Congress of the United States
House of Representatives
Washington, D.C. 20515

December 15, 2003

The Honorable Joshua Bolten
Administrator
The Office of Management and Budget
725 17th Street, NW
Washington, DC 20503

Dear Mr. Bolten:

We are writing to express serious reservations about the sweeping proposal of the Office of Management and Budget (OMB) to control the peer review of information in federal agencies.

As strong supporters of scientific integrity in policymaking, we believe that peer review is an important tool for assessing the quality of information used by federal agencies. However, the OMB proposal is a wolf in sheep's clothing. Under the guise of promoting sound science, OMB is advancing a far-reaching policy that will impede efforts to protect health and the environment and open the door to conflicts of interest in the regulatory process. This proposal is an unprecedented attempt by OMB to exert control over federal agencies, not a genuine effort to improve the quality of science.

The focus of the proposal is misplaced. There is a serious and growing threat to science in federal agencies, but the threat is not insufficient peer review. For political reasons, the Bush Administration has repeatedly distorted scientific data, manipulated scientific advisory committees, gagged scientists, and provided misleading information to Congress and the public. Yet the new OMB proposal ignores this growing politicization of science. In fact, it actually erects new roadblocks to the use of high-quality science in agency decision making.

We urge you to focus your efforts on protecting federal scientists and advisory committees from undue political interference, rather than making it even harder for these experts to do their jobs. The proposal you have put forward should be abandoned or significantly revised.

Overbroad Scope

Under the OMB proposal, agencies must develop a process for peer review of "significant regulatory information," and they must conform to an extensive prescribed peer review of "especially significant regulatory information."

The definitions of these two terms, however, are so broad as to make the peer review policy unmanageable. Enormous amounts of information produced by an agency would be subject to the new policy. Under the OMB definitions:

- "Regulatory information" is "*any* scientific or technical study that is relevant to regulatory policy" (emphasis added). This definition has no meaningful boundaries. The word "study" "refers broadly to *any* research report, data, finding, or other analysis" (emphasis added). The phrase "relevant to regulatory policy" is defined as information that "*might be* used by local, state, regional, federal, and/or international regulatory bodies" (emphasis added). Thousands of agency sites, data-driven reports, policy statements, and other agency materials "might" be used by a local, state, or federal agency.

- Information is considered "significant" when "the agency can reasonably determine that dissemination of the information will have or does have a clear and substantial impact on important public policies or important private sector decisions." This definition is so vague and unpredictable as to be meaningless. To avoid legal challenges, agencies will adopt a broad definition of "significant."

- Information becomes "especially" significant when it is disseminated in support of a major regulatory action; has a possible impact of over $100 million per year on important public policies or private actions; or is deemed by the Administrator to be of "significant interagency interest or ... relevant to an Administration policy priority." This definition affords the OMB Administrator total control. Any information presented by any federal agency can be subject to peer review as long as it is determined to be "relevant" to the Administration's agenda.

Peer review makes sense for certain kinds of agency actions. For example, the National Institutes of Health and other science-based agencies use peer review to determine which scientific proposals are of the highest merit and the most deserving of federal funds. Agencies also commonly use peer review in the formulation of major scientific work products and plans.[1] For example, prior to disseminating a five-year research plan on the health effects of mercury, EPA submitted its draft for internal, and then external, peer review.[2]

The proposed definitions, however, are so broad that they would sweep in all kinds of agency actions that with good reason have never been subject to peer review. For example:

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[1]General Accounting Office, *Federal Research: Peer Review Procedures at Federal Science Agencies Vary* (Mar. 1999) (GAO/RCED-99-99) (online at http://www.gao.gov/archive/1999/rc99099.pdf).

[2]EPA, *Mercury Research Strategy* (Sept. 2000) (online at http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=20853).

- **Federal Reserve.** Federal Reserve Chairman Alan Greenspan makes specific predictions about the fate of the U.S. economy before Congress and in other public appearances. These pronouncements have tremendous implications for U.S. businesses, but it would be counterproductive for Chairman Greenspan to submit them in advance to external peer review.

- **Weather Forecasts.** When the National Weather Service predicts a major storm, it has immediate implications for businesses and governments in affected areas. It would appear completely unworkable, however, to obtain peer review of this information on a regular basis.

- **Veterans Administration Drug Prices.** The Veterans Administration negotiates prescription drug prices for the Federal Supply Schedule. Once disseminated, these prices have an important impact on what state and local governments may seek to pay for prescription drugs. However, it would be absurd to force the Veterans Administrations to conduct peer review during negotiations.

This list could go on and on. Each year, the Coast Guard decides to open or close bridges, the Agriculture Department sets policies on the production and pricing of a wide variety of crops, and the Department of Justice issues guidelines to federal prosecutors. All of these actions may involve information that meets the broad guidelines of the OMB plan.

The only alternative to wasting enormous amounts of time and money in needless peer review is selective enforcement of the plan. But such an approach would allow politics to dictate how and when burdensome peer review requirements are applied, furthering the politicization of science.

Burdensome One-Size-Fits-All Approach

OMB's sweeping proposal will significantly impede some of the most important efforts by science-based agencies to protect the public health and environment. This is because OMB proposes an elaborate four-stage process for peer review for information that meets the broad definition of "especially significant" information. Complying with this process will bring crucial regulatory initiatives to a standstill.

In the first stage, the agency must establish the boundaries of the peer review process. This involves determining each of the scientific inputs to its effort that could be considered "especially significant." Countless pieces of data could meet this broadly defined term. The agency must develop a specific charge to the peer review committee that addresses every one of these inputs and provides the committee with all relevant documents. This process alone could take many months.

In the second stage, the agency must provide for public comment on the charge to the peer review committee. This comment period is an opportunity for interested parties to send the agency thousands of pages of documents. After the public comment period is over, the agency must furnish all the comments to peer reviewers "with ample time for consideration." This process also could take many months.

In the third stage, the peer reviewers actually do their work and the agency responds. The reviewers must write a report addressing the agency's charge. The agency then must then develop a detailed response that explains:

> the agency's agreement or disagreement with the report(s), including any recommendations expressed therein; the basis for that agreement or disagreement; any actions the agency has undertaken or proposed to undertake in response to the report(s); and (if applicable) the reasons the agency believes those actions satisfy any concerns or recommendations expressed by the report(s).

This process could again take many months.

Finally, in the fourth stage, after the agency finally attempts to take action, interested parties may prevent or stall regulatory action in court on the grounds that some aspect of the peer review process was inadequate. Even if peer review guidelines are not held to be judicially reviewable by themselves, the issue could be raised to lengthen a general challenge to regulation. The litigation process could take years.

These delays may apply even in emergency situations. Even when a rule, report, or policy imminently threatens the public health, agencies cannot proceed until the OMB Administrator certifies that the peer review requirements can be waived. This new process in effect gives OMB, a budget agency, a veto over the ability of agencies to respond to public health and environmental emergencies.

The end result is that agencies will be forced to spend many months and millions of dollars pursuing this elaborate one-size-fits-all approach to peer review. For example, the CDC could be forced to delay epidemiological investigations while conducting peer review; USDA could be forced to waste months of time in peer review of urgently needed food safety guidelines, and EPA could be forced to delay the development of protections against newly recognized toxins. There are hundreds of regulatory actions across federal agencies that could be similarly bogged down.

OMB attempts to justify its sweeping approach by quoting scientists and organizations in support of the principle of peer review of agency action. But this rationale provides no justification for the OMB approach. The question is not whether peer review can be helpful, but

whether there is any need for this sweeping and time-consuming OMB-controlled peer review policy.

OMB also cites GAO as a strong supporter of peer review.[3] Yet, in a 1999 report also referenced in the proposal, GAO does not suggest that a uniform policy is needed. To the contrary, GAO cites experts from the White House Office of Science and Technology Policy who assert:

> [A]gencies' peer review practices should not be dictated uniformly for every agency or for all types of federally funded research. Rather, the practices should be tailored to agency missions and type of research.[4]

Conflicts of Interest

For many health and environmental rules, the benefit to the public must be carefully weighed against the economic losses to one or more industries. It is critically important that the regulatory process be able to produce this assessment objectively. Unfortunately, in guidelines on the selection of peer reviewers, OMB's proposal discourages the use of unbiased experts in favor of individuals associated with companies that have an interest in forestalling or weakening regulation.

The proposal requires agencies to select peer review committee participants who are "independent of the agency." This means that participating experts may not be receiving or seeking agency funding, may not have taken part in multiple peer reviews for that agency in recent years, and may not have participated in even one peer review on the same topic.

Despite the significant implications of this policy change, OMB does not provide any evidence that agency-funded scientists, who are generally the leaders in their fields, are biased. In fact, the proposal's references fail to support this allegation. For example:

- OMB cites statements from the *New England Journal of Medicine* and *Nature* that generally pertain to industry, not agency, funding.[5]

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[3]Testimony of the General Accounting Office, House Committee on Science, Subcommittee on Energy and Environment, *Peer Review: EPA's Implementation Remains Uneven,* 105th Cong., 8 (Mar. 11, 1997) (GAO/T-RCED-97-95).

[4]General Accounting Office, *supra* note 1, at 2.

[5]J. Drazen and G. Curfman, *Financial Associations of Authors*, New England Journal of Medicine, 1901–02 (June 13, 2002); Philip Campbell, *Declaration of Financial Interests*, Nature, 751 (Aug. 23, 2001).

- OMB references agency guidelines and a National Research Council report as support for the idea that "external" experts may be more objective than "internal" reviewers.[6] Yet these sources do not classify scientists who have simply received agency funding as "internal" and therefore do not support OMB's contention that agency funding produces bias.

- OMB states that publication guidelines of the American Geophysical Union (AGU) indicate that "'real or perceived conflicts of interest' include the review of papers 'from those in the same institution.'"[7] In fact, this provision deals not with peer review but rather with appropriate conduct for editors of scientific journals. The guidelines advise editors against "handling papers from present and former students, from colleagues with whom the editor has recently collaborated, and from those in the same institution." The provision has nothing to do with whether scientists can objectively review agency actions.

- OMB claims that the Inspector General of EPA has "encouraged the agency to do a better job of 'consistently inquir[ing] whether peer review candidates have any financial relationship with the agency.'" In fact, the OIG report cited by OMB only refers to agency funding as a presumptive disqualifier if a potential peer reviewer has a client or employer "with a direct financial stake in the particular specific party matter under review . . . [such as] a Federal grant or contract to the potential peer reviewer or his/her employer that relates to the matter under review)."[8] In other words, EPA only disqualifies scientists who stand to gain from the matter at hand, not all scientists receiving significant agency funding. Furthermore, the OIG report explicitly states that "[p]eer reviewers can come from EPA, another Federal Agency, or from outside the federal government."[9]

In marked contrast to its strict treatment of agency-funded experts, the proposal permits the participation of scientists with multiple forms of ties to regulated industries. Individuals are excluded from peer review committees only if they "have financial interests in the matter *at issue*" (emphasis added). Scientists with extensive industry ties in the past, and those with

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[6]National Research Council, *Peer Review in Environmental Technology Development Programs: The Department of Energy's Office of Science and Technology* (1998).

[7]American Geophysical Union, *Guidelines to Publication of Geophysical Research* (rev. Oct. 2000) (online at http://www.agu.org/pubs/pubs_guidelines.html).

[8]Environmental Protection Agency Office of Inspector General, *Science Policy Council Handbook: Peer Review* (2nd ed.), 60 (Dec. 2000) (online at http://epa.gov/osp/spc/prhandbk.pdf).

[9]*Id.* at 21.

extensive industry ties in the present but no financial interest in the matter "at issue," are acceptable.

This approach is exactly backwards. The proposal treats experts affiliated with agencies with the greatest suspicion, when evidence indicates that industry-funded scientists consistently produce research and opinions that are more likely to favor industry.[10]

OMB also opens the door to conflict of interest in the management of the peer review process. The proposal allows agencies to contract with private firms to select peer review panels. Such panels are not governed by the fairness and disclosure rules of the Federal Advisory Committee Act (FACA). The only requirement is that "the agency shall ensure that the firm itself possesses independence (and the appearance of independence) from the agency." The proposal includes no language to ensure that the firm is independent of regulated industries or other interest groups.

Lack of Foundation

For a policy that claims to advance the cause of sound science, the OMB proposal is based on remarkably flimsy evidence. There is no evidence presented of harm to the public from existing peer review procedures. There is not even a systematic analysis of current agency peer review practices or of any problems associated with current practice. In fact, the only citation that discusses any alleged problems is a 2002 report by the EPA Office of Inspector General.[11] This report dealt with a small subset of one agency's actions. Its executive summary prominently states: "The rules included in the pilot study were not a representative statistical sample of EPA rules, and we did not identify all of the critical science inputs for every rule."[12]

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[10] *See, e.g.,* H. Stelfox et al., *Conflict of Interest in the Debate over Calcium Channel Blockers*, New England Journal of Medicine, 101–106 (Jan. 8, 1998); J. Yaphe et al., *The Association between Funding by Commercial Interests and Study Outcome in Randomized Controlled Drug Trials*, Family Practice, 565–8 (Dec. 2001); S. Leopold et al., *Association between Funding Source and Study Outcome in Orthopaedic Research*, Clinical Orthopedics, 293–301 (Oct. 2003); B. Djulbegovic et al., *The Uncertainty Principle and Industry-Sponsored Research*, Lancet, 635–8 (Aug. 19, 2000); J. Lexchin et al., *Pharmaceutical Industry Sponsorship and Research Outcome and Quality: Systematic Review*, British Medical Journal, 1167–70 (May 31, 2003); L. Kjaergard et al., *Association between Competing Interests and Authors' Conclusions: Epidemiological Study of Randomised Clinical Trials Published in the BMJ*, British Medical Journal, 249 (Aug. 3, 2003).

[11] Environmental Protection Agency Office of Inspector General, *Science to Support Rulemaking* (Nov. 15, 2002) (Report 2003-P-00003) (online at http://www.epa.gov/oig/reports/2002/SSRulemaking.pdf).

[12] *Id.* at i.

Moreover, OMB presents no budget or cost analysis of its proposal, despite its obvious burdens. Nor is there any indication, despite the significance of this regulatory action, that the evidence supporting the OMB proposal itself was peer reviewed.

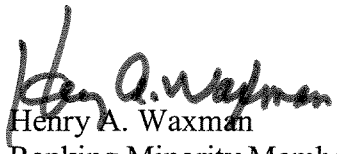
Conclusion

There is a serious problem related to the integrity of science at federal agencies, but it has nothing to do with peer review. In recent months, leading scientists and scientific journals have called attention to the politicization of science in the Bush Administration.[13] The Administration has stacked advisory committees, released misleading statements by the President, given inaccurate responses to Congress, altered web sites, suppressed agency reports, issued erroneous international communications, and censored federal scientists.[14] The editor of *Science*, Donald S. Kennedy, wrote that the Bush Administration is invading areas "once immune to this kind of manipulation."[15] The beneficiaries of these scientific distortions are important supporters of the President, including social conservatives and powerful industry groups.

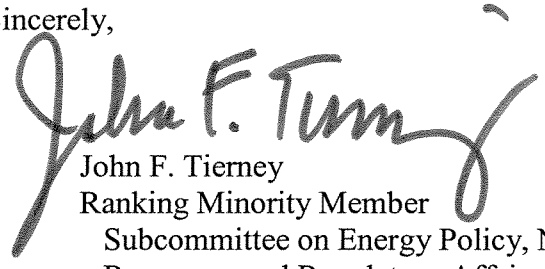
Unfortunately, the OMB proposal does nothing to address these threats to scientific decision making. Instead, it further hampers federal agencies' ability to make, use, and disseminate good science.

We urge OMB to drop or significantly revise its ill-advised peer review proposal and instead focus on the urgent need to protect government scientists and scientific advisory committees from damaging political interference.

Sincerely,



Henry A. Waxman
Ranking Minority Member
Committee on Government Reform



John F. Tierney
Ranking Minority Member
Subcommittee on Energy Policy, Natural Resources and Regulatory Affairs
Committee on Government Reform

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[13]*See, e.g.*, David Michaels et al., *Advice without Dissent*, Science, 703 (Oct. 25, 2002); Martin McKee and Richard Coker, *The Dangerous Rise of American Exceptionalism*, Lancet (May 10, 2003); *No Way to Run a Superpower*, Nature, 861 (Aug. 21, 2003).

[14]Minority Staff, Government Reform Committee, *Politics and Science in the Bush Administration* (Aug. 2003) (online at www.politicsandscience.org).

[15]Donald Kennedy, *An Epidemic of Politics*, Science, 625 (Jan. 31, 2003).

Sherrod Brown
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