



October 22, 2009

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VIA Facsimile and U.S. Priority Mail

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Re: Scientific Integrity – How OMB and OSTP can collaborate to improve the integrity of the regulatory process

Dr. Holdren and Administrator Sunstein:

President Obama's commitment to improving scientific integrity in the regulatory process is central to both of your offices' work. In light of two troubling episodes involving OMB interventions in Environmental Protection Agency (EPA) science programs, we write to suggest some opportunities for your offices to collaborate in ways that will further the President's scientific integrity objectives. Specifically, we request that you work together to clarify the extent of OMB's role in reviewing agency science, which we believe should be quite limited.

Both of these episodes pre-date Professor Sunstein's confirmation and may well be the product of staff steeped in the culture of OMB regulatory review under the Bush Administration. The episodes represent a direct assault on scientific integrity because they involve attempts to reverse conclusions by agency experts at the behest of regulated industries whose central objections were rooted in concerns about potential future compliance costs, not the accuracy of EPA's science. Compounding the offensiveness of this interference is the fact that the decisions that were derailed involved efforts to analyze scientific research that were preliminary to any regulation of industry activities.

The first episode involves EPA Administrator Lisa Jackson's efforts to revamp the procedures through which toxicological profiles are added to EPA's Integrated Risk Information System (IRIS) database. Administrator Jackson took a process that the Bush Administration had twisted into a gauntlet of recurring review by potentially regulated entities and streamlined it to (ideally) produce scientifically robust toxicological reviews quickly and efficiently. One of the key elements in Administrator Jackson's reforms to the IRIS assessment process was eliminating an OMB-controlled interagency review process and vesting in EPA staff the responsibility of running all reviews. OMB had a history of giving industry, the Department of Defense, the Department of Energy, and other potential regulatees excessive control over the fate of IRIS profiles. The Government Accountability Office (GAO) highlighted the problems in a March 2008 report, *Chemical Assessments: Low Productivity and New Interagency Review Process Limit the Usefulness and Credibility of EPA's Integrated Risk Information System* (GAO-08-440).

On October 14, 2009, EPA posted on its IRIS website documents indicating that OMB is continuing to intervene in the IRIS assessment process in a way that directly contravenes the President's scientific integrity objectives. As Professor Steinzor explained in an October 19, 2009 post on CPR Blog (www.cprblog.org), OMB filed comments on three chemicals' toxicological profiles that delve deeply into the scientific content of EPA's documents. The OMB staff's comments chided EPA for failing to respond to industry-friendly peer reviewers with as much deference as those reviewers would have liked.

The second episode involved OMB's oversight of the Endocrine Disruptor Screening Program (EDSP). OMB staff forced upon EPA changes to the EDSP that would enable the pesticide industry to flood EPA with old and outdated test data instead of fulfilling the agency's EDSP orders for new chemical assays. As a result, there is a real danger that the EDSP's testing efforts, already behind schedule because of the Bush EPA's delays, will be postponed for many more years. Center for Progressive Reform Policy Analyst Matthew Shudtz has written about the issue in an October 20, 2009 post to CPR Blog (www.cprblog.org).

Following White House Chief of Staff Rahm Emanuel's January 20, 2009 memorandum calling on all branches of the Executive Department to put Bush-era rules on hold for review by Obama appointees, OMB and EPA could have undone the changes made to the EDSP to satisfy the pesticide industry during the Bush Administration. But instead of doing that, OMB approved the skewed policy in March and EPA published it as final in the *Federal Register* on April 15, 2009. To make matters worse, OMB staff continued meeting with and taking comments from industry advocates after April 15, providing an audience for their unchanging critique of the EDSP under the guise of reviewing EPA's Information Collection Request for the EDSP as part of the Paperwork Reduction Act.

OMB's interventions into EPA's EDSP and IRIS process bring to light several opportunities for OSTP and OMB to collaboratively improve the integrity of regulatory science.

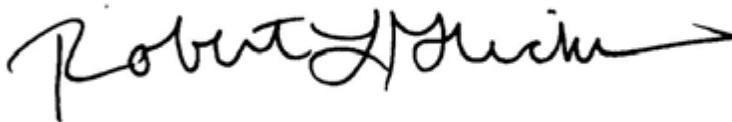
- ***OMB should stop reviewing individual rules, agency policies, and agency technical documents.*** EPA, in particular, has a rulemaking process that is driven by science and science-policy decisions that are best left to the agency's experts. When OMB reviews individual rules, policies, or technical documents, it becomes enmeshed in the regulatory minutiae that are outside the area of expertise of a political office.
- ***In any case where OMB insists on providing scientific commentary, the documentation should provide the identity and relevant qualifications of the staff responsible for the commentary.*** By virtue of their position within the Executive Office of the President, OMB staff have significant influence over agency staff. As a matter of transparency and scientific integrity, OMB reviewers should provide information about their educational and professional experience, much like external peer reviewers do.
- ***Paperwork Reduction Act reviews should be timed to coincide with the regulatory agencies' rulemaking timelines.*** The EDSP episode highlights how advocacy groups can manipulate the PRA review process to get a second (or third) bite at the apple, by framing their comments on the substance of a rule as comments on a related Information Collection Request.

No doubt, there are many other opportunities for OSTP and OMB to develop government-wide regulatory policies that can enhance the integrity of regulatory science. We hope that my suggestions will spur that collaboration and we welcome the opportunity to speak with either of you about these and other related ideas.

Sincerely,



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