Winifred DePalma <wdepalma@citizen.org>
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To: OMB_peer_review@omb.eop.gov

cc:

Subject: Public Citizen's Comments to Revised Bulletin on Peer Review

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Joan Claybrook, President

May 28, 2004

Dr. Margo Schwab
Office of Information and Regulatory Affairs
Office of Management and Budget
NEOB Room 10201
725 17th Street, NW
Washington, DC 20503
OMB_peer_review@omb.eop.gov

Re: Revised Information Quality Bulletin on Peer Review

Dear Dr. Schwab:

Public Citizen is a public interest organization with 160,000 members nationwide. For 33 years, Public Citizen has represented consumer groups, labor unions, and public health organizations in standard-setting proceedings and in litigation involving numerous federal regulatory agencies. We submitted comments to the original Proposed Bulletin on Peer Review[1] and now respond to the request for comments to the Revised Draft Bulletin published in the Federal Register on April 28, 2004.[2]

In revising the bulletin, the Office of Information and Regulatory Affairs (OIRA) has moderated those elements of the original proposal which provoked strong opposition from the scientific and academic communities and attracted widespread unfavorable attention from the media. The Revised Draft Bulletin no longer establishes overt political control over agencies' release of emergency health and safety information to the public or brands all publicly-funded researchers as biased, with no comparable stigma applied to industry-funded scientists.

However, the revisions do not go far enough to shield federal administrative activity from political interference and industry pressure or to protect against dangerous delay in developing needed new safeguards. The Revised Draft Bulletin continues to suffer from the following serious defects:

- No need has been shown for a costly and burdensome across-the-board process;

[1] "Proposed Bulletin on Peer Review and Information Quality," (Original Draft Bulletin), 68 Fed. Reg., 54023 (September 15, 2003).
[2] "Revised Information Quality Bulletin on Peer Review," (Revised Draft Bulletin), 69 Fed. Reg. 23230.

- The Revised Draft Bulletin still exhibits unjustified hostility toward publicly-funded scientists and inadequate concern regarding pro-industry conflicts of interest;
- Different review standards still apply depending on whether or not industry wants the government to act;
- Application of the peer review procedures is still determined by a political entity rather than the agency that has the relevant expertise and legal mandate;
- The revision worsens the problems of insufficient transparency and lack of public accountability of the Original Draft Bulletin; and
- The Revised Draft Bulletin will inevitably lead to delay in protecting public health, safety and the environment.

Moreover, the Revised Draft Bulletin broadens the coverage of agency information to reach "facts" as well as studies, and adds international trade and financial information to the categories exempt from review due to what appears to be mere political expedience and industry convenience.[3] In short, this bulletin is a colossal waste of agency and government time and resources, and no evidence of its merit or cost-effectiveness has been presented, and it should be totally abandoned.

No Need Has Been Shown For a Costly and Burdensome Across-the-Board Process.

A number of participants at a 2003 National Academy of Sciences (NAS) workshop on the original Draft Peer Review Bulletin,[4] and many of those who filed written comments, pointed out that OIRA has not provided a single example of flawed agency science that would have been improved by the proposed procedures. Faced with this critical questioning of the need for a systemwide peer review process, OIRA has again failed to produce any examples of inaccurate scientific information used by federal agencies.

The Revised Draft Bulletin Still Exhibits Unjustified Hostility Toward Publicly-Funded Scientists and Inadequate Concern Regarding Pro-Industry Conflicts of Interest.

Where the Original Draft Bulletin characterized receipt of substantial funding from an agency, but not from a regulated industry, as a factor relevant to a potential panel member's bias, independence, or conflict of interest,[5] the Revised Draft Bulletin draws a distinction between grants that are awarded on the basis of "investigator-initiated, competitive, peer-reviewed proposals," which are not considered to raise issues of conflict or independence, and all other forms of public funding.[6] By implication, the many scientists whose public research funding is

[3] Although national security and foreign affairs appear now to be exempt only if "compliance with the Bulletin would interfere with the need for secrecy or promptness," we renew our objections to exemption of these catetgories of information. 69 Fed. Reg. at 23241. If peer review enhances the quality of science, secrecy should not be grounds for exemption, and disseminations that are legitimately time-sensitive should be reviewed as soon as practicable.

[4] "Peer Review Standards for Regulatory Science and Technical Information," Science, Technology, and Law Program, The National Academies, November 18, 2003.

[5] Original Draft Bulletin, 68 Fed. Reg., at 54027.

[6] Revised Draft Bulletin, 69 Fed. Reg. at 23241.

provided through other means, such as cooperative agreements or contracts, are still stigmatized as biased. Moreover, there are no comparable criteria for assessing independence or absence of conflicts of interest on the part of researchers who receive funding from regulated industries, where the conflict of interest is most compelling. Universities and journals that have considered the implications of corporate-sponsored research have identified elements of such relationships that might lead to competing loyalties, conflicts of interest and/or compromised independence, such as a sponsor's involvement in study design, limitations on a researcher's access to all of the study data, or sponsor's control over when or whether research results can be published.[7] Potential panelists should be required to disclose the terms of any corporate-sponsored research and to affirm the absence of any constraint on their independent assessment and disclosure of scientific information. If OIRA proceeds with imposition of government-wide peer review procedures, we request that the following provisions be added to Section III. 2. Selection of Reviewers:

- The agency shall bar participation by any scientist who is bound by a confidentiality agreement that relates to disclosure of scientific information relevant to the review.

- Receipt of research funds from a private entity that would be affected by the subject matter of the review necessarily raises issues as to lack of objectivity and conflicts unless the researcher has absolute control over the study design of the research, has access to all of the study data, and has absolute control over dissemination of the results and conclusions of the research. In the absence of these showings, the researcher should be barred from participation.

In addition, by beginning the section on "Conflicts" with instructions for handling participation by scientists who have conflicts of interest,[8] the Revised Draft Bulletin appears to be condoning the appointment of such scientists. OIRA should instead make it clear that appointment of scientists who have conflicts of interest is prohibited, except in those limited circumstances in which their participation is legally permitted, and should further direct the agencies to conform to the public disclosure practices mandated by the Federal Advisory Committee Act for the NAS in managing a confict when it is unavoidable.[9] Accordingly, if OIRA proceeds with imposition of government-wide peer review procedures, we request that the following provision be added:

- No individual who may have a conflict of interest shall be appointed to serve as a peer reviewer unless the agency determines that the appointment does not create undue

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[7] See, for example, Columbia University, Faculty Handbook, Appendix H, "Regulations Governing Externally Funded Research and Instruction," accessed May 26, 2004, http://www.columbia.edu/cu/vpaa/fhb/app/app_h.html; International Committee of Medical Journal Editors, "Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication, Conflicts of Interest," accessed May 26, 2004, http://www.icmje.org/index.html#conflicts.

[8] 69 Fed. Reg. at 23240.

[9] 18 U.S.C. §208(b)(3); 5 U.S.C. App. 2, §15 (b)(1); The National Academies, "Policy on Committee Composition and Balance and Conflicts of Interest," May 12, 2003. See, also the Food and Drug Administration's "Draft Guidance on Disclosure of Conflicts of Interest for Special Government Employees Participating in FDA Product Specific Advisory Committees," 67 FR 6545 (February 12, 2002).

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imbalance in the overall composition of the committee and the need for the reviewer's expertise outweighs the potential danger posed by the conflict of interest, in which case the conflict of interest shall be publicly disclosed sufficiently in advance of the appointment to give the public a reasonable opportunity to comment.

Different Review Standards Still Apply Depending on Whether or Not Industry Wants the Government to Act.

With its complete exemption for adjudications and permit applications,[10] the Original Proposed Bulletin highlighted the pro-industry bias of the peer review proposal. When industry sought government action on its behalf, industry science needed no review, but when industry wanted to be able to block or delay government imposition of a regulatory constraint, peer review of the government's science would be required. The Revised Draft Bulletin lessens this disparity by creating an exception to the exemption for adjudications, licensing and permit proceedings, if they involve disseminations that are scientifically or technically novel and likely to have precedent-setting influence. However, it is not clear whether the distinction between influential information and highly influential assessments applies or how one would calculate the impact of a drug approval or a permit to use a pesticide.

While the revision to the exemption is positive, it immediately raises a basic question. If peer review is necessary and/or useful to the government's assessment of industry applications only if the applications involve information that is scientifically or technically novel - why is there a different standard for mandatory peer review of government science? If OIRA proceeds with imposition of government-wide peer review procedures, we request that the procedures apply only to disseminations that are scientifically or technically novel and complex.

Application of the Peer Review Procedures is Still Determined by a Political Entity Rather than the Agency that Has the Relevant Expertise and Legal Mandate.

Although the Revised Draft Bulletin raises the level at which the more prescriptive "additional peer review requirements" apply from a $100 million impact on the private sector to a $500 million effect, the OIRA Administrator can require that any information be subjected to the heightened procedures, either by overruling an agency's finding that the $500 million threshold amount is not met, or by classifying the information as having "significant interagency interest." Thus, OIRA inappropriately maintains its potential control over virtually all agency disseminations.

Furthermore, the new section on "Alternative Procedures" that has been added to the Revised Draft Bulletin places authority to approve an alternative scientific procedure or process in the hands of a non-scientific entity, OIRA.

The Revised Draft Bulletin Worsens the Problems of Insufficient Transparency and Lack of Public Accountability of the Original Draft.

[10] Original Draft Bulletin, 68 Fed. Reg. at 54027.

As in the Original Draft Bulletin, there is no requirement that information about panel members' funding sources and potential conflicts of interest be disclosed to the public.[11] In addition, the Revised Draft Bulletin now countenances withholding reviewers' names from the public and directs agencies to balance the need for transparency with the "need to protect the privacy of scientists."[12] Scientists who participate in the review of agency science are performing a public function and can have no reasonable expectation of privacy.

OIRA also instructs agencies to consider conducting confidential peer review "when premature disclosure of a sensitive report to a public panel could cause harm to governmental or private interests" or when "an assessment may be so sensitive that it is critical that it achieve a high level of quality before it is publicized."[13]

Timely disclosure of reviewers' identities, qualifications, and potential sources of conflict and bias is essential in order for the public to monitor the functioning of government and take action when necessary to ensure that agencies carry out their statutory mandates.

The Revised Draft Bulletin Will Inevitably Lead to Delay in Protecting Public Health, Safety and the Environment.

In its summary of comments on the Original Draft Bulletin, OIRA acknowledges that many commenters pointed out that there was no cost/benefit analysis of the Bulletin itself and expressed concern that the proposed peer review procedures would cause delays in regulatory decision-making. In response, OIRA provides estimates of financial outlays running from $5,000 to over $1 million and of time delays ranging from two weeks to over two years.[14] OIRA then directs agencies to assess the "cost" of delay by using a form of analysis that gives equal weight to a dollar of compliance costs paid by a company and to a dollar's worth of averted harm ("monetized benefits").[15] Not only does this cynical calculus make totally unwarranted assumptions of accuracy in quantifying and monetizing costs and benefits,[16] but it betrays a refusal to accept the premises behind federal health, safety, and environmental statutes and the rightful claims of their intended beneficiaries. Is OIRA willing to tell Congress that the laws it

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[11] See, by contrast the FDA's "Draft Guidance on Disclosure of Conflicts of Interest for Special Government Employees Participating in FDA Product Specific Advisory Committees," 67 FR 6545 (February 12, 2002), which, though imperfect, does require public disclosure of panel members' financial conflicts.

[12] 69 Fed. Reg. at 23236.

[13] Id., at 23234 and 23237.

[14] "Summary of Public and Agency Comments on Proposed Bulletin on Information Quality and Peer Review, Including Responses by OMB." April 15, 2004, p. 11-12.

[15] Under this type of analysis, the "cost" of a two year delay in regulating a harmful chemical, for example, would not be the total needless death and suffering that result from two year's additional exposure, but rather the dollar amount that can be assigned to the death (and nothing for the suffering) minus the cost savings realized by the chemical company in not having to stop harming the public for another two years.

[16] See, for example, Office of Management and Budget, "Informing Regulatory Decisions: 2004 Draft Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities, "February, 2004, p. 3., in which OIRA admits that "monetized" costs and benefits could be calculated for only half of the year's social regulations; in many instances, agencies were unable to quantify all benefits and costs and the monetized estimates that OMB presents necessarily exclude the unquantified benefits; and the benefits of a reduced risk of terrorism have proven very difficult to quantify and monetize.

enacts will be considerably delayed by this process, and to be up-front about its unwarranted interference in Congressional priorities and deadlines for rulemaking?

Conclusion

Testifying before the House Government Reform Committee last July, OIRA Administrator John D. Graham disclosed a "strategy of trying to induce more sound science as a check on regulatory power" and said "[w]e have to have more science and peer review check from the outside community on the power at agencies …"[17] This fundamentally inappropriate use of "peer review" - to "check" the power of regulatory agencies - reveals the obstructionist intent behind the proposal.

The hypocrisy and reach of the revised proposal remain stunning: OIRA, with little scientific expertise, is demanding more so-called "science" by highly scientific agencies and yet itself frequently demands substantive changes in science-based rules without basis in fact, such as in the rule regarding tire pressure monitoring systems, which had to be contested in court, and in which three federal Court of Appeals judges concurred with Public Citizen that OMB's efforts to weaken the standard were illegitimate and contrary to the record. OIRA's meddling with substantive agency duties to implement public safeguards enacted by Congress must stop.

Sincerely,
Joan Claybrook
President

Peter Lurie, MD, MPH
Deputy Director
Public Citizen's Health Research Group

Winifred De Palma
Regulatory Affairs Counsel
Public Citizen's Congress Watch

[17] H.R. 2432, Paperwork and Regulatory Improvements Act of 2003, July 22, 2003 Transcript, pp. 17 and 41.