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Record Type: Record

To: Mabel E. Echols OMB\_Peer\_Review/OMB/EOP@EOP

cc:

Subject: Peer review Comments

12 December, 2003

Joshua B. Bolten, Director Office of Management and Budget 725 17th Street, N.W. NEOB Room 10201 Washington, DC 20503

Dear Director Bolten,

As a physical scientist, who has sat on many review panels for NASA and NSF, I am very concerned about the proposal from The Office of Management and Budget. The OMB should withdraw the proposed Bulletin "Peer Review and Information Quality" and engage the scientific community in an open, transparent discussion of the need and structure of peer review in regulatory science. The proposed OMB Bulletin is fundamentally flawed in its intent as well as content. Implementation in its current form would serve little value; its costs will be substantial, and its benefit, at least to the public's health and environment, will likely be negative.

Concern for the proposed Bulletin was raised during a recent workshop held at the National Academy of Sciences. Of the many potential issues, I note the following:

- -- There is no evidence that the current system is not working. Many speakers pointed out that not a single example has been raised demonstrating inappropriate or flawed federal regulations being promulgated as a result of failure to peer review.
- -- There currently exist many models of scientific peer review in government agencies. The authors of the OMB proposal should examine this extensive experience and see what works well (and what doesn't), and on that basis determine if changes are needed.
- -- It is likely that implementation of the proposal will lead to delay, increased and unfunded costs, and confusion.

  Although the OMB touts the need for cost-benefit analyses in government regulations, there has in this instance been no assessment of the costs of the proposed Bulletin in terms

either of diversion of agency resources or of delayed regulatory protection.

- -- The proposal's conflict of interest requirements appear to be written in a way that will preclude the participation of academic scientists whose work is supported by federal funding, but not exclude industry scientists who work for regulated parties.
- -- If implemented, this proposal would have numerous not yet known and perhaps unintended consequences. For example, as the Bulletin is currently written, the critical decision whether to release information to the public without further review in the event of a public health emergency is removed from the public health agencies and transferred to an OMB administrator.
- -- Centralizing authority for regulatory scientific peer review in the Office of Management and Budget, an office with few scientists and whose workings are particularly opaque, opens the potential for behind-the-scenes intervention to change policy under the guise of questioning the science.

Recognizing that peer review of science in the regulatory context is an important process, the scientific community should be engaged in this discussion. The National Academy of Sciences is an appropriate forum for such a discussion. The Academy has issued several important reports on agency peer review, as well as on broader issues relating to the role of science in regulation. The OMB should withdraw the proposed Bulletin and engage the scientific community in an open, transparent process.

Sincerely, Prof. Steven Federman Dept. of Physics and Astronomy Univ. of Toledo Toledo, OH 43606