

December 12, 2003

Dr. Margo Schwab
Office of Information and Regulatory Affairs
Office of Management and Budget
725 Seventeenth Street N.W.
New Executive Office Building
Room 10201
Washington, D.C. 20503
OMB_peer_review@omb.eop.gov

Re: Proposed Bulletin on Peer Review and Information Quality, 68 FR 54023-29

Dear Dr. Schwab:

We are writing to communicate the views of the American Association for the Advancement of Science (AAAS), the world's largest general scientific society, on certain key issues raised by the Office of Management and Budget's (OMB) Proposed Bulletin on Peer Review and Information Quality published in the Federal Register on September 15, 2003.

As the publisher of the world's preeminent peer-reviewed scientific journal, *Science*, we are committed to upholding the values of scientific peer review and to ensuring to the maximum extent possible the quality of information in support of the conduct of research as well as the dissemination of research results. We applaud the intent of the OMB Proposed Bulletin that recognizes independent peer review as a "critical element in ensuring the reliability of scientific analyses." As the Proposed Bulletin states, peer review should encompass participation by those "in the field with requisite training and expertise" with reasonable transparency to assure public confidence and "meaningful review of the work as a whole."

Selection of Peer Reviewers

As part of the independent peer review process for "especially significant" information, the OMB Proposed Bulletin outlines procedures for selecting independent peer reviewers, and establishes a set of four factors for determining whether an individual possesses a "real or perceived conflict of interest."

In February 2003, the AAAS Board and Council issued a joint resolution on federal scientific advisory committees that states, "it is essential that federal agencies receive scientific, technical and medical advice that represents a diversity of informed views regarding the need for, and evaluation of, research and regulation in order that research and regulatory decisions are based on the best available scientific knowledge." AAAS urges that the final Bulletin support the principles embodied in this statement.

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AAAS supports the reviewer selection criteria so long as OMB makes clear that these criteria are considerations and not requirements. We are concerned, however, that the second factor to be considered in selecting peer reviewers, -- i.e., whether the reviewer "(ii) has, in recent years, advocated a position on the specific matter at issue" -- may be broadly interpreted to include scientific positions. The term "position" is not defined. For example, if a scientist were to state in an article in a scientific journal or at a professional conference that a certain size of particulate matter has been shown to cause asthma in children, would this constitute advocating a position? A statement based on a preponderance of peer-reviewed scientific evidence should not be construed as advocacy, and AAAS is concerned that qualified experts could be excluded from peer review panels due to such an interpretation.

Furthermore, the Proposed Bulletin states that "If it is necessary to select a reviewer who is or appears to be biased in order to obtain a panel with appropriate expertise, the agency shall ensure that another reviewer with a contrary bias is appointed to balance the panel." Simply holding a contrary opinion is not a sufficient qualification for participating in a peer review study. AAAS urges that the OMB Bulletin be revised to ensure that *all* reviewers possess the requisite scientific, medical and technical expertise.

Public Disclosure

Furthermore, in the case of especially significant regulatory information, the Proposed Bulletin would require that agencies publicly disclose the names of reviewers in the final peer review report. While transparency is a laudable goal, the ability of federal agencies to attract qualified scientists to participate in peer review will be severely hampered if the scientists feel unable to be candid in their critiques. This is especially true in cases where reviewers work as individuals rather than as a group of reviewers and a clear association can be made between a person and his or her comments. We urge OMB to make clear in the final Bulletin that such individual comments will not be associated with individual reviewers.

Waivers for Compelling Cases

AAAS appreciates the recognition that in the interest of imminent national security or public health threats, all or some of the peer review requirements may be waived. However, as we interpret the language, the final decision is made only by the Administrator of OIRA (though he may consult with the Director of OSTP). OMB should take care to consult thoroughly with each federal agency regarding the waiver process to protect against unintended consequences. This is especially important in cases involving new drugs and therapies that have an obvious economic impact on the private sector, but may raise serious health concerns later, after FDA approval. In this example, we are concerned that the FDA

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may unintentionally be delayed in removing a questionable drug or therapy until after an additional level of peer review has been completed.

Founded in 1848, AAAS strives to advance science for the benefit of all people through its projects, programs, and publications in the areas of science policy, science education and international scientific cooperation. The Association and its journal, *Science*, have nearly 140,000 individual and institutional subscribers, plus 272 affiliated organizations in more than 130 countries, serving a total of 10 million individuals.

We welcome the opportunity to comment on this Proposed Bulletin. Should you or your staff wish to discuss these matters further, please contact Dr. Albert H. Teich, Director of Science & Policy Programs (telephone: 202 326 6600, e-mail: ateich@aaas.org).

Sincerely,

Floyd E. Bloom
Chairman, Board of Directors

Alan I. Leshner
Chief Executive Officer

cc: John H. Marburger III
Director, Office of Science & Technology Policy