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To: omb_peer_review@omb.eop.gov
cc:
Subject: Comments of the NFIB Legal Foundation

<<05-28-04 Peer Review Guidelines with LH.doc>>

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05-28-04 Peer
Review Guideline...

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LEGAL FOUNDATION

*Protecting the Rights of
America's Small Business Owners*

May 28, 2004

Sent Via Electronic Mail

Dr. John Graham, Director
Office of Information and Regulatory Affairs
Office of Management and Budget, NEOB, Room 10235
725 17th Street, NW
Washington, D.C. 20503

Re: Comments on OMB's Revised Information Quality Bulletin for
Peer Review

Dear Dr. Graham:

The NFIB Legal Foundation is pleased to submit these comments on the Office of Management and Budget's "Revised Information Quality Bulletin on Peer Review" (hereafter referred to as the "revised Bulletin"). The revised Bulletin proposes a uniform method for conducting peer reviews at all federal agencies and outlines requirements for such reviews.

The NFIB Legal Foundation, a 501(c)(3) public interest law firm, is the legal arm of the National Federation of Independent Business (NFIB), which is the nation's oldest and largest organization dedicated to representing the interests of over 600,000 small-business owners throughout all 50 states. NFIB is very engaged in the federal regulatory process and has worked hard to reduce the regulatory burden on small business. NFIB has also worked to ensure that regulations are based on sound scientific principles and believes that a uniform peer review policy is an effective way to make the regulatory science more competent and credible.

The NFIB Legal Foundation appreciates OMB's recognition that effective peer review is critical to promoting high-quality science and fair regulatory policies. We recognize that peer-review is not a "magic bullet" when it comes to assuring the quality of scientific data it is part of an ongoing scientific process to that end. What proper peer review does do, however, is ensure that the data on which public policy decisions will be based has a degree of scientific validity, and that such a determination is made at an early stage in the determinative process. For example, had the science upon which the decision

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to lower threshold reporting requirements for lead under the Toxics Release Inventory been peer-reviewed before that decision was made, it likely would have been demonstrated to be invalid, and there would have been little (if any) justification for the new requirements. That the regulated community had to wait until after the rule was finalized for that review is simply not good public policy. It wastes the time and resources of both the government and the thousands of small-business owners who must comply with the rule.

OMB's issuance of peer review guidelines has done much to raise awareness of peer review's importance. We are, however, disappointed to find that some of the provisions contained in the proposed September 15, 2003 Bulletin have been removed from the revised Bulletin. In particular, we are concerned about changes that limit the scope of the strict mandatory Section III peer review guidelines and the decision to offer the agencies several exemptions, including an emergency waiver provision and an "alternative scientific procedure". As a result of these changes, and several others discussed below, the revised Bulletin provides agencies discretionary authority that threatens to undermine the credibility of the peer review process.

Currently, there are no government-wide standards concerning peer review and many federal agencies have no formal peer review policies at all. In-house reviews by federal agencies are inadequate, unbalanced and often reflect overt bias on the part of agency employees who serve as reviewers. Additionally, agency reviews have been limited in scope and failed to look broadly at how science supports major regulations. In response to these concerns, the revised Bulletin requires independent peer review for science that underlies significant federal regulations. While some federal agencies already conduct peer reviews of regulatory science, the new guidelines would establish agency-wide standards for peer reviews.

Although the revised Bulletin is an important step in establishing balanced peer review government-wide, we are disappointed with the amount of discretionary authority the revised Bulletin provides agencies. We believe that agencies may use these exceptions to avoid scrutiny of influential, but potentially controversial, regulatory policies.

First, we are concerned about OMB's decision to narrow the scope of revised Bulletin Section III to cover only "highly influential scientific assessments" (as opposed to all influential information proposed in the September 15, 2003 Bulletin) that have a \$500 million annual impact (as opposed to a \$100 million annual impact proposed in the September 15, 2003 Bulletin). We believe that the scope is too narrow. Federal agencies routinely issue regulations and policies that do not have a cost impact of \$100 million, much less \$500 million a year, yet they still contain many attributes that make them good candidates for peer review. For example, comments NFIB recently filed on the Office of Information and Regulatory Affairs' Draft Report of Congress on the Costs and Benefits of Regulation noted that, out of the 350 final rules published in the Federal Register in 2003, just over one-tenth (37) were considered "major" rules with a cost of \$100 million or more. Of those thirty-seven rules, only twelve were regulatory in nature (and only six of them had cost estimates). Raising the threshold for data quality to over \$500 million

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would realistically mean that only a handful of rules, per year, out of hundreds, would be subject to strict peer review standards.

Second, we are concerned about the emergency waiver provision that permits an agency to waive all of the peer review requirements of the revised Bulletin when warranted by a "compelling rationale". Without any guidelines for this waiver, we foresee instances wherein agencies may utilize this provision simply for expediency rather than because a true emergency exists. We are also disappointed to see that the revised Bulletin permits agencies to use alternative scientific procedures in lieu of peer-review procedures. Again, we foresee instances wherein agencies may utilize this provision simply for expediency rather than because the alternative scientific procedure will accomplish the same goals as a peer review.

Third, the revised Bulletin provides agencies greater flexibility in determining the type of information appropriately disclosed about the peer review process. For example, the revised Bulletin allows agencies to determine when comments of peer reviewers should be disclosed and when peer reviewers should deliberate in public. This flexibility is problematic, since we believe the credibility of the peer review process is greatly diminished if the peer review process is not transparent and disclosed to the public.

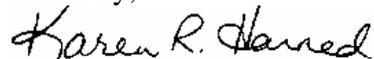
Fourth, we note that many regulations are never subject to peer review because agencies identify the rules as amendments to existing regulations. Nevertheless, these "amendments" often add new regulatory and paperwork burdens on small business. We respectfully request OMB use this opportunity to encourage agencies to perform some sort of review of amendments to existing regulations.

Conclusion

We appreciate the opportunity to comment on the revised Bulletin once again and to offer our comments on this important effort to improve federal regulatory policies through independent and objective peer review. Small business is heavily regulated by federal agencies, and federal regulations and policies impose significant costs. It is, therefore, imperative that federal regulations and policies are based on good science that supports accurate and balanced decisions.

Please do not hesitate to contact us if you require any additional information, or if you have any questions.

Sincerely,



Karen R. Harned, Executive Director
Elizabeth Gaudio, Staff Attorney
NFIB Legal Foundation