



Center For Progressive Regulation
P. O. Box 218
Riderwood, MD 21139
www.progressiveregulation.org

Board of Directors

Thomas McGarity
Sidney Shapiro
Rena Steinzor
Lisa Heinzerling
Christopher Schroeder

Sidney A. Shapiro
785 864-9222
sshapiro@ku.edu

May 27, 2004

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

Re: Revised Information Quality Bulletin on Peer Review

Dear Dr. Schwab:

OMB has proposed a revised Bulletin that would supplement existing procedures under the Information Quality Act (IQA)¹ by requiring peer review of regulatory information and by specifying the procedures under which that review would take place.² OMB obviously has listened to its many critics. It has made substantial improvements in its proposed Bulletin, particularly in the areas of financial conflicts of interest, bias and independence. OMB has also made an effort to reduce the burden of imposing peer review on agencies, but the proposed Bulletin is still too broad. In addition, the Bulletin permits agencies to engage in secret and unbalanced peer review.

The Center for Progressive Regulation (CPR) appreciates the opportunity to comment on these proposals. We incorporate those of our earlier comments to which OMB has not responded in its revised policy.³

CPR is an organization of academics specializing in the legal, economic, and scientific issues that surround health, safety, and environmental regulation. As our website indicates, www.progressiveregulation.org, CPR's mission is to advance the public's understanding of the issues addressed by the country's health, safety and environmental laws and to make the nation's response to health, safety, and environmental threats as effective as possible. The Center is committed to developing and sharing knowledge and information, with the ultimate aim of preserving the fundamental value of the life and health of human beings and the natural

¹ Treasury and General Appropriations Act for Fiscal Year 2001, Pub. L. No. 106, § 515 (2001).

² Revised Information Bulletin on Peer Review, 69 Fed. Reg. 23230 (2004).

³ Letter to Dr. Margo Schwab from CPR (Dec. 7, 2003).

environment. CPR circulates academic papers, studies, and other analyses that promote public policy based on the multiple social values that motivated the enactment of our nation's health, safety and environmental laws. CPR seeks to inform the public about scholarship that envisions government as an arena where members of society choose and preserve their collective values. We reject the idea that government's only function is to increase the economic efficiency of private markets.

The Center also seeks to provoke debate on how the government's authority and resources may best be used to preserve collective values and to hold accountable those who ignore or trivialize them. We seek to inform the public about ideas to expand and strengthen public decision-making by facilitating the participation of groups representing the public interest that must struggle with limited information and access to technical expertise.

SUMMARY

- Because scientific journals use a form of peer review for publications, OMB erroneously assumes that the government should use some form of peer review to verify any information that might influence some member of the public. Even if peer review is useful to journal editors, the goals of scientific publication and sound governance are simply not the same thing.
- OMB permits agencies to keep secret from the public the names and affiliations of peer reviewers of “influential” scientific information. This practice is not only antithetical to the principle of public accountability; it makes it impossible for the public to know whether agencies are complying with OMB’s requirements concerning independence and conflicts-of-interest. OMB requires agencies to disclose the names and affiliations of peer reviewers in the peer review of “highly influential” scientific assessments, and it should have the same requirement for “influential” scientific information. Moreover, OMB should require that this disclosure be made at the beginning of the peer review process rather than at the end in both situations.
- OMB does not require agencies to obtain “balanced” peer review of “influential” scientific information. While OMB discusses the importance of balanced review in its preamble, there is no such express requirement in the language of its proposed Bulletin. The absence of such a requirement is particularly troublesome in light of the fact that agencies are permitted to keep the identities and affiliations of reviewers secret. OMB does have an express requirement for balance in the peer review of “highly influential” scientific assessments. OMB should have the same requirement for “influential” scientific information.
- OMB continues to use as a trigger for peer review whether or not the dissemination of the information is likely to have a clear and substantial impact on the public, regardless whether the information is unreliable or whether peer review is necessary to ensure its objectivity. Since OMB requires agencies to seek outside scientific advice on such a broad basis, it obviously distrusts agency scientists to undertake the job of evaluating scientific information. OMB, however, fails to reveal the source of this distrust. We see

no basis to prevent an agency from issuing a document on the basis of the advice of its own scientists unless the scientific assessment to be disseminated sets a new precedent or is reasonably controvertible.

- OMB increases the breath of its peer review requirement in this draft by including “factual inputs” and “data” in the category of influential information. OMB has properly limited the category of “highly influential” information to “scientific assessments” only, and it should do the same for “influential” information. Requiring review of every factual input and piece of data that could have a substantial impact on the public casts the peer review net too broadly and will create endless delays.
- While OMB insists on peer review in rulemaking whether or not the scientific information is novel or controversial, it exempts scientific information disseminated in the course of an individual agency adjudication or permit proceeding unless it is novel or controversial. CPR does not understand why OMB has different tests as to when peer review is required for rulemaking and for adjudication. In fact, peer review is more necessary in adjudication because information receives less scrutiny and because it is submitted by regulated industries, which obviously can impact the impartiality of the information
- As related in our previous comments, CPR maintains that OMB lacks the legal authority to impose peer review on agencies in light of Congress’ express refusal to give OMB that authority. We also continue to maintain that the Information Quality Act does not apply to rulemaking or adjudication, which means that OMB cannot cite the IQA as authority for imposing peer review in those contexts.

SECRET PEER REVIEW

OMB usefully gives agencies considerable discretion to design procedures for the peer review of “influential scientific information” to reflect the tradeoff between timeliness and the depth of peer review, requiring only that peer review is characterized by both “process” and “scientific” integrity.⁴ OMB, however, goes too far when it gives agencies the discretion to conduct secret peer review.

OMB authorizes agencies to keep the names and affiliations of reviewers confidential.⁵ The justification is that scientific journals keep reviewers’ identities secret in order to encourage candid comments and promote the participation of qualified scientists.⁶ Although OMB recognizes that such confidentiality “may not always add to the credibility of the review process,”⁷ it is content to leave it to agencies to determine whether a more transparent peer review process is worth it.

⁴ 69 Fed. Reg. at 23234/1.

⁵ *Id.* at 23236/1-2.

⁶ *Id.*

⁷ *Id.* at 23236/2.

OMB erroneously assumes because scientific journals use a form of peer review for publications that the government should mimic this process. The goals of scientific publication and sound governance are simply not the same thing, however. CPR therefore strongly opposes secret peer review, and we urge OMB not to permit it. As we noted in our earlier comments, “[i]t is difficult to see why the public should trust a peer review process that operates behind a veil of secrecy.”⁸ Indeed, it makes a mockery out of OMB’s requirements concerning conflicts of interest⁹ and independence¹⁰ because the public cannot verify compliance when an agency keeps secret the names and affiliations of its reviewers.

Moreover, OMB has failed to establish the necessity of secret peer review. Disclosure is not a bar to the recruitment of outside reviewers. Agencies like EPA and FDA have successfully recruited scientists for peer review under the Federal Advisory Committee Act, (FACA), which requires them to disclose the identity of reviewers and the content of their opinions.¹¹ We recognize that agencies will need many more peer reviewers because of the Bulletin, and this may make it more difficult to recruit scientists who are willing to serve in the open, but the remedy for this problem is to narrow the scope of the peer review required, as CPR proposes next. CPR also recognizes the necessity of protecting confidential business information and other sensitive information, but this does not require keeping the identity of peer reviewers and their advice secret.

OMB concludes that the “degree of public disclosure of information about reviewers should balance the need for transparency with the need to protect the privacy of scientists.”¹² The public’s right to know outweighs the need to protect the privacy of individual scientists, who, after all, can simply not participate in peer review if they want to keep secret their name and/or affiliations.

We note with approval that OMB requires agencies to disclose the names and affiliations of peer reviewers when agencies subject “highly influential” scientific assessments to peer review.¹³ This requirement, however, should be changed to require that these disclosures be made at the beginning of the process rather than at the end for all peer review that occurs under the Bulletin. FACA’s requirements relating to certain committees of the National Academy of Sciences provide that the Academy shall provide public notice of the names and brief biographies of those it appoints or intends to appoint, and provides that the Academy should provide for public comment prior to appointment, or immediately thereafter.¹⁴ In addition, the disclosure should state whether or not the peer reviewer has had any prior relationship with the issue to be reviewed, as a peer reviewer or in some other capacity. Adopting these recommendations is necessary for the public to hold agencies accountable for ensuring that the peer review that does occur is balanced.

⁸ Letter to Margo Schwab, *supra* note 3, at 5.

⁹ 69 Fed. Reg. at 23240, §II4.

¹⁰ *Id.*, §II3.

¹¹ 5 U.S.C. App. II.

¹² 69 Fed. Reg. at 23236/2.

¹³ 69 Fed. Reg. at 23241, §II5.

¹⁴ 5 U.S.C. App. 2 §15(b)(1).

BALANCED PEER REVIEW

There is another problem with OMB's effort to give agencies flexibility for the peer review of "influential" information. While OMB now recognizes the importance of selecting peer reviewers to represent a diversity of scientific perspectives relevant to the subject being reviewed,¹⁵ it only requires "balanced" review for "highly influential" scientific information. Whereas Section III of OMB's proposed Bulletin specifically requires balance,¹⁶ there is no similar language in Section II, which specifies the procedures for "influential" scientific information. OMB merely requires that peer reviewers "shall be selected on the basis of necessary technical or scientific expertise, and should not have participated in the development of the work product."¹⁷ The absence of such a requirement is particularly troublesome in light of the fact that agencies are permitted to keep the identities and affiliations of reviewers secret.

We can think of no good reason to omit this requirement except that OMB is attempting to make peer review as easy as possible for agencies because it has required it in so many instances. But, as we suggest below, the answer to making peer review less burdensome for agencies is to restrict it to instances where it is necessary and appropriate.

SCOPE OF PEER REVIEW

Since CPR criticized the initial Bulletin as "overbroad,"¹⁸ we support OMB's decision to narrow the category of scientific information for which an agency must employ additional peer review requirements.¹⁹ The proposed Bulletin, however, is still too broad because OMB insists on universal peer review for any significant scientific information. In addition, while OMB has properly limited the category of "highly influential" information to "scientific assessments" only, the "influential" category covers "factual inputs" and "data." Requiring review of every factual input and piece of data that could have a substantial impact on the public casts the peer review net too broadly and will create endless delays. CPR renews its request that OMB limit peer

¹⁵ *Id.* at 23235/1-2.

¹⁶ *Id.* at 23240, §III2a.

¹⁷ *Id.*, §II3.

¹⁸ Letter to Margo Schwab, *supra* note 3, at 1.

¹⁹ 69 Fed. Reg. at 23240, §II1. We are assuming that Section III only applies when scientific assessments have a clear and substantial impact on public policies with a potential impact of \$500 million or more, has a clear and substantial impact on private decisions with a potential impact of \$500 million or more, or "involves precedent setting, novel, and complex approaches, or significant interagency interest." See Summary of Public and Agency Comments on Proposed Bulletin on Information Quality and Peer Review (April 15, 2004), at 4. The actual language used in the proposed rule, however, is ambiguous that this is OMB's intention. Section III establishes three categories of information subject to the additional procedures: (1) if scientific information has a "clear and substantial impact on important public policies," (2) if scientific information has a "clear and substantial impact on private sector decisions with a potential effect of more than \$500 million in any year," or if the information "involves precedent setting, novel, and complex approaches, or significant interagency interest." OMB should clarify that the phrase "with a potential effect of more than \$500 million in any year" modifies both "private sector decisions" and decisions with a "clear and substantial impact on important public policies".

review to circumstances where scientific assessments set a new precedent or are reasonably controvertible.²⁰

OMB assumes that because peer review “is one of the important procedures used in science”²¹ that it should require agencies to seek outside review for all significant scientific information. As we mentioned earlier, OMB assumes that because peer review “is one of the important procedures used in science”²² that it should require agencies to seek outside review for all significant scientific information. OMB, however, ignores two important protections that adequately vet scientific information in most contexts. First, if agencies can call on the expertise of their own scientists, they can provide the necessary perspective for the agency to evaluate and create information. Second, if the information is subject to rulemaking, the quality of the information is vetted by those processes. We continue to believe that peer review is wasteful and will unnecessarily delay the dissemination of important information in any other circumstance.

OMB obviously distrusts agency scientists to undertake the job of evaluating scientific information because it requires that an agency consult outside scientists for practically any significant information that an agency might disseminate. OMB, however, fails to reveal the source of this distrust. We see no basis to disqualify agency scientists from reviewing the research results of other scientists or to prevent an agency issuing a document on the basis of the advice of its own scientists. It may be that OMB believes that agency scientists lack the expertise to undertake this task, but it offers no evidence that this is the case.

OMB does suggest that universal peer review is necessary because “independence in a reviewer means that the reviewer was not involved in producing the draft document to be reviewed.”²³ It is, however, overbroad in the context of significant time and money constraints to delay the publication of useful government information while it is peer reviewed unless it is reasonably controvertible or novel.

OMB does seek to justify requiring peer review for information that will be the subject of notice and comment rulemaking. It contends first that the “selection of participants in peer review is based on expertise, independence, and the absence of a conflict of interest.”²⁴ It also observes that “notice-and-comment procedures for agency rulemaking do not provide an adequate substitute for peer review, as disinterested experts – especially those most knowledgeable in a field – often do not file public comments with federal agencies.”²⁵

While we acknowledge that those who file comments are often not impartial, rulemaking participants are not shy about pointing out to an agency alleged flaws in the science on which the agency is relying, which is a sufficient safeguard in most instances that the agency will not proffer an unwarranted interpretation of the science. Indeed, an agency’s failure to respond to a critical, significant comment about the science on which it is relying would be grounds for a

²⁰ See Letter to Margo Schwab, *supra* note 3, at 4.

²¹ *Id.* at 23231.

²² *Id.* at 23231.

²³ *Id.* at 23235.

²⁴ *Id.* at 23231.

²⁵ *Id.*

judicial remand.²⁶ An agency may wish to seek more impartial advice about the science it is using prior to rulemaking, but it can consult its own scientists, which meets OMB's requirement that the agency obtain advice from those with the requisite "expertise, independence, and absence of a conflict of interest." This is why CPR maintains that peer review is justified only in cases where the information to be disseminated "sets a new precedent or is reasonably controvertible." In these circumstances, outside peer review -- particularly by "those most knowledgeable in the field" -- augments the agency's own scientific expertise in cases where such consultations are most necessary and useful.

Moreover, we would be more impressed with OMB's arguments as to the necessity of peer review in the context of rulemaking if it did not take an inconsistent position regarding adjudication. While OMB insists on peer review in rulemaking whether or not the scientific information is novel or controversial, it exempts scientific information disseminated in the course of an individual agency adjudication or permit proceeding ... unless the agency determines that the influential dissemination is *scientifically or technically novel* and likely to have precedent setting influence on future adjudications and/or permit proceedings."²⁷ As CPR pointed out in its earlier comments,²⁸ scientific information in adjudication typically receives much less scrutiny than in rulemaking. Thus, we don't understand why OMB has different tests as to when peer review is required for rulemaking and for adjudication. Indeed, one would think it is more necessary in adjudication, not only because there is less scrutiny, but because the information disseminated in adjudications and permit proceedings is largely information that is submitted by regulated industries, which obviously can impact the impartiality of the information.

CPR believes that OMB has the correct definition of when peer review should apply concerning adjudication, and we urge OMB to apply the same standard in rulemaking. If OMB continues to insist on a broader standard for rulemaking, it should explain and justify why the same broad standard should not apply to adjudication. CPR hastens to add that we continue to believe that OMB lacks legal authority to require peer review in either rulemaking or adjudication,²⁹ but if we are wrong, we do not see how OMB can distinguish adjudication from rulemaking concerning the issue of when peer review is required.³⁰

* * * *

²⁶ Motor Vehicle Mfgs. Assoc. v. State Farm Mutual Automobile Ins. Co., 463 U.S. 29 (1983).

²⁷ 69 Fed. Reg. at 23242, §VIII3 (emphasis added). There is some confusion about this exemption. Section I3, *id.* at 23239, entirely excludes "adjudicatory processes" from the definition of "dissemination," which is inconsistent with section VIII3, which contains the exemption indicated in the text.

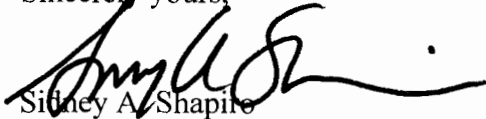
²⁸ Letter to Margo Schwab, *supra* note 3, at 11-12.

²⁹ *Id.* at 3-4

³⁰ *Id.*

CPR appreciates the opportunity to comment and congratulates OMB on its vastly improved Bulletin. We do believe, however, that there is more work to be done.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Sidney A. Shapiro', written over the printed name.

Sidney A. Shapiro
Board Member and Treasurer