

**Congress of the United States**  
**House of Representatives**  
**Washington, DC 20515**

May 26, 2004

The Honorable Joshua Bolten  
Director  
The Office of Management and Budget  
725 17<sup>th</sup> Street, NW  
Washington, DC 20503

Dear Mr. Bolten:

In December several of us wrote expressing a number of concerns about the proposed Peer Review Guidelines. We indicated that the proposal was unjustified, overly broad, burdensome, and did not appropriately guard against appointment of reviewers with conflicts of interest. We also expressed our concern that the proposal provided the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (OMB) with excessive authority over the production and dissemination of government information. The revised proposal does not address these concerns.

In our view, the revised guidelines do not strengthen peer review policies across the federal government. Instead they invite politicization of science at federal agencies by placing control over the development and dissemination of federal information in a policy office -- OIRA. The proposal is not tailored to ensure that the more rigid peer review requirements imposed by this Bulletin are restricted to "the more important information disseminated by the federal government." These procedures will obstruct the dissemination of agency information, particularly in matters related to public health and safety and the environment.

The proposal continues to grant OIRA excessive authority over the development and dissemination of agency work products. The proposal remains unjustified, overly broad, and burdensome. Despite the addition of language indicating that agencies may be permitted some flexibility in applying the criteria established in the Bulletin, we still believe the prescribed structure is too rigid and inflexible to permit agencies to tailor peer reviews to individual information products they produce. The proposal still does not safeguard the established review process from manipulation by special interests.

We do note that the adoption of some of our recommendations and some of the recommendations of the scientific community has resulted in an improved draft. In particular, we support the exemption for time-sensitive medical, health and safety information. The elimination of the restriction on the ability of federally-funded scientists to serve as peer reviewers of agency information also represents an improvement.

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However, these modifications do not address our major concerns with the proposal. We continue to believe the proposal is unjustified and burdensome. The proposal should be withdrawn or substantially revised to maintain agency authority over the development and review of information.

Our comments on specific problems with the revised guidelines follow.

*The Proposal Remains Unjustified*

The proposal states: "A large variety of authorities have argued that peer review practices at federal agencies need to be strengthened." This statement is not supported by any recent assessment of peer review practices at federal agencies. If OIRA or the Office of Science and Technology Policy (OSTP) undertook such a review in the development of this Bulletin, the summary document and its findings have not been cited or discussed in the justification of the Bulletin.

In addition, none of the studies cited in footnotes 4, 5, 6 and 7 of the Bulletin provide justification for any such broad-based statement. These references do not provide the background to support the need for this Bulletin or for the establishment of agency peer review policies by OIRA. Six of the ten studies cited are five or more years old.<sup>1</sup> The four recent studies neither survey nor assess federal agency peer review processes.<sup>2</sup> The 2002 GAO study on the Endangered Species Program does not address peer review policies used in that program at all. The 2001 GAO study of EPA's Science Advisory Board (SAB) addressed issues related to the selection of reviewers serving on SAB panels. EPA has since altered its policies and now utilizes an appointment process similar to that of the National Academy of Sciences.

The continued citation of 2002 report on a pilot study by EPA's Office of the Inspector General is troubling. This report is an obvious example of something that would never have withstood peer review as a representative study. The Report states: "The rules included in the pilot study were not a representative statistical sample of EPA rules, and we did not identify all of the critical science inputs for every rule."<sup>3</sup> This study provides no justification for altering EPA's peer review procedures.

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<sup>1</sup> U.S. General Accounting Office, Federal Research: Peer Review Practices at Federal Agencies Vary, GAO/RCED-99-99, Washington, D. C., 1999; Carnegie Commission on Science, Technology, and Government, Risk and the Environment: Improving Regulatory Decision-Making, Carnegie Commission, New York, 1993; National Academy of Sciences, Peer Review in the Department of Energy—Office of Science and Technology, Interim Report, National Academy Press, Washington, D.C., 1997; National Academy of Sciences, Peer Review in Environmental Technology Development: The Department of Energy – Office of Science and Technology, National Academy Press, Washington, D. C., 1998; Carnegie Commission on Science, Technology, and Government, In the National Interest: The Federal Government in the Reform of K-12 Math and Science Education, Carnegie Commission, New York, 1991; National Research Council, Science and Judgment in Risk Assessment, National Academy Press, Washington, D. C., 1994.

<sup>2</sup> National Academy of Sciences, Strengthening Science at the U.S. Environmental Protection Agency: Research-Management and Peer Review Practices, National Academy Press, Washington, D.C., 2000; U.S. General Accounting Office, EPA's Science Advisory Board Panels: Improved Policies and Procedures Needed to Ensure Independence and Balance, GAO-01-536, Washington, D.C., 2001; U.S. Environmental Protection Agency, Office of Inspector General, Pilot Study: Science in Support of Rulemaking 2003-P-00003, Washington, DC, 2002, U.S. General Accounting Office, Endangered Species Program: Information on How Funds Are Allocated and What Activities are Emphasized, GAO-02-581, Washington, D.C., 2002.

<sup>3</sup> U.S. Environmental Protection Agency, Office of Inspector General, Pilot Study: Science in Support of Rulemaking 2003-P-00003, Washington, DC, 2002. (p. 10).

The 1998 and 1999 studies of DOE's Office of Science and Technology (OST) done by the National Academy of Sciences (NAS) found that OST had made "significant improvements in its peer review process since the program began in October 1996."<sup>4</sup> The NAS study of EPA's Science done in 2000 contains recommendations that management of peer review be separated from the management of a document's production.<sup>5</sup> No recommendation suggests that management of the peer review process should be separated from the agency. The report cites a Science Advisory Board study attributing improvements in EPA's peer review policy to greater involvement of EPA's Office of Research and Development in the peer review process.<sup>6</sup>

Neither of the Carnegie Commission reports cited provide justification for an OIRA-managed, uniform federal peer review policy. The report on math and science education has little to say about peer review even in the Department of Education and the National Science Foundation, the two federal organizations addressed in the report.<sup>7</sup>

The Carnegie Commission report on Improving Regulatory Decision-making contains minimal reference to peer review. It does not contain any recommendation for oversight of agency peer review policies by OIRA. In fact, the report contains a chapter devoted to regulatory review procedures in the Executive

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<sup>4</sup> National Academy of Sciences, Peer Review in Environmental Technology Development: The Department of Energy – Office of Science and Technology, National Academy Press, Washington, D. C., 1998. "The committee finds that OST has made significant improvements in its peer review process since the program began in October 1996. Throughout the committee's study, OST has continued to change its peer review procedures in an effort to improve the program's effectiveness. In particular, OST has revised its review criteria to focus on technical issues, has developed a more systematic approach for selecting projects to be reviewed, and has modified its list of required documentation for the peer reviews. OST also has made a number of policy changes since this committee issued its interim report in October 1997 (see Table I and the main body of this report for more details on these policy changes). Although in many cases it is too early to judge the actual results of these changes, the committee is encouraged that OST senior management appears to be committed to this improvement process." (p.6)

<sup>5</sup> National Academy of Sciences, Strengthening Science at the U.S. Environmental Protection Agency: Research-Management and Peer Review Practices, National Academy Press, Washington, D.C., 2000. "Change the agency's peer-review policy to more strictly separate the management of the development of a work product from the management of the peer review of that work product, thereby ensuring greater independence of peer reviews from the control of program managers, or the potential appearance of control by program managers, throughout the agency." (p. 145)

<sup>6</sup> *ibid.* The SAB "praised the Agency's diligence and high-level management commitment to peer review." (p.120). Significantly, the SAB also concluded that "the key to success in implementing the peer review process has been the involvement of ORD [Office of Research and Development] in the oversight role, and that 'ORD scientists have an understanding of the importance of peer review in developing good scientific and technical products'" (p.123).

<sup>7</sup> Carnegie Commission on Science, Technology, and Government, In the National Interest: The Federal Government in the Reform of K-12 Math and Science Education, Carnegie Commission, New York, 1991. The report does not provide an assessment of federal peer review policies. The report refers to the peer review policies of NSF favorably. The report states: "NSF accesses the best research capabilities in the nation, including cognitive science and learning research that should inform strategies for educational improvement. It is experienced in running competitive programs to support the best ideas arising outside the government and has an excellent reputation for integrity, technical sophistication, and the use of peer judgment in program selection."

Office of the President – some of which is critical of past Administrations that utilized regulatory review to stifle legitimate agency actions.<sup>8</sup>

Your proposal asserts that more widespread use of peer review will result in fewer legal challenges to federal regulations. This is an assertion with no basis in experience. The EPA rule establishing a National Air Quality Standard for fine particulate matter<sup>9</sup> included an extensive amount of information that was peer reviewed. The criteria documents synthesized information from hundreds of peer reviewed published studies.<sup>10</sup> The criteria documents themselves were subject to peer review by the Clean Air Scientific Advisory Committee.<sup>11</sup> The epidemiological studies referenced in the rule were peer reviewed, audited, and re-analyzed by the Health Effects Institute<sup>12</sup>. The rule was still challenged. Effected parties bring legal challenges because they wish to block or initiate regulatory activity to achieve a desired policy outcome. Peer review will not resolve divergent policy preferences. It is unreasonable to expect science to resolve policy differences.

In summary, OIRA cannot provide any current analysis that identifies any systemic problem with peer review processes at federal agencies. The revised Bulletin provides no estimate of the potential scope and cost of the proposed changes. OIRA should hold its initiatives to the same standard it applies to federal agencies. The government should not adopt costly new procedures without estimating the costs and without clearly demonstrating that such policies are needed to address an identified problem.

### *Unbalanced Approach to Federal Information Review*

The revised proposal has reduced the scope of information subject to the review procedures mandated by the Bulletin. This has been accomplished through the use of exemptions, leaving unbalanced application of mandated review of federal information.

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<sup>8</sup> Carnegie Commission on Science, Technology, and Government, Risk and the Environment: Improving Regulatory Decision-Making, Carnegie Commission, New York, 1993. Chapter 3: The Executive Office of the President: Policy Formulation and Regulatory Review.

<sup>9</sup> National Ambient Air Quality Standards for Particulate Matter; Final Rule. Federal Register July 18, 1997, Vol. 62, No. 138: 38651-38701.

<sup>10</sup> Air Quality Criteria for Particulate Matter (Criteria Document), EPA/600/P-95-001aF through EPA/600/P-95-001cF, April 1996.

<sup>11</sup> U.S. EPA, Clean Air Science Advisory Committee, Closure by the CASAC on the Draft Air Quality Criteria for Particulate Matter, EPA-SAB-CASAC-LTR-96-005, 1996, U.S. EPA Clean Air Science Advisory Committee, Closure by the Clean Air Scientific Advisory Committee on the Staff Paper for Particulate Matter, EPA-SAB-CASAC-LTR-96-08, 1996; U.S. EPA Clean Air Science Advisory Committee, CASAC Closure on the Air Quality Criteria for Ozone and Related Photochemical Oxidants, EPA-SAB-CASAC-LTR-96-001; U.S. EPA Clean Air Science Advisory Committee, CASAC Closure on the Primary Standard Portion of the Staff Paper for Ozone, EPA-SAB-CASAC-LTR-96-002.

<sup>12</sup> Health Effects Institute, Reanalysis of the Harvard Six Cities Study and the American Cancer Society Study of Particulate Air Pollution and Mortality, A Special Report of the Institute's Particle Epidemiology Reanalysis Project. Final version, July 2000.

Information related to public health, safety and the environment continues to be subject to the prescriptive peer review approach mandated by the Bulletin. Information related to economic, tax, trade, and national security policy is exempt from this policy, despite its significant impact on government and private expenditures and its importance to policy-making. Information supporting the entry of products into the marketplace is exempt. Information supporting the removal of products from the marketplace that endanger health and safety is covered unless emergency powers are invoked. This pattern of exemptions does not conform to the stated purpose of the Bulletin to promote more uniform review procedures for information of similar import to public policy.

The broad nature of exemptions numbered 1, 6, and 7 would permit different levels of review and public scrutiny to be applied to information generated by different federal agencies on the same topic. For example, it is clear that any information produced by EPA will be subject to this Bulletin, while much, if not all, information produced by the Department of Defense (DOD) will be exempted because it is “*related to national security.*” (emphasis added)

Currently, DOD and EPA hold differing views of the human health risk of perchlorate in drinking water. DOD and EPA each have produced information to support their view. There is no assurance under this policy that information produced by DOD will be subject to the same review and public scrutiny as the information produced by EPA. There is also no assurance EPA’s information already produced under a more transparent and public process will be given deference in setting policies related to standards for perchlorate in drinking water or to set clean up standards for contaminated areas.

The scientific community undoubtedly welcomes the exemption for information produced by government-funded scientists using extramural or intramural funds from federal agencies. This is a useful exemption that will continue to permit scientists to disseminate their findings to their colleagues and to the public.

However, we note this exemption only holds “if those information products are not represented as the views of a Department or agency.” If a journal article were to be cited as part of an agency document synthesizing information from multiple journal articles or combining agency-generated information with work produced through extra-mural funding, it may be subject to the review procedures mandated by the Bulletin. The articles on the health effects of particulate matter published by researchers at Harvard University and by researchers at the American Cancer Society<sup>13</sup> provide such an example. An author producing information for public distribution has no control over the ultimate use of this information by federal agencies or other organizations. OIRA may insist, even over the objection of the agency, that a peer reviewed journal article should also be reviewed under the procedures required by the Bulletin if the work is utilized to develop and implement policy.

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<sup>13</sup> Dockery, D.W., C. A. Pope, III, X. Xu, J.D. Spengler, J. H. Ware, M. E. Fay, B. G. Ferris, Jr., and F.E. Speizer, An Association Between Air Pollution and Mortality in Six U.S. Cities, *New England Journal of Medicine*, Vol. 329: 1753-1759 (December 9) 1993; Pope, III, C. A., M. J. Thun, M. M. Namboodiri, D. W. Dockery, J. S. Evans, F. E. Speizer, and C. W. Heath, Jr., Particulate Air Pollution as a Predictor of Mortality in a Prospective Study of U. S. Adults, *American Journal of Respiratory and Critical Care Medicine*, Vol. 151: 669-674, 1995.