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Subject: Mercatus Center - Marshall Institute

Dear OMB: 12/15/03 RE: Peer Review Guidelines

Attached, and below, please find a joint comment on the proposed peer review guidelines, filed on behalf of the Mercatus Center at George Mason University and the George C. Marshall Institute.

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December 15, 2003

Public Interest Comment on

Proposed Bulletin and Guidelines for Peer Review and Information Quality[1]

The Regulatory Studies Program (RSP) of the Mercatus Center at George Mason University is dedicated to advancing knowledge of the impact of regulation on society. As part of its mission, RSP conducts careful and independent analyses employing contemporary economic scholarship to assess rulemaking proposals from the perspective of the public interest.

The George Marshall Institute (GMI) is a non-profit organization whose mission is to promote the use of sound science in improving public policy on important issues for which science and technology are major considerations.

The Proposed Bulletin and Guidelines on Peer Review and Information Quality ("proposed guidelines") published by the Office of Management and Budget and the Office of Science and Technology Policy address issues that are central to the mission of both RSP and GMI. Accordingly, we have consulted with each other, and with scientists who have experience with policy development as well as with peer review, in order to develop this joint comment. Our comment on the proposed guidelines does not represent the views of any particular affected party or special interest group, but is designed to evaluate the effect of the proposal on overall public welfare.

I. Introduction

Whether they involve human medicines, endangered species, air and water quality, industrial chemicals, transportation safety, or consumer products, the stakes involved in federal regulatory decisions are enormous. OMB's periodic reports on the benefits and costs of federal regulation show that hundreds of billions of dollars turn on these decisions, but it is also true that lives are at stake, on both sides of the equation. It is important to get these decisions right, within the limits of human knowledge and analytical and policy development processes.

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[1] Prepared by Brian F. Mannix, Senior Research Fellow, Mercatus Center at George Mason University, and Jeff Kueter, Executive Director, George C. Marshall Institute. This comment does not represent an official position of George Mason University, and the views expressed herein should not be attributed to anyone other than the authors.

The proposed guidelines on peer review and information quality are an important advance, and we applaud OMB and OSTP for undertaking this effort. Peer review is an established process for quality control in the scientific community. While it is most closely associated with the publication of journal articles and the awarding of grants, the peer review process can and should be applied to the use of science in public policy.

We recognize that peer review is not perfect, as evidenced by well-documented examples of flawed science passing one level of peer review. Yet peer review—combined with independent replication—is the best way to achieve the highest standards of quality. The scientific peer review process needs to be adapted to the particular requirements of the rulemaking process. The proposed guidelines will consume additional resources if they are properly applied, and therefore should include a "look-back" provision to allow for a review of their value produced after a few years.

Our comments on the guidelines will be limited to a few specific points.

Clearly Define the Issues to be Addressed by Reviews

To be most effective and to elicit the most useful information for decision makers, the issues put before a peer review panel must be clearly defined and focused on scientific matters and analytical rigor. The proposed guidelines allow agency discretion in constructing the agendas for their peer review panels. Our review suggests the need for an independent, third party to review those agendas to ensure they meet the conditions of clarity and limited scope before they are put to peer review panels. The peer review process should be limited to methodological issues and to identifying and distinguishing facts from conjecture and hypothesis.

The Need for Good Faith

The proposed guidelines, like any regulation, may have unintended consequences and ultimately should be judged on their results rather than on their intent. And there is a particular reason to be concerned that the guidelines may not work in practice as well as we might hope.

Academic peer review relies on the good faith and integrity of the participants. It suffers when, for example, competition for grant money, or academic rivalries and personality conflicts, taint the reviews. Even so, it is robust enough to overcome these difficulties; indeed, one of the reasons peer review has been so successful is that it handles such problems much better than does a hierarchical system of review.

When applied to regulatory decisions, peer review is subject to a whole new set of stresses. In addition to scientists, the stakeholders will include many with strong economic, political, or religious interests. Agency managers will need to be vigilant ensure the integrity of the peer review process and to identify important biases. That does not mean that policy advocates and stakeholders should be excluded, but it does

mean that the agency's decision processes must maintain a clear distinction between scientific judgments and policy judgments. Again, the process must be focused on distinguishing facts from conjecture and hypothesis.

Because peer review relies on good faith, it may not be possible simply to mandate a sound process, or to impose it on those who are not interested in pursuing it. If agencies comply with the letter of the peer review requirement but violate its spirit, the outcome will not be an improvement. Since agency buy-in is essential, we urge OMB and OSTP to work with agency managers to implement the guidelines in the spirit they are intended.

Peer Review is Not a Shield for Orthodoxy

Note that peer review should never be permitted to shelter a preferred scientific theory from valid criticism. The peer review process improves science, but it is not designed to guarantee a right answer, nor even a single answer, to important questions. Indeed, it is intended to force competing scientific views to "jostle" each other so that controversies are illuminated and eventually resolved. In the rulemaking context, there is a danger that the "official" peer review process will cause competing theories to be ignored, or that after conducting a peer review an agency will shut its ears to alternative views or new information during a subsequent public comment period. Peer review is an imperfect noise filter, and agencies need to be on guard not to tune out the signal while suppressing the noise.

Agencies can avoid the potential of this problem arising by ensuring that their peer review process is open to a diversity of views. Requiring the representation of conflicting interests on peer review panels may be one way of addressing the problem. Another technique that may prove useful is the use of a formal "devil's advocate" within the peer review process to ensure that the panel considers alternatives before arriving at a consensus view.

Transparency vs. Confidentiality

In an attempt to maintain impartiality, academic peer reviews are sometimes done blind or double-blind; although it is not always possible to maintain the anonymity of authors and reviewers. The proposed guidelines instead stress transparency. We believe this is the right choice. In a rulemaking process, transparency must be paramount. That is a fundamental principle of the Administrative Procedures Act, the various Executive Orders on federal rulemaking, the Paperwork Reduction Act, and the Information Quality Act; the proposed guidelines complement all of these. We urge OMB and OSTP to integrate the proposed guidelines with these other requirements, and to work with the agencies to ensure the transparency of their procedures.

Access to data and the procedures to replicate findings are critical. Academic peer review rarely examines the underlying data presented in a journal submission. Instead, researchers seek to replicate the findings and examine the data in the context of a larger process that expands scientific understanding. This iterative process cannot be applied in

the regulatory arena; and the importance of regulatory decisions, and their costs and consequences, demands open access. For that reason, we believe that the underlying data, models, and other information necessary to replicate the results of science used to justify regulatory action must be available to the public and all interested parties.

Conflicts of interest

The question of how to handle conflicts of interest is not easily resolved. The proposed guidelines correctly recognize that such conflicts come in a variety of flavors. We have spoken to one scientist with considerable experience who believes that peer review can always be conducted while strictly observing a policy that tolerates no conflicts. We have spoken to others who argue that such a strict policy will make peer review less effective in many cases, and altogether impossible in a few. More importantly, a strict "no conflicts" policy in the context of a rulemaking would be fundamentally unfair, since those with an interest in a rulemaking must be permitted to participate in the scientific debate. In addition, a strict no-conflicts policy places an extraordinary burden on those who have to decide exactly what is, and is not, a material conflict. We come down, again, in favor of transparency through full disclosure of potential conflicts. Agencies should strive to assemble peer review panels that are as independent as practical, but should use disclosure, rather than exclusion, for dealing with most identifiable conflicts of interest.

Meeting the Daubert Standard

Our final point is to urge OMB and OSTP, in promulgating the proposed guidelines and monitoring their implementation, to strive for compatibility with the criteria set forth by the United States Supreme Court in *Daubert* v. *Merrell Dow*.[2] The court listed four criteria for the admissibility of expert testimony under the Federal Rules of Evidence:

(1) whether the methods upon which the testimony is based are centered upon a testable hypothesis;
(2) the known or potential rate of error associated with the method;
(3) whether the method has been subjected to peer review; and
(4) whether the method is generally accepted in the relevant scientific community.

A court would not be expected to apply the Daubert criteria during the review of an agency regulation, which would be governed by the Administrative Procedures Act and applicable case law. But the objective of the Daubert criteria—identifying sound and reliable science in the context of an adversarial proceeding—is essentially the same as the objective of the proposed guidelines. Moreover, at different times, the same scientific findings might be evaluated under the Daubert criteria and under the proposed guidelines. It seems reasonable to expect that the standard for what constitutes acceptable science in a rulemaking should not fall below what a court would find admissible in a civil suit.

[2] Daubert v. Merrell Dow Pharmaceuticals (92-102), 509 U.S. 579 (1993).