

# United States Senate

WASHINGTON, DC 20518

February 25, 2004

The Honorable Joshua Bolten  
Director  
The Office of Management and Budget  
725 17<sup>th</sup> Street NW  
Washington, DC 20503

Dear Mr. Bolten:

We are writing to express our opposition to the Proposed Bulletin on Peer Review and Information Quality published in the Federal Register on September 15, 2003. This proposal would have a major impact on the role of science in federal regulation. As strong supporters of science in the public interest, we agree with the Office of Management and Budget (OMB) that federal regulatory decisions should be based on the best available science. Unfortunately, the current proposal will ensure neither sound nor timely regulatory decisions, and will likely add inefficiencies and significant monetary costs to the current peer review system. We ask that you fully address our concerns, or withdraw your proposal.

We note that OMB's proposal recognizes the validity and adequacy of the approach to peer review taken by professional scientific journals, but differs markedly from their methods. Scholarly scientific journals do not disqualify reviewers based on the number of recent reviews they have conducted or for any perceived "advocacy of a position." Scientific journals also do not attempt to include reviewers of a "contrary bias" on panels.

Our first concern with the proposed bulletin is that the selection criteria for peer reviewers will exclude from reviewing federal scientific research precisely those experts who are the most competent to do so. Those potentially disqualified fittingly include reviewers with "financial interests in the matter at issue," but also inappropriately include those "currently receiving or seeking substantial funding from the agency through a contract or research grant." While this potentially *does not* exclude an academic scientist pursuing basic research with partial funding by a federal agency, it potentially *does* exclude an industry scientist employed or funded by a corporation affected by an agency decision. Further, the proposal to limit the frequency of panel participation by individual reviewers (to one review in some cases) will exclude the most qualified scientists from serving and quickly depletes the pool of available reviewers. We fear that this pair of rules would produce imbalanced peer review panels in which industrial voices – the regulated parties – are disproportionately loud.

Second, we are concerned that the proposed selection criteria concerning reviewers who "appear to be biased" are overly vague, and the proposed remedy for bias misguided. Reviewers can be disqualified if they have "advocated a position on the specific matter at issue." It is unclear whether such an 'advocated position' relates to personal statements, policy positions or published scientific results. A particular scientific conclusion over a body of work, even on a politically-charged issue, does not necessarily indicate bias and should not automatically preclude inclusion on a peer review panel. Further, the proposed bulletin suggests that if a reviewer who "is or appears to be biased" must be selected, the rules require the selection of an additional reviewer with "contrary bias." Elimination of bias by balancing viewpoints is inappropriate in cases where a vast majority of scientists have reached a consensus opinion, such as in climate change. Under the proposed rule, future panels would be constructed to contain an even split of viewpoints, vastly over-representing marginal opinions in many cases.

Third, we are concerned by the broad extent to which the proposed regulations will be applied to the federal agencies, and the extent of control given to the Administrator of the Office of Information and Regulatory Affairs. The Bulletin states that all science that is "significant regulatory information" or "relevant to an Administration policy priority" would be subject to peer review. Simply put, this proposal would potentially require that almost all information collected by the agencies for the monitoring of public health and safety be subjected to an identical, time consuming, and costly peer review process. Further, the OIRA Administrator will make the ultimate decision on which information is to be peer reviewed. OIRA is a budget agency with expertise in regulation – not in the science used in regulation. The OIRA Administrator will hold vast control over the speed with which regulatory decisions based on scientific information can be made. No single office should be in a position to permit or impede regulatory scientific information across the federal government.

In light of these concerns, we ask that you respond to us on the following questions before implementing any new rules regarding peer review:

- Has public health been compromised in any way by the current peer review structure? Will the proposed changes benefit public health in ways not currently achieved?
- How will OMB ensure the exclusion from a peer review panel of a funding recipient or employee of a private company who is potentially or actually affected by a peer reviewed regulation?
- What form of advocacy does OMB envision as a disqualification for a potential expert: scientific publication, policy statement, media interview, or other? Is a scientific opinion based on years of rigorous scientific results considered bias? Does OMB intend to conduct reviews of bias or to direct agencies to compile information on the "biases" of their potential reviewers? If so, what steps will be taken to remove bias from this process?
- Is OMB proposing that the designation of a scientific expert with 'contrary bias' would take precedence over another scientist's requisite expertise in determining the most qualified experts to be appointed to a review panel?
- How much control will the Administrator of OIRA have over the selection of peer review panels and the selection of which science must be reviewed? How will OMB and OIRA prevent duplicate peer review of previously published science? Will the OIRA Administrator override panel selections by individual agencies, even when those agencies have more expertise in the science considered and thus the suitability of individual reviewers?
- If an existing peer review panel recommends that an agency take swift action to respond to an emergency or public health harm, would the new policy allow OIRA to countermand that action and require additional peer review?

Given these concerns and the importance of the proposed changes, we feel the issue of federal scientific peer review deserves much more thorough consideration before any changes are adopted. We look forward to a timely response to the questions and concerns we have raised in this letter and hope to work with you to develop a policy that will be practical and effective.


Sincerely,

  
RON WYDEN

  
PATRICK LEAHY

  
\_\_\_\_\_  
TOM HARKIN

  
\_\_\_\_\_  
DON COBURN

  
\_\_\_\_\_  
HILLARY RODHAM CLINTON

  
\_\_\_\_\_  
EDWARD KENNEDY

  
\_\_\_\_\_  
HERB KOHL

  
\_\_\_\_\_  
JIM JEFFORDS