

(OSTP), proposes to issue new guidance to realize the benefits of meaningful peer review of the most important science disseminated by the Federal Government regarding regulatory topics. The proposed bulletin would be issued under the authority of Section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Pub. L. 106-554; H.R. 5658); 44 U.S.C. 3504(d)(1), 3506(a)(1)(B); Executive Order No. 12866, as amended. Part I of the Supplementary Information below provides background and the request for comments. Part II provides the text of the proposed bulletin.

DATES: Interested parties should submit comments to the Office of Information and Regulatory Affairs (OIRA), Office of Management and Budget, at the address shown below on or before December 15, 2003.

ADDRESSES: Due to potential delays in OMB's receipt and processing of mail, respondents are strongly encouraged to submit comments electronically to ensure timely receipt. We cannot guarantee that comments mailed will be received before the comment closing date. Electronic comments may be submitted to:

OMB_peer_review@omb.eop.gov. Please put the full body of your comments in the text of the electronic message and as an attachment. Please include your name, title, organization, postal address, telephone number, and e-mail address in the text of the message. Comments may also be submitted via facsimile to (202) 395-7245. Comments may be mailed to Dr. Margo Schwab, Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW., New Executive Office Building, Room 10201, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Dr. Margo Schwab, Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW., New Executive Office Building, Room 10201, Washington, DC 20503 (tel. (202) 395-3093).

John D. Graham,

Administrator, Office of Information and Regulatory Affairs.

SUPPLEMENTARY INFORMATION:

Part I—Background and Request for Comment

A "peer review," as used in this document for scientific and technical information relevant to regulatory policies, is a scientifically rigorous review and critique of a study's methods, results, and findings by others in the field with requisite training and

expertise. Independent, objective peer review has long been regarded as a critical element in ensuring the reliability of scientific analyses. For decades, the American academic and scientific communities have withheld acknowledgement of scientific studies that have not been subject to rigorous independent peer review. Peer review "has been an essential part of the American science scene and one of the reasons why American science has done so well." Columbia University Provost Jonathon R. Cole (quoted in Abate, Tom, "What's the Verdict on Peer Review?" 21st Century, volume 1 (No. 1), Spring 1995, Columbia University); *see also* GAO Report, Peer Review Practices at Federal Science Agencies Vary, at 1 (March 1999) ("To help ensure the quality and integrity of the research, U.S. science has traditionally relied on independent reviews by peers.").

Independent peer review is especially important for information that is relevant to regulatory policies. Agencies often develop or fund the science that underlies their regulations, and then oversee the peer review of those studies. Unless the peer review is conducted with genuine independence and objectivity, this can create at least the appearance of a conflict-of-interest. For example, it might be thought that scientists employed or funded by an agency could feel pressured to support what they perceive to be the agency's regulatory position, first in developing the science, and then in peer reviewing it. Scientists with a financial interest in the subject matter of a study (*e.g.*, ties to a regulated business) face a similar issue. Given that genuinely independent and objective peer review can provide a vital second opinion on the science that underlies federal regulation, the peer review of such information should be carried out under proper and clearly-articulated procedures.

Scientists and government officials have recognized the importance of peer review in regulatory processes:

- Joint Presidential/Congressional Commission on Risk Assessment and Risk Management: "Peer review of economic and social science information should have as high a priority as peer review of health, ecological, and engineering information." Risk Assessment and Risk Management in Regulatory Decision-Making, vol. 2, at 103 (1997).

- The National Academies' National Research Council: "[B]enefit-cost analysis should be subject to systematic, consistent, formal peer review." Valuing Health Risks, Costs, and Benefits for Environmental Decision Making, at 207 (1990).

- Congress' General Accounting Office: "Peer review is critical for improving the quality of scientific and technical products * * *." GAO Testimony Before the House Subcommittee on Energy and Environment, Committee on Science, at 8 (Mar. 11, 1997).

- Sally Katzen, Former Administrator of OIRA: Scientific inferences "should pass muster under peer review by those in the same discipline, who should have an opportunity for such review to ensure that the underlying work was done competently and that any assumptions made are reasonable." Testimony Before the Environment, Energy, and Natural Resources Subcommittee of the House Committee on Government Operations (Feb. 1, 1994).

In addition, many bipartisan legislative proposals have supported independent, external peer review. *See, e.g.*, S. 343, the "Comprehensive Regulatory Reform Act of 1995;" S. 1001, the "Regulatory Procedures Reform Act of 1995;" S. 291, the "Regulatory Reform Act of 1995;" H.R. 1022, the "Risk Assessment and Cost-Benefit Act of 1995." In 1999, for instance, a bipartisan coalition (including Senators Frist and Daschle, among many others) proposed to require agencies to conduct genuinely independent and transparent peer reviews of their most important risk assessments and cost-benefit analyses. *See* S. 746, the "Regulatory Improvement Act of 1999."¹

Existing agency peer review mechanisms have not always been sufficient to ensure the reliability of regulatory information disseminated or relied upon by federal agencies. While most agencies have policies that require or encourage peer review, they do not always conduct peer review according to their own policies—even for major rulemakings. Indeed, an agency Inspector General recently found that although one agency had issued extensive agency peer review policies and mandates, "[t]he critical science supporting the [agency's] rules was often not independently peer reviewed. Consequently, the quality of some science remains unknown." EPA OIG, Science to Support Rulemaking, at ii (Nov. 15, 2002) (emphasis supplied).

Even when agencies do conduct timely peer reviews, such reviews are sometimes undertaken by people who

¹ This legislative proposal was sponsored by a bipartisan coalition of 21 Senators, including Senators Levin, Thompson, Daschle, Frist, Moynihan, Voinovich, Stevens, Rockefeller, Abraham, Breaux, Roth, Robb, Cochran, Lincoln, and Enzi.