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To: mschwab@omb.eop.gov, omb\_peer\_review@omb.eop.gov  
cc: David Korn <Dkorn@aamc.org>, hgarrison@opa.faseb.org  
Subject: Comments from AAMC and FASEB

Dear Dr. Schwab,  
I tried to send this message earlier, but it's not clear that it got through our system. Please disregard if it's a duplicate.

Attached are AAMC's and FASEB's comments on the revised information quality bulletin on agency peer review. I am cc'ing Dr. David Korn of AAMC and Dr. Howard Garrison of FASEB on this message. We'd be glad to answer any questions about these comments.

Thank you,  
Steve Heinig

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OMB peer bulletin  
Revision res...

- OMB peer bulletin Revision response\_DK3.final\_1.pdf



May 28, 2004

The Hon. John D. Graham, Ph.D.  
Administrator, Office of  
Information and Regulatory Affairs  
Office of Management and Budget  
Executive Office of the President  
725 17<sup>th</sup> Street  
Washington, DC 20503

By electronic mail: [OMB\\_peer\\_review@omb.eop.gov](mailto:OMB_peer_review@omb.eop.gov)

**Re: Revised Information Quality Bulletin on Peer Review, 69 FR 23230-42**

Dear Dr. Graham:

We are pleased to respond on behalf of the Association of American Medical Colleges (AAMC) and the Federation of American Societies for Experimental Biology (FASEB) to the information quality bulletin in the above-referenced notice from the *Federal Register* on April 28. The bulletin requires federal agencies to undertake peer review of influential scientific information before such information is publicly and officially disseminated by an agency. It also instructs agencies on the standards and procedures necessary for such review and sets forth exemptions and permissible alternatives to satisfy these requirements.

As you know, the AAMC, representing its member medical schools, teaching hospitals, and academic societies, and FASEB, representing 22 societies with more than 60,000 member scientists, were among the 187 organizations and individuals commenting on the original draft bulletin issued on September 15, 2003. We considered the draft bulletin to be overly restrictive and to deviate inappropriately from widely accepted norms in scientific peer review. The AAMC and FASEB were especially concerned that the then-proposed requirements could unduly hamper or prevent timely response by federal public health agencies to significant new and credible research findings that in their professional judgment merited rapid dissemination.

The revised bulletin is far less prescriptive, more hospitable to established practices of peer review and their accepted variants, and more deferential to the needs and prerogatives of agency decision-making. For example:

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- In Section III concerning peer review of highly influential scientific information, the revised bulletin explicitly states that scientific expertise alone should be the principal qualification for members of peer review panels; such expertise is to be balanced among relevant, legitimate scientific viewpoints and disciplines. Scientists receiving peer-reviewed federal research grants are not considered de facto to lack independence from their funding agencies in serving on review panels. Potential conflicts of interest among reviewers are to be addressed through applying or adapting existing federal ethics rules for government employees (including temporary employees) or adapting the National Academies' policies for managing such conflicts.
- Agencies are permitted more latitude to rely on earlier peer review of influential scientific information (we understand that this latitude does not extend to information defined by OMB as highly influential). Agencies may rely on alternative, credible scientific organizations, such as the National Academies, for review of influential information prior to dissemination, and, may also presume the quality of information that has already been vetted by the NAS.
- Section VIII provides several well-considered exemptions from mandated review, including an exemption (no. 4) for any "medical, health, or safety dissemination where the agency determines that the dissemination is time-sensitive or is based primarily on data from a recent clinical trial that was adequately peer reviewed before the trial began."
- Section XI makes clear that the bulletin creates no new legal right of action for interested parties to seek to enjoin or reverse a federal decision that is based on peer-reviewed scientific information. In other sections, the OMB has clarified that the bulletin is not intended to interfere with the conduct of federally funded, peer-reviewed research or with an investigator's own publication or dissemination of research findings, even if the investigator is a federal employee.

The OMB's Office of Information and Regulatory Affairs has obviously examined and considered carefully the comments of the research community. The revised bulletin sufficiently addresses the central concerns expressed in our joint comment letter of December 4, 2003. However, we have a few additional suggestions for the revised bulletin that would clarify its intent and aid in the agencies' implementation.

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- Regarding section VIII's exemption no. 4 referenced above, the AAMC and FASEB note that agencies may receive important medical, health or safety information from rigorous, previously peer-reviewed studies other than clinical trials. *Accordingly, we consider the reference to clinical trials to be exemplary and not exclusionary* (as we had offered clinical trial examples in our comments on the original draft bulletin). We recommend that to avoid misunderstanding the exemption be clarified: "...where the agency determines that the dissemination is time sensitive or is based primarily on data from a recent clinical, epidemiological, or other study dealing with the public's health or safety, for example a clinical trial, which was adequately peer reviewed before the study began."
- In its discussion of definitions, the notice states that the bulletin covers only "influential scientific information," in contrast to the influential scientific, financial, or statistical information circumscribed by the data quality law. *The bulletin does not provide a rationale for why it applies only to scientific information and not financial or statistical information, and we believe that it should.*

We encourage OMB to continue actively to seek the scientific community's input in establishing viable processes for scientific assessment and resolution of controversial scientific issues. The burden rests on OMB to ensure that agencies' implementation of the peer review standards does not lead to overly restrictive or unnecessarily recursive processes that could impede the use of credible scientific findings to support timely agency dissemination and policy making. Implementation will also clearly depend on the conscientiousness of agency leadership in assembling high quality review panels and dedicating sufficient time and resources for adequate assessments.

The AAMC and FASEB, therefore, strongly endorse the bulletin's provision (in section IX) for creation of an interagency working group co-chaired by OIRA and the White House Office of Science and Technology Policy (OSTP) to monitor progress in the implementation of this bulletin. We believe that the OSTP, as the President's lead office for coordinating science policy and practice across federal agencies, should play a major role in overseeing implementation of this bulletin. Our organizations urge that this working group periodically schedule public meetings so that the scientific and other affected communities can monitor the progress of trans-agency implementation and continue to provide informed input as this process evolves.

Finally, in its notice the OMB cites opinions that a robust and rigorous federal process for peer review of influential scientific information within the executive branch may "reduce the temptation for courts and legislators to second-guess agency actions [based on scientific

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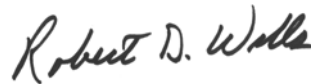
findings].” We hope that this may be the case, but are sobered by our awareness of too many instances—many new, but many persisting in some form for decades—where scientific information is vigorously challenged by affected parties, in every available forum, not so much on legitimate scientific grounds but largely to protect perceived self interests. Accordingly, we would prefer to regard the peer review bulletin initiative as a well-intentioned experiment that will need careful, ongoing monitoring for unanticipated adverse effects.

AAMC and FASEB appreciate the opportunities that they have had for constructive interaction with OIRA during the evolution of the peer review bulletin. We are gratified that our central concerns regarding the timely dissemination of information important to the public health have been addressed so closely.

Sincerely,



Jordan J. Cohen, M.D.  
President, AAMC



Robert D. Wells, Ph.D  
President, FASEB

Cc: The Hon. John Marburger, Ph.D.,  
Director, Office of Science and Technology Policy