistent with agency policy,” and top management officials (such as assistant or regional administrators) must “determine whether proposed products require review by the Office of Public Affairs for policy or other issues.”<sup>78</sup>
- **NIH:** The Office of the Director must approve information that “includes any discussion of Federal policy, has policy implications, or makes public health practice recommendations.”<sup>82</sup>

The picture that emerged from interviews was that scientists understood the rationale for policy reviews, and many of them felt that their information products would be cleared as long as they made clear distinctions between the research’s conclusion and the agency’s policy.

A CDC branch chief acknowledged that the Centers “exercise everything which is considered to be a policy statement ... There are very definitely marching orders.” But this, the branch chief felt, “was a good idea because I think if there are policy statements then they would be written in Atlanta [agency headquarters].” At EPA, a project director said that the intent of the policy-related review is to make sure an information product “doesn’t say anything that’s really inappropriate on policy. It’s not the science but whether it’s extending from the science and drawing conclusions that cross over into policy.”

Of concern to some was the lack of consensus about what constitutes policy. “It seems to be up to the agency to determine what they consider to be a policy statement, and sometimes they can be quite broad,” said a CDC manager. “The interpretation can be pretty draconian at times.” Some scientists felt that the goal of review was not to achieve accuracy and clarity about policy, but to avoid disseminating information that might call agency policy decisions into question. A number of scientists felt their agencies only wanted results that supported their predetermined policies. “There are a number of people who have had their research killed because the people at the top don’t think it would benefit their message,” said a CPSC statistician. This seemed to be of particular concern to FDA scientists:

- An FDA senior manager stated, “If the research conclusions didn’t come out the way people wanted them to, they would never be presented.” The scientist continued, “The point of research was to make sure that you were supporting FDA policy.” Where findings seemed to suggest a flaw in agency policy, “the response is usually that the research has been done incorrectly.”
- FDA scientists said that if their research was leading towards a possible conflict with agency policy, they were

required to bring it to the attention of the Program Office. General Counsel was included in subsequent discussions, and “they would generally say to stop the research if it was going to come out that way.”

- An FDA economist reported being told by a center deputy director, “I literally cannot understand why you cannot write regulatory impact analyses that always support our position. I just don’t get that.”

To some, this was a violation of core research principles. “My belief is that science is a search for truth, and if you are a researcher working within the FDA who comes up with something that points to a flaw in your own policy, that research should be published,” said a senior manager at the FDA.

Nonetheless, this scientist noted that it was possible for researchers to influence policy at the margin: “Our overall policy is good but here is a little tweak you could make to improve it.’ That kind of thing you could probably get through, but nothing that would say ‘this whole policy is ridiculous.’ The FDA doesn’t necessarily want to publish anything that may cause them to change a regulation, or to change any policy.”

## **THE IMPACT OF ANTICIPATED REACTIONS ON CLEARANCE DECISIONS**

Agencies have their own methods (explicit or not) of classifying information products as sensitive. From interviews, it became clear that some clearing officials are reluctant to approve dissemination of information products that may upset a particular industry or the public.

Some scientists also suggested that media attention on a particular topic was enough to earn it the label of “sensitive.” CDC scientists reported that their agency was often wary of publishing information that might arouse fear in the general public—even though such publications might contain important public-health information.

Several scientists reported instances in which clearing officials delayed or refused approval for an information product that would harm an industry or agency’s image or raise an issue related to sexual activity:

- A scientist at CPSC reported that the 2003 annual report on the safety of all-terrain vehicles was delayed because the agency’s general counsel had a “hands-off” attitude towards the industry of which he had recently been a part. The report was released a year late, and the scientist had at one point been led to believe the general counsel would never approve its release.
- A physician with the DOD said a colleague was told he would never be able to publish data on sexually transmitted infections rates among Marines stationed in Southeast Asia. “He told an audience of 150 military personnel that he could never get this past the chain of command, and everybody giggled and nodded their heads.”
- That DOD physician also reported that his commanding officer discouraged him from publishing a story about a contractor’s use of toxic pesticides in embassy housing in the country where he was stationed, which was associated with an employee’s death, because the commanding officer felt it could be embarrassing to the embassy.
- A CDC scientist reported that the agency’s then-director refused to allow publication of a paper on bioterrorism in food in Oregon, because the director had come from the industry and did not want to “make waves” for them. The paper was never published.

A scientist with experience at multiple agencies stated, “The agency will find all types of trivial things that need to be ‘fixed’ to delay publication.” The interviewee continued, “There is no avenue to complain because it is made to look as if this is just part of the process.” In some instances, self-censorship has also been reported because scientists were convinced they could never get their work approved.

## **REVIEWERS’ CREDENTIALS**

Scientists throughout the federal government repeatedly stressed that scientific review should be conducted by scientists. Many interviewees expressed concern that their work was being reviewed by administrative

personnel who lacked scientific training, expertise in the subject matter, or familiarity with the structure and format of scientific writing. Scientists stated that feedback from knowledgeable reviewers would be helpful, but the review process as currently practiced yields few useful comments. Examples include:

- An industrial hygienist at NIOSH said, “I’m not so sure that I find our own branch and section management review so helpful. They’re often not subject-matter experts ... Sometimes there is a danger with this much review.”
- “Often times a case is made in scientific terms, and it’s a little weird to have the non-scientists who are reading you make your case in scientific terms,” said a NIOSH senior scientist.
- “You may be a nutritionist and find that an economist is reviewing your work for appropriateness,” commented an FDA senior manager.

In one FDA unit, a scientist reported, research was reviewed first by the FDA branch chief, then by the associate director of the division, and then by the office director, who was an attorney reviewing its legal implications. This might have been more acceptable to scientists if the attorneys reviewing the research had received some training regarding the subject matters they were to review.

An FDA senior manager called these kinds of review “oppressive” and “inappropriate for the [scientific] environment,” and attributed his decision to retire in part to the office director’s insistence that “you just have to live with whatever change the attorneys make.”

Personal bias towards certain branches of science also seemed to influence decision-making at the FDA. In some instances, reviewers did not consider certain specialties to be strong science—a typical clash was between the “hard” laboratory sciences such as physics, chemistry, or biology and “soft” social sciences, such as sociology, economics, or psychology.

Such feelings about the review process were not uniform across agencies, however. According to a DOD medical doctor, “there was always a ... review and it was based on science.”

## BENEFITS OF THE PROCESS

Despite the frequent characterizations of the review process as burdensome or onerous, a number of scientists commented on ways that it could improve quality and help the agency reach consensus. “The clearance process can be an effective tool to shape things in one way or another,” said one scientist.

Several NIOSH scientists found value in their agency’s review process:

- The multiple layers of review have “forced studies to be designed to avoid the criticisms on inadequate methodologies ... It forces more discipline because everyone knows that there is a certain standard for agency research.”
- “They want to ensure the science is correct, what is being said is based upon what was found, and make sure that the information is palatable to a wide audience—industry, labor, scientists, and the general public—and that things are worded so that they are not inflammatory.”
- “The process can make things more concise and create an overall better product.”

Several EPA scientists also spoke favorably about the process, and indicated they were able to publish without significant constraints:

- “I think that the process is reasonable and that the people who complain probably don’t understand why certain checks and balances are needed,” said an EPA project director, who also acknowledged that it was “cumbersome ... Some of this depends on management’s ability to recognize important factors that will need additional review, and having those reviewed early to avoid a delay in publication.”
- An EPA statistician said, “Sometimes the review comments seem to be off the mark and it is an extra hurdle to go through, but it also gives us some protection to have the evidence go through that process.”
- “By the time a paper reached the administrator for signature, everyone would presumably be on board,



although it was a fairly involved process to bring that about," stated a senior science advisor with experience at the EPA and DOD.

## THE USE OF DISCLAIMERS

Most agencies allow their employees to publish their research in journals or other outside publications, or to make presentations in scientific forums and other external settings, provided they use a disclaimer. The goal is generally to ensure that the distinction between the conclusions of an individual and a scientific agency is clear. According to an interviewee, FDA attorneys have created a boilerplate disclaimer to be used in every speech and publication; its use was "highly encouraged by management," but it was not clear that everyone complied. "Disclaimers are very appropriate," said an FDA division director. "A scientist does not speak for the agency."

Typically, disclaimers will state that a researcher is publishing work "in a private capacity" or that the conclusions do not necessarily reflect the views of the employer agency. Some agencies also have rules about the nature of the biographical information a government scientist may include in externally disseminated documents.

Disclaimers are often required when scientists are doing work on their own time, which may or may not be related to their agency scientific work. A VHA manager explained, "When I do courses, I don't speak for the agency. I speak for the work I've done, which doesn't necessarily represent agency policy. That's the disclaimer we put on everything."

Disclaimers may be required even if the research has been reviewed and cleared by agency officials. Interviewees reported that NIOSH and EPA's National Center for Environmental Assessment require that all publications and presentations have a disclaimer, while the EPA's Office of Drinking Water requires either that the agency not be mentioned at all, or that the information product include a disclaimer.

These are official policies relating to disclaimers:

- **CDC:** Employees must receive advance approval for work conducted outside of CDC, if the work "requires

the use of professional qualifications readily identified with CDC employment ... This work includes service on boards or committees that may write or publish information products ... Approval may not be granted if the work is determined to be compensated and related to the employee's official duties."<sup>74</sup>

Once the work is approved, an employee may use the CDC affiliation in connection with outside information products as "one of several biographical details ... provided the title is given no more prominence than other significant biographical details." CDC employees may also allow their titles to be used if the following disclaimer appears on the information product: "This (article, book, etc.) was (written, edited) by (employee's name) in (his, her) private capacity. No official support or endorsement by the Centers for Disease Control and Prevention, Department of Health and Human Services is intended, nor should be inferred."<sup>74</sup>

- **CPSC:** A disclaimer is required on articles submitted for publication unless the text is approved, or the Office of General Counsel determines it is not necessary. Even if the information product does not relate to CPSC policies, objectives, or operations, it must contain a disclaimer if the authors identify themselves as Commission employees. The disclaimer must state "that the views expressed are not necessarily the views of the Commission. Articles not concerning the CPSC are still subject to regulation on employee standards of conduct."<sup>76</sup>
- **DOI:** DOI limits the extent to which employees may use their official title in outside teaching, speaking, or writing. As at the CDC, agency policy says that an employee's title or position may be "one of several biographical details," provided that the title or position is "given no more prominence than other significant biographical details." The employee's title may be used in an article published in a scientific or professional journal provided it is accompanied by a disclaimer "satisfactory to the agency stating that the views expressed in the article do not necessarily represent the views of the agency or the United States."<sup>91</sup>



- **FDA/CDER:** “Personal activities,” which are specifically defined by CDER, are not subject to clearance, “regardless of whether they deal with topics bearing on the work of CDER or the Agency.” However, if the personal activity pertains to FDA programs or policy, CDER officials may require a disclaimer that reads as follows: “This [article, book, speech, etc.] was [written, edited, prepared] by [employee’s name] in his/her private capacity. No official support or endorsement by the Food and Drug Administration is intended or should be inferred.”<sup>80</sup>

As noted earlier, the FDA Amendments Act states that if an article or presentation has not been cleared within 30 days after submission for review, the employee “may submit the article for publication or presentation with an appropriate disclaimer as specified in the policy.”<sup>79</sup>

- **NIH:** The NIH policy states that the clearance process normally eliminates the need for a disclaimer, but one may still be required to make clear that the work does not necessarily represent the NIH view. (The policy does not elaborate further regarding circumstances under which such a disclaimer may still be necessary.) Investigators may also need disclaimers to identify data that is preliminary or incomplete, or to describe potential sources of error.<sup>82</sup>

Scientists differed in their views about the utility of disclaimers. Some saw disclaimer requirements as appropriate, while others questioned why an agency would seek to distance itself from work produced by its scientists. For some, disclaimer requirements made them feel unsupported and isolated from their agencies. A senior manager with experience at FDA and NIOSH recalled, “I got to be so frustrated at one point, I gave a talk and said ‘the views expressed here do not reflect any views or positions of FDA, and in fact don’t even reflect my own views.’”

Disclaimer policies seem more likely to frustrate scientists when they require disclaimers in addition to, rather than in place of, official agency clearance. “We are still arguing about disclaimers,” a CDC branch chief said. “If they’re saying we don’t speak for the agency, why can’t we just say anything we want? Instead, it still has to be cleared.”

## AUTHORSHIP

CDC, NIH, and USGS spell out requirements for authorship, with each one requiring that a person listed as an author must have made a “substantial” or “significant” contribution to both the research and the resulting publication. Both CDC and NIH base their authorship criteria on the Uniform Requirements for Manuscripts Submitted to Biomedical Journals, developed by the International Committee of Medical Journal Editors.

These are the official policies:

- **CDC:** Authorship credit is to be based on three conditions, all of which must be met:
  - Substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data.
  - Drafting the information product or revising it critically for important intellectual content.
  - Final approval of the version to be published.<sup>92</sup>

The CDC policy also states that “all persons designated as authors should qualify for authorship, and all those who qualify should be listed. Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content. At least one author, usually the first, should take responsibility for the integrity of the work as a whole, from inception to publication/distribution.”<sup>92</sup>

Any disputes about author designation or author order that cannot be resolved at the division or office level should be resolved by the center’s associate director for science, if possible. If it cannot be resolved at the center level, it goes to the Office of the Chief Science Officer for “final arbitration and ruling.”<sup>92</sup>

- **NIH:** The NIH states that the “privilege of authorship should be based on a significant contribution to the conceptualization, design, execution, and/or interpretation of the research study, as well as on drafting or substantively reviewing or revising the research article, and a willingness to assume responsibility for the

study.” Individuals who do not meet these criteria but provide advice, financial resources, “occasional analyses,” or other kinds of support should be acknowledged in the text, but not listed as authors.<sup>93</sup>

A variety of practices among disciplines makes it impossible to formulate universal standards, but NIH policy advises each research group, laboratory, or branch to “discuss and resolve questions of authorship, including the order of authors, before and during the course of a study.”<sup>93</sup>

- **USGS:** “Authorship should be restricted to those who contributed substantially not only to the investigation, providing original data and interpretation of that data, but also to the content of the information product. Senior authorship is normally assigned to the person who was responsible for the most substantive interpretations of the information product and had the principal role in preparing the information product. Authors should be listed in a sequence reflecting their role in the study.” Individuals with administrative or supervisory responsibilities, or those who provide relatively routine technical assistance, are not to be included as authors.<sup>94</sup>

In interviews, one NIOSH scientist confirmed the concept contained in these policies, stating, “The person who does the most work is the lead author.”

Another commented on the relationship between the lead author and the co-authors. “Once a draft is approved by co-authors, then the co-authors do not have any more say in the work. Some lead authors will keep their co-authors abreast of any changes that occur throughout the review process so that there are no surprises once the manuscript has been published. Not all scientists are courteous about this.”

Several scientists also discussed situations in which authors had chosen to have their names removed from papers. In some instances, that reflected disagreement on how the data were interpreted, or what conclusions were reached. In others, particularly where the authors came from several different agencies, a challenging review process seemed likely to hold up publication of the work unless they withdrew.

According to a CDC branch chief, the agency does not “regard papers as written by the authors. Although that might sound strange, they regard them as written by the agency ... I would separate those ... I write the paper, I publish it, my name is on it, and if it gets grief and it’s all wrong, I take the heat.”

## Communicating with the Public

As scientists noted when speaking about disseminating information products, government science is funded by taxpayers, and taxpayers have a right to learn from agencies’ scientific work. Many scientists feel an obligation to communicate with the public about their work. At the same time, agencies seek to ensure the correctness and consistency of their communications, and often require scientists to follow specific procedures when communicating publicly.

For most of the scientists interviewed, the main way they communicated with the public was by speaking with the news media. Scientists may also speak at meetings that are open to the public and press, or communicate with academic researchers or other interested individuals.

## A GOVERNMENT-WIDE POLICY OF SCIENTIFIC OPENNESS

Promoting “a culture of scientific openness” is official federal government policy, according to the OSTP.<sup>22</sup>

The OSTP’s “Core Principle for Communication of the Results of Scientific Research Conducted by Scientists Employed by Federal Civilian Agencies” is designed to foster such a culture. Part of a set of principles issued in 2008 to guide the release of scientific research results and to comply with the America COMPETES Act of 2007, this principle reads, in part:

Robust and open communication of scientific information is critical not only for advancing science, but also for ensuring that society is informed and provided with objective and factual information to make sound decisions. Accordingly, the Federal government is committed to a culture of scientific openness that fosters and protects the open exchange of ideas, data and

information to the scientific community, policymakers, and the public.<sup>22</sup>

Two supporting principles—one focused on communicating with the media and one on open exchanges of research data—follow from this core principle, OSTP states:

- **Communicating with news and information media:** “Agencies should provide for the widest practicable and appropriate dissemination of factual information concerning agency scientific activities and their results,” and should develop and update policies regarding employee interactions with the public and the press.<sup>22</sup>

Agency policies should be designed to ensure that “employees may freely and openly discuss with the public, subject to classification restrictions and consistent with existing laws and regulations, scientific and technical ideas, approaches, findings, and conclusions based on their official work.”<sup>22</sup>

- **Open exchange of research data and results:** “Research data produced by scientists working within Federal agencies should, to the maximum extent possible and consistent with existing Federal law, regulations, and Presidential directives and orders, be made publicly available consistent with established practices in the relevant fields of research.”<sup>22</sup>

Agencies are to develop and update “clear guidelines regarding processes for sharing research data and results generated by Federal scientists,” consistent with the Information Quality Act. Research data does not include trade secrets, confidential information, and individually identifiable medical information.<sup>22</sup>

A memorandum accompanying these principles instructed federal agencies to update OSTP about their progress toward finalizing communication and data-sharing policies by July 31, 2008. A year after the deadline, not all agencies had responded, and information about those that had communicated with OSTP was not publicly available at press time.<sup>95</sup>

Online searches of agency policies and the interviews with federal scientists suggest that most agencies have

not yet developed consistent and clearly articulated strategies in line with the principle that agency employees should share their scientific work with the media, the general public, and one another.

## **COMMUNICATING WITH THE MEDIA: OFFICIAL AGENCY POLICIES**

Where formal policies are in place to govern the interactions between government scientists and the media, they tend to require, or strongly encourage, employees to seek prior approval before being interviewed. However, many agencies appear to offer little or no guidance on the subject.

An explicitly restrictive policy at USDA’s FSIS states that only executive management staff and staff from the Congressional and Public Affairs Office are authorized to communicate with the media. Media requests received elsewhere in the agency are to be put in writing and routed to the Congressional and Public Affairs Office.<sup>96</sup>

That office coordinates the agency’s official responses, including determining the focus of the news story, identifying the agency representative to whom the reporter should speak, and coordinating with that individual “on information available for public release.”<sup>96</sup>

NIH policy allows employees to “respond orally to questions and requests for information” from the news media or to “appear as a member of a discussion panel or seminar and on radio or television broadcasts without prior approval,” so long as the appearance does not require written text and is not specifically disallowed by an institute, center, or department policy. Speakers are advised to limit their comments to subjects within their field of experience and to present only official DHHS and NIH positions in discussions of policy.<sup>82</sup>

For news media interviews, responses, or appearances, employees are encouraged to seek advice from the relevant institute or center communications office, or for Office of the Director employees, from the NIH Office of Communications and Public Liaison.<sup>82</sup>

Some agencies distinguish between media inquiries made to their headquarters and those that come in to regional offices.

- CPSC policy requires that inquiries to CPSC headquarters be referred to the Office of Information and Public Affairs (EXPA), which will either respond directly or coordinate a response from a staff person with appropriate expertise (such as a project manager, analyst, economist, or attorney).<sup>76</sup>

There are a number of exceptions to this policy. Inquiries made directly to the offices of commissioners do not need to be referred to EXPA. As well, the executive director and the general counsel may respond directly to press inquiries they believe to be within their “special area of expertise,” and the Commission secretary may respond to scheduling inquiries.<sup>76</sup>

- Media inquiries to CPSC regional offices are left to the discretion of regional directors, although they are advised to “refer media inquiries relating to matters of potential national exposure of high-level Commission policymaking” (such as the agency budget, Congressional testimony, and certain matters of policy) to EXPA. According to the policy, “If the Director of EXPA determines that any such matter requires notification to any Commissioner (including the Chairman), then the Director will notify all Commissioners immediately.”<sup>76</sup>

Field-level media contacts that fall within the jurisdiction of regional directors include sharing product safety information (such as press releases, fact sheets, project hazard updates, injury data, consumer alerts, and educational material), responding to inquiries with publicly available information about hazards, and initiating meetings and briefings to discuss upcoming CPSC programs and provide background information for immediate or future use.<sup>76</sup>

The EPA does not have an agency-wide media policy at all, instead allowing regional and other offices to set their own policies, according to the agency’s response to a Union of Concerned Scientists Freedom of Information Act request. These policies vary considerably. For example:

- EPA Region 4 requires that all media calls be transferred immediately to the Office of External Affairs (OEA), which “is responsible for coordinating and overseeing all contacts with the media.” Along with coordinating

responses to media inquiries, OEA “will accompany staff during interviews” as it deems appropriate.<sup>97</sup>

- By contrast, EPA Region 8 emphasizes that EPA’s policy is “to operate with the maximum degree possible of public openness, disclosure and responsiveness,” and notes that “news outlets are a legitimate extension of the public and are dealt with as such. Employees are authorized to deal with the public and the media and are responsible and accountable for those contacts.” The policy also states that “program staff may respond within their area of expertise to day-to-day inquiries from news outlets and are responsible for the content of those contacts, for knowing if a communication strategy is in place, or if a spokesperson is appointed for a given issue.”<sup>98</sup>

Employees are required to complete a Record of Communication form after any media contact and to submit it to their supervisors, the communications office, and the Congressional liaison.<sup>98</sup>

CDC, FDA, and NIOSH do not appear to have formal, agency-wide policies about employee interactions with the media publicly available online.

## **COMMUNICATING WITH THE MEDIA: WHAT SCIENTISTS SAY**

Most of the scientists interviewed, regardless of their agency, position, or rank, acknowledged the complexity of interacting with the media. Scientists working on potentially controversial topics were particularly concerned about saying the wrong thing in a media interaction.

While agency protocols obviously influence each scientist’s perspective on contacts with the media, personality differences may also play a role. Overall, a majority of scientists spoke in somewhat negative terms about the agency press or public affairs officials who have authority to decide who speaks to the media and what they can say. However, some scientists felt comfortable with the current approach at their agencies, and appreciated having the assistance of a media person. Others felt they should have unrestricted access to the media without a “minder,” while still others preferred not to speak with the media at all.

A senior manager with experience at USDA and NIOSH suggested that agencies' approaches to media communication are shifting as agencies better understand the importance of communication and the need for communication training. "There has been a slow evolution to where there is starting to be a realization that the communication stuff is really a different skill set than the science."

### ***A Broad Pre-approval Requirement***

Whether or not an agency has a formal policy in place, the perception among scientists at most agencies is that some sort of pre-approval is required to speak with the media. For example, despite a written policy that seems to suggest otherwise, a majority of the NIH scientists said that media contacts must be pre-approved by public affairs officials, according to a Union of Concerned Scientists survey.<sup>99</sup> According to interviewees working at CDC, some scientists have experienced having to seek clearance up the ranks of DHHS for the talking points they prepare for interviews on high-profile topics.

There is a sense among scientists at many agencies that approval requirements have grown more stringent in recent years. For example, a senior epidemiologist with NIOSH would in the past routinely set up an interview, and simply inform the agency media office of what was likely to transpire. "I would call the media office and would say 'this is what they are going to ask me, this is basically what I'm going to say,' and that was fine." Now, by contrast, "they want a lot more detail, they want everything pre-approved, they want a prepared statement, and they don't want open interviews directly with scientists."

Some scientists noted that a shift had taken place under the Bush administration, especially during the 2004 election year. "Suddenly when people called us and asked for information, we were told not to give it out," said a CPSC scientist. "I was like, 'Whoa, we are being funded by taxpayer dollars here, why aren't we talking to the taxpayers?'"

Federal agencies at which scientists said they are expected to seek pre-approval for media contacts include CDC, DOD, FDA, HUD, NIOSH, USDA, and VHA. Scientists gave the following examples of agency approaches:

- **DOD:** Protocol dictates that all media requests be routed to the DOD public affairs office, which tries to determine what questions will be asked and helps prepare agency scientists for upcoming interviews.
- **FDA:** At the FDA, "there are fairly strict guidelines" for media interviews, according to a senior manager. Anyone contacted by the media is to immediately notify the press office, which then sets up a telephone or in-person interview, and generally listens in on the conversation. "It was clear that when you spoke to the media you were now speaking for FDA and you were not giving your own thoughts, you were giving FDA thoughts."

Despite standard operating procedures dictating that fairly high-ranking personnel at FDA could speak with the media, this scientist indicated that permission was not always granted, even at that level.

- **NIOSH:** NIOSH procedures require that any scientist contacted by the national media inform a press relations person, describe what the interview will be about, and seek approval to participate, according to a team leader. If the topic is considered controversial, media personnel may offer help in creating talking points in advance of the interview. Those who are less experienced in working with the media may be given more "hand-holding."

One NIOSH epidemiologist felt that procedures generally worked well, but added, "I also know what I'm allowed to say, and not, from years of doing this ... they usually just say 'okay' ... They want a heads-up, and they certainly have an expectation that I know what the rules are."

The overarching requirement is to be careful not to speak for the agency itself, but to confine comments to research findings, according to the epidemiologist. "I can't talk about NIOSH policy, can't say 'NIOSH says,' 'NIOSH does' ... I can talk a little bit about my personal opinion of research findings, but I have to be careful that it doesn't come across as an endorsement."

After an interview, according to a team leader, the process is to "summarize the questions that were asked



and your responses and then send it to the press officers, your division chief, and your branch chief. They wanted to be sure they weren't caught off guard." If they were not quite comfortable with an answer, management "could call the reporter back and say 'we want to revise X, Y, and Z answers.'"

A senior scientist was less sanguine about NIOSH policies, indicating that they had changed substantially since 2001. Historically, "you would field a reporter's questions, ask them to send you what they write so you can check it for errors, send it to the institute press officer, and inform your management chain ... It is totally changed now. Nowadays, we are not allowed to even talk to the press. You refer all inquiries to the OD [Office of the Director] of NIOSH."

Several scientists noted that while their agencies expected media requests to be directed to a press or public affairs office, they were flexible about giving the "go-ahead" for an interview to take place. In some agencies, approval appeared to be almost *pro forma*. For example:

- A DOD employee who worked in medical science said that while 95% of the agency's media requests were submitted to public affairs, "once we had an ongoing relationship, public affairs would say 'don't worry about it, just go ahead and tell them whatever they need to know.' There was some flexibility on certain topics."
- "I don't recall a time that I was not allowed to speak to the press," said a HUD manager. "The protocol was that if I did get a call, I contacted the public affairs office. They would decide, based on the nature of the story, whether they wanted to listen in or not."

A CPSC scientist reported that the press office's reach extended beyond members of the media to academic researchers. "I was prevented from talking to academic researchers who were researching the same things I was researching because the political appointees did not want me to say anything that didn't coincide with the message they wanted to get out. They wanted total control of the message. The only people allowed to talk to people on the outside, including academic researchers, was the press office."

## LITTLE AWARENESS OF FORMAL POLICIES

Many of the scientists interviewed stated that they were not aware of formal agency policies governing scientists' interactions with members of the media. Scientists who held supervisory positions seemed to have a better sense of agency expectations for media interactions than more junior scientists did, but their knowledge often came from experience rather than from explicit policies or training. Scientists who reported an absence of formal policies or training generally did not consider this absence to be a problem.

- An environmental health officer at IHS said that he informed his supervisor about an upcoming interview and was told "something along the lines of 'don't say anything stupid.' There is no formal protocol, and I think that is a good policy."
- An OSHA manager summed up his agency's approach as "[there were] no written policies, I just had to be very careful with what I said."
- According to a senior manager at NIOSH, employees were not aware of written policies, but "everybody knew as soon as you got out of the Center, you didn't talk off the reservation."
- A division director from CDC had a similar experience: "No one ever handed me a set of written policies. It is expected, if it is a high-profile activity, that you will speak with senior science people and policy people. If it is specifically scientific, there are no guidelines really."
- For a medical scientist with DOD, there were some very clear, informal guidelines to follow: "Be truthful, be factual, don't say if you don't know, and try to speak in a clear, concise manner."

Some scientists noted that agency protocols were enforced inconsistently. An EPA medical officer said, "I was actually pretty free to interact with the media," while an EPA environmental engineer said the policy was "don't talk to them. If a reporter calls you, immediately report it to public affairs." One scientist stated that instructions on media inquiries depended



on both the department in which a scientist worked and the subject matter involved.

The decision to allow DOD staffers to speak openly to the press also seemed to depend in part on where they were stationed and what they were working on. One DOD scientist said, "I was once told not to talk to the media, where I have had colleagues who were encouraged to talk to the media."

### **Determining Who Gets Interviewed**

Once a media request is forwarded to the appropriate media or public affairs office, a question as to who will actually be interviewed may arise. Requests for information can sometimes be dealt with at an administrative level. "Some questions would go through administration officers to be answered routinely in a certain consistent way, based on agency policy," said a DOD medical officer.

Often, however, greater subject knowledge and communication skills are needed to translate scientific information accurately, and to communicate effectively with the media or the public. Some media requests are directed to scientists involved in the research, often with guidance from the public affairs or press office. On sensitive or high-profile issues, especially those with significant policy implications, more-senior people or political appointees may be asked to step in to represent the agency. Under some circumstances, according to an EPA scientist, a presidential appointee may initially be asked to take a media call on a high-profile issue, but then defer to a subject matter expert who was "deemed responsible."

Many scientists questioned the appropriateness of turning over an interview to a manager or political appointee with less expertise. "Sometimes I was upset because I probably know more about it than the person being asked to speak," said a senior manager at FDA. "But on the other side, it was nice to be able to take those calls and just refer them to another office to handle. It also makes for a consistent response from the agency."

A chemist understood the frustration of scientists who have expertise but are not permitted to speak to the media. "You spend two years on a project and you're the authority, and then somebody comes and asks about it

and somebody else says, 'I'll respond to that.' ... That's the prerogative of the people higher up in management."

Having more senior people speak with the media does not always help reporters understand the science and can create confusion. However, according to an epidemiologist, "NIOSH is scared to death of lawsuits," and will choose whomever they deem most trustworthy to be interviewed. Several scientists emphasized the importance of scientific rigor in describing their work to the media:

- "I would prefer to provide the information to the media," said a health systems specialist with the VHA. "Otherwise information gets lost in translation."
- "In my experience, I do not think that the public affairs office's young aides in the Secretary's office are qualified to determine how to translate scientific evidence into what they think is understandable," said a HUD manager. "They are not scientists."
- "I think our concern is that things we say can be misrepresented, or they may be edited in terms of emphasis in such a way that ... the main point of what we're trying to say gets lost," said a senior behavioral scientist who had worked at both CDC and NIH.
- "The science matters, so the idea that you simply turn this over to the press office and have them create whatever they want out of it is not my idea of being a responsible scientist," said a scientist who had worked at several federal agencies. "It is *your* work."

A certain resentment was apparent among some scientists when higher-ranked personnel were brought in as agency spokespeople, even though they knew little about the subject:

- "I have to say, honestly, I was mad about it," said a NIOSH team leader. "They were coming to me because I was a recognized expert in this area ... It might have been best to let a scientist represent the agency as a subject matter expert, but the politics trumped that." In this instance, the scientist who had initially been approached by the media had to create talking points for the agency director who was actually interviewed.

- “Only very high people give responses [to the media]. I feel like a child,” said a NIOSH senior scientist. “It has kept me from wanting to go through the hassle.”
- “We are not considered subject matter experts where I work anymore,” said a CDC branch chief. “We’re not ‘experts,’ so the media has a very hard time being allowed to talk to us.”

“I know that conveying information accurately to the media is not something I’m used to doing, and there could be ramifications for everybody if it isn’t done accurately,” added a NIOSH industrial hygienist. “So I’m comfortable with someone who’s experienced in working with the media conveying information.”

### **Preparing for an Interview**

A media interview can be an intimidating experience, especially for scientists who have not been asked often to participate in one. “Civil servants are very, very petrified of the press,” said an FDA senior manager. Scientists engaged in sensitive research are especially likely to be leery. A NIOSH team leader said they “fear repercussions” and feel they have to be very careful about expressing an opinion that could be picked up by the national media. An FDA scientist said he would always ask that a media contact send him questions in advance so that he could prepare a response.

Some scientists thus found press officers valuable gatekeepers who could help them hone their focus in advance of interviews and develop talking points:

- One scientist, who has worked at both NIH and FDA, said, “It’s helpful because they are on your side, they coach you.”
- A CDC medical epidemiologist praised the communications office for helping to guide the interaction and identifying parts of a project that are of greatest interest to the media.
- “Public affairs would help to translate what I had to say into something that was perhaps understandable to the reporters,” said a HUD manager. “It is always a challenge to translate science into something that can be absorbed by the public.”

Some agencies provide fairly rigorous training in dealing with the media. An EPA medical officer said, “I thought that both CDC and EPA were sophisticated in their training. They had a lot of public communication, written communication, and media courses ... they put folks in front of a camera to talk about how to interact, how to do public health messaging.”

NIOSH scientists reported that their agency provides training, with an emphasis on translating science into something accessible to the public and developing a “single overriding communication objective.” The goal is to stick with prepared talking points, regardless of what the reporter asks. A CDC branch chief also mentioned spending significant time preparing talking points.

A medical scientist with DOD stated, “As a mid-level scientist and science manager ... I was sent to specifically study Congress, how the judicial system operated, and how the federal government operated.” The scientist considered it an excellent experience that would not have been available in either the private sector or academia.

On the other hand, training was not always perceived as adequate. “I thought that there probably should have been more media training. We did have some, but it was sort of random, *ad hoc* training,” said an FDA senior manager. This individual took it upon himself to guide younger, less experienced scientists through their media sessions.

### **Public Affairs Office Participation**

Once an interview is scheduled, scientists at many agencies—including CDC, DOD, FDA, HUD, and the VHA—said that a press or public affairs person sometimes listened in person, or on the telephone. Several agency staff said that press office representatives were present primarily to see what happened and what was said, and did not interfere. “We don’t do anything without someone from public affairs in the room,” said a VHA scientist. “[But] there is no censorship there.”

Nonetheless, it can have a “chilling effect,” according to a CDC branch chief, who said a press officer was on the line during every media interview. “Press officers usually don’t say anything while on the line, they are there more

as a reminder to keep on track with the talking points. You know they are there.”

## **VARYING ATTITUDES TOWARD AGENCY OVERSIGHT**

An environmental engineer at EPA captured the overall ambivalence some scientists have towards approval requirements. “On the one hand, as the agency you need to speak as one voice, you cannot have people undermining that. On the other hand, we’re a public agency and we work for the taxpayers, and I think we should be as open as possible.”

Tension between scientists and agency media offices sometimes ran high. In a Union of Concerned Scientists survey, CDC scientists reported difficulties speaking freely with reporters.<sup>99</sup> This was confirmed by a CDC branch chief who said that speaking to the media had become much more controlled in recent years. “There is much more oversight now when you speak to the media ... It is a very, very difficult area.” This individual said that reporters had to formulate their questions “in some way that the CDC press office will decide that I can answer them.”

Some scientists, especially those at senior levels, found ways to work around certain agency approval requirements. One approach was to speak “off-the-record” with reporters on deadline with whom they had long-standing relationships. Once the agency press office approved the request, the scientists could then speak in an “on-the-record” capacity.

A veterinary medical officer at USDA described another “workaround” strategy. After being told specifically that “if an issue came up, we should not talk to the media,” the scientist referred inquiries to the district office. However, this individual would also talk to a reporter who called at home. “If a reporter called me at home, on my personal time, I would deal with it myself.” The scientist indicated that it would definitely be a problem if the agency learned of the media contact, but did not expect that to happen.

Several scientists also described actions by press officers or public affairs representatives that seemed overtly intended to discourage media contacts. A CDC branch

chief said that the press office would “tell reporters that you’re out of town when you’re not.” Another CDC scientist said, “You have to get clearance to speak with the media, and you cannot tell the media that you must have clearance to speak with them ... It keeps media and scientists from speaking with one another.”

One scientist indicated that her agency would “do almost anything to keep reporters from interviewing me. They would say things to the reporters such as ‘oh, you have the wrong person, she really doesn’t know anything about this’ or ‘she’s shy and she won’t give interviews.’” Even when questions were being asked about a specific paper she had published, the press office told her, “We don’t think you’re the one who can answer these questions, this is really an issue for another office.”

Others felt more comfortable with a process they saw as designed primarily to have the agency speak with a single voice. According to an OSHA manager, “It would certainly have been my preference, as a manager, that any requests from the media go through the agency’s press office and there would be some kind of attempt to think through what was going to be said to the press before any agency person, including scientists, would get an interview.”

An EPA project director agreed. “There needs to be oversight, make sure that the right person is contacted, and that’s what the public affairs office does.”

An epidemiologist who has worked at EPA and NIOSH said the media contact process had not been problematic. “We’re encouraged to talk about our work with the media when we’re contacted. We just need to make sure we involve our press officer and give him the option to either participate with us or to let us handle it on our own.”

Along the same lines, a CDC medical epidemiologist said that it was probably best for CDC to track media inquiries and make sure they are referred to appropriate spokespeople, rather than be handled randomly. “I’m sure there’s some distortion of the message that occurs on some issues, but I can’t say I’ve ever experienced that myself.”

Most scientists felt that a certain amount of oversight is appropriate when scientists (or other federal employees) are speaking for agencies, provided that the oversight

process does not interfere with a scientist's ability to communicate effectively. A CDC epidemiologist described an ideal "happy medium between making sure the spokes-person doesn't say something that is totally at odds with where the agency stands [and] being totally in control of everything, and not having any respect for your staff to be able to know what to say."

## AGENCY COMMITMENTS TO SHARING DATA

Another important method for communicating results of scientific work to the public is federal agencies' sharing of data they collect. Many agencies make various databases available to the public, including the following:

- CDC's Web-based Injury Statistics Query and Reporting System<sup>100</sup>
- EPA's Integrated Risk Information System<sup>101</sup>
- FDA's Adverse Events Reporting System<sup>102</sup>
- NIH's Major Histocompatibility Complex Database<sup>103</sup>
- USDA's National Nutrient Database<sup>104</sup>
- USGS's Real-Time Water Data for USA<sup>105</sup>

In its 2008 memo, OSTP called for agencies to adopt "clear guidelines" for sharing research data and results generated by government scientists.<sup>22</sup> In 2009, publicly available policies on data sharing were found on the websites of CDC,<sup>106</sup> EPA,<sup>107</sup> and USGS.<sup>108</sup>

The CDC, EPA, and USGS policies emphasize the importance of ensuring data quality and dealing appropriately with confidentiality, privacy, and security. CDC makes each of its centers responsible for developing specific procedures to meet these goals.

The value of data sharing is described as follows:

- "CDC believes that public health and scientific advancement are best served when data are released to, or shared with, other public health agencies, academic researchers, and appropriate private researchers in an open, timely, and appropriate way. The interests of the public—which include timely releases of data for further analysis—transcends whatever claim scientists

may believe they have to ownership of data acquired or generated using federal funds. Such data are, in fact, owned by the federal government and thus belong to the citizens of the United States."<sup>106</sup>

Making data available, according to the CDC policy, will improve its quality and consistency and build trust with outside partners and the public by providing an opportunity for them to openly critique CDC investigations.<sup>106</sup>

- "Access to government information is essential in order for EPA employees to accomplish EPA's mission of protecting human health and the environment and for citizens to be informed about their environment." As such, it is EPA policy that the agency's information products (regardless of format and with appropriate exceptions) "will be created, collected, maintained, and managed in a manner which will promote access."<sup>107</sup>

At the same time, each agency recognizes the importance of adequate safeguards. The CDC, for example, notes that the data release and sharing policy "balances the desire to disseminate data as broadly as possible with the need to maintain high standards and protect sensitive information ... CDC also recognizes the need to maintain high standards for data quality, the need for procedures that ensure that the privacy of individuals who provide personal information is not jeopardized, and the need to protect information relevant to national security, criminal investigations, or misconduct inquiries and investigations."<sup>106</sup>

CDC and USGS emphasize the importance of timely data sharing in their policies, although only CDC provides a specific timeframe for releasing information:

- CDC centers should include procedures to release data "as soon as possible after they are collected, scrutinized for errors, and validated. This release should occur no more than one year after these activities."<sup>106</sup>
- USGS policy states that publication or other methods of release should occur as promptly as possible. It also provides a strategy for early release when there is an immediate demand for the data and prompt publication is not possible: "The material should be released in open-file format, including appropriate

announcements, and where applicable, the reports thus released should contain an adequate statement of their preliminary nature and that the information may be subject to change.”<sup>108</sup>

Both the CDC and USGS suggest the importance of fairness in their policies. CDC “strives to have data release policies that are fair to all users, regardless of their organizational affiliation.”<sup>106</sup> USGS staff are prohibited from disclosing information to others “until the information is made available to all, impartially and simultaneously” through publicly released information products approved by the Director (“except to the extent that such release is mandated by law”).<sup>108</sup>

## Inter-agency Data Sharing and Communication

**B**ecause many public health issues involve the work of multiple agencies, federal scientists often wish to communicate and share data with colleagues at other agencies—but scientists at some agencies find it difficult to do so.

Interviews with scientists suggest that they can often face challenges in gaining access to data generated by other scientists within their own agencies, or elsewhere within the federal government. The extent and nature of the challenges depend on the agency and the department. For example:

- NIOSH scientists described data-sharing difficulties due to both bureaucratic and technological constraints. One scientist noted that a poor intranet system makes it difficult to communicate even within the agency; scientists may be unaware of research their colleagues are conducting.

A further challenge noted at NIOSH is the Memorandum of Understanding (MOU) between OSHA and NIOSH, which limits NIOSH access to OSHA data. Some interviewees believe the intention behind the MOU is to allow OSHA to prevent analyses agency management may not like. Scientists could see no scientific rationale for this MOU, and reported that its restrictions on the use of OSHA data, which

date to the Bush Administration, are cumbersome, unworkable, and mostly political in nature. A team leader at NIOSH working within these restrictions expressed great frustration, saying, “I feel that it was politically motivated ... They don’t want to have their data analyzed ... and studies done because they are afraid of what we might conclude or ... discover, and that we might publish and that would be embarrassing for them.”

- VHA scientists suggested that access to information has become more restricted in recent years, even though data sharing is still needed to complete certain types of assessments and research. They suggested that difficulties in data sharing might stem from turf sensitivities as well as the recent development of incompatible data systems.
- A statistician at EPA reported that the OMB and the Paperwork Reduction Act make it difficult to obtain data from state agencies. “It has been burdensome and has greatly slowed down our access to environmental information.” Without current data, it becomes more difficult for the agency to explain and defend its proposed rules.

Despite barriers, many federal agencies expect and need to be able to work together on issues of common concern. A HUD manager offered the example of EPA and HUD collaborating on environmental health issues related to housing, and suggested that EPA’s Office of Research and Development should do more to support this process. According to this scientist, the problematic lack of coordination between these two agencies was evident in the aftermath of Hurricane Katrina, when EPA and HUD sent inconsistent messages to the public about indoor mold, and the inconsistencies reduced the messages’ effectiveness. A similar problem arose when EPA issued a new rule on renovation and remodeling, which would have allowed for less-effective lead paint remediation procedures that HUD prohibited in federally assisted housing because they were insufficiently protective. The HUD manager felt that because the two agencies had not worked together, EPA’s rule failed to consider the most up-to-date research that HUD had conducted.



On the other hand, the HUD manager described a good experience when HUD coordinated with EPA and CDC to develop an evidence-based public health law that defined a lead-paint hazard. According to this scientist, HUD alone would not have been able to develop the legislative language and support its passage, thus defining an evidence-based health standard. The inter-agency collaboration and coordination were essential to the success. A medical officer spoke to the fact that when agencies work together, "it's really hard to politically get around two departments simultaneously."

An EPA scientist praised the coordination of agencies addressing the Libby, Montana Superfund site in EPA Region 8. He explained that EPA oversaw collaboration between EPA Region 8 employees, a regional health administration, a regional health administrator for HHS, and a regional health administrator for EPA. "It was very effective because you had so many dedicated people to look across the spectrum instead of ... each little group coming and doing their thing and getting out of Dodge."

In general, interviewees felt that the quality of the science tends to improve when agencies share information with experts in related areas of the field. Several scientists provided examples of effective data sharing, including the following:

- An EPA scientist noted that the American Waterworks Association and the Association of State Drinking Water Administrators provide data to the branch of the EPA that monitors contaminants in the water. This benefits the EPA because these outside stakeholders can typically obtain data and perform surveys more quickly than the federal government can.
- A HUD manager described a collaborative effort among scientists, through the President's Task Force on Environmental Health Risks and Safety Risks to Children, which was composed of "agency scientists at fairly high levels." The task force produced interagency reports on lead and asthma, and initiated the National Children's Study, which is investigating environmental influences on children's health.
- An EPA project director spoke highly of the Children's Health Protection Advisory Committee, which is "a

body of researchers, academicians, health care providers, environmentalists, children's advocates, professionals, government employees, and members of the public who advise EPA on regulations, research, and communication issues relevant to children."<sup>109</sup>

Data sharing seems to work most smoothly when the agencies involved have developed mechanisms designed to facilitate information exchange. A scientist at the EPA Office of Ground Water and Drinking Water stated that internal access to data is relatively straightforward and that mechanisms are in place to exchange data and documents with outside agencies, which improves the final product. "Everything is pretty public," said another EPA scientist. "We have a tracking process that tells you where [the document] is in the process. We tried to make it as public and transparent as we could."

While some agencies evidently promote information-sharing between agencies, others seem to discourage it. Concerns about barriers to inter-agency scientific communication arose repeatedly during interviews, and some scientists suggested that their agencies are too fearful of problems that might be caused by such contact.

A senior manager at FDA said that scientists were not allowed to contact colleagues in other agencies to discuss a scientific topic. Although this individual nonetheless did so, "it was completely discouraged. You would get in trouble ... It was not, in that sense, a scientific atmosphere."

The prohibition extended well beyond communications with scientists. "We were told we should not communicate with anybody outside of the Center without going through the attorneys," said an FDA scientist. "You should never talk to anybody in Health and Human Services, the Office of Management and Budget, and of course you would never speak with anybody from Congress." Anyone who wanted to have a conversation with staff in those offices was required to be accompanied by a member of FDA's legislative office, who would lead the conversation. "You couldn't say anything unless the attorney more or less approved it."

On the other hand, a statistician at EPA said that it was easy to communicate with external experts but that intra-agency dialogue could be problematic. "Sometimes it



feels like there are barriers between branches and divisions in EPA." A NIOSH medical officer concurs, stating, "I think we don't share our information as well as we should ... with our coworkers, so we don't have to reinvent the wheel every time."

## COMMITTEE PARTICIPATION

During interviews, some scientists noted that they had engaged in communication and data sharing with colleagues within and outside of federal agencies by participating on committees, including interagency working groups, international committees, and review panels. Of the scientists who stated that they had represented their agencies on committees, most considered their committee service to have been a positive experience.

Scientists found that committee participation was a means of gaining additional information from colleagues either within or across agencies, as well as aiding in building communication and data sharing with said colleagues. It appeared that agencies would sometimes place their scientists on committees with the goal of staying abreast of new and relevant information. An EPA project director stated, "[I was placed on the committee with] the understanding that I would bring back information and brief them regularly on the study and how it's going, and that was factored into our planning of [our own research]."

Some scientists serving on committees reported that they received training to ensure they followed agency policies, while others did not. A research chemist from NIOSH stated that NIOSH scientists serving on committees were required to go through ethics training, whereas an EPA assistant center director's experience with training was limited to being told to "keep your mouth shut."

## Professional Development

Interactions with colleagues from scientists' disciplines are crucial for professional development. For many scientists, attendance at professional meetings is the most important way for them to build professional relationships, receive feedback on projects, and learn about new developments in their fields. Nonetheless, many scientists felt their agencies did not fully appreciate the benefits of attending scientific meetings.

While some agencies actively encourage their scientists to attend outside meetings and conferences, others are reluctant to do so. Scientists' comments indicate that permission to attend meetings and conferences seems to depend, at least in part, on the agency involved and the supervisor and/or political appointee under whom a scientist works.

Formal agency policies on meeting attendance generally do not appear to be available online. One exception comes from FDA's CDER, which states, "Participation in an outside meeting represents a substantial effort and cost for the Agency and Agency resources should be used to maximum effect. In general, the meetings in which CDER staff participate should be open to the public, not specific to one or a few drug companies, and not arranged or sponsored by for-profit organizations." When staff members receive a request to speak on a CDER policy matter, it must be forwarded to an "Authorizing Official," who will decide whether CDER should supply a speaker and, if so, which employee is best qualified to represent the agency on the particular subject.<sup>110</sup>

According to several scientists, participation in professional meetings seems to have been curtailed in recent years, in many instances due to funding reductions, but most scientists indicated they could attend one or two such events a year. Many scientists agree that attending meetings is essential to their professional development, and should not be viewed merely as a perk.

In interviews, many scientists emphasized the benefits of outside meetings and conferences, and some felt their agencies did not fully appreciate how much could be gained:

- "Those who are viewing the literature see a growing amount of studies coming out of Asia, from China, Japan, Korea," said a NIOSH industrial hygienist. "It concerns me that it's becoming harder and harder for US scientists, in the government anyway, to interact with anyone from other countries."
- "I think that scientists going to scientific meetings is a fantastic way to improve your science, and we just need more money dedicated to that," said an FDA

senior manager. "Attending meetings is viewed as a perk, which is kind of silly."

- A NIOSH research chemist emphasized how much easier it is to work in person with scientists, rather than by conference call or another similar medium. "As far as I am concerned, there is no substitute for it. You have to be able to travel, that is absolutely essential, because if you can't travel you're isolated and you die as a scientist. You have got to be able to travel to present your own work, to listen to other people present their work, to interact with other scientists, to foster future collaborations, and so on."
- "There should be a commitment to professional development ... there should be resources to do that," said a HUD manager. "Managers should recognize that is part of their job, to get those resources."

Finances were a significant barrier, with some agencies encouraging participation in professional events but unable to pay for it. CDC sets aside \$1,000/year in Individual Learning Accounts,<sup>111</sup> which can be used to pay meeting registration costs, but not for transportation or lodging.

Scientists at NIOSH noted that their agency's method for distributing research funding makes it difficult for scientists to travel because it does not account for the entire life cycle of a research project. It generally covers the data collection, analysis, and manuscript writing, but does not cover the costs of distribution and dissemination of information at conferences. As an industrial hygienist from NIOSH put it, "You end up with the funding for the study, but then you have nothing to go to meetings on, so you're competing for discretionary funds along with all of the other folks in your branch with similar needs."

In some instances, scientists reported paying their own way, and even using vacation time, to attend conferences and meetings. One administrator who has worked at a number of government agencies recalled spending \$10,000 of personal funds one year to give talks because information dissemination was necessary but the agency was under severe financial constraints. Other scientists reported similar situations:

- "I know one woman, an economic researcher from FDA, who her whole career she paid for meetings out of pocket," said an FDA senior manager. "She couldn't get the money to go. She felt it was important for her career, so she paid for it herself, but most people would just not go."
- "We were not encouraged to participate, but it was important to me personally," stated a CDC branch chief. "I would take vacation time and attend at my own cost."
- "The travel budget at HUD was always inadequate," recalled a HUD manager. "I had to pay for my own travel."
- "I had a hard time getting [time off work] to go to yearly meetings that I needed to get my continuing education credits," reported a veterinary medical officer at USDA. "They never paid for any of that."
- A senior manager at FDA said, "The government does not pay for your participation in professional societies, and they cannot give you time off to participate ... it is part of ... what Congress decides to pay for. It is viewed as a perk rather than a necessity. It is thought that societies may influence you and you may influence societies."

Complex approval processes may also discourage some scientists from seeking agency support for travel to meetings. "It is so burdensome to go through our travel requirements that oftentimes it is just easier for me to set up travel with an NGO [non-governmental organization] and take a vacation day," a CDC epidemiologist said.

Scientists at higher levels within their agencies seemed to have more positive experiences. A VHA manager said that funding for conferences "hasn't been much of an issue," but acknowledged that it was easier for those in higher positions at the agency. Likewise, a CDC branch chief said, "I give a lot of talks at scientific meetings and there is basically zero oversight in that."

The bias toward allowing senior scientists, but not their lower-ranking counterparts, to attend conferences was a source of frustration to a CPSC statistician. "I was discouraged from going. There was very little budget, and the

people who got to go were long-time senior people who were shown to be incredibly loyal and not likely to be seen as a 'loose cannon.'"

On the other hand, a DOD medical scientist indicated that all researchers were encouraged to develop professionally, to be actively involved with pertinent professional organizations, and to attend national and international meetings. "We strongly encouraged our junior researchers to present at least two or three international meetings a year. Funding was always available for quality papers to quality organizations."

Some agencies require, or at least strongly prefer, scientists to actually be presenting a paper in order to attend an event. "If you want to go, then you have to show why you're going, and that means you have to present something," said an assistant center director at the EPA. Such requirements can present barriers for scientists working on multi-year projects, who would welcome colleagues' input but may not be ready to make a presentation. "You are not allowed to attend and participate at a conference unless you have a manuscript ready to go to a journal," said a senior NIOSH epidemiologist. "If you are doing a 10-year research program, you can imagine the chilling effect."

At some agencies, scientists scheduled to make a presentation were expected to make the same presentation in advance to colleagues and sometimes supervisors who offered feedback. A common practice at FDA and NIOSH, this was generally considered helpful for junior people but somewhat burdensome for those who are more experienced. "It may be more valuable for newer people, but for experienced scientists, frankly it's a waste of time," said a NIOSH research chemist. At FDA, the intent is to make sure a presentation "goes out in a certain way," said a senior manager. "People would go through their slides, give their talk, and as they were doing it, they were getting feedback—'change that slide,' 'don't say this, say that.'"

According to scientists, some agencies impose other restrictions on conference attendance. During the Bush administration, a restriction was placed on the number of CDC employees who could attend any one conference.

Two scientists reported that if more than 20 employees wanted to attend a single event, a memo or letter had to be written describing the necessity for the larger number. Some interviewees believed the restriction was imposed to reduce the potential for scientists to abuse the travel privilege, and branch and division management were said to be sympathetic to researchers hampered by the limitation but unable to do anything about it.

Likewise, a NIOSH epidemiologist reported that the agency had customarily sent approximately 90 people to the industrial hygienists' annual conference, because more industrial hygienists are employed at NIOSH than at any other federal agency, and this is their main conference. But "somebody in CDC just made a blanket determination that only 12 NIOSH people could attend ... it was purely bureaucratic and had no objective correlated to what was needed."

Some scientists considered scientific-meeting attendance useful in principle, but had personally decided to reduce or halt their own travel to professional scientific events. In a few cases, scientists disliked attending meetings or felt that they had already been to enough of them. More often, scientists felt their agencies made travel too difficult. With reductions in administrative staff, some scientists are left to arrange travel logistics on their own, and feel unable to spend the necessary time doing so. In other cases, scientists simply find it too difficult to arrange for time away from the office. According to a CPSC statistician, "CPSC didn't want us to be out of the office ... employees were not even allowed to go to our own Commission meetings unless we had a role there ... We were supposed to be working."

## Influences on Government Science

Scientists in many federal agencies are subject to numerous influences. Congressional representatives, agency managers, and political appointees may exert their influence explicitly, or scientific activity may be shaped in more subtle, bureaucratic ways. There may also be considerable public- and private-sector influence, either exerted directly on an agency, or through elected officials.

Most scientists said these influences were a significant burden on their work, especially when they were asked to redirect their work, often quickly, in response to shifting “political whims.” However, some also acknowledged that outside influences could bring new ideas and new voices to the table and help identify issues appropriate for agency study. “There is not a lot of interference but there is lots of debate,” said a HUD scientist. “This should be encouraged among staff and outside experts.”

Scientists distinguished between what they considered to be appropriate influences, such as an organization requesting that an agency study a particular topic, and attempts to influence science inappropriately, such as a member of Congress pressuring an agency to slant or suppress findings that might displease a constituent group. They also noted that some forms of influence, such as requirements imposed by Congress, might be appropriate but could still cause the agency to direct its energies away from work scientists considered crucial to their agencies’ missions.

### **WIDESPREAD INFLUENCE**

Although some scientists were surprised to discover the extent to which government science is shaped by internal and external forces, many were willing to accept it. One interviewee said that whether they work in government or the private sector, scientists are never entirely independent.

Some scientists also indicated that attempts to exert influence come from all political perspectives. “It’s not just the Bush Administration, it is everyone in DC,” said one. Likewise, an FDA senior manager said influence is exerted by “both political parties.” A medical officer with experience at multiple agencies explained, “Certain issues were elevated and certain ones were lowered based on political interests, and monies tend to flow the same way.” This scientist did not see a pattern of influence based on who was in office.

Comments from scientists with experience at several agencies illustrate the pervasive nature of influence on government science:

- “The first time I found out that decisions were made politically, I became indignant,” said the FDA senior manager. “Then, after a while you realize that this is the world you live in.”
- A health systems specialist at the VHA made a similar remark: “We work for a political agency, and this is just the way it is.”
- A NIOSH team leader said, “I used to think that politics had nothing to do with what we do here, when I was very new. But the longer I’ve been here and the higher I’ve gone ... I think politics are more important than I thought ... They influence what’s done ... They influence what the agency chooses to pursue to research.”
- A senior manager at FDA stated, “I always said the FDA is a science-led and science-driven agency, but in fact they are not. It is an agency that executes the laws that Congress says they should.” When the law and the science do not mesh, “the law trumps the science.”

### **CONGRESSIONAL INFLUENCE ON RESEARCH PRIORITIES**

When asked about influence on their work, many scientists identified Congress as a major force in shaping their research priorities. Elected officials often push agencies to conduct specific studies that will please their constituents, whether or not they are truly appropriate research topics, or meet needs identified by agency scientists. For example:

- A DOD physician said, “I thought there was way too much money being spent by DOD on things like Howitzers that were appropriate for fighting Soviet forces.” This individual thought that work was being funded to “give money to some district in Kansas,” despite the opposition of military officers who were saying “we don’t need that piece of junk, it’s 15 years past what we need. We need to do more malaria research.”
- According to an EPA scientist, after Congress set aside some funds to conduct a long-term study as part of a recommendation made by the EPA’s Science Advisory Board, a Congressional representative expected that

some of the funds would be used to complete a specific risk assessment on the health effects of trona, a byproduct of a power plant in Alexandria, Virginia. "It seemed that the expectation was that the EPA would drop everything and look into the issue," said the scientist. Some at the EPA saw this as a "political ploy" to satisfy constituents, not necessarily to meet scientific needs.

- A NIOSH scientist reported that after residents in Endicott, New York raised concerns about high rates of cancer within a community where IBM was located, Congress put pressure on NIOSH to conduct a study, even though some scientists who had investigated the issue did not see enough evidence to support further research.
- A supervisory chemist at FDA sums up the political influences on federal scientists' work: "You're in Washington, that's just the name of the game. If a Congressman wants to give \$5 million to do research on an issue and they get it voted on by their colleagues, you either do it or find another job."
- A research chemist from NIOSH expressed frustration with Congressional earmarks: "Get the boutique projects out of there." This scientist described members of Congress as focusing too exclusively on their districts and having an attitude of "it may not have anything to do with improving whatever in the US, but it's going to help my district."

Regardless of how worthy the research may be, Congress sometimes mandates studies without considering the agency's capacity to undertake them. For example, a CDC division director pointed out that if legislation is passed requiring the agency to investigate a particular disease or chemical exposure, it may have to cut the budget of other established programs to fund the new work. A medical epidemiologist from CDC stated, "It's very frustrating to people who know that there's a big public health problem out there that we know what to do with, but we can't do that because we're being told to do something else that is totally pointless."

Funding seems to be part of the reason the EPA does not always act on the recommendations of its Science

Advisory Board. Every year, the board identifies the topics it believes should be researched and submits a report to the Administrator, who "usually nods and smiles and says 'thank you,'" according to one scientist. "But that is sometimes all that happens ... If the funds of the agency are already spoken for, how are they to be redistributed based upon the report, particularly when everyone is already busy working on their projects?"

Members of Congress may not only require some studies; they can also prohibit others. Examples from scientists included the following:

- A senior behavioral scientist with experience at CDC and NIH spoke of Congressional staffers reading through research abstracts to find projects that, as they claimed, were "encouraging sex work" or at least not discouraging it, or "encourag[ing] sex among gay men or other populations that displeased certain elements of the social conservatives." This was seen as an attempt to micromanage Congressional funding to agencies.
- According to an epidemiologist at CDC, research on gun violence is strictly off limits. "It's a Congressional mandate that says CDC cannot ... do any kind of policy evaluation or intervention that restricts access to guns." The scientist found this problematic, since "guns are the main weapon for homicides and non-fatal injuries" in the US.

Some scientists expressed concern about members of Congress lacking sufficient scientific understanding to make informed decisions about scientific priorities. A CDC epidemiologist summed up what many scientists feel about political involvement in science, saying, "Policymakers are pushed by different kinds of interests, and sometimes those interests have nothing to do with evidence, but rather personal interests ... If we could at least get them to look at the evidence and factor it into their decision making, I think that would be a step forward."

Political officials also may not recognize the scientific complexities of a research question. "A Senator can ask, 'what are you doing about mold?' but it's almost the wrong question," said an EPA project director. "It's only part of a bigger question."



## CONGRESSIONAL BUDGET THREATS

During the interviews, several scientists explained that agencies angering Congress risk seeing their funding slashed, or even revoked completely. Several NIOSH scientists noted that during the days of the “Contract with America” (an agenda of the Republican majority in the 104th Congress), their agency was threatened with outright elimination. These scientists agreed that the experience has had a lasting impact on agency personnel.

Since then, a NIOSH team leader explained, the agency has been less bold. New initiatives have “been noticeably in non-controversial areas ... It just seems to be a strategy, it’s almost like a survival mechanism.” The fear is that if the agency pursues controversial occupational health issues, “our head will be put on the chopping block once again.”

During the 104th Congress, OSHA was also a target, and agency personnel speaking in public had to tread carefully. An OSHA scientist described commenting in public that the agency would continue with its rulemaking on ergonomics (a still-controversial regulatory issue) unless told not to. The next day, members of Congress threatened to cut OSHA’s budget dramatically—and they followed through on the threat.

The OSHA scientist also reported that the agency “ran in a very defensive mode” for a few years following criticism from leadership from the House of Representatives. “What happens in that kind of situation is that the political battles are fought at the upper levels of the agency and the scientists do their best to hunker down below the radar and continue to do their work, hoping that what they are doing isn’t going to get caught up in the political battle ... and that at some point the agency will move forward and do something with their work.”

## EXECUTIVE-BRANCH INFLUENCE

Presidentially appointed agency leaders exercise influence over their agencies’ scientific work in both overt and subtle ways. It is expected that agency priorities will shift with each new administration, but agency heads’ management styles and interest-group ties can also change how agencies conduct scientific work.

Some CDC scientists brought up the example of a proposal by the CDC director appointed by President George W. Bush to add an additional layer of management between the CDC centers and the Office of the Director, which would increase review requirements. NIOSH objected, believing that this would slow down the agency’s work, and both Congressional and industry representatives agreed. NIOSH was ultimately exempted from the additional review, but all of CDC’s other centers were subject to it, and some scientists feel that the reorganization has indeed hampered the agency’s work.

Scientists at other agencies also noted slowdowns linked to leadership changes. “They’ve essentially slowed down our research by increasing the bureaucratic responsibilities for scientists and reducing the amount of administrative support we have,” said a NIOSH epidemiologist. An EPA medical officer suggested, “Sometimes priority resetting from senior levels, in the agency, is designed to keep a project from moving forward.”

Agency leadership can also interfere with science-based regulatory decisions. At FDA, the controversial topic was the emergency contraceptive Plan B. Despite strong recommendations from relevant advisory committees and the professional review staff of CDER, the FDA long delayed approval to grant Plan B nonprescription drug status.

In 2005, FDA’s assistant commissioner for women’s health and director of its Office of Women’s Health (one of the authors of this report) resigned in protest, and characterized the agency leadership as “disregarding the scientific and clinical evidence and established review process and ... taking an action that harms women’s health.”<sup>6</sup> (In 2006, Plan B was approved for over-the-counter sale to women over the age of 18, despite recommendations that evidence did not indicate a need for age restrictions.)

In 2007 the *Washington Post* reported that the FDA intended to redirect 30% of the Office of Women’s Health budget to uses elsewhere in the agency—a move widely seen as retaliatory. This move would have effectively halted further operations, since the funds that remained would have been required for staff salaries and projects already underway.<sup>12</sup> Congress restored the funding, but the message had been sent.



Other concerns about scientific work being negatively affected by non-scientists who are appointed by presidents or brought in by appointees included the following:

- A CPSC statistician said, “I think that the political appointee needs to be removed from the process. The scientist needs to be able to work in an atmosphere that is free of fear, of both reprisal and free of fear from what will happen if their results don’t turn out to be what the political appointee wants them to be.”
- “We got an increase in the concentration of attorneys at the top, and attorneys do not think like scientists,” said an FDA senior manager.
- A NIOSH research chemist suggested, “If there was any way the research team could be elevated so it doesn’t have to answer to the policy wonks, that would be a really good thing. The same applies to agencies where scientists are subservient to the attorneys and the policy people.”

Some scientists spoke about political appointees influencing scientific work in order to benefit the industries or interest groups to which they had ties. An EPA environmental engineer spoke about conducting a Superfund site evaluation while being supervised by someone who was a past employee of a company responsible for the site’s contamination. The scientist reported that his supervisor said, “Hey, you know, don’t . . . don’t upset these guys. Do a good study, but don’t go overboard.” The scientist stood up to the supervisor to ensure an honest study was conducted, but felt that his career as an EPA scientist suffered as a result.

As noted previously, scientists also spoke about agency appointees halting or delaying release of papers that would have harmed the all-terrain-vehicle and food industries for which the appointees had previously worked.

In addition to being headed by political appointees with a great deal of influence, agencies are affected by the White House Office of Management and Budget (OMB). A scientist with experience at multiple agencies spoke about working on a federally mandated report that contained information to which OMB objected. “They insisted a huge amount of exposure information come out, which

we felt considerably weakened the report. We caved in because we had no real choice. If you wanted to transmit your report, you will give in.”

The same scientist noted that the same OMB staff are assigned to work with the same agencies over and over again. Agency administration “knows they will have to work with them on the next report, so they’re not particularly interested in getting into a quarrel with them because they know they’ll be back.” While this may accommodate the needs of administrative staff, “it does not work very well as far as getting high-quality science through such a review process, because the administrative people are always looking to the next act and the scientists tend to be thinking about the data they’re trying to see presented.”

Collegial relationships can also influence scientific activities. For example, a CDC scientist suggested agency functions may be affected by ties between senior managers who previously worked together in other environments. An agency may also deal with other government agencies differently than it would deal with private industry. For instance, if another agency were responsible for polluting a site, it would be “harder for our agency to see the polluting agency as a polluter and not as a government agency,” one ATSDR scientist noted.

## **PUBLIC-SECTOR INFLUENCE**

Some federal scientists reported that some organizations and segments of the public distrust their agencies’ findings. This seems to be an issue in particular for those whose agencies work directly on consumer safety (e.g., CPSC and FDA).

A CDC branch chief attributed this distrust to misconceptions of relationships between industry and the federal scientists: “There’s a kind of suspicion . . . which is very weird and kind of hard to deal with . . . because our decisions are based on our own ideas and information and there’s other issues” the public may not be aware of.

A scientist with experience at both FDA and NIH commented that pressures from public-interest groups tend to focus on issues that the general public can more easily grasp: “I think everybody thinks they are at least an amateur expert on energy policy or pollution control. But

everybody doesn't think they are even an amateur expert on cancer drugs."

Advocacy groups often promote research on specific diseases, and they may urge their members of Congress to mandate agency research on a particular condition or treatment. Although such advocacy efforts have the potential to draw resources from other priorities, some scientists welcome them. Several scientists commented that advocacy groups can play an important role in directing resources to important issues that might otherwise go unaddressed.

An industrial hygienist at NIOSH supports advocacy influence or support even if the advocates' statements are not fully accurate. "I can tolerate some inaccuracy in their statements, because they are at least pushing the agenda in the right direction."

### **General Public**

Several scientists spoke about a more subtle form of influence: the public's overall view of science and scientists. A public that does not understand how science works or see the importance of various scientific disciplines is likely to undervalue federal scientific work. Scientists commented on this:

- An epidemiologist with experience at NIOSH and EPA stated, "In this country we don't have a great emphasis on prevention, and much of the work that we do at NIOSH and CDC is in the area of prevention ... We don't think very foresightedly about what we need in the future, and research is all about deriving information and understanding that will help you move into the future."
- A NIOSH team leader identified a combination of media and misunderstanding of science as a cause of confusion: "People don't understand epidemiology ... They don't realize that it's the weight of evidence, no one study can really answer the question ... So people get confused when they hear one study and then the next week or two they hear another study that addressed the same question but came up with a different answer ... They don't understand what that means."

- An EPA branch chief noted, "Sometimes research raises more questions than it answers ... It's not definitive, occasionally it's not even helpful."

- An FDA project manager said, "A lot of research is focused on what's novel and what's new, a lot of regulation is focused on what is solid and sustainable ... At the same time, we were required to use validated methods—validated and reproducible. Well, there's a tension because what's new is typically not validated, it's not known if it's reproducible and valid, otherwise you're wasting everyone's time."

- A HUD manager suggested, "There has always been an undercurrent of anti-intellectualism in America, but that can be overcome ... it's important that we produce products that are meaningful to people, so the science should be relevant."

### **Tribal Influence**

Scientists whose agency experiences involved tribal groups noted that Native American and Native Alaskan tribes have historically had little chance of making an impact on the research that is conducted in and around their tribes—whether on their physical environment or their people and culture. Some federal agencies have made efforts to bring members of the tribes into discussions that affect them, but these efforts do not overcome all of the obstacles that tribes face in working with the federal government.

A scientist with experience at the EPA and DOD explained, "Tribes frequently have had some difficulty getting into the process. In some cases, the tribe might have 100 people, they are not going to have 10 people in their Department of the Environment, and 10 people is not a lot to cover what is going on." The scientist considered tribes to have too little influence to ensure that their concerns were addressed. "Generally speaking, they have relationships with their regions and so the regions tend to express their points of view or come force an issue."

This scientist reported having a positive experience with the National EPA Tribal Science Council, which consists of one person from each EPA office and one tribal representative from each region. The Council "was created in

partnership with tribal representatives to help integrate Agency and tribal interests, specifically with respect to environmental science issues.”<sup>113</sup>

According to an IHS medical director, some tribes have exerted a positive influence on research. For example, “in the past, data has been taken and published without tribal approval or knowledge (e.g., rates of alcoholism in a community lead to a reversal of federal funding and increase stigmatization). The research genuinely improved [with tribal input] because the tribes help put the data in context.”

### **Employee Groups**

Some NIOSH scientists spoke about the increasing difficulty of conducting research involving groups of employees who may be exposed to a workplace hazard. Employees who do not understand the potential benefits of NIOSH research, or who fear negative consequences from it, are less likely to participate. One scientist suggested that employers may encourage workers to fear NIOSH research efforts.

Employees can request that NIOSH conduct Health Hazard Evaluations at their workplaces, but interviewees reported that the number of worker requests for these evaluations is declining.

One scientist noted that the term “research” can be intimidating to those who have little experience with it, so employees of a factory where NIOSH would like to conduct research might be fearful of what the agency is doing. “I do think it is getting to be more of a problem, because of the economy, jobs leaving the country. We get fewer requests” for evaluations, a NIOSH medical officer explained. “[That’s probably because] they just don’t want to make waves.”

### **PRIVATE-SECTOR INFLUENCE**

Perceptions about the nature and extent of private-sector influences on government science vary, but many scientists find them disturbing:

- A USDA division director stated, “The primary concern at USDA is industry, not public health.” This individual also noted that industry came to the table

for discussions with more technical knowledge and information than advocates for public health. “The USDA was much more inclined to be very closely aligned with the industry that they regulated; there were strong relationships with the leaders of the industries.”

- An FDA scientist said the agency only spent money on research when it wanted to “explain away toxicological problems.”
- “I believe that research is underfunded because the areas where we could gain ground are stifled,” said a NIOSH senior epidemiologist. The avenues of research that are stifled “are perceived as having negative outcomes or political interests.”
- A senior manager at FDA stated, “A couple of times in industry meetings I was told to say things I didn’t believe in, and I decided it was time to look for another job. There will be a time when your opinion does not jive with the agency.”
- A statistician from CPSC stated, “It is commonly accepted that there is influence from industry ... the influence is stronger from industry than from others.”

Although such influence may come from close relationships between industry groups and agency officials, some scientists noted that industries can also win favorable outcomes by fighting and criticizing government work:

- A senior epidemiologist from NIOSH stated, “The biggest obstacle to making changes that are better for the environment is the whole antagonistic situation between industry and the government and science in this country. They would rather fight than cooperate, they would rather pay lawyers than set up preventive programs.”
- An environmental engineer from EPA believes that “because the results of research will affect some company’s bottom line, [there] is a strong incentive for that company to criticize the government research. They have a strong vested interest in trying to make our research results [look like] ‘junk science.’”

Some scientists also observed that industry concerns did not always prove valid. One scientist who worked at both FDA and EPA said that industries had opposed both FDA's decision to ban lead-soldered cans in 1995 and the EPA's 1997 "cluster rule" pertaining to discharges into the air and water. This scientist noted that industry had warned that stricter requirements for their manufacturing processes would make their products too expensive for consumers to afford, but that did not happen in either case.

Scientists provided examples of private-sector interests influencing agency science:

- A branch chief at the CDC was told to "back off" releasing data about an air pollutant because "it would inhibit their ability to pass an amendment. They claimed that it would halt the passage of an amendment and be problematic for the industry." The scientist was able to publish limited data on the findings, but was told to "drop the issue. It then drops off the radar of all other scientists because if CDC dropped it, it must not be important."
- A veterinary medical officer working for FSIS to ensure the safety of meat attempted to enforce a regulation at a meat processing plant. After the plant manager called the scientist's supervisor, the scientist was told that there must be a "mistake" in the assessment of enforcing the regulation and to back off on the terms of enforcement. The scientist noted that there is even a committee where "industry advises FSIS."

Some agencies actively seek out partnerships with industry. An epidemiologist with experience at EPA and NIOSH stated that an increase in industry interference has forced the "involvement of parties that wouldn't ordinarily be part of ... NIOSH day-to-day research ... There's been an increased urging of all staff to increase what they call partnerships with people who are potentially producing the hazardous materials that we're studying ... It has great potential for there being conflict of interest."

These partnerships can be financial in nature. For agencies facing budget challenges, partnerships that bring funds to the agency can be attractive. CDC even has a foundation whose mission is to "unite a wide range of private

sector partners with CDC scientists to achieve common goals,"<sup>114</sup> which one scientist described as a mechanism for obtaining industry funding for agency research.

While many scientists interviewed expressed concerns about industry influence on agency science, some scientists felt that industry involvement was appropriate and could be beneficial:

- A DOD interviewee noted junior researchers can sometimes be placed with private companies for a year or two to gain experience, and that industry had stepped in to develop ideas that originated with government scientists in the space program.
- At OSHA, a scientist commented that where outsiders may perceive that undue influence is being exerted on the agency, some internal staff believe there is balance.
- A HUD manager said the housing industry was "committed to protecting kids" from hazards such as lead paint but had legitimate concerns that should be factored into agency policies. "My experience with the housing industry is that they just wanted to know why they had to do something, and what they needed to do."

### ***NIOSH's Right of Entry***

In interviews, several NIOSH scientists voiced concerns that their agency was bowing to industry pressure in failing to make use of their right of entry. A NIOSH epidemiologist explained:

Historically we were given as a right from Congress what we call "right of entry." We actually carry a card that says we have the right to enter your premises, we have the right to do this study, and it's actually in the federal law that we have the right to enter a factory or a workplace. We have a right to interview employees in private; we have a right to do biological measurements. Through the '80s and '90s this really went unchallenged.

According to a senior scientist at NIOSH, this changed early in the Bush administration, when "the NIOSH attorney and the CDC attorney said 'we are not going to enforce

our legal right to entry ... we don't want to get too high on the radar so we're not going to [use it]."

NIOSH scientists reported that the agency's reluctance to use its right of entry makes it difficult for them to conduct health hazard evaluations regularly and without interference. They also suggested that NIOSH's meeker stance has emboldened employers, so that on the occasions when the agency does conduct evaluations, they find employers to be less cooperative than in the past. A NIOSH industrial hygienist explained that corporate lawyers know the agency is unlikely to challenge employers who don't allow NIOSH employees to enter their workplaces, and "they can't find any real good reasons why [cooperating] would be good for their company."

Nowadays, NIOSH scientists report that agency personnel must essentially beg for entry into workplaces, and provide evidence of potential exposure before they can study workplace conditions. However, one scientist explained that where evidence of exposure does exist, an employer can say "okay, come back in a year and we'll let you do the study." Then the employer can remedy problems before NIOSH employees return; this can protect the workers' health going forward, but does not allow for investigating workers' past exposures or collecting information that could benefit other workers in the future.

## WORKING IN AN ATMOSPHERE OF INFLUENCE

Some scientists who had worked at an agency for several years noted shifts in their agencies' overall attitudes in the face of constant pressure from Congress, the executive branch, and the public and private sectors.

Scientists voiced frustrations about agencies failing to respond to public-health issues—even when data showed a threat to health—because of a lack of political will. Some also expressed concern about agencies coming to view limiting health risks as more of an individual responsibility, rather than something a federal agency should address. For instance, a HUD manager was disturbed to note a national-level shift away from addressing housing deficiencies and toward "blaming mothers and blaming the victims, which is inappropriate

and wrong and not supported by the science." This reflects "a disastrous change in policy" that in his view was driven more by industry than by science.

A NIOSH research chemist shared a similar perspective, describing the shift toward placing safety responsibilities on workers, rather than on job sites: "There is this perception that NIOSH research is not needed ... that if you happen to work in a very hazardous job, then that's your fault, you're accepting that responsibility, and if you don't like it, quit." That attitude stands in contrast to an agency philosophy that the scientist describes as a "responsibility to not just do research, but to communicate it and to have an impact and to make sure we actually are making things better."

Over time, the influences exerted on scientific agencies can alter overall attitudes. An EPA environmental engineer felt that the culture had shifted, growing more autocratic and less idealistic over time. "You don't see the passion for the environment or the same commitment to public service, the same idealism that there used to be."

Even if an agency's overall attitude changes, individual scientists can still promote what they view as the right actions for science and public health. In some cases, taking these stands can harm scientists' careers, as these interviewees noted:

- "The truth of the matter is bureaucracy is the culture of 'to get along you go along,'" said an FDA senior manager. "If you want to be kept on the promotion track, you don't buck things like that. That can harm your career, and believe me, it harmed mine."
- A NIOSH research chemist said that outspoken scientists may pay a price. "As a scientist, if we came out and said what we really thought, publicly, it would have been individual punishment as well as institutional punishment."
- A team leader at NIOSH spoke of a report written by a colleague that had concluded an association exists between a chemical application and illness. The author of the report "got pressure from supervisors who were getting pressure from the governor's office to change the conclusions." The scientist reported that when the



author refused, his travel expenses were audited, a \$6 error was found, and the scientist was then terminated.

Scientists who take principled stands on scientific matters do not always suffer career damage; in some cases, they convince their superiors, and in others they conclude that agency management has the right and responsibility to make the ultimate decisions. A NIOSH epidemiologist described taking a dispute to upper management and going several levels above an immediate supervisor, but still getting a “no” answer. At a certain point, this individual recognized, “I’ve taken this as far as I can and now it’s the agency’s decision ... You have a choice to either say ‘I can’t accept that ‘no’ answer, I’m leaving,’ or ‘I have to live with that ‘no’ answer.’”

### **THE IMPORTANCE OF SUPPORTIVE MANAGEMENT**

Whether pervasive influence shifts agency attitudes and harms scientists’ morale depends in large measure on the extent to which managers prevent inappropriate influence from interfering with scientists’ work. Some of the interviewees who served in managerial roles commented on steps they took to buffer their scientists from outside pressures. “We felt very committed to try to protect junior scientists from some of the bureaucratic problems associated with Congressional committees and oversight,” said a medical scientist at DOD.

Other scientists expressed gratitude for supportive managers. According to an OSHA manager, a trade association sought the firing of a scientist because they did not like the findings of a paper the scientist wrote. The scientist’s manager refused to discipline the scientist “for functioning as a capable scientist operating within standard operating principles of academic publication.”

This scientist also reflected on the overall role of influence on agency work. “One of the things that most impressed me about working for the federal government was the extent to which outside organizations attempt vigorously to influence the agencies. That seems like a fact of life, and I don’t think that it is necessarily inappropriate,” he said. “How those attempts at influence are handled by the agencies is what is important.”

## **Follow-up Survey Results**

As noted in the Methodology section, 30 of the original 37 interviewees participated in an anonymous online follow-up survey. The objective of this survey was to determine if scientists felt that change, either positive or negative, had occurred at their agencies since the initial interviews took place. The survey was conducted during July and August 2009, approximately six months after the Obama administration began.

Of the 30 scientists who responded, 18 were still employed by the federal government at one of the following agencies: VHA, IHS, CDC (including NIOSH and ATSDR), USDA, or EPA. Scientists no longer employed by the federal government provided various reasons for their departures: retirement, resigned for another position outside of the government, or other. One of the scientists who selected “other” reported being “forced out of work due to an injury.”

Questions addressed the same areas covered in the interviews: workplace supportiveness, access to data, research review processes, publication clearance processes, communication with media and the public, ease of attending professional meetings, feedback processes, and overall work environment. On each topic, respondents were asked, “How do you feel things have changed, if at all, since the new administration began?” and given four options from which to choose:

- Change for the better
- Change for the worse
- No change
- N/A

Results appear in Table 8.

In most of the areas, the majority of respondents did not perceive change. In two areas, responses indicated that a substantial minority perceived improvements. Regarding scientists’ ability and willingness to provide feedback, 33% reported improvement. And, according to 30% of respondents, the overall work environment has changed for the better.



**Table 8: Results of Follow-up Survey**

<b>Question: How do you feel things have changed, if at all, since the new administration began in regard to...</b>	<b>Change for the better</b>	<b>Change for the worse</b>	<b>No change</b>	<b>N/A</b>
Providing a supportive workplace?	20%	10%	50%	20%
Access to data?	10%	3%	16%	27%
The research review process?	17%	7%	53%	27%
The publication review/clearance process?	3%	3%	66%	28%
Scientists' communication with the media and the public?	7%	3%	59%	31%
Scientists' ability to attend meetings, conferences, etc.?	7%	17%	52%	24%
Scientists' ability and willingness to provide feedback on scientific activities and processes?	33%	7%	37%	23%
The overall work environment?	30%	13%	33%	23%

*Percentages may not total 100 due to non-responses on some questions*

Despite indications that some scientists perceive improvements at their agencies, comments reflected a belief that change comes slowly, if at all, to federal agencies. Some scientists felt that entrenched managers and civil-service leadership would hamper improvements, and several noted that funding concerns have not abated and may worsen further.

## LEADERSHIP

Many respondents expressed optimism about the Obama administration addressing some of the problems with agency environments and processes:

- Yes, I anticipate it changing, because the agency I worked for has just received new leadership from the Obama administration. However, that took a long time after the election, and the effects have not yet been felt—the new leadership has only been in place a few weeks.
- Possibly, because we have a new director at CDC who just started about a month ago. Dr. Frieden has stated

that any reorganization will be “transparent” and that a team approach will be encouraged in the agency. So it is possible that progressive change will occur at CDC and ATSDR, but I have a “wait and see” attitude.

- The new administration clearly values science and has put well-qualified scientists in leadership positions. The willful anti-intellectualism of the past 8 years seems (thankfully) past—for now.
- If the new leadership proves itself competent and transparent, the atmosphere can only get better.
- I hope things will change for the better (i.e., less administrative oversight) once new leadership is established in our institute.

Comments regarding leadership were not uniformly positive, however:

- If anything, I expect it to get worse. I don’t think the new director will be happy about science that doesn’t completely support his views.

- Not in the immediate future. We have had no change in leadership at any level and no change in policies and programs, including those implemented during the Bush years.

In some cases, low expectations for improvement stemmed not from dissatisfaction with an agency's leadership but from a belief that new appointees will find it difficult to change entrenched processes and cultures:

- I do not anticipate it changing. The culture of secrecy at my former agency is too entrenched, and I don't believe that even new leadership from the administration is capable of changing it.
- The review process is too entrenched at my former agency, and I don't believe that the administration has the power to change it. There are people in place who exert political influence over the content of reports, and until/unless they are removed, the review process will still suffer from political interference (even from the long arm of the previous administration's burrowed appointees).
- Probably no change because the bureaucratic system in place during the previous administration is now entrenched in our agency.

## MANAGEMENT

Only a few scientists identified improvements in management at their agencies, and some others expressed hope that they would see positive changes soon:

- Much better, more ethical attitude.
- A more open and rational approach to management will eventually make everyone feel more confident and less confused.
- Top-down management approach currently prevails; hopefully more bottom-up ideas will be better received in the near future.
- I work in a Branch that usually requires a manuscript before attending conferences. Recently, I was able to attend a very small meeting without a paper (I had funding from another government agency), and I

made many good contacts for developing my project. To only network with other scientists after the research is completed deprives the scientist of the valuable input that could improve a project during its design, planning and analysis stages.

By contrast, other scientists did not report changes in their agencies' management practices, and did not anticipate any improvements in the near future:

- To provide feedback, there must be an open environment with respect of the individual. This still does not exist at my former agency.
- Key people in the upper leadership have been given tremendous power in the past 6-8 years and are reluctant to change anything.
- Change will be slow to come. Middle management remains a barrier to open sharing of ideas and information.

## FUNDING

While a few scientists expressed optimism about their agencies benefiting from increased funding in the Obama administration, more respondents were concerned that the national financial situation would lead to damaging budget cuts:

- I expect things to get worse with budget cuts—there are few support staff and inadequate support services now and I expect that to worsen.
- I'm very concerned about future funding for science in light of consideration of the magnitude of the national debt.
- Scarcity of resources has increased unhealthy competition among staff, and reluctance to share information and resources.

Given that the survey was conducted approximately six months after the start of the Obama administration, it does not capture all of the changes that the administration is likely to make. Scientists' responses indicate a cautious optimism about agencies' ability to improve, combined with concerns about the difficulties of changing policies and practices at federal agencies.

# Recommendations

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The recommendations below address the issues around which scientists expressed the most need for change. Addressing scientists' concerns can improve morale at federal agencies, which will in turn improve scientists' productivity and lead to better government. These recommendations are often restatements of suggestions made by multiple scientists about how to ensure that their work proceeds efficiently and can be translated quickly into public benefits. Each recommendation section includes an overarching principle as well as specific recommendations to address the issues raised.

While the majority of the recommendations apply to agencies, White House offices and OPM also have a role to play in ensuring that the recommended policies are adopted. This leads to the first overarching recommendation pertaining to all other recommendations in this report.

## **OVERARCHING RECOMMENDATION: ENSURING POLICY CONSISTENCY AND CLEAR COMMUNICATION**

The White House OSTP and OMB should ensure that agencies adopt the policies described in this report's recommendations, and that the policies are generally consistent across agencies and appropriate within each agency's mission and scope. These policies should be clearly and actively communicated to agency leadership, scientific managers, and the federal scientific workforce.

When OPM policies (for instance, those regarding hiring and promotion) conflict with the recommendations in this report, OPM should revise its policies to allow agencies to follow the recommendations.

## **Management**

Managers of scientists play a key role in the production and dissemination of science from federal agencies. They must be able to communicate effectively between scientists who carry out research and the upper management and lawmakers

who shape and fund research priorities. When lawmakers or interest groups attempt to exert inappropriate influence on scientific work, managers must buffer scientists from these attempts and defend scientists' adherence to scientific principles.

In interviews, several scientists voiced criticisms about managers who have insufficient scientific training to understand scientists' work or empathize with them—or, on the other end of the spectrum, scientists who have been promoted to management positions despite lacking managerial skills. Agencies should choose managers who have sufficient skills and knowledge to work productively with scientists, and provide sufficient training so they can carry out their responsibilities effectively.

**PRINCIPLE:** Agencies should hire and promote managers who have the training and skills necessary to facilitate scientists' ability to conduct and disseminate scientific work.

**Recommendation:** Agencies should recruit and train managers who will buffer scientists against undue influence and ensure that the agency pursues its scientific mission.

**Recommendation:** Agencies should hire managers who have enough scientific training to translate between scientists and upper management and policymakers.

**Recommendation:** Agencies should provide management training to those who will be managing scientists.

**Recommendation:** Agencies should not require scientists to become managers in order to advance in their professional careers.

**Recommendation:** Agencies should evaluate and address perceived and real inconsistencies in the treatment of scientists on different career pathways (e.g., PHS vs. civil servants).

**Recommendation:** Agencies should minimize administrative duties that detract from scientists' ability to conduct their work.

## Feedback

The scientists interviewed for this study voiced many insights and suggestions about how their agencies could improve, but few shared these thoughts with their agencies. Although a few scientists noted instances in which agencies solicited and considered suggestions from scientists, many felt that formal avenues for feedback were either nonexistent or useless. Several scientists suggested that anyone providing feedback on agency actions or policies would risk retaliation, and that employees would only feel comfortable providing feedback if it could be given anonymously.

**PRINCIPLE:** Agencies should encourage honest feedback from scientists, and use it to inform decisions about policies and practices.

**Recommendation:** Provide a formal and anonymous means by which scientists can provide feedback to relevant colleagues, including upper management, without fear of retaliation.

**Recommendation:** Provide regular and follow-up training to ensure that all managers and supervisors are properly trained to understand employees' rights and to comply with the procedures that protect whistleblowers.

## Approving Proposed Research

Many of the scientists interviewed felt that the time and effort required to obtain agency approval for research projects is excessive—and these resources could be better spent on conducting the research, rather than writing lengthy research proposals. Scientists from NIOSH were particularly concerned about long proposals required for relatively small amounts of research funding. Although agencies have a duty to use taxpayer dollars wisely and support only the most worthwhile research, they must balance this requirement against the toll that extensive application processes take on scientists.

Scientists whose research involves surveys must also have their information collection approved by the OMB. Although OMB has made some improvements to the process by which it evaluates requests to collect information,

some scientists still considered the process to be excessively burdensome.

**PRINCIPLE:** Agencies should limit the time and effort required by scientists proposing research to what is necessary to ensure that the agency is supporting high-quality research.

**Recommendation:** Agencies should streamline intramural proposal processes to the extent possible.

**Recommendation:** Agencies should make the time and effort required to propose research commensurate with the amount of funding being sought.

**Recommendation:** OMB should streamline the process for approving information collections subject to its oversight, and facilitate the process for the scientists involved.

## Disseminating Scientific Work

Although the process for clearing research results for publication varies across agencies, information products must often be reviewed by multiple individuals before being submitted to a journal or otherwise disseminated. Agencies must ensure that the information products they disseminate are accurate and of high quality, but they must also avoid procedures that interfere with the timely communication of scientific information or discourage scientists from pursuing future publications.

Some scientists suggested that their agencies have used the clearance process to delay or even prevent the publication of findings that could ignite controversy. Congress addressed this issue at one agency with a provision in the Food and Drug Administration Amendments Act of 2007: It requires an FDA policy that gives reviewing officials 30 days to provide written clearance; if the deadline is not met, authors can submit the article for publication with a disclaimer stating that it does not represent the agency's viewpoint.

Scientists also expressed concerns about unclear and inconsistently applied agency policies on dissemination; reviewers lacking expertise in the relevant subject matter; and extensive time required to respond to all reviewer

comments, although not all comments were necessarily useful or relevant.

The issue of scientific publications produced on scientists' personal time also arose in some interviews. Even though such publications usually include a disclaimer stating that the work represents only the view of the author and not that of the agency where the author is employed, some agencies still require scientists to submit these publications for agency clearance.

**PRINCIPLE:** Agencies should disseminate scientific work in a timely fashion, and the clearance process should not be a tool for slowing down the dissemination of scientific information that may be deemed unfavorable.

**Recommendation:** All agencies should have clear policies on review and clearance, and apply them consistently and in a timely fashion.

**Recommendation:** Agencies assigning reviewers to review the content of scientific output should ensure that the reviewers have expertise in a relevant field.

**Recommendation:** Agencies should encourage expeditious and focused reviews.

**Recommendation:** Agencies should have processes for expedited clearance of time-sensitive materials.

**Recommendation:** Agencies should allow scientific work conducted on agency time but not approved by the agency within a reasonable timeframe to be published with a disclaimer that it represents only the views of the author(s) rather than the agency.

**Recommendation:** Agencies should allow scientists to disseminate scientific work done on their own time, provided they attach any necessary disclaimers, without receiving agency approval. Scientists should not face retribution if they exercise this right.

## Communicating with the Public

**A**gency policies governing scientists' interactions with the media tend to require, or strongly encourage, employees to seek prior approval before being interviewed. Some agencies require that all media

inquiries be routed through the media office, and some specify that someone from the media office must be present (in person or on the phone) during conversations between reporters and scientists.

Although some scientists appreciate the involvement of the media office, several of those interviewed raised concerns. In some cases, political appointees or members of upper management are the ones chosen to respond to media inquiries, even though they know less about the subject at hand than the scientists who research it. When scientists do speak to members of the media, the involvement of media-office personnel may have a chilling effect on what scientists say. These situations not only frustrate scientists, but may lead to the public missing important information.

The National Institutes of Health has a policy that appears to strike a balance: It allows scientists to respond to oral questions without preapproval, so long as they are limited to the speaker's field of expertise and policy statements present only official agency policy positions. However, a survey by the Union of Concerned Scientists found that NIH scientists think that media contacts must be pre-approved, which suggests that the implementation of this policy is uneven.

In 2008, the OSTP instructed agencies to develop and update media policies to ensure that "employees may freely and openly discuss with the public, subject to classification restrictions and consistent with existing laws and regulations, scientific and technical ideas, approaches, findings, and conclusions based on their official work."<sup>22</sup> Agencies do not appear to have developed such policies yet.

**PRINCIPLE:** As directed by the OSTP principles, agencies should develop policies that "provide for the widest practicable and appropriate dissemination of factual information concerning agency scientific activities and their results" and ensure free and open discussion.

**Recommendation:** Agencies should have clear policies on scientists' communication with the media and the public, and ensure that they are understood and consistently enforced.

**Recommendation:** Agencies' default policy should be to allow scientists to handle media inquiries directly and interact with reporters without the presence of media office representatives; under certain circumstances (e.g., when the topic is a policy rather than technical issue) it may be necessary for the media office to play a more central role.

**Recommendation:** Agencies should not require scientists to speak with the media; those who wish to do so should be offered media training or be allowed to shift inquiries to the media office.

## Inter-agency Data Sharing and Communication

**D**uring interviews, some scientists raised concerns about the difficulty of sharing data or other information with colleagues at other federal agencies. Incompatible data systems and restrictive Memoranda of Understanding between agencies were two of the problems raised, but a few scientists also stated that they were discouraged from contacting colleagues at other agencies directly about topics of common interest.

While agencies do have a responsibility to ensure that confidential and sensitive data are protected, they should be able to fulfill this responsibility while allowing for communication and data sharing between agencies.

**PRINCIPLE:** Scientists should be able to communicate and share data freely and efficiently across federal agencies.

**Recommendation:** Agencies should develop and communicate clear policies on data sharing.

**Recommendation:** Agencies should end explicit or perceived prohibitions on inter-agency communications.

**Recommendation:** Agencies should examine the need for establishing MOUs with other agencies before data sharing occurs; when MOUs are deemed necessary, they should be developed quickly and in a straightforward manner.

**Recommendation:** Agencies should identify ease of data sharing as a priority when making decisions about data systems.

## Professional Development

**T**he scientists interviewed agreed on the importance of agency scientists engaging with colleagues within their fields of study. Many scientists emphasized that attending professional meetings and conferences was an important component of professional development. Nonetheless, scientists often find it difficult to secure agency support for attending such meetings.

Agencies have limited travel budgets and must ensure that sending scientists to meetings will help advance agency goals. It is appropriate to require a certain level of meeting participation by scientists (such as presenting a poster or talk), but some agencies take the requirement too far. As an example, NIOSH scientists indicated that conference participation is not supported until a scientist is ready to submit a full manuscript to a journal. It is reasonable to require that scientists be delivering a presentation, but not to require that they have a manuscript ready for submission to a scientific journal. Agencies must recognize the importance of professional engagement for their scientists and make every effort to secure and award adequate funds for meeting attendance.

Scientists also expressed frustration about arbitrary limits placed on the number of agency employees who could attend a single conference, and about what some of them saw as preferential treatment of more-senior scientists seeking to attend meetings.

**PRINCIPLE:** Scientists should be encouraged to maintain their professional standing and pursue professional development through engagement with their scientific colleagues, to the extent possible given their agencies' resources.

**Recommendation:** Agencies should ensure that requirements determining which scientists are eligible for support to attend professional meetings and conferences are flexible, appropriate, and applied consistently.

**Recommendation:** Agencies should allow all scientists for whom attendance at a particular meeting is appropriate to attend without imposing arbitrary limits on the total number of employee attendees.



## Influence

Scientists described influences on their work from members of Congress, appointed agency leadership, the OMB, and the public and private sectors. They distinguished between what they considered to be appropriate influences, such as an organization requesting that an agency study a particular topic, and attempts to influence science inappropriately, such as a member of Congress pressuring an agency to slant or suppress findings that might displease a constituent group.

Scientists also noted that some forms of influence, such as requirements imposed by Congress, might be appropriate but could still cause the agency to direct its energies away from work scientists considered crucial to their agencies' missions. Likewise, while scientists recognized newly appointed agency directors' right to redirect scientific resources, they often felt frustrated when they were told to halt work on research they had been conducting for several years.

In general, scientists saw influence from the private sector as being more problematic than influence from the public sector—although some scientists stated that they did not see inappropriate private-sector influence

operating at their agencies. In some cases, scientists reported that senior agency personnel's ties to certain industries caused them to suppress or ignore findings that could have negatively affected those industries' reputations or profitability.

Allowing for appropriate influence from stakeholders while protecting the integrity of science from inappropriate pressures requires vigilance and sound judgment. Agencies should ensure their leadership and management are equipped to make these judgments and protect scientists from inappropriate influence that could compromise the integrity of their work.

**PRINCIPLE:** Agencies should protect scientific work from inappropriate influence.

**Recommendation:** Agencies should adopt policies and training programs for both managers and scientists that affirm agency commitment to scientific integrity and help employees distinguish between appropriate and inappropriate influence on scientific work.

**Recommendation:** Agencies should have policies in place to ensure transparency regarding input from political actors as well as private- and public-sector stakeholders.

# Conclusion

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The roles and responsibilities of scientists who work for the federal government in science-based agencies cannot be simplified into a sound bite or single issue. This study and the recommendations that have emerged from it call for ensuring a balance that will protect the fundamental principles of scientific method, integrity, freedom of inquiry, and dissemination of results as well as one that will achieve the missions and goals of the scientific agencies as established by our elected representatives.

The commitment and pride of scientists who work in federal agencies is remarkable. Their dedication to the public mission of our health and environmental agencies was demonstrated repeatedly throughout this study. Individual scientists within federal agencies, their managers, agency leaders, the relevant offices at the White House, and Congress all play critical roles in creating a work environment that promotes the morale and productivity of the scientific workforce that ultimately benefits the public.

The principles that are outlined in this report start with valuing the scientific workforce and establishing policies that are consistent across the federal government while being tailored appropriately for the mission and scope of each agency. Transparency, consistency, and accountability must be key elements in these policies.

The OSTP, along with the OMB, should bring agencies' leadership together to establish common policy approaches. Specific policies should address

- Improving management training and overall management approaches for scientific projects and staff, including promoting opportunities for honest feedback without fear of retaliation;

- Minimizing the bureaucratic maze needed to initiate new research and to allow for publication or other dissemination of research results, with or without disclaimers;
- Providing the opportunity for scientists to communicate with the public, while also providing any support or training that scientists need to improve their skills in public communication;
- Promoting engagement with federal scientists at other agencies and with the larger scientific community, including sharing of data and professional opportunities; and
- Minimizing the impact of inappropriate influence from non-scientific directions, while recognizing the appropriate roles of elected officials and the public in shaping the missions, scientific work, and policies of the agencies.

Concerns about scientific integrity and the politicization of science have been raised across several administrations, and peaked during the first decade of the 21st century over issues ranging from climate-change research and reproductive-health issues to regulatory standards. It is notable that in follow-up research conducted after the 2009 inauguration, several scientists who participated in this research did not anticipate that the change in administration would significantly alter their agencies' approach to science. Change in large agencies with hierarchical structures is difficult and takes time. This presents a challenge to both the new leadership and the existing career scientists to initiate and maintain new strategies and approaches for improving and sustaining the scientific workforce.

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# Appendix A: Interview Guide

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## Scientists in Government: An Examination of Their Rights and Responsibilities in Civil Society

**T**hank you for taking the time to speak with us about this topic. The information you will provide will be very important for our research on the effects of federally-employed (past and present) scientists within the U.S. political environment. We are working on the Scientific Knowledge and Public Policy (SKAPP) project with the School of Public Health and Health Services (SPHHS) at the George Washington University (GWU), and we would like to learn more about the relationship between government scientists (both social and laboratory), science, and policy making within civil society.

All of the information you provide will be kept confidential and private—your name or any other identifying information will not be attached to any answers given. Please feel free to share any information, ideas, thoughts, and/or beliefs regarding science and politics—whether positive or negative.

### SECTION I: OVERVIEW

1. Name of organization
2. Title [management/supervisory] OR [non-supervisory/staff]
3. Demographics
  - a. Male/Female
  - b. Race: \_\_\_\_\_
  - c. Age Range: 25-35 36-45 46-55 55+
  - d. Academic background (e.g., MD, PhD, MS, MPH, etc.): \_\_\_\_\_
4. What are your prior experience(s) or affiliation(s) with federal agencies, other than your current agency?
5. What is the number of years of involvement that you have with your current agency and/or previous experience(s) with federal agencies?

*Probe 1:* Specify years with current agency.

*Probe 2:* Specify years with other agencies and name other agencies.

*Probe 3:* Specify job titles and scientific responsibilities.

*Probe 4:* Which presidential administrations have you worked under? In which agencies and in what capacities?

6. What are your primary roles and responsibilities as a scientist in your current and/or previous position(s) with federal agencies?

*Probe 1:* What are the primary differences between your current position and previous position(s) with other federal agencies, if any?

7. How does your agency (past and present) foster a workplace ethic for scientists that is consistent with its mission?

*Probe 1:* What efforts are made to effectively work toward the agency's mission?

*Probe 2:* How could the agency improve upon this?

### SECTION II: RESEARCH

1. What is the research results review process? When does it occur?

*Probe 1:* What are the avenues to go through to have research results reviewed? Are there standard operating procedures? Where are they?

*Probe 2:* At what point in the process is research reviewed?

*Probe 3:* What are the layers of review? How many are there? How easy/difficult are they to navigate?

*Probe 4:* How are research results utilized to create internal and external policies?

*Probe 5:* How are controversial—both political and scientific—topics handled? Is there efficient support from supervisors?

*Probe 6:* What do you think of this process?

*Probe 7:* How could this process be improved, if at all?

*Probe 8:* What difficulties have you encountered or observed in this process? How were they handled?

2. When research is conducted, who receives authorship?

*Probe 1:* What, if any, difference is there for internal or external reports/publications?

*Probe 2:* What do you think of this process? Are there standard operating procedures? Where are they?

*Probe 3:* How could this process be improved, if at all?

*Probe 4:* What difficulties have you encountered or observed in this process? How were they handled?

3. What kind of influence exists from non-career personnel, who may or may not be scientists, upon scientific research?

*Probe 1:* Under what circumstances would a non-career personnel interject in a scientific determination?

*Probe 2:* What difficulties have you encountered or observed? How were they handled?

4. What kind of influence exists from members of Congress upon scientific research?

*Probe 1:* Under what circumstances would a member of Congress interject in a scientific determination?

*Probe 2:* What difficulties have you encountered or observed? How were they handled?

5. What kind of influence exists from state, tribal, or local government/elected officials upon scientific research?

*Probe 1:* Under what circumstances would a state, tribal, or local government/elected official interject in a scientific determination?

*Probe 2:* What difficulties have you encountered or observed? How were they handled?

6. What kind of influence exists from the private sector upon scientific research?

*Probe 1:* Under what circumstances would the private sector involve themselves in a scientific determination?

*Probe 2:* What difficulties have you encountered or observed? How were they handled?

7. What is the venue in which scientists can provide feedback on the processes that exist regarding research?

*Probe 1:* How often is feedback generally provided? Are there standard operating procedures? Where are they?

*Probe 2:* How does feedback affect existing protocols?

*Probe 3:* What type of mechanism/tool is used to gather feedback?

*Probe 4:* What do you think of this process?

*Probe 5:* How could this process be improved, if at all?

*Probe 6:* What difficulties have you encountered or observed? How were they handled?

### **SECTION III: PUBLICATION & DISSEMINATION**

1. What is the publication process? Are scientists encouraged/discouraged to publish?

*Probe 1:* What are the requirements to be met prior to publication? What is this process?

*Probe 2:* What is the difference in protocol between internal and external publications, if any?

*Probe 3:* Who has ownership of the research?

*Probe 4:* Under what circumstances would a scientist be hindered from publishing research in peer-reviewed scientific journals?

*Probe 5:* Are you aware of publications being hindered? What was the outcome?

*Probe 6:* Under what circumstance would there be an exclusion or alteration of technical information from an agency document?

*Probe 7:* What do you think of this process?

*Probe 8:* How could this process be improved, if at all?

*Probe 9:* What difficulties have you encountered or observed? How were they handled?

2. What is the dissemination process, if different than the publication process?

*Probe 1:* Who has access to the data and when?

*Probe 2:* What are the protocols when releasing data to the media and the public? Are there standard operating procedures? Where are they?

*Probe 3:* Under what circumstances would information be restricted from being disseminated? What, if any, situations have you been privy to this occurring? What was the outcome?

*Probe 4:* What do you think of this process?

*Probe 5:* How could this process be improved, if at all?

*Probe 6:* What difficulties have you encountered or observed? How were they handled?

3. How, if at all, are “minders” used at your agency?

*Probe 1:* What are the protocols to follow when speaking with the public/media?

*Probe 2:* What do you think of this process?

*Probe 3:* How could this process be improved, if at all?

*Probe 4:* What difficulties have you encountered or observed? How were they handled?

4. What kind of influence exists from non-career personnel in regard to the release of research findings to the public?

*Probe 1:* Under what circumstances would non-career personnel interject in the publication and/or dissemination of research findings?

*Probe 2:* What difficulties have you encountered or observed? How were they handled?

5. What kind of influence exists from Congress in regard to the release of research findings to the public?

*Probe 1:* Under what circumstances would a member of Congress interject in the publication and/or dissemination of research findings?

*Probe 2:* What difficulties have you encountered or observed? How were they handled?

6. What kind of influence exists from state, tribal, or local government/elected officials in regard to the release of research findings to the public?

*Probe 1:* Under what circumstances would a state, tribal, or local government/elected official interject in the publication and/or dissemination of research findings?

*Probe 2:* What difficulties have you encountered or observed? How were they handled?

7. What kind of private-sector influence upon the release of research findings to the public are you familiar with?

*Probe 1:* Under what circumstances would the private sector involve themselves in the publication and/or dissemination of research findings?

*Probe 2:* What difficulties have you encountered or observed? How were they handled?

8. What is the venue in which scientists can provide feedback on the processes that exist regarding publication and dissemination of research findings?

*Probe 1:* How often is feedback generally provided?

*Probe 2:* How does feedback affect existing protocols?

*Probe 3:* What type of mechanism/tool is used to gather feedback?

*Probe 4:* What do you think of this process?

*Probe 5:* How could this process be improved, if at all?

*Probe 6:* What difficulties have you encountered or observed? How were they handled?

## **SECTION IV: REPRESENTING A GOVERNMENT AGENCY**

1. In what capacity and under what circumstance, if any, have you represented your agency (past and/or present) in a public and/or private arena?

*Probe 1:* What are the written policies that you had to abide by? Where are they?

2. What are the guidelines to follow when responding to requests of information from outside the agency?

*Probe 1:* Are you allowed to respond to such inquires?

*Probe 2:* What do you think of the policies? Are there written standards of operation?

*Probe 3:* How could they be improved, if at all?

*Probe 4:* What difficulties have you encountered or observed? How were they handled?

3. What policies does your agency abide by when you represent the agency either in public or private arenas?

*Probe 1:* What do you think of the policies? Are there written standards of operation?

*Probe 2:* How could they be improved, if at all?

*Probe 3:* What difficulties have you encountered or observed? How were they handled?

4. What access does the public and media have to agency information (e.g., research findings, board meeting minutes, agency policies, etc.)?

*Probe 1:* What do you think of this process? Are there written standards of operation?

*Probe 2:* How could this process be improved, if at all?

*Probe 3:* What difficulties have you encountered or observed? How were they handled?

5. If there is scientific data that you, as an individual scientist, feel is necessary/appropriate to disclose to the public and your agency disagrees, how would you handle this situation?

*Probe 1:* Under what circumstances would you feel able to reveal this opinion?

*Probe 2:* Would you fear retribution from your agency and/or colleagues?

*Probe 3:* To your knowledge, has this happened before and what was the outcome?

6. In what ways are you encouraged (or not) to participate in scientific professional training, societies, and organizations?

*Probe 1:* How is participation in these activities paid for?

*Probe 2:* What is the process you must adhere to in order to participate in such activities? Are there written standards of operation? Where are they?

*Probe 3:* What difficulties have you encountered or observed? How were they handled?

## **SECTION V. RECOMMENDATIONS**

1. What types of managerial skills are best suited for working with scientists in a political environment? Why?

*Probe 1:* How could these skills be instilled?

*Probe 2:* What kinds of training would be beneficial for managers to attain such skills?

2. What types of skills do scientists need to work in government?

*Probe 1:* How could these skills be instilled?

*Probe 2:* What kinds of training would be beneficial for scientists to attain such skills?

3. How could scientific protocols, in your agency, be improved?

*Probe 1:* What is the method by which scientists can provide feedback to improve upon the scientific protocols of your agency?

*Probe 2:* Is this method effective? Why or why not?

4. How could internal and external publication and dissemination protocols be improved, at your agency?

*Probe 1:* What is the method by which scientists can provide feedback to improve upon these protocols at your agency?

*Probe 2:* Is this method effective? Why or why not?

5. Is there anything that we have not yet discussed that you believe to be pertinent to our research? What?

*Thank you!*

# Appendix B: Synopsis of Institutional Review Board (IRB) Approved Application

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**PRINCIPAL OBJECTIVES:** The goal of the project is to provoke and shape the public discussion about the rights and responsibilities of government scientists, as part of the larger effort to ensure that government uses the best science to protect and promote the health and well-being of Americans.

**JUSTIFICATION FOR STUDY & CONTRIBUTION:** This project aims to develop a generally accepted set of principles on the rights and responsibilities of government scientists that asserts the values of scientific integrity, freedom, and openness, while affirming the responsibility to support the public mission of the employing agency.

**SUBJECT RECRUITMENT:** As many as 100 subjects may be asked to participate in the study with the anticipation that approximately half will be willing and able to participate. Five sampling strategies in qualitative inquiry will also be used to determine saturation of data. These strategies are Snowball or Chain, Criterion, Opportunistic, Combination or Mixed, and Convenience (Marshall & Rossman, 1999). Due to the qualitative nature of the study, more or fewer subjects may be asked to participate to reach saturation.

**SUBJECT IDENTIFICATION:** Subjects will be identified by investigators in conjunction with the Advisory Board. The Advisory Board's responsibility and potential contact with subjects lies only in the recruitment section of the study. The selection criterion is that subjects will have been employed (either past and/or present) by a government agency in a scientific capacity. Subjects will also be recruited through employment and professional associations.

**SUBJECT PARTICIPATION:** Subjects will participate in one 60-90 minute in-person or telephone interview, that will be audio recorded and hand-written/typed notes taken during the interview. Subjects may be asked to participate in a 15-30 minute in-person or telephone follow-up interview for clarification of previously asked or additional questions.

**DATA COLLECTION:** Data will be qualitative in nature. An interview guide will be used to probe the subjects on the questions relating to the study objectives.

**INFORMED CONSENT:** Informed consent will be obtained through the use of an informed consent form. The consent form will be offered to the subject to read in front of the interviewer and then the subject will be offered a copy of an information sheet discussing the study.

**RESEARCH-SPECIFIC RISKS:** There are no physical risks associated with this study. There is, however, the possible risk of loss of confidentiality.

**STEPS TO MINIMIZE RISK:** Some of the questions asked as part of this study may make subjects feel uncomfortable. They are able to refuse to answer any of the questions, they may take a break at any time during the study, and they may stop their participation in this study at any time. Due to the slim chance of a breach of confidentiality, a request of a waiver has been made for signed consent forms.

**ASSURANCE OF CONFIDENTIALITY/ANONYMITY:** Every effort will be made to keep subjects' information confidential, however, this cannot be guaranteed. The informed consent form will include language to ensure this. All research materials will be kept in a secure location available only to the research team.

**RESEARCH DATA & MATERIALS:** Not all research data and materials will be destroyed at the end of the study. Audio tapes, hand-written/typed notes, and consent forms will be kept in a locked and secure environment where only the research team has access. The items may be used in the future for verification and clarification of analysis. Subjects will agree to possible future use of such materials as part of their consent to participate in the study.

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