



April 3, 2009

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Via U.S. Mail and Electronic Mail at info@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

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Re: Scientific Integrity in the Obama Administration

Dear Dr. Holdren:

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. We write to you today in response to President Obama's March 9, 2009 memorandum on scientific integrity. As you well know, scientists, their work, and the entire scientific process were subject to ideological attack from the last administration, so we commend you for spearheading this administration's efforts to restore integrity to the federal government's treatment of the scientific endeavor.

Understandably, President Obama wants to move quickly to ensure that all departments in his administration have established procedures to prevent the politicization of science. Difficult questions regarding climate change, toxic chemicals, and consumer products loom on the horizon, and the agency officials tasked with resolving those questions need to be able to rely on the science at their disposal.

We urge you to open a formal public comment period on the memorandum to make full use of the short timeframe that President Obama has allotted for your work in this area. Obviously, your work is not generally subject to public comment, but the Administration has already shown its openness to seeking input from a variety of stakeholders on issues that create a high level of public interest (e.g., the Office of Management and Budget's decision to seek public comment on its revisions to the Executive Order on Regulatory Review, 74 Fed. Reg. 8819). The full host of issues related to scientific integrity implicates a large body of academic research and practical

experience from dozens of disciplines and subspecialties in science, political science, law, sociology, and other fields. A public comment period would provide experts from all those fields an opportunity to help build the knowledge base from which your recommendations grow, as well as a chance to evaluate alternative strategies for improving scientific integrity.

We also urge you to develop a more complete set of reforms in response to President Obama’s invitation. The President’s memorandum highlighted a number of specific reform proposals, like hiring practices, transparency, and whistleblower protections. We applaud these initiatives and believe that they are vital first steps toward restoring clean science to the Executive Branch. The Center for Progressive Reform has published a white paper that includes a number of recommendations that largely parallel those outlined in specifics by President Obama. A copy of *Saving Science from Politics: Nine Essential Reforms of the Legal System* is attached, and it is available electronically at <http://www.progressivereform.org/articles/SavingScience805.pdf>.

The President did not stop with an itemized list of reforms, however. He also identified the need for more general reforms – “such additional procedures ... 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.” As a starting point, we offer three related threats on the integrity of science used for regulation that must also be addressed to improve scientific integrity in the regulatory process. Again, these concerns and our more specific recommendations for reform are detailed in *Saving Science from Politics*.

Problem 1: Disparate Treatment of ‘Private’ versus ‘Public’ Research

For agencies like the Food and Drug Administration, Environmental Protection Agency, and Occupational Safety and Health Administration, federal policies that accord privately funded research “most 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: Federal agencies should require private research used for regulation to satisfy at least the same transparency and disclosure requirements as are currently applied to publicly funded research. For example, 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.

Problem 2: Bias and Conflicts of Interest on Scientific Review Panels

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 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. Unfortunately, under existing laws panels can be populated in ways that are badly imbalanced and do not accurately represent the views of the scientific community. 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 biases and conflicts of interest. The National Academies have issued a statement on bias and lack of objectivity that hints at 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. Screening for biases and potential problems with objectivity should also focus on whether an individual's public statements reflect a close tie to the positions or perspectives of a particular group's extreme views. If such a tie exists, it should cut against seating

that person on an advisory committee. 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.

Problem 3: Excessive Secrecy

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. First, CBI protection should be limited for some classes of information. Specifically, certain toxicological, ecotoxicological, 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.

Conclusion

We have briefly highlighted some of the most important issues related to scientific integrity in the regulatory process. Additional details on these and many other ideas can be found on the Center for Progressive Reform's website (<http://www.progressivereform.org>) in our "Clean Science" section.

We commend you and the President for taking on the important task of restoring integrity to the federal government's use of science.

Sincerely,

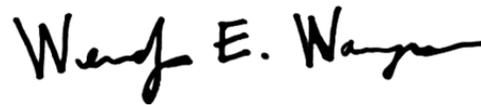


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