Government Relations Office
400 C Street, N.E.
Washington, DC 20002

John Fitch, Jr.
Phone: 202-547-0441
Fax: 202-547-0726
E-mail: jfitch@nfda.org

William Isokait
Phone: 202-547-0877
Fax: 202-547-0726
E-mail: wisokait@nfda.org

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National Funeral Directors Association

Dr. Margo Schwab
Office of Information and Regulatory Affairs
Office of Management and Budget
New Executive Office Building, Room 10201
725 17th Street, N.W.
Washington, D.C. 20503

Re: Office of Management and Budget Proposal for Peer Review and Information Quality (August 29, 2003)

Dear Dr. Schwab:

The National Funeral Directors Association (NFDA) represents more than 14,000 funeral homes in all 50 states. It is the leading funeral service organization in the United States, providing a national voice for the profession. The average NFDA member is an independently owned and operated business with fewer than 10 employees that has been in the same family for over 60 years. Most NFDA members provide services to families in small towns and cities with populations of less than 50,000.

NFDA members are subject to a wide variety of federal and state workplace safety and health and environmental regulations and have a great interest in the scientific and technical analysis used to support the ever-expanding regulatory burden on employers, particularly small businesses. The NFDA supports the Office of Management and Budget (OMB) proposal to issue new guidance requiring meaningful peer review of important science used to support federal regulatory initiatives.

Federal Courts and Scientific Validity

Federal courts have rejected "junk science" as a basis for establishing causation. The U.S. Supreme Court established the standard for the admission of scientific and medical expert testimony and evidence in *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993). *Daubert* and the cases that followed demand that scientific or medical evidence submitted to establish a link between a medical condition and an allegedly related incident or exposure must be based on recognized, generally accepted methodologies before it can be admitted into evidence. According to the Supreme Court, evidence that does not rise to this standard must be excluded from the record.

It is even more important that the science and technical analysis used to support federal regulatory initiatives be held to the same high standards. The effect of most judicial decisions is limited to the parties to the case. However, regulations typically apply to entire industries and often have significant direct and indirect economic impacts on the regulated community. Given the scale, potential costs and uncertain benefits of many regulatory initiatives, the NFDA believes that regulatory policy must be based on solid science, and agrees that this science must be objectively and independently evaluated. Following are NFDA comments on specific aspects of the OMB Bulletin.

Section 1. Definitions

The term "peer review" is used throughout the Bulletin. However, it is not defined. The NFDA recommends that the following definition of peer review be inserted after the term "major regulatory action." This definition is based on the discussion of the objectives and elements of peer review in pages 1 and 2 of the Bulletin.

> "Peer review" means a scientifically rigorous review and critique of methods, findings and conclusions of significant regulatory information which is conducted by a third party or parties who possess the requisite training, experience, expertise, objectivity and independence.

Section 2. Peer Review of Significant Regulatory Information

The NFDA agrees that federal agencies should conduct an appropriate and scientifically rigorous peer review on all significant regulatory information that the agency intends to disseminate.

The authority to regulate should not include the authority to promulgate and impose regulatory burdens for undocumented hazards. Small businesses are subject to many of the same regulatory mandates as the largest industries in this country. Environmental Protection Agency (EPA) waste handling and disposal regulations are an example. These regulations simply do not fit the nature and volume of waste that small businesses produce. They are extremely complex, difficult for small businesses to understand and apply, and result in exorbitant disposal costs for small amounts of waste.

The NFDA urges the OMB to revise the Bulletin to require federal agencies to specifically assess the impact upon small business of the information subject to peer review. Such an assessment is essential before the costs, benefits and efficacy of regulatory initiatives can be realistically evaluated.

Section 3. Additional Peer Review Requirements for Especially Significant Regulatory Information

Selection of Peer Reviewers

The OMB proposal specifies that "peer reviewers shall be selected primarily on the basis of necessary scientific and technical expertise." The NFDA believes that scientific and technical

expertise is the only basis upon which to select the reviewers of scientific and technical information. Any other criteria are irrelevant and will create the reliability weaknesses and appearance of conflict-of-interest issues that the OMB initiative is intended to eliminate. Such expertise is also essential to both identify conditions and practices needing regulation and to properly assess regulatory mandates for maximum effectiveness and minimum burden.

The NFDA is also concerned about peer reviews in which one industry is represented, but others with different perspectives are not. Peer reviewers should be free of any particular bias, agency or otherwise. In the real world it is often difficult to find reviewers who are sufficiently expert, current and familiar with the subject matter and are also free of associations that could create a conflict-of-interest. For this reason, in addition to information about connections to the agency initiating the review, the reviewing agency should acquire and disclose detailed information about the ties and backgrounds of peer review candidates as they relate to other organizations, institutions and industries with an interest in the issues to be reviewed.

The NFDA urges the OMB to revise the final Bulletin to specify that peer reviewers shall be selected exclusively on the basis of necessary scientific and technical expertise, as well as require disclosure of peer review candidates associations with organizations and institutions that have an interest in the issues to be reviewed.

The NFDA agrees that peer reviewers should be independent of the agencies that select them in order to maintain their objectivity. The NFDA does not believe that agency employees should serve on peer review panels. It is not realistic to expect agency employees to be completely objective about agency regulatory initiatives or the science underlying them and, again, it will create the appearance of conflicts-of-interest.

Charge to Peer Reviewers

The NFDA agrees that federal agencies should be required to provide peer reviewers with an explicit written charge describing the purpose and scope of the review, and the expertise required to perform it.

Information Access

The NFDA agrees that peer reviewers should be provided with the information necessary to understand the data, methods, results and conclusions of the material to be reviewed, as well as relevant background information on potential sources of controversy.

Opportunity for Public Comment

The NFDA agrees that interested parties should be provided with an opportunity to comment on the results of peer reviews before the reviewers prepare their final report.

Peer Review Reports

The NFDA agrees that peer reviewers should be directed to issue a final report and that the report should include the content specified in the OMB Bulletin.

Consultation With OIRA and OSTP

The NFDA agrees that agencies should consult with the Office of Information and Regulatory Affairs (OIRA) and Office of Science and Technology Policy (OSTP) concerning the sufficiency of their planned peer review policies. However, the NFDA believes that this consultation should be mandatory with respect to specific documents covered by the Bulletin, not "upon request" of the agency.

The consultative process should also require federal agencies to establish a realistic completion time line that includes the peer review procedure. This is necessary to ensure that a meaningful peer review can be performed while still complying with any applicable statutory or other deadlines.

Certification in Administrative Record

The NFDA agrees that agencies that rely on significant regulatory information should certify how they have complied with the requirements of the Bulletin.

The NFDA appreciates the opportunity to comment on the OMB Bulletin. Please include these comments in the record of the OMB proceedings on this matter.

Sincerely,

William A. Isokait

William A. Isokait
Director of Advocacy