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To: Mabel E. Echols OMB\_Peer\_Review/OMB/EOP@EOP  
cc: president@WHITEHOUSE.GOV, sf.nancy@mail.house.gov  
Subject: Poor peer review proposal

Joshua B. Bolten, Director,  
Office of Management and Budget  
725 17th Street, N.W., NEOB Room 10201,  
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Dear Director:

As you know, the Office of Management and Budget (OMB) has proposed a significant change that will affect the government's use of science in regulation. If allowed to become final, this "Peer Review and Information Quality" proposal could potentially cause serious damage to the federal system for protecting the public's health and environment. Although scientific peer review is important in the regulatory context, the approach outlined in the OMB proposal is inappropriate.

The Office of Management and Budget should withdraw the proposed Bulletin and engage the scientific community in a discussion of the need and structure of peer review in regulatory science.

The scope of the proposed OMB bulletin is extraordinarily broad, requiring peer review prior to dissemination of not only scientific and technical research reports, but also any data, findings, or analyses that are "relevant to regulatory policy." For a newly designated category of "especially significant regulatory information," the proposal establishes uniform criteria for selection and operation of external peer review panels, requires additional public comment periods, and mandates consultation with the OMB's Office of Information and Regulatory Affairs (OIRA) at various stages of the process.

Virtually every provision in the OMB Bulletin would simply delay actions by regulatory agencies. The OMB would be injected into every executive agency's scientific decision-making processes and required to approve the "peer review" used to reach scientific conclusions. One particularly egregious provision threatens to make it impossible for federally funded researchers to be part of peer review panels - - because prior funding or the intention to seek future funding from an agency would prohibit the agency from using these scientists as independent reviewers - but not exclude industry scientists who work for regulated parties from being part of the panels.

National Academy of Sciences Workshop The Science, Technology, and Law Panel  
of the National

Academy of Sciences (NAS) held a workshop on the proposal on November 18, 2003. Speaker after speaker, all invited by the NAS because of their expertise in the use of science in regulation, disparaged elements of OMB's proposed rule. The complaints were diverse and no one attempted a comprehensive review or offered a way to fix all its faults. The transcript of the workshop is posted on the Science, Technology, and Law website ([www.nationalacademies.org/stl](http://www.nationalacademies.org/stl)).

\* In Summary

This proposed OMB Bulletin "Peer Review and Information Quality" is fundamentally flawed in its intent as well as content. Implementation in its current form would serve little value; its costs will be substantial, and its benefit, at least to the public's health and environment, will likely be negative.

\* An Alternative Approach

Recognizing that peer review of science in the regulatory context is an important process, the scientific community should be engaged in this discussion. The National Academy of Sciences is an appropriate forum for such a discussion. The Academy has issued several important reports on agency peer review, as well as on broader issues relating to the role of science in regulation. The OMB should withdraw the proposed Bulletin and engage the scientific community in an open, transparent process.

The following is a summary of the issues raised about the OMB proposal,

-- There is no evidence that the current system is not working. Many speakers pointed out that not a single example has been raised demonstrating inappropriate or flawed federal regulations being promulgated as a result of failure to peer review.

-- There currently exist many models of scientific peer review in government agencies. The authors of the OMB proposal made no attempt to examine this extensive experience and see what works well (and what doesn't), and on that basis determine if changes are needed.

-- The OMB Bulletin is unclear and confusing on many points. It is likely, however, that implementation of the proposal will lead to delay, increased and unfunded costs, and confusion. Although the OMB touts the need for cost-benefit analyses in government regulations, there has in this instance been no assessment of the costs of the proposed Bulletin in terms either of diversion of agency resources or delayed regulatory protection.

-- It will be difficult to obtain independent, knowledgeable peer-reviewers to review the large numbers of documents, many of which will contain no new science. The new demand for peer reviewers is likely to have negative consequences on the already strained peer review systems utilized by many agencies.

-- The proposal's conflict of interest requirements appear to be written in a way that will preclude the participation of academic scientists whose work is supported by federal funding, but not exclude industry scientists who work for regulated parties.

-- The proposal appears to exempt a large proportion of regulatory documents where the science emanates from the regulated industry, where many would argue the science is in most need of peer review.

-- The proposal also exempts foreign affairs and national defense from peer review, although scientific peer review in this realm would be valuable in many instances. There is no need for a blanket exemption for national defense issues, as a case-by-case national security exemption policy could handle any security-sensitive issues. The exclusion of these areas from the peer review proposal suggests that the objective of the proposal is not to improve regulatory science but rather to hamper environmental and public health protection.

-- If implemented, this proposal would have numerous not yet known and perhaps unintended consequences. For example, as the Bulletin is currently written, the critical decision whether to release information to the public without further review in the event of a public health emergency is removed from the public health agencies and transferred to an OMB administrator.

-- Centralizing authority for regulatory scientific peer review in the Office of Management and Budget, an office with few scientists and whose workings are particularly opaque, opens the potential for behind-the-scenes intervention to change policy under the guise of questioning the science.

Thank you for the opportunity to bring these remarks to your attention.

Mindful of the responsibilities which stand before you, I am,

Yours sincerely,  
Robert E. Rutkowski

cc:  
Nancy Pelosi  
Andrew H. Card, Jr.

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