



May 13, 2009

Office of Science and Technology Policy
Attn: Scientific Integrity Recommendations
725 17th Street NW
Washington, DC 20502

To Whom It May Concern,

In response to the April 23, 2009 Federal Register Notice "March 9, 2009 Presidential Memo on Scientific Integrity: Request for Public Comment," we are submitting the attached comments. Our recommendations address four of the principles (A, B, D, and E) from the Presidential Memo.

As members of the George Washington University School of Public Health and Health Services' Department of Environmental and Occupational Health and Department of Health Policy, we are aware that scientific integrity in the federal government is essential to strong public health protections. Our Project on Scientific Knowledge and Public Policy (SKAPP) examines the intersection of science and policy, and over the past few years we have identified and suggested solutions to many abuses of science in policymaking.

We are currently conducting a study on the rights and responsibilities of scientists in government. While the study will not be completed until later this year, our preliminary findings have identified several areas for improvement that fall within the scope of the Presidential Memorandum and may be useful in OSTP's deliberations. Our submission, attached to this letter, discusses these preliminary findings.

We applaud President Obama for his attention to this issue and are grateful to have the opportunity to provide comments regarding implementation.

If we can provide further information, please do not hesitate to contact us at eohsfw@gwumc.edu.

Sincerely,

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President Obama's memorandum on scientific integrity is a welcome and necessary response to problems that have harmed federal scientists' effectiveness and morale. At the George Washington University's Project on Scientific Knowledge and Public Policy (SKAPP), we are particularly concerned about this issue because we have heard serious concerns voiced by scientists from several federal agencies during interviews conducted for our Scientists in Government project.¹ Our research included interviews with 37 scientists who are current or past employees of 16 federal agencies. We conducted in-depth qualitative interviews with them, focusing on their agencies' policies and practices to provide supportive workplaces for scientists; research protocols; publication procedures; policies on representing the agency in outside venues; and other areas for which the study participants had comments or recommendations.

The study is not yet completed. However, our preliminary findings identified several areas for improvement that fall within the scope of the Presidential Memorandum. Based on these findings, we make the following recommendations:

- To contribute to retention and effectiveness of federal scientists (Principle a), managers hired to oversee scientists should have both scientific backgrounds and strong managerial skills.
- With regards to the appropriate rules and procedures to ensure scientific integrity (Principle b), agencies should adopt policies and procedures to protect science from interference that may come from within or outside the agency; at the same time, agencies should assess the possibilities for streamlining the internal review processes for scientific documents, to ensure that integrity goals are not leading to misguided burdens on scientists' time.
- To ensure timely access to research findings and other scientific materials (Principle d), agencies should streamline their clearance processes for scientific materials that are to be published or otherwise disseminated.
- To ensure that scientists feel able to speak up about possible compromises to scientific integrity (Principle e), agencies should assess the grievance procedures and feedback mechanism available to scientists who have concerns about research protocols or processes.

(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.

We recommend that managers hired to oversee scientists have scientific training as well as strong managerial skills.

Recommendation: The Managers of Scientists. Results from our interviews suggest that the quality of management of scientists within federal agencies has been mixed at best. Some scientists identified what they believed to be a harmful trend of placing attorneys in management positions (accelerated during the previous administration); they suggested it might have been

¹ The Scientists in Government study is being conducted at the George Washington University (IRB # 030823); results are currently being analyzed, and a report will be issued in late 2009. More information is available at <http://www.defendingscience.org/Scientists-in-Government-Project.cfm>.

motivated by a desire to protect the agency from criticism rather than to promote the science. Many stated that those assigned to manage scientists should be scientists themselves, or at the very least have a sufficient understanding of science to recognize why scientists take the steps they do (e.g., study design and methodology). When asked if this understanding could be acquired through training offered in the workforce, the response was generally “no.”

At the same time, scientists recommended that their managers have good managerial skills, which many of them considered to include both effective communication and the ability to buffer scientists under their supervision against problematic actions by agency leadership or senior management. Examples of such actions included undue political pressure that scientists felt could compromise the integrity of their work, and new practices or procedures that would take time away from scientific work without adding value. Some noted that good scientists do not necessarily possess these skills, and recommended that scientists should not be required to take on management roles, to which they may be ill-suited, in order to continue advancing within their agencies.

Many of the participants acknowledged that it could be challenging to find managers who possess both good managerial skills and sufficient scientific backgrounds. However, through our conversations, this emerges as an essential component for selecting managers who will allow scientists to function effectively, maintain morale (which affects retention), and uphold scientific integrity. Below are some examples of responses to questions regarding the management of scientists:

Senior Economist - FDA - July 14, 2008

“Well, you absolutely have to have...political skills, and those can’t be taught, you have to learn them; you have to learn about bureaucratic fighting...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 just not a nastier work environment on earth than being in a bureaucracy, it is incredible. It is very, very hard, and believe me I have seen a lot of people come in that just weren’t tough, and they are just not able to make it— they have to leave. You have to be willing to be stabbed in the back a thousand times.”

Branch Chief - CDC, PHSC - May 27, 2008

“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... An unwillingness to rock the boat [is] what the Director of the CDC is wanting; [directors] surround themselves with “yes men”...there is a herd mentality, don’t ... be an outlier and it is rewarded. If you have a dissenting or different view, you are not rewarded.”

Senior Epidemiologist - NIOSH - June 20, 2008

“The manager doesn’t necessarily have to be a scientist, but somebody working with scientists...there has been a tendency to put people in managerial positions who have less education, who are not scientists, and this has not gone over well with the scientists. Because it appears[people] are put into positions because they will go along with the program. And I think people in managerial positions need to appreciate the science. You cannot be an expert in every field of science, but I think you need knowledge of the science as well as training in management,

working with people. I think that the trends have been to promote the least educated, least experienced people, the most malleable people.”

(b) Each agency should have appropriate rules and procedures to ensure the integrity of the scientific process within the agency.

Although many of the rules and procedures governing the research process are appropriate, in some cases the procedures slow the production and use of science without adding value. At the same time, additional safeguards or practices are necessary to protect the integrity of the science against undue influence from both inside and outside of the agencies.

Recommendation #1: Streamlining the Approval Process. Agencies should streamline the research review/clearance process and ensure that those who are reviewing the research are knowledgeable about scientific methodologies and the subject matter. Many scientists stated that lengthy internal review processes for publications, journal articles, research protocols, conference presentations, and other materials produced by scientists caused substantial delays without adding value. In some cases, scientists felt the internal review was unnecessary; for instance, internal review might be redundant for a study that would undergo peer review at the journal to which it would be submitted, and unnecessary for a conference presentation that would include a disclaimer about it representing only the views of the author, not agency policy. In several cases, scientists who identified the problem of a cumbersome internal review process felt that these internal reviews were conducted by people who lacked sufficient understanding of the science and provided comments that were not useful. (And even unhelpful comments require scientists to take the time to respond.) Scientists estimated that the internal review process could last as long as a year and that this could seriously delay the publication or availability of science needed to address pressing public health or environmental problems.

At the same time, a few of the scientists described review processes lasting as little as 3-4 weeks, and some scientists felt that feedback they received during internal reviews was useful. We recommend that agencies conduct a review of their internal-review policies to identify opportunities for streamlining, cutting unnecessary or redundant reviews, and ensuring that each stage in the process is valuable toward the goals of producing high-quality science and upholding scientific integrity. Agencies should also adopt goals for turnaround times on different types of products (journal articles, conference presentations, etc.) to promote quick review by those whose feedback on the item is essential.

Senior Epidemiologist - CDC/ASTDR - June 5, 2008

“We don’t really get good feedback ... most of the time we get comments that we think are irrelevant or off the mark...I think it is important to really hear from knowledgeable people about things that are not right with our protocols and our studies, but the kinds of comments that we receive haven’t been that great.”

Senior Economist - FDA - July 14, 2008

“It had to always be an attorney, who would then review, and a lot of the time the review was to make sure that there was nothing that the attorney didn’t consider to be somehow embarrassing or too far reaching. I regarded it as a little bit oppressive, this kind of review, I felt that the

review should have stayed with the scientists, within the scientists themselves, I felt. First of all, so in my particular unit, you'd have the researchers would complete the research, it would go to their branch chief, who was a specialist in the area, who would do a review, then it would go to me to do a review, and I felt that should have been sufficient, but then it would go to these attorneys to do review. If it was on one of the topics that the FDA considered to be sensitive, then it would go to an additional layer of review by somebody who had a responsibility in this particular area. So it was pretty intense."

Recommendation #2: Undue Influence. We asked scientists whether they had witnessed or experienced the exertion of undue influence (e.g., to conduct a particular study, alter or suppress results, etc.) on agency science by an outside party (industry, consumer group, member of Congress, etc.). Several scientists provided examples of undue external pressure, with Congress being one of the most frequently mentioned (e.g., a member wanting a study to be conducted in his or her district). In a few cases, though, scientists stated that pressure from Congress had been welcome, because it forced the agency to address an important health issue, and sometimes even provided extra funding for them to do so. At the same time, others noted that Congressional influence could interrupt existing research and hurt the credibility of the findings.

In many cases, multiple levels of influence may coalesce; industry or constituents may pressure members of Congress into advocating for a particular study or research approach, and the agency's leadership may push the scientists to accede to those requests, even when they know them to be contrary to integrity of the agency's science. For instance, several scientists at the National Institute for Occupational Safety and Health (NIOSH) expressed the opinion that Congress's attempt to eliminate NIOSH in the mid-1990s – which many believed to be motivated by industry's desire for less regulation – had caused the agency to stop collecting data in ways opposed by industry or individual employers. Chiefly, scientists observed that NIOSH no longer exercises its "Right to Enter" workplaces to collect information about employee exposures; now, they only enter when the employer gives them permission. The NIOSH scientists who spoke of this described situations in which the agency was unable to collect reliable data to answer many of its important research questions with regard to worker health and safety.

Policy Analyst - OSHA - August 26, 2008

"...one of the things that most impressed me about working for federal government was the extent to which the agencies operate under influence, the extent of 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 ... How that influence is addressed or how those attempts at influence [are] handled by the agencies is what is important."

Statistician - U.S. Consumer Product Safety Commission – July 29, 2008

It is commonly accepted that there is influence from industry ...the influence is stronger from industry than from others.

Division Director - USDA, PHSC - May 27, 2008

"It was very clear that at USDA, that anything that would harm industry, it would be handled with kid gloves."

(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.

As mentioned above, many scientists expressed frustration about the lengthy internal review process for scientific materials, and some of them noted that it can even take a long time for materials such as online facts sheets and data to be approved for dissemination. Also, some scientists said they had been discouraged from publishing, either due to the lengthy and burdensome clearance process or because their jobs did not allow adequate time for manuscript preparation.

Recommendation: Streamline Clearance Process. The agencies should streamline their clearance processes for scientific materials to be published or otherwise disseminated, so that research findings may be made available to the public and the larger scientific community in a timely manner.

Senior Epidemiologist - CDC/ATSDR - June 5, 2008

“We’re encouraged to publish; at the same time the clearance process sometimes gets very burdensome, that’s a discouraging factor. The process is burdensome...that needs to be streamlined so that we can publish more. The other thing is of course, if you don’t have any funding you can’t...publish stuff. So that is another issue. The funding issue and the clearance process burden.”

Senior Epidemiologist – NIOSH – June 20, 2008

“You learn as a survivor to change what you have to change to get things through, and if there is something that is really, really ... worth fighting for, you have to know when to pick your battles, and try and do it in a way that is going to succeed.”

(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.

A lack of formal, effective grievance procedures and confidential feedback venues were major concerns among our interview participants. Many felt that they could not express their concerns regarding scientific protocols or processes for fear of retribution. Some had actually experienced retribution or seen another scientist experience it, and stated that speaking out against an agency policy or practice could be extremely demoralizing and detrimental to a scientist’s career.

Recommendation: Review Grievance Procedures & Feedback Forums. Agencies should conduct thorough reviews of their current grievance procedures and feedback mechanisms – including soliciting extensive anonymous input from their scientists – to determine if revision or additional mechanisms or safeguards may be necessary to give scientists sufficient avenues to identify concerns about how science is conducted at federal agencies.

Environmental Engineer - EPA - January 13, 2009

“No [feedback venue], not at all...but it really would be useful to have that. I know everybody says ‘oh, you have the Inspector General’ but...if you’re known to have gone to the Inspector General your career’s over...you’re a snitch.”

Statistician - U.S. Consumer Product Safety Commission – July 29, 2008

“...they asked me to change the date on [the report], to reflect that it hadn’t been finished so long before...I refused to do it initially, and we went back and forth about it a number of times. So that in some respect [that was] the way I was expressing my discontent with the process, but I am aware of no formal process for saying something is out of ‘whack’ here. I felt that I had to re-date it to keep my job. She said we need to cover this one for the general counsel.”