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To: OMB_peer_review@omb.eop.gov

cc:

Subject: Comments on Revised Peer Review Bulletin

Please find attached OMB Watch's comments on the revised peer review bulletin in pdf format.

If there are any problems or questions concerning these comments please feel free to contact me.

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May 28, 2004

Dr. Margo Schwab
Office of Information and Regulatory Affairs
Office of Management and Budget
725 17th Street, N.W.
New Executive Office Building, Room 10201,
Washington, DC 20503

Emailed to: OMB_peer_review@omb.eop.gov

Re: Revised Bulletin on Peer Review

Dear Dr. Schwab:

OMB Watch appreciates the opportunity to comment on the Office of Management and Budget's (OMB) Revised Peer Review Bulletin, published in the Federal Register April 28, 2004. The revised bulletin continues to propose a uniform standard of peer review for all federal agencies with strict requirements for agencies conducting peer review. OMB has made significant revisions to the bulletin after its initial draft bulletin received strong opposition from scientists, environmentalists, and public interest groups. While many of the changes attempt to address several of the sharp criticisms, the new proposal fails to correct some of the most fundamental complaints.

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 databases. Additionally, OMB Watch is very engaged in agency regulatory processes, encouraging agency to develop sensible rules and be more responsive to public need.

Overview

The bulletin's improvements can be summed up as a general increase in flexibility for the individual agencies engaging in scientific peer review. The new proposal allows individual agencies to choose, on a case-by-case basis, the most appropriate format for peer reviewing information. In contrast to the draft bulletin, agencies are given more flexibility to use government scientists and government-funded scientists as reviewers. The revised proposal also exempts "time-sensitive medical, health, and safety determinations" from the peer review

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requirements. This important improvement will prevent vital health and safety warnings from being delayed in the bureaucracy of this policy.

As mentioned above, the changes, while welcome improvements, are limited and ignore the most important and fundamental problems. The new proposal still does not sufficiently establish a clear need for government-wide peer review requirements. Nor does OMB adequately address serious assertions that it lacks the legal authority to establish such requirements, and would be an inappropriate office to oversee peer review programs. Indeed, most of the improvements made in the revised proposal are limited to a lower category of information entitled “influential scientific information.” OMB retains overly strict and prescriptive peer review requirements for the most important information that it calls “highly influential scientific assessments.”

Although OMB Watch commends OMB's efforts to improve the bulletin in response to public comments, the changes fall far short of ensuring that the peer review policy will not interfere with the regulatory process and delay agencies' actions to protect the public and accomplish their missions. The remainder of this analysis will focus on the most troubling components of the revised bulletin and recommend specific improvements the final bulletin should adopt.

Authority

OMB Watch continues to contest OMB's legal authority to establish these peer review requirements. In the revised proposal, OMB asserts that its legal authority is implied from a series of laws and executive orders including the Information Quality Act, the Paperwork Reduction Act, and Executive Order 12866 - Regulatory Planning and Review. None of these authorities provide a direct mandate for OMB to undertake this authority. OMB should seek specific and explicit approval from Congress for such a precedent setting proposal with government wide impacts rather than cobbling together implied authority from a variety of sources.

In fact, Congress considered government-wide peer review requirements several times in the past – both as part of larger regulatory reform measures or as stand-alone proposals – and failed to enact such legislation. Congress' inability to decide on an appropriate government-wide peer review policy clearly indicates the lack of consensus on this issue. Congress should be allowed to continue to wrestle with and resolve this important and complex matter. OMB's action appears to circumvent the ongoing long-term legislative process.

Therefore, OMB Watch reiterates our position that OMB should withdraw the draft bulletin and engage in a new process that would identify peer review problems and develop specific policies accordingly. Once OMB has a fully informed policy proposal, it should seek congressional approval before implementing any policies.

Problem Definition

OMB does not adequately address another critical complaint consistently voiced against the original bulletin – the policy attempts to solve a problem that does not exist. OMB fails to establish that agencies suffer from a fundamental government-wide peer review problem,

although it does try to bolster its case with additional citations in the revised proposal. OMB claims “various authorities have argued that peer review practices at federal agencies need to be strengthened.” However, many of the supporting reports only address agency-specific issues pertaining to peer review or focus narrowly on aspects of peer review that fall short of justifying a government-wide policy.

Of course, individual instances of peer review problems and failings exist within agencies. After all, no system is perfect. But such examples seem to indicate that these “problems” are limited and infrequent – exceptions that prove the rule that government peer review works well. There is no reason to fix something that is not broken, unless the effort seeks not to repair, but simply to alter. OMB’s modifications to the peer review process at the agencies will dilute scientific information, delay regulations and reduce agency control.

OMB clearly continues to fall far short of demonstrating that a fundamental or overarching problem exists throughout the federal agencies’ peer review programs. Without a clearly identified problem, OMB Watch recommends significantly limiting the scope of this policy and engaging in an effort to explore the current use of peer review throughout government agencies in order to discover any consistent or reoccurring problems.

Oversight

An additional complaint raised against the original bulletin was that OMB placed itself in an oversight role for federal peer review, a role that the office has never played and is poorly qualified for assuming. (Even if OMB were qualified, the office should not be involved in substantive review of agency peer review.) The revised proposal, while less clear on specific oversight functions, retains the principle that OMB will supervise implementation of scientific peer review. For instance, the bulletin no longer includes the requirement that agencies obtain OMB’s approval for peer review plans. However, the revised bulletin does not expressly state that OMB cannot insert itself into agencies’ peer review activities and dictate changes to agencies’ plans. There are also several sections that practically require OMB assert oversight and control over agencies’ implementation of scientific peer review.

One example of OMB’s continued oversight role is in the selection of information for the “highly influential scientific information” category. The revised bulletin proposes this new category of information, which would require agencies to follow stricter, more prescriptive and much slower peer review activities. “Highly influential” is defined as information that “could have a clear and substantial impact on important public policies (including regulatory actions) or private sector decisions with a potential effect of more than \$500 million in any one year or that the dissemination involves precedent setting, novel and complex approaches, or significant interagency interest.”

Careful examination of this definition reveals that it establishes no clear or useful criteria. The only quantitative figure, the \$500 million number, is not sufficient or objective, as it is practically impossible to consider the cost of scientific information. Specifically, the bulletin instructs agencies to consider the financial impact of releasing information. While agencies have considerable experience estimating the costs and benefits of implementing a specific regulation,

there has been little call to consider the financial impact information dissemination. Additionally, an agency could not estimate the cost of the regulation that the science will support as scientific studies are done years before a regulatory path is selected.

In the end, OMB will be the primary decision maker for the selection of information qualifying as “highly influential.” The \$500 million effect is essentially no more than a guess, and the remaining criteria are all entirely subjective. Who decides what constitutes “precedent setting,” “novel,” or “significant interagency interest?” Given the other oversight authority OMB has granted itself in the bulletin, that office seems the most likely candidate. Agencies may choose to review studies as “highly influential” just to avoid facing the need to re-review information if OMB determines that it qualifies and has not been sufficiently reviewed. In such a case, agencies are changing their normal activities and delaying the regulatory process because of possible interference from OMB. Agencies are the most knowledgeable in determining which information is “highly influential” and which is not. OMB should alter the definition to make it clear that agencies, and not OMB, make determinations.

The revised bulletin also places OMB in an oversight role by vesting the agency with authority to approve alternative peer review plans and exemptions from the strictest peer review requirements. The bulletin continues to explain that the only other approved alternatives to the specific requirements of OMB's peer review policy, is having the National Academy of Sciences (NAS) manage either the original study or a peer review of the agency's scientific study. In giving NAS this authority, OMB acknowledges the academy's scientific expertise. What becomes confusing is why NAS, the country's premiere scientific body, is not also granted the authority to approve agencies' alternative peer review plans. For better consistency and objectivity, OMB Watch recommends that authority for approving alternative peer review plans be shifted from OMB to NAS.

An interesting provision in the revised bulletin proposes that OMB and the Office of Science and Technology Policy (OSTP) establish an interagency panel to foster learning about peer review techniques. OMB Watch strongly supports that creation of such an interagency panel. Such a panel should have preceded the bulletin and been used to guide any effort to develop government wide peer review policies. While we support the interagency panel on peer review, we question the appropriateness of placing two political offices as supervisors of the panel. OMB Watch recommends that OMB shift responsibility for establishing and coordinating the interagency panel to a more objective and scientific body – specifically NAS.

Overall, the revised bulletin grants far too much influence over the scientific peer review process to the politically motivated offices of OMB and OSTP. Such power would enable an administration to easily influence peer reviews and in turn, the rulemakings that would follow. Would scientific review really be improved by granting an 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. OMB Watch recommends the final bulletin grant oversight authority to an objective scientific body, such as the NAS or an interagency review panel.

Selection of Reviewers

During the comment period for the draft bulletin, numerous commenters raised concerns over the imbalance in treatment between government experts and those from industry. The bulletin established a double standard, making it almost impossible for agency experts or government-funded scientists to participate as peer reviewers. In the revised bulletin, OMB reduced some of the restrictions preventing agency or agency-funded scientists from serving as peer reviewers. “[W]hen a scientist is awarded a government research grant through an investigator-initiated, peer-reviewed competition, there generally should be no question as to that scientist's ability to offer independent scientific advice to the agency on other projects,” according to OMB. Unfortunately, the use of “investigator-initiated, peer-reviewed competition” for grants varies between agencies, and for several key agencies this provision would leave many scientists receiving grants potentially unavailable for operating as peer reviewers.

For the most important peer reviews, OMB openly maintains the double standard. Agency employees may be peer reviewers for the more basic peer reviews, as long as they do not possess a conflict of interest and comply with applicable federal ethics requirements. However, OMB's stricter peer review requirements for “highly influential scientific information” continue to bar federal employees from serving as peer reviewers. This could include recipients of agency grants, since the revised bulletin again only exempts “investigator-initiated, peer-reviewed competition” grants from the independence-based ban for agency employed peer reviewers. On the other hand, the bulletin still allows scientists with business associations directly related to the information under review to participate as reviewers.

Basically, the revised bulletin treats government and industry scientists relatively equally in terms of conflicts of interest. However, OMB creates a new criterion for evaluating perspective peer reviewers called “independence”, which it defines as independence from the agency. Therefore, government employed or funded scientists can be eliminated as peer reviewers on the basis of either conflicts of interest or independence, while industry scientists can only be eliminated based on conflict of interest issues. It should also be noted that the conflict of interest provision seems weaker for industry interests. The revised bulletin merely instructs agencies to “**consider** (emphasis added) the conflict of interest policy used by the National Academy of Sciences.” Therefore the bulletin permits weaker restrictions for industry scientists but demands a strict ban on agency scientists. OMB Watch recommends OMB strengthen the conflict of interest provision by requiring agencies to adopt the National Academy of Sciences conflict of interest policy.

The selection of peer reviewers was perceived as a highly controversial provision in the original proposal, raising concerns that it would tilt peer review in favor of business interests. OMB improved the provision but not sufficiently. OMB Watch recommends that OMB require that agencies use the National Academy of Sciences' conflict of interest policy as a minimum standard for themselves. While attempting to solve the conflict of interest provision, OMB also created a new problem by unfairly establishing a selection criterion that only applies to agency employed and funded scientists. OMB Watch urges OMB to either drop the independence criteria or develop parallel language to screen out those scientists that possess questionable independence from industry perspectives, even if specific conflicts of interest are not identified.

Regulatory Delay

The original proposal imposed several new peer review tasks and requirements that would likely significantly delay the regulatory process at agencies, including those addressing areas of health, safety and environment. OMB's revised bulletin actually exacerbates this problem by adding several new layers of bureaucracy to the peer review process. As most participants will readily attest, governmental peer review does not occur swiftly. Agencies already must locate an adequate number of qualified peer reviewers, schedule the review with enough time to accommodate the reviewers' often busy calendars, examine the responses, and develop a final product. The OMB proposal would add substantial new burdens to an already over-burdened process, likely delaying many of the peer reviews and the regulations that follow.

The public comment process is a typically positive and useful tool for many government activities such as rulemakings. However, this type of procedure, when applied to peer review, would likely cause unnecessary delays with little benefit. OMB Watch remains a strong proponent of the public comment tool. Nonetheless, there are situations that call for public comments and others that do not. There seems to be very little need for "public" comment in scientific process of peer review. The public is already ensured its ability to comment during any and all rulemakings by agencies. Since rulemaking represent agency action, they remain the most appropriate setting for public comments allowing submitters to fully discuss the information, agency choices, and policy proposal. While the new proposal appears to grant agencies decision-making authority over the appropriate level of public involvement for each peer review, the flexibility is very limited. The revised proposal requires an open public comment period for peer review plans as well as the peer review process itself.

The original proposal required agencies to notify and obtain approval from OMB's Office of Information and Regulatory Affairs (OIRA) for all peer review plans. OMB Watch strongly objected to this unnecessary control and oversight by OMB. In the new proposal, OMB requires agencies to develop and maintain a Peer Review Agenda, describing the basic elements for each planned peer review. Agencies must post the agendas and "accept and consider" public comments submitted on the peer review plans. This requirement seems extremely onerous. The bulletin appears to require public notification and input before the peer review activity can occur. Agencies should retain flexibility so they can act as quickly as possible on peer review when necessary. If circumstances raise the importance of one peer review, the agency should not have to wait for public input and approval of the plan before proceeding ahead with the review. Additionally, the requirement of posting all peer review plans and accepting public comments, seems to be a subtle method for OIRA to retain the oversight ability outlined in the original proposal. OMB Watch recommends removing the requirement for accepting and considering public comments on peer review plans in the final bulletin.

Additionally OMB still requires agencies to provide an opportunity for the submission of comments from other interested agencies and persons during the peer review process for all "highly influential information." Public comments during a scientific peer review represent a useless and burdensome requirement that will delay the entire process, especially for politically contentious issues or studies that are likely to lead to strict regulations. The purpose of selecting

qualified experts to review material is to utilize their extensive awareness and understanding of relevant science and findings. Even if submitters had new data or studies that reviewers were unaware, the peer review process is not the appropriate time for these experts to familiarize themselves with new material. Such new studies should be submitted to the overseeing agency for consideration before any regulatory action. 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. OMB Watch recommends that OMB remove the requirement for peer reviews of “highly influential information” to include a public comment period and allow agencies to select on a case-by-case basis when to use the public comment process. OMB Watch further recommends that when public comments are accepted during peer review, agency regulators receive and respond to the comments rather than allowing the process to interfere with the scientific peer review.

OMB does acknowledge the possibility of peer review procedures impeding regulatory action when it warns agencies to “avoid open-ended comment periods, which may delay completion of peer reviews and complicate the completion of the final work product.” But nowhere in the revised bulletin does OMB establish definitive restrictions on either the length or number of times a single study may be subjected to peer reviews. While too often agencies fail to meet deadlines or schedules, creating such provisions within this bulletin would be the best method of preventing “paralysis by analysis” – endless delays because of continual information evaluations. OMB Watch recommends OMB include a stronger protection against delay by establishing a restrictions on the length of time a peer review operates and the number of peer reviews a single study may undergo before dissemination.

Conclusion

OMB Watch continues its recommendation that OMB withdraw the bulletin because OMB lacks any statutory authority to propose comprehensive peer review requirements. We further recommend that OMB convene an interagency committee to investigate peer review techniques and flaws. The bulletin could give this interagency committee a launching point for discussing the merits of a government-wide policy versus agency specific improvements. If at some point OMB wishes to pursue a government-wide policy, then the proposal should be sent to Congress for consideration and possible authorization.

If OMB insists on pressing forward with this proposal we would recommend that, at a minimum, the following changes be made:

- Limit the bulletin's scope while exploring any consistent or reoccurring problems in government agencies' use of peer review.
- Shift the oversight authority on peer review plans, including granting exemptions, to a more objective and qualified agency such as the National Academy of Science or an interagency peer review panel.
- Require agencies to adopt the National Academy of Sciences conflict of interest policy.
- Drop the “agency independence” criteria or develop parallel language to screen out those scientists that possess questionable independence from industry perspectives.
- Eliminate the requirement for a public comment period on peer review plans.

- Remove the requirement that agencies accept public comments during peer reviews of “highly influential information” and instead allow them flexibility to decide when to use the public comment process.
- Clarify that any public comments accepted during peer review are received and responded to by agency regulators and not the expert peer reviewers.
- Establish a restriction on the length of time a peer review may operate and a limit on the number of peer reviews a single study may be subjected to before dissemination.

Thank you for considering these comments.

Sincerely,



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