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To: Mabel E. Echols OMB_Peer_Review/OMB/EOP@EOP

cc:

Subject: "Peer Review and Information Quality" proposal

Joshua B. Bolten
Director, Office of Management and Budget
725 17th Street NW
NEOB Room 10201
Washington, D.C. 20503

Dear Mr. Bolten:

The Office of Management and Budget should withdraw the "Peer Review and Information Quality" proposal and engage the National Academy of Sciences in a discussion of the need for and structure of peer review for science used in the regulatory process.

On November 18, 2003, you invited the National Academy of Sciences' Science, Technology, and Law Panel to address this proposed rule. All speakers, selected for their expertise in the use of science in regulation, disparaged the proposal. No one was able to offer a comprehensive review and offer proposals to fix the faults identified. I summarize these faults below. In November, the American Public Health Association also stated it opposed the peer review proposal as presented by OMB.

The apparent intent of this proposed rule is to see that science used in the regulatory process is peer-reviewed before such use, so that only "sound science" is employed in establishing federal regulation over economic and industrial activity. However, agencies employing science in establishment of regulations currently use a system of science advisory boards which perform exactly this peer review function.

First fault: There is no evidence that the current system of science advisory board and other federal agency regulatory science review functions is not working. Michael Taylor, former deputy commissioner of the Food and Drug Administration, stated: "It offers peer review as a solution, but nowhere defines the problem."

Second fault: The authors of the OMB proposal made no attempt to examine the extensive experience of federal agencies with many different models of scientific peer review to determine what has, and has not, worked well in various applications. Instead, the OMB imposes one model a bunch of bureaucrats with no scientific credentials made up on everybody; this is a classic command-and-control Stalinist socialistic approach at odds with the stated political philosophy of the Bush Administration in regards to regulatory matters.

Third fault: The OMB Bulletin is unclear and confusing on many points when one tries to imagine how it could be implemented by an agency in practice. It appears likely to me that implementation of the proposal will lead to delay, increased and unfunded costs, and confusion in the regulatory process. The OMB and Bush Administration tout the need for cost-benefit analyses in government regulations. In this instance which cries for such analysis, none whatever has been done.

Fourth fault: Implementation of this rule will vastly increase the demand for "independent," knowledgeable peer-reviewers to review the vast numbers of documents, many of which contain no new science which would sensibly require evaluation for validity. There is no comprehension by the OMB as to where peer reviewers may be obtained, or how they can be paid for services rendered.

Fifth fault: The proposal's conflict of interest requirements appear to exclude the participation of academic scientists whose research is supported by federal funding, while allowing industry scientists who are paid salaries by the regulated parties to conduct peer reviews of science applicable to regulation of these parties.

Sixth fault: The proposal appears to exempt a large proportion of regulatory documents from peer review when the science emanates from the regulated industry. It is this regulated industry-generated "science" which is most in need of independent peer review by scientists having no fiduciary interest in the regulated industry.

Seventh fault: As written, the Bulletin transfers to an OMB administrator responsibility for such critical decisions as whether to release information about a public health emergency to the public without further review occurring first. Qualified public health practitioners, not politicized bureaucratic functionaries, should be making decisions about public release of information bearing on public health and safety.

Eighth fault: The proposal provides a blanket exemption for foreign affairs and national defense science from peer review. There is no need for a blanket exemption; current case-by-case national security exemption provisions appear to be handling security-sensitive matters perfectly well. Because of the particular importance of the accuracy of science used to make decisions on national security matters, it appears to me that scientific review of such science is particularly important to the national interest.

Ninth fault: The proposal centralizes authority for regulatory scientific peer review in the OMB, an office with few scientists whose workings are opaque. This invites behind-the-scenes intervention to change public regulatory policy under the guise of evaluating the science used to generate that policy.

This proposal needs to be withdrawn, and the above faults fixed in collaboration with the National Academy of Sciences. Then a Bulletin can be produced which describes a workable, feasible scientific review process for science used to inform federal regulations and decisions. As scientists, we want to see "sound science" used for federal decision-making and released for public information, and "junk science" identified as such and repudiated. As written, the OMB Bulletin's implementation would likely make matters worse, not better, in this regard.

Sincerely yours,
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