



December 15, 2003

Dr. Margo Schwab
Office of Information and regulatory Affairs
Office of Management and Budget
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Re: Draft Bulletin on Peer Review

Dear Dr. Schwab:

OMB Watch appreciates the opportunity to comment on the Office of Management and Budget's (OMB) Draft Bulletin on Peer Review, published on August 29, 2003. The bulletin proposes a uniform standard of peer review for all federal agencies and outlines a variety of strict requirements for agencies conducting peer review. Through the draft bulletin OMB proposes agencies peer review all "significant regulatory information," add public comment periods to all peer reviews, and obtain input and approval of their peer review policies from the Office of Information and Regulatory Affairs (OIRA) and the Office of Science and Technology Policy (OSTP). While OMB Watch supports the constructive use of expert peer review, we cannot support the overly restrictive and fundamentally flawed process that OMB proposes in its Draft Bulletin.

OMB Watch is a nonprofit research and advocacy organization that has government accountability and improving citizen participation as its core mission. Public access to government information has been an important part of our work for more than 15 years and we have both practical and policy experience with disseminating government information. For example, in 1989 we began operating RTK NET, an online service providing public access to environmental data collected by EPA. Additionally, OMB Watch is very engaged in agency regulatory processes, encouraging agency rules to be sensible and more responsive to public need.

Establishing comprehensive peer review policies may increase the impact and influence of academics and scientific experts in the regulatory process or it could easily backfire and give politics greater influence over science. Peer review is the process by which experts in the field review and critique studies, papers and proposals to assure the quality of the research. Since peer review is typically a positive and beneficial process, OMB's desire to increase and improve its use in agencies is not unreasonable. It is certainly appropriate that government establish policies that help agencies efficiently develop credible information useful in the regulatory

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process. However, these policies should not allow politics to influence the scientific process or interfere with the rulemaking processes.

These comments will outline the numerous shortcomings that OMB Watch has identified within the draft bulletin. These flaws are so extensive and fundamental to the approach utilized by OMB that OMB Watch firmly believes that they are uncorrectable. Therefore, OMB Watch strongly urges OMB to withdraw the draft bulletin and engage in a new process to identify peer review problems and develop useful policies. Such a process should be done through the legislative process with the purview of Congress.

Authority

Before reacting to the bulletin, OMB Watch wishes to clarify that we do not believe that OMB has the legal authority to propose comprehensive peer review policies for all federal agencies. OMB asserts that its authority for the peer review bulletin derives from the Data Quality Act (DQA). However, the DQA, a slim 15 line rider on an appropriations bill that received no congressional discussion or debate, does not explicitly convey to OMB either the authority or the obligation to establish federal peer review guidelines. In stark contrast to the vague origins of OMB's claimed authority, Congress previously considered and rejected several proposals to mandate peer review requirement.¹ Given Congress' express and specific decision, it is presumptuous for OMB to infer from the DQA that Congress had changed its mind.

OMB also claims that the peer review proposal follows from authority and responsibility conferred upon the agency under the Paperwork Reduction Act (PRA). However, we believe that OMB is overreaching with this interpretation as well. OMB's authority under the PRA is limited to how agencies manage and disseminate information they collect. Congressional actions since passage of PRA make this lack of authority clear. Congress passed the PRA in 1980 and over the intervening years has considered and rejected several pieces of legislation that would specifically require peer review. Congress would not consider these proposals if the authority had already been granted to OMB under the PRA. This suggests that OMB's draft bulletin oversteps the intentions of Congress.

OMB should immediately withdraw the draft peer review bulletin as the agency lacks the specific statutory authority for the proposal. If OMB believes that federal agencies need overarching peer review requirements, it should instead submit its ideas to Congress for consideration and possible authorization. Congress, as the legally appropriate body to consider such a course of action, would then be given the opportunity to deliberate how such policies would impact government operations. We hope Congress would temper any approach it authorized with the knowledge that flexibility and judgment are critical tools federal agencies need to accomplish their primary goals—a tempering clearly lacking in OMB's draft bulletin. As we noted during previous legislative consideration of peer review legislation, we are dubious about one-size-fits-all approaches to regulatory reform.

¹ OMB obviously acknowledges this point in its Supplementary Information when it notes, "many bipartisan legislative proposals have supported independent, external peer review." However, OMB does not mention that those proposals were never enacted.

Problem Definition

In addition to lacking authority, OMB lacks a specific overarching problem in federal peer review. It is therefore unclear what the bulletin aims to solve. While the draft bulletin's supplementary information contains allegations of problems with federal agencies' peer review policies and implementation, there is no evidence or substantiation of these claims. OMB does not expand on its description of the problems beyond vague charges of inconsistent peer review policies and biased implementation. OMB also does not explain any research or processes that lead to its identification and understanding of the problems with peer review. Problem definition is a key component to any effective policy. Without adequately defining the problem, if any, OMB cannot hope to develop an effective solution.

While peer review is neither foolproof nor perfect, it is used as effective policy throughout the federal agencies, according to numerous academic, scientific and regulator experts at the recent National Academy of Sciences Workshop on the draft peer review bulletin. Presenter after presenter noted that while room certainly exists to improve peer review policies and implementation, those improvements would best be achieved by incremental and targeted policies. Since no fundamental or overarching problem exists in peer review as it is used by federal agencies, it would be foolish of OMB to propose reinventing the wheel with a standardized process.

OMB's failure to establish a need for the overarching peer review policy is another indication that the draft bulletin should be withdrawn.

Process

OMB, an agency inexperienced in peer review, drafted this bulletin to dictate universal requirements for that process with little or no consultation with agencies more experienced in peer review. In the draft bulletin, OMB even acknowledges the importance and usefulness of peer review expertise in other agencies. The bulletin directs that "an interagency group of peer review specialists and program managers" periodically meet to recommend "best peer review practices" and "other steps to expedite and improve agency processes." The obvious question is why such a process did not take place prior to OMB's development of the bulletin.

OMB should have elicited more input from those involved in every aspect of the peer review process prior to drafting any guidance. Agencies and individuals versed in peer review should have been engaged. The various peer review programs in place should have been analyzed and cataloged, noting the strengths and weaknesses of different approaches. After completing this survey of peer review, an interagency effort could have developed a proposal that would work more harmoniously with the existing peer review programs. This proposal would require precision to counter weaknesses in peer review but allow the majority of agency programs, which are working effectively, to continue unaffected. Instead, OMB's unjustified efforts to seize dominion over science and information have resulted in a cumbersome and intrusive policy that will likely weaken agencies' peer review programs as well as their regulatory actions.

Scope

OMB proposes far too broad a scope for its standardized peer review process. Many agencies have active and successful peer review programs tailored to fit their needs, utilizing a wide variety of peer review techniques depending upon the situation, the information, the intended use of the information and many other factors. On some issues, peer review can be an extensive and inclusive process complete with public meetings and reports in which the comments of peer reviewers are publicly available. However, on other matters agencies may choose to have reviewers remain anonymous to encourage honesty and candor by eliminating concerns of souring relations with a colleague. Double blind peer reviews, in which both the reviewers and the author remain anonymous, are used to prevent reviewers from being influenced by a researcher's reputation or lack of one.

Agencies may also elect to refrain from a traditional peer review for some information. Several agencies make excellent use of standing Science Advisory Boards in place of peer review. These dynamic and flexible approaches have developed out of the realization that peer review is not one thing but actually a field of activities. There is no one-size-fits-all peer review technique and agencies have realized this over the years. However, OMB is proposing an all-encompassing mandate that agencies use peer review for all "significant" information. For "especially significant" information, the proposal restricts agencies flexibility even further by requiring a very specific peer review process.

The draft bulletin would require that agencies "have an appropriate and scientifically-rigorous peer review conducted on all significant regulatory information that the agency intends to disseminate." Some information, such as grants and routine statistical information, are exempt from the requirement. OMB appears to restrict the scope by asserting that for significant information "peer review undertaken by a scientific journal may generally be presumed to be adequate." However, OMB immediately undercuts this statement and sends mixed signals to agencies by noting that "this presumption is rebuttable." The overly broad scope of the bulletin strips agencies of flexibility in deciding review methods outside of peer review to confirm information quality and will cause significant delays in the regulatory process by forcing agencies to engage in unnecessary peer reviews that waste resources.

OMB's draft bulletin also mandates extremely specific peer review requirements on "especially significant" information. The draft bulletin defines especially significant information as meeting one of the following criteria:

- (i) the agency intends to disseminate the information in support of a major regulatory action,
- (ii) the dissemination of the information could otherwise have a clear and substantial impact on important public policies or important private sector decisions with a possible impact of more than \$100 million in any year, or
- (iii) the Administrator determines that the information is of significant interagency interest or is relevant to an Administration policy priority.

The bulletin's broad definition would force agencies to engage in intensive formal reviews for extensive amounts of information. The first two criteria create a great deal of uncertainty because agencies frequently do not know how the information will be used until after research is concluded. The first criterion is difficult to apply because often when research is conducted it is unclear if it will spur a major regulatory action. The second criterion is equally difficult since even when research is meant to guide a regulatory action, typically the cost cannot be accurately estimated until the details of the proposal are known. Agencies would have to treat a broad range of information as "especially significant" as precaution against the information being unusable if it qualifies as especially significant under the criteria.

The third criterion grants OMB's OIRA the authority to impose its judgment on information's qualification as especially significant upon any federal agency. For the OIRA administrator to make such a determination, presumes a level of review by OIRA that never previously existed. If done through the PRA review, it significantly expands the review criteria beyond the scope intended by the statute. It is questionable whether OIRA should be the reviewing agency. It is uncertain how widely OIRA would demand the category of "especially significant" be applied.

The bulletin requires that agencies "have a formal, independent, external peer review" which meets all the bulletin's restrictive requirements for any information fitting the definition of "especially significant." Overuse of such an extensive process would create massive delays and waste enormous resources. Backlogs of information awaiting peer review will develop, preventing agencies from peer reviewing important information in a timely manner. Such backlogs will carry over and delay regulatory actions.

Shift of Authority to OMB

The bulletin eliminates the critical agency flexibility to respond quickly to an emerging issue such as a newly identified threat to health or safety. The bulletin does allow the strict peer review requirements to be waived in cases of imminent health hazards, homeland security threats and other emergencies. Only OIRA's administrator may grant such a waiver, once again questionably shifting significant new authority to OMB. The bulletin would strip agencies such as the Environmental Protection Agency, the Food and Drug Administration, and the Center for Disease Control, of the authority to use their specialized experience to act quickly in response to emergencies. These are the agencies that have been charged with protecting the health and welfare of citizens, but OMB relegates them to making cases to OIRA that a health emergencies necessitate waivers. OMB has never held authority to make critical health and safety decisions and peer review should not be used as subterfuge for engaging in such decisions.

The bulletin contains several troubling references that may increase political influence over the peer review process. One provision would require agencies to "consult with OIRA and OSTP concerning the sufficiency of their planned peer review policies." This formalizes the review expansion implied in the third criteria for especially significant information. OMB proposes establishing a new layer of political review for agency activities that never existed before. The bulletin does not explain what purpose or benefit this new layer of review is supposed to achieve.

The bulletin also allows OIRA to interfere with individual peer reviews by requiring agencies to “discuss with OIRA how the agency plans to review a specific document covered by the Bulletin and whether such a plan is sufficient.” Agencies must engage in this process “upon request.” OMB does not specify who may request such a consultation; the authority could be limited to OIRA or open to all parties. The provision enables OIRA to insert itself into any peer review process in the federal government, an enormous expansion of authority and influence. Additionally, the bulletin notes that this consultation will qualify as one of the pre-dissemination quality procedures required under the Data Quality Guidelines. Another significant shift of authority since previously under the Data Quality Guidelines agencies conducted their pre-dissemination reviews internally without any required consultation.

These policies would enable the administration to easily influence the peer review process and ensure a desired political outcome from a scientific process. The Bush administration has already dismissed scientific evidence of global warming that counters its position on the issue and so heavily rewrote a global warming chapter in EPA’s Report on the Environment the agency eliminated the chapter entirely. Would scientific review really be improved by granting the administration, indeed any administration, more authority and influence over science? OMB Watch thinks not. No White House office, particularly one as highly political as OMB, should have such influence over the “objective science” that policymakers use.

Cost & Burden

OMB estimates that the costs of implementing the peer review policy proposed in the draft bulletin would be negligible; even though those inexperienced with peer review acknowledge the likely costs would be substantial. Under the draft bulletin the number of peer reviews being performed throughout the federal government would dramatically rise and the duration and complexity of those reviews would increase. Such a surge in peer review activity would require a vast number of reviewers. Currently, agencies find it difficult to locate an adequate number of reviewers. Though peer review is traditionally a professional courtesy performed by experts for free, financial compensation would likely be required to acquire the large numbers of needed reviewers. This would represent an obvious and major increase in costs that is not reflected in the bulletin.

Compliance with the bulletin would also raise agencies’ management costs as they dedicate additional resources to administer the increasing number of complex reviews. For example, just the act of locating enough reviewers to meet the heightened demand will significantly burden agencies. With such unproven and highly questionable benefits, the resources agencies would have to expend would be better used in other ways. It is particularly ironic to witness OMB, a fervent advocate of cost-benefit analysis, ignore the costs of its own intrusive policy.

FACA

OMB inappropriately advises agencies how to avoid complying with the Federal Advisory Committee Act (FACA) by contracting management of peer review to outside consultants. Congress specifically passed FACA to ensure that agencies’ advisory committees, including peer

review panels, are accountable, open, and fair. However, OMB appears comfortable allowing agencies to thwart Congress' intentions and avoid FACA's requirements. OMB's instructions run directly contrary to OMB's stated goal for the entire draft bulletin. This provision of the bulletin reduces the requirements and oversight established specifically to improve the quality and trustworthiness of advisory committees.

The bulletin explicitly states that agencies "may retain a firm to oversee the peer review process" and that "peer review panels selected and supervised by outside consultants are not governed by the Federal Advisory Committee Act." However the bulletin specifically directs agencies to instruct these consultants to "comply with principles consistent with those set forth in this Bulletin." It is especially troubling that OMB would expressly order that agencies pass along its ideas and principles to any consultants, but encourage agencies to ignore Congress' wishes. OMB should advise agencies to instruct consultants used in peer review to incorporate the principles of FACA. Agencies should be encouraged use FACA's specific procedures, such as public meetings and minutes, as much as possible unless they would interfere with a selected form of peer review such as double blind reviews.

Unbalanced Treatment

The draft bulletin contains imbalances in the treatment of government experts and those from industry. OMB proposes several restrictions to ensure reviewers are independent from the agencies, but offers no provisions to assure that private scientists are independent from biased organizations such as regulated industry. OMB assumes that scientists associated with or funded by government agencies will alter their advice to support agency work in order to improve prospects of future funding. This is evidenced by its suggestion that agencies disqualify experts connected to the government in any way. Agency employees are all but eliminated from performing peer review even if they are not involved in the particular information under review. This approach prevents agencies from maximizing the talents and expertise they employ. OMB's approach means that if agencies are lucky enough to hire scientific leaders, they may only craft policy and never critique policy developed by colleagues.

OMB proposes as criteria for consideration of peer reviewers:

- (i) has any financial interests in the matter at issue;
- (ii) has, in recent years, advocated a position on the specific matter at issue;
- (iii) is currently receiving or seeking substantial funding from the agency through a contract or research grant (either directly or indirectly through another entity, such as a university); or
- (iv) has conducted multiple peer reviews for the same agency in recent years, or has conducted a peer review for the same agency on the same specific matter in recent years.

The focus is clearly on eliminating agency employed or funded experts while in stark contrast there are no corresponding provisions for industry scientists or those funded by industry. OMB implies that industry employed scientists will remain objective if they do not directly work on or have a stated position on the issue under review. This stricter rule for public funded scientists will create a significant imbalance in the selection of peer reviewers and provide industry with greater access and influence over the process.

The double standard under OMB's bulletin is obvious when one considers the following example. If a university scientist meets all of the standards except that he/she receives funding from the agency, then that scientist cannot participate in the peer review. However, if that same scientist's funding derived from an industry affected by the issue then the scientist could participate in the peer review.

It is unfair for OMB to accuse publicly funded researchers of bias towards agency information. These are scientists that have elected to dedicate themselves to the public interest not agency interest, typically accepting a substantially lower financial compensation in the process. Agencies also utilize strict policies and procedures to ensure objectivity in decision-making and prevent punitive or retributinal actions based on a displeasing outcome in a peer review. Therefore OMB's unsubstantiated implication that future funding and agency loyalty motivate publicly funded scientists is utterly unfounded. Meanwhile, such a pressured bias among industry-funded scientists might be more reasonable given the greater independence of industry decisions and the profit oriented focus. However, OMB conspicuously avoids this issue in the draft bulletin.

OMB Watch also believes the second criteria for selecting peer reviewers is overly broad. OMB recommends not allowing experts that have taken a position on an issue to participate in peer reviews related to that issue, apparently to avoid the appearance of bias. It should be noted that this restriction would eliminate a large percentage of true experts on an issue. After all, technical and scientific expertise on an issue typically develops from long-term research complete with conclusions and positions. While such positions should be disclosed, they should not automatically prevent participation. The criteria for peer reviews should focus on conflicts of interest and clear bias in the outcome and not implied bias.

Disclosure

OMB also sought input on the idea of limiting peer review scientists' disclosure requirements to just five or ten years. Coupled with other provisions in the draft bulletin that weaken safeguards against bias and impropriety, reducing the disclosure requirement would create too many opportunities for mischief and undue influence. Disclosure requirements were established, just like FACA, to improve accountability and understanding in the process as well as inspire greater confidence in agency decisions. OMB should first explore other options for burden reduction before advocating rollbacks in an important safety measure against abuse.

While OMB raises the issue of disclosure requirements, it fails to actually propose or detail any comprehensive disclosure requirements for peer reviewers. This glaring omission weakens the bulletin's credibility as an attempt to establish universal standards for peer review throughout the federal government. Strong disclosure requirements, critical components in assuring the fairness and objectivity, should be fully developed in any peer review policy proposals. If the development of the bulletin had included participation by agencies more experienced with peer review then disclosure requirements would certainly have been covered more completely. OMB also omits any discussion or recommendation for how much information about peer reviewers' funding and professional relations will be made available to public.

Public Comment Process

While OMB Watch is a strong proponent of public comment processes, we do not see how mandating a public comment period for all peer reviews improves the process. The purpose of peer review is to collect informed and objective feedback on a study or document from a select group of experts. The much broader purpose of public comment is to gather diverse feedback on any aspect of a report or proposed rule. While both should be used when appropriate and can even be useful when done together, it should not be assumed that they should always overlap as proposed.

OMB proposes that agencies “provide an opportunity for other interested agencies and persons to submit comments” and that reviewers consider the submitted comments before concluding their review and preparing their report. Requiring scientific experts review and consider all public comments represents a significant burden on reviewers and in certain cases a tremendous waste of resources. On many issues the expert peer reviewers have knowledge of and access to all the relevant studies and accepted data. New data submitted through a public comment process would likely, in addition to being biased, not be publicly available or peer reviewed and therefore would not be credible or useful.

Mandating a public comment period in peer review also invites biased parties, such as regulated industry, to delay future regulatory action by flooding related peer reviews with contrary data and studies. Additionally, the requirement would likely exacerbate an existing imbalance in access and influence in the regulatory process. It is unlikely that many groups other than industry would have the resources and motive to actively participate in the public comment processes of the extensive number of peer reviews that would occur under the bulletin.

Allowing public comments in the peer review process introduces the risk of biased parties influencing and delaying what is supposed to be an objective scientific process. Agencies should retain the ability to decide, on a case by case basis, when the benefits of allowing public comments outweighs the risk of tainting the objective process of peer review.

Peer Review Report

Another troubling requirement contained within the draft bulletin is the requirement that peer review panels produce detailed reports on their findings. Peer review reports are not new and many agencies' peer review programs produce them. However, OMB's policy mandates what information the report will include such as “the names, organizational affiliations, and qualifications of all peer reviewers,” which could vastly change the way an agency does its reports. As noted above, there can be important advantages to conducting anonymous peer reviews and even double blind reviews, but the draft bulletin eliminates these approaches without consideration for their advantages. Once again OMB Watch recommends that agencies maintain the flexibility to format peer review reports as they judge appropriate, from short summary reports that preserve anonymity to detailed reports that delineate the identity and reactions of each reviewer.

OMB Watch believes that agencies should commit to publicly disclosing as much as possible about their peer review programs and individual reviews without compromising effectiveness. Where agencies believe some degree of anonymity is needed a summary report could explain the results including the identity and qualifications reviewers without attributing specific comments to any individual reviewer. Alternatively, agencies could provide a comprehensive list of active reviewers but not reveal the peer reviews in which each participates.

OMB Watch also recommends that information on funding history be included when agencies provide information to the public about peer reviewers. Currently agencies often require disclosure of such information to the agencies but do not necessarily transfer that information to the public. Agencies could require potential reviewers to sign a waiver allowing the information to be made public to avoid privacy problems.

Centralized Peer Review

Another disconcerting section of the bulletin requests comments on whether agencies should retain the ability to self-select peer reviewers. OMB remarks that a centralized body in charge of appointing reviewers and overseeing peer reviews might be an improvement. OMB Watch strongly disagrees with this characterization and urges OMB to abandon any consideration for such centralized peer review. A centralized organization managing peer review throughout the federal government would have an excessive amount of control over the process. A single peer review entity would be extremely vulnerable to political manipulation that is more difficult to exert broadly in a decentralized system.

Since the “outside entity” is not even identified as a government agency it could be a consultant or industry group, opening the peer review process to additional influences. While OMB notes that it is not proposing such a system in this bulletin, the request for comments indicates the office’s interest in this approach and could well signal the direction of future guidance.

Conclusion

First and foremost OMB Watch urges the withdrawal of the bulletin because OMB lacks any statutory authority to propose comprehensive peer review requirements. If OMB wishes to pursue the matter of peer review then its proposals should be sent to Congress for consideration and possible authorization.

No matter how OMB’s draft bulletin is examined the conclusion is clear—it should be withdrawn. OMB Watch has exposed a number of flaws in the draft bulletin so fundamental that OMB cannot repair them during a simple public comment process. Specifically:

- OMB does not have clear statutory authority to propose comprehensive peer review standards.

- It has not been established that a peer review problem even exists, much less has the supposed problem been defined enough to evaluate the bulletin's effectiveness as a possible solution.
- The isolated process used to develop the bulletin failed to incorporate the extensive peer review experience that other federal agencies possess which would have fundamentally alter the bulletin's structure and content.
- The bulletin's overly broad scope will eliminate agency flexibility and delay regulatory actions as the number and complexity of peer reviews increase dramatically.
- The bulletin would questionably shift a great deal of authority and oversight to White House offices and away from experienced agencies, potentially opening the objective process of scientific peer review to political manipulation.
- The cost and burden of implementing the bulletin, likely to be significant, is not adequately considered.
- The bulletin inappropriately lays out how agencies may completely avoid FACA requirements by using outside consultants.
- Agency experts and government-funded scientists are unfairly targeted for disqualification from participating in peer review while no provisions are proposed to restrict industry-associated experts.
- The bulletin does not propose any disclosure requirements for peer reviewers' funding and professional history.
- Requirements for public comment periods and detailed peer review reports strip agencies of flexibility often critical in designing productive and candid peer review programs.

Sincerely,



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