December 15, 2003

Dr. Margo Schwab
Office of Information and Regulatory Affairs
Office of Management and Budget
725 17th St., NW
New Executive Office Building, Room 10201
Washington, DC 20503
OMB_peer_review@omb.eop.gov

Re: Notice and request for comments on Proposed Bulletin on Peer Review and Information Quality (published in Federal Register, Vol. 68, No. 178, September 15, 2003.)

Dear Dr. Schwab:

The Association of American Universities (AAU) and the National Association of State Universities and Land-Grant Colleges (NASULGC) jointly submit these comments on behalf of this nation’s leading public and private research universities. We join with the OMB in reaffirming the indispensable role of the peer review process in science and academia. Scientific peer review is the foundation upon which the American scientific research enterprise is built. In addition, we fully support the use of peer review in the process of developing effective federal regulatory policy.

While we agree with the Office of Management and Budget (OMB) that information disseminated by the federal government should be as accurate and valid as possible, we believe that the proposals included in the published notice lack clarity and could be interpreted in ways that would fail to achieve their stated objectives.

OMB has proposed criteria that an individual must meet in order to be chosen as a peer reviewer, including whether the person under consideration is being funded or is seeking funding from the agency by which he or she is being considered. The stated rationale for this criterion is to avoid “real or perceived conflicts of interest.” By mandating that individual agencies “shall strive” to exclude from peer review individuals receiving support from the agencies, the OMB regulation has the potential to exclude the most qualified scientists from the peer review process, thus compromising the quality of expertise brought to bear on science conducted in the development of federal regulatory policies. Our strong belief, shared by many others in the scientific community, is that full disclosure of possible conflicts of interest by potential peer reviewers should more than adequately address conflict of interest concerns. This is, in fact, a common and effective practice in much of the scientific community.

The proposal to exclude such individuals from the peer review process would be even more problematic in highly specialized areas of science as it would bring about a situation in which the pool of potential peer reviewers would be too small, thus creating the possibility of not having peer review at all.
A further concern is that these guidelines could be applied too broadly. We are concerned that even agencies that currently disseminate very little regulatory information, such as the National Science Foundation (NSF) and the National Institutes of Health (NIH), could be affected by the new procedures. The notice states that,

“Regulatory information” means any scientific or technical study that is relevant to the regulatory process. Information is relevant to the regulatory process if it might (emphasis added) be used by local, state, regional, federal and/or international regulatory bodies.

We believe this definition to be too open-ended and ambiguous, potentially bringing about unintended consequences that could impede federal support for fundamental research.

We reiterate our support for the peer review system and its applicability to the process by which federal agencies develop sound regulatory policies. However, for the reasons stated above, we believe that the proposed guidelines in their current form could weaken the process. We urge that the OMB further clarify the proposed guidelines to ensure that no unintended harm is done to the peer review system in applying it to the development of federal regulatory policy.

We appreciate this opportunity to comment on this very important matter.

Cordially,

Nils Hasselmo
President
Association of American Universities

C. Peter Magrath
President
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