May 13, 2009

Via Electronic Mail at scientificintegrity@ostp.gov

Dr. John Holdren, Director
Office of Science and Technology Policy
Executive Office of the President
725 17th Street, N.W.
Washington, D.C. 20502

Re: Center for Progressive Reform Comments on the President's March 9, 2009 Memorandum on Scientific Integrity

Dear Dr. Holdren:

Thank you for providing an opportunity for interested parties to comment in a more formal fashion on President Obama's memorandum on scientific integrity. As we noted in an earlier letter to you, restoring scientific integrity to government decision-making is of utmost importance to the protection of public health and the environment, and we commend you and the President for addressing the issue as one of your first initiatives.

The Center for Progressive Reform (CPR) is a 501(c)(3) nonprofit research and educational organization with a network of Member Scholars working to protect health, safety, and the environment through analysis and commentary. CPR believes sensible safeguards in these areas serve important shared values, including doing the best we can to prevent harm to people and the environment, distributing environmental harms and benefits fairly, and protecting the earth for future generations. CPR rejects the view that the economic efficiency of private markets should be the only value used to guide government action. Rather, CPR supports thoughtful government action and reform to advance the well-being of human life and the environment.

We would like to take this opportunity to reiterate the recommendations that we made in our April 3 letter, as well as expand on some other ideas that we feel would help improve the state of scientific integrity in the federal government. We have organized

Rena I. Steinzor
Jacob A. France Research Professor,
Director, Environmental Law Clinic
University of Maryland School of Law
500 W. Baltimore Street
Baltimore, MD 21201

www.progressivereform.org

410.706.0564
410.706.2184 (fax)

rsteinzor@umaryland.edu

our recommendations according to the outline of President Obama's memorandum. Additional details on our recommendations can be found in two CPR white papers: *Saving Science from Politics: Nine Essential Reforms of the Legal System* (hereinafter, *Saving Science*), and *Protecting Public Health and the Environment by the Stroke of a Presidential Pen: Seven Executive Orders for the President's First 100 Days* (hereinafter, *By the Stroke of a Pen*). The white papers are available online at:

http://www.progressivereform.org/articles/SavingScience805.pdf, and
http://www.progressivereform.org/CPR_ExecOrders_Stroke_of_a_Pen.pdf.

Principle (a): Ensuring Selection and Retention of the Best-Qualified Candidates for S&T Positions

One tool for incorporating the best judgment of the scientific community into policymaking is the use of scientific advisory panels made up of outside experts. Many agencies are even required by law to use them. For example, the Environmental Protection Agency (EPA) has a number of scientific advisory panels and turns to them for counsel when deciding how much of a given pollutant in the air is unsafe or when a pesticide presents an unreasonable risk. One of its most influential panels—the Clean Air Science Advisory Council—is established by statute. Similarly, the Food and Drug Administration (FDA) regularly uses outside experts to inform its work on new and existing drug reviews.

During the last Administration, problems with conflicts of interest and imbalance plagued several high-profile peer review panels. In 2002, for instance, Health and Human Services Secretary Tommy Thompson intervened in the selection process for an advisory panel on lead poisoning issues, removing a noted pediatrician, blocking two other respected public health scientists, and installing four industry-tied panelists. Soon after, the panel ignored a call from the public health community for a tighter standard on lead.

Recommendation: Agencies should improve the processes that they use to screen potential advisory committee members for conflicts of interest and bias. Waivers of conflicts of interest should be rare, rather than routine. (For additional details, see *Saving Science*, pp. 24-31, and *By the Stroke of a Pen*, pp. 24-25.)

- All agency efforts to screen for conflicts of interest and bias should be documented, as should all final decisions and the reasoning behind those decisions. A list of potential committee members should be subject to public notice and comment.
- Agencies should also screen potential advisory committee members for a broad spectrum of employment, financial, and other interests that might sway the individual's

decisionmaking. Conflicts screening should also focus on both past and future interests of the potential committee member and her immediate family, no matter how small. Competitive advantages that might accrue to an individual's employer or other business partner should not be overlooked.

- Agencies should establish processes for assessing and resolving potential conflicts that come to the agencies' attention after a panel has been seated.
- Agencies need to strengthen their oversight of contractors who conduct peer review, to ensure that their policies for conflicts screening are adequate and properly implemented.
- Agencies must stop exploiting loopholes to escape the requirements of the Federal Advisory Committee Act (FACA), especially the statutory mandate that panels be balanced for bias. Advisory committees must not use contractors, "special government employees," non-voting participants, or subcommittees to avoid the Act's good-government mandates.
- The National Academies have issued a statement on lack of objectivity that defines the types of information that a legitimate committee-selection process should be designed to uncover (http://www.nationalacademies.org/coi/bi-coi_form0.pdf). For one, the focus should be on views stated and actions taken in a public forum. Examples are analyses and conclusions published in research articles, statements made at conferences and other public speaking engagements, and any statements made as an expert witness. These statements are most likely to reflect an individual's most strongly held beliefs and do not threaten privacy concerns.
- Agencies should do internet-based background searches to complement the questionnaires that potential committee members already complete.

Principle (b): Ensuring the Integrity of the Scientific Process Through Agency Rules and Procedures

For agencies like the FDA, the EPA, and the Occupational Safety and Health Administration (OSHA), federal policies that accord privately funded research "favored science" status are at the root of most high-profile problems tied to scientific integrity. Companies seeking approval to market chemicals, pharmaceuticals, and pesticides rightly bear the burden of demonstrating through research that their products are safe and effective. Sometimes they commission that research; sometimes they conduct it in-house. Both approaches are cause for concern about bias, intentional or otherwise, because the sponsor has a vested interest in the findings. But once the research is submitted, it is largely insulated from scrutiny by public health scientists, including agency scientists, because the underlying data are not required to be shared with the public and may not even be supplied to the agency. By contrast, all of the data underlying research submitted by federally funded researchers must be made available to the public through the Freedom of Information Act.

Recommendation: Wherever possible, federal agencies should require all research used in regulatory decisionmaking to satisfy at least the same transparency and disclosure requirements as are currently applied to publicly funded research.

- The public should have access to a privately funded study's underlying data as well as information about the relationship between researchers and their sponsors. Like the top biomedical journals, agencies should require the disclosure of sponsor identity, the types of support provided, the role of the sponsor in the research process, and the researchers' level of control over the study and data.
- The President should also instruct agencies to take this information into account when determining the weight-of-the-evidence tied to an individual study. So, for instance, extensive sponsor control over all facets of a scientific study might cause the agency to give the study less weight in formulating the appropriate, science-based regulatory response. Likewise, a researcher's or sponsor's refusal to disclose data should justify increased skepticism regarding the reliability of that study.

Principle (c): Ensuring that Scientific and Technological Information is Reliable

Peer review is an essential step toward ensuring the reliability of scientific and technical information. Federal agencies use an array of different mechanisms to engage experts in peer review of the information that informs regulatory decisions. Congressionally established scientific advisory boards, National Academy review committees, FACA committees, and ad hoc peer review panels are all used on a regular basis. This broad array of commonly used peer review mechanisms reflects the fact that decisions about how peer review should be conducted must turn on the type of information at issue, levels of scientific understanding, and regulatory goals. In 2004, OSTP consulted with the Office of Management and Budget during the development of the Information Quality Bulletin for Peer Review. That document outlines the considerations that agencies should make when choosing the appropriate type of peer review procedures. Unfortunately, certain agencies have not fully heeded the good science-policy principles outlined in the Bulletin. Of particular concern is EPA's process for reviewing Integrated Risk Information System (IRIS) documents. Following revisions to the IRIS assessment process in 2008, political review of important scientific documents is masquerading as some sort of peer review.

Recommendation: The President should direct EPA's Office of Research and Development to review the procedures the agency uses to develop IRIS risk assessments, with an eye toward streamlining the process so as to encourage the swift

development of assessments, particularly for substances that must be regulated under existing statutory authorities (e.g., the Clean Air Act and Safe Drinking Water Act).

- OMB should not be involved in reviewing individual IRIS assessments because it does not have the scientific expertise to make sensible judgments.
- Officials from other agencies, particularly agencies that might be affected by regulations tied to particular IRIS assessments, should only be involved in the IRIS assessment process during the public notice and comment stage.
- Peer review of IRIS assessments should conform with the recommendations described in the EPA Inspector General's Evaluation Report, "EPA Can Improve Its Process for Establishing Peer Review Panels." (Report no. 09-P-0147, April 29, 2009, *available at* http://www.epa.gov/oig/reports/2009/20090429-09-P-0147.pdf)

Principle (d): Maximizing the Legitimate Public Release of Scientific and Technological Information Relied Upon by Agencies

Federal agencies have also been complicit in regulated businesses' attempts to shield useful risk information from the public through overbroad use of the trade secrets doctrine. By simply stamping any submission to an agency as a "trade secret" or "confidential business information" (CBI), manufacturers increase the likelihood that risk-averse agency Freedom of Information Act officers will keep that submission under lock-and-key, out of the reach of both the general public and any other federal or state official who lacks the proper security clearances. Not only does this secrecy limit public access to this information, including access by public health professionals such as doctors, it limits the transparency and thus the credibility of agency decisions.

Recommendation: All of the information that goes into federal regulatory decisions would benefit from the disinfecting power of sunlight. Now that the Attorney General has re-established the "presumption of disclosure" under the Freedom of Information Act, federal agencies should consider three reforms to their CBI policies. (See *Saving Science*, pp. 32-36.)

- First, CBI protection should be limited for some classes of information. Specifically, certain toxicological, eco-toxicological, and other physicochemical information should never be kept secret because of its importance to the protection of public health, worker safety, and natural resources.
- Second, all information that is submitted to the government and alleged to be worthy of CBI protection should be accompanied by a thorough explanation of why such protection is warranted.

- Third, in the rare instances where the government allows regulatory-relevant information to be protected as CBI, these trade secret protections should "sunset" after a set period of time, unless submitters justify the extension of protection.

Principle (e): Exposing Instances When Scientific or Technological Integrity Has Been Compromised

In recent years, White House staff and agency political appointees have been caught rewriting draft rulemaking notices and scientific reports to distort the candid opinions of career scientists and even outside peer reviewers. Endangered species decisions, climate change reports, and the Bush Administration's proposals to control mercury from power plants were all compromised by ideological re-drafting of scientists' work. Expanded administrative recordkeeping requirements could prevent – or at least minimize – such inappropriate interference.

Recommendation: In the interest of regulatory transparency and as a way to protect federal scientists, agencies should revise their recordkeeping policies to memorialize agency scientists' pre-decisional findings. (See *Saving Science*, pp. 18-20.)

- Agencies should explicitly exempt the products, analyses, and discussions of scientific research from the deliberative process privilege.

Principle (f): Ensuring Reliability of Science and Technology Through Whistleblower Protections and Other Procedures

The structure of whistleblower protections is an unsatisfactory system, insofar as they rely primarily on back-end, reactive protections. Federal scientists should be able to rely on well-designed decisionmaking procedures and clearly defined role boundaries for political appointees so that the need to become a whistleblower does not arise.

Recommendation: In addition to the recordkeeping changes suggested above, agencies should establish enforceable ethics guidelines to protect federal scientists from political interference. (See *Saving Science*, p. 21.)

- Ethics guidelines should establish clear prohibitions against abusive actions, like attempts to coerce or intimidate scientists.
- Ethics guidelines should prohibit scientific misconduct, such as altering or mischaracterizing scientific conclusions and information.

- Ethics guidelines should be adopted through notice and comment rulemaking, to ensure transparency in the process and result in the creation of legally binding rights and duties.

Conclusion

We thank you and the President for taking on the important task of restoring integrity to the federal government's use of science. We appreciate this opportunity to comment.

Sincerely,

Rena I. Steinzor
Jacob A. France Research Professor,
University of Maryland School of Law

President, Center for Progressive Reform

rsteinzor@law.umaryland.edu
410-706-0564

Matthew Shudtz

Policy Analyst, Center for Progressive Reform

mshudtz@progressivereform.org
202-747-0698