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Subject: comments on revised peer review guidelines

As requested, please find comments both below in the body of this message and attached (note: footnotes did not copy to the body of the message, they are only in the attachment). If they are not transmitted adequately or if you have any other questions, please contact Stuart Shapiro at stuartsh@rci.rutgers.edu or 732-932-2499 ext 870. Thank you for your attention and consideration.

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Comments on The Office of Management and Budget's Proposed Bulletin on Peer Review and Information Quality.

OMB has requested comments on its proposal to require agencies to conduct peer review of significant regulatory information (69 FR 23230). These comments are in response to that request. I (along with my colleague David Guston) commented on the previous version of these guidelines (68 FR 54023) and I am happy to see that OMB has carefully considered the many comments they received and modified the bulletin. The revised peer review bulletin is a significant improvement upon the initial version.

The most significant improvements involve the increase in agency discretion in management of the peer review process. In academic and funding settings, peer review varies considerably in its format. If it is to be applied to the regulatory setting, similar variance will have to be allowed. By allowing agencies a greater degree of choice in the implementation of peer review, OMB has increased the possibility that agencies will both learn from each other and will be able to better understand which aspects of peer review are appropriate for them.

OMB has also made a significant improvement by exempting regulatory impact analyses (RIAs) from the requirements of the bulletin. As noted in our previous comments, peer review is no guarantor of the truth in science. This problem will be even greater for economic analysis since there is less consensus in the social sciences than the natural sciences about what constitutes appropriate work. By exempting RIAs, OMB is removing the requirement for peer review from the area where it is least likely to have beneficial effects.

While the revised guidelines better tailor peer review as a positive influence on the regulatory process, I continue to have some concerns. These concerns, which are detailed below, fall into three categories. First, the benefits of a formal peer review process remain uncertain., Should the guidelines be finalized, either OMB or an independent panel should revisit their efficacy after a short period of time. Second, if the

¹ Dr. Shapiro is an assistant professor of public policy and has written on, researched and teaches a class on the regulatory process. Prior to his appointment at Rutgers University he was a desk officer in OIRA for five years reviewing regulations primarily in labor and health policy. These comments were written with help from David Guston and Rob Alderfer.

bulletin is to be finalized, there are several areas where additional discretion can and should be given to agencies regarding the implementation of peer review. Finally, the bulletin is unclear about how individual studies will be determined to be “highly influential” and hence subject to the stricter provisions of the bulletin.

1. The need for the bulletin.

One of our primary concerns in our comments on the proposed bulletin was that OMB had not adequately articulated the need for a peer review requirement in the regulatory process. In a rough “back of the envelope” cost benefit analysis, we argued that the cost of a peer review requirement was likely to be high (a best guess of \$325 million per year) while the benefits were highly uncertain.

In response to public comments, OMB has done an excellent job of finding outside sources that had previously recommended peer review in the regulatory process. However, OMB has not come up with any examples of regulations that would have likely been improved had peer review been a part of the regulatory process. Absent such examples, I remain unconvinced that peer review will lead to better regulations. That said; the reconstituted guidelines are far less likely to have the harmful effects that the proposed guidelines would have had.

Will the benefits of the guidelines justify their costs (the principle that OMB holds agencies to when reviewing regulations under Executive Order 12866)? In its “Summary of Agency Comments on Proposed Bulletin on Information Quality and Peer Review, Including Responses by OMB,” OIRA gives a brief analysis of the costs and benefits of the bulletin. While not fully enumerating the costs and benefits of the bulletin, OMB calculated the increased net benefits per rule and the decreased probability of judicial reversal that the bulletin would need to produce in order to produce net benefits. I believe that the OMB analysis shows that a peer review requirement is very unlikely to have benefits that outweigh² its costs.

This demonstration is clearest in the case of the analysis of avoiding judicial reversal. OMB assumes that 30% of rules face judicial or legislative reversal. This assumption is not documented and appears to be unreasonably high. Not only is it unlikely that 30% of all rules subject to the guidelines will be reversed in the absence of peer review, it is even more unlikely that such a high percentage will be reversed on grounds of technical insufficiency.³

OMB concludes that if the reversal rate were reduced to 25.7% from 30%, the benefits of the guidelines will outweigh their costs. But what if OMB had used a baseline

² The standard in Executive Order 12866 is whether benefits justify their costs. In the case of peer review, where it is unlikely that equity concerns will justify negative net benefits, benefits outweighing costs should be seen as the same standard as benefits justifying costs.

³ Reversal on the grounds that the regulation is contrary to statute or in violation of the Administrative Procedure Act is far more likely.

reversal rate that was lower than 30%? The chart below demonstrates how much the guidelines would have to lower the reversal rate in order to produce net benefits.⁴

Baseline Reversal Rate	Rate would need to be lowered to:
30%	25.7%
25%	21.5%
20%	15.2%
15%	9.9%
10%	4.6%
5%	impossible

If the baseline rate of reversal were a more realistic 10%, peer review would have to cut it by more than half. If it is 5%, peer review cannot cut it enough to produce benefits that outweigh the costs.

Furthermore, it may be unrealistic to assume that peer review will reduce the reversal rate at all. As noted in our earlier comments, peer review may increase the rate of judicial reversal, even for rules with net economic benefits. Opponents of such rules will use negative peer reviews as evidence that agency action was unwarranted. Though such negative reviews may merely reflect disagreement inherent in the scientific process, it is quite possible that the court will see the negative peer reviews and reverse the regulatory effort. Therefore this bulletin is extremely unlikely to lead to a decreased reversal rate of regulations that will justify the delay in the regulatory process the guidelines will impose.

The question of added net benefits is more difficult. OMB argues that for a rule that yields \$1 billion in net benefits, the peer review requirements would have to add \$60.9 million in net benefits in order to justify a likely two-year delay in its promulgation.⁵ Will peer review add 6% in net benefits to rules? Peer review may indeed add net benefits to some rules. It is also likely to decrease net benefits for some rules. It is easy to envision a scenario in which scientists peer reviewing the documents supporting a rule lead agencies to more protective or precautionary standards. These standards may be less cost effective.

It is impossible to know whether the instances where peer review adds net benefits will be more common than the instances where it decreases them. If positive net benefits are more common, will they be sufficiently more common to yield an average of 6% increase in net benefits? My guess is that they won't but I have no more basis for that assessment than anyone arguing the opposite. This argues for an assessment of the peer review requirements after they have been in effect for a relatively small amount of time.

⁴ These numbers are calculated using a 3% discount rate. At a 7% discount rate, the other rate used by OMB, the numbers are even more stark.

⁵ Again, assuming a 3% discount rate.

A number of commenters on the proposed bulletin⁶ suggested that OMB utilize the National Academy of Sciences to study the issue of peer review in the regulatory process. I concur with this suggestion and think that such a study would be beneficial prior to adoption of these guidelines. However, if OMB is determined to proceed with the peer review bulletin, I believe that such a review should still be undertaken. Specifically, an outside group such as NAS⁷ should be commissioned to examine, in a year or two, how the regulatory process has been changed by the peer review bulletin. OMB should charge this outside group with the following questions:

1. Have any regulations been changed by peer review?
2. What are the expected benefits and costs of these changes?
3. How long have rules been delayed by the peer review requirements?
4. How have the peer review requirements helped or harmed rules in surviving judicial review? (It may take longer than two years before this question can be answered.)

If OMB were to commit to this “peer review of peer review” upon issuing a final bulletin, it would greatly add to the credibility of OMB’s commitment to a peer review requirement that creates net benefits to the regulatory process.

2. Agencies should be given more discretion.

As noted above, the revised guidelines give agencies considerably more discretion than the original proposal. Since the work done by every agency is different as is the institutional setting of each agency, it is important to allow agencies to vary their practices, rather than implement a “one size fits all” approach. With that principle in mind, there are several areas where additional discretion should be given to agencies.

In the academic journal and funding contexts, peer review is often an anonymous process. In the regulatory setting there is a need for openness and transparency. On the other hand anonymity provides a greater likelihood of peer reviews that are honest and unbiased. OMB must understand that by deciding this tradeoff against anonymity, a disincentive for participation as a regulatory peer reviewer has been created. Agencies should be given the option of conducting peer review anonymously for both “influential” and “highly influential” scientific assessments.

For influential scientific assessments, it may have been OMB’s intention to include this discretion. The preamble to the April 28 bulletin states, in reference to influential scientific assessments, “The degree of public disclosure of information should balance the need for transparency with the need to protect the privacy of scientists.” The bulletin itself should include this statement. For highly influential scientific assessments, the bulletin requires disclosure of the names of reviewers. This disclosure should not be required but rather left to the discretion of the agency with a statement similar to the one for influential scientific assessments.

⁶ Including David Michaels and a group of “former regulators.”

⁷ Of course if NAS is conducting numerous peer reviews for agencies, consideration will need to be given as to how this “meta-peer review” can be conducted objectively.

Another area where the preamble appears to indicate an OMB intention to give agencies discretion is the disposition of the reviewer's comments for influential scientific assessments. The preamble notes, "agencies should determine whether they will consider reviewer comments confidential or make them available to the public once the reviewed document is disseminated." The bulletin however says, "A detailed summary or copy of the reviewer's comments shall be made available to the public . . ." The formulation in the preamble is the superior one.

Agencies should also be given complete discretion in managing public participation in the peer review process. OMB notes in the preamble to the bulletin, "Peer review should not be confused with public comment and other stakeholder processes." Indeed an important intent of OMB in requiring peer review appears to be to ensure greater expert involvement in the regulatory process. The purpose of public comments is very different. The revised bulletin is an improvement upon the September 2003 proposal which required a comment period. However, OMB should clearly state that agencies have complete discretion in determining the amount of public participation required for each peer review. Furthermore, OMB should remove Section III (4) from the peer review bulletin.

3. The "highly influential" determination

One of the most crucial aspects of the bulletin is the increased set of requirements for "highly influential scientific assessments." Agencies are given less discretion regarding the management of peer review for assessments that fall in this category. Where a degree of agency discretion remains, it is reasonable to expect that OIRA will give greater attention to agency decisions pertaining to peer review in this category. It is clear that the parameters defining "highly influential scientific assessments" will ultimately have a significant impact on the efficacy of the peer review management process.

The bulletin states that highly influential scientific assessments are those,

which the agency or the Administrator determines is a scientific assessment that:

- (i) 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 year, or
- (ii) involves precedent setting, novel, and complex approaches, or significant interagency interest.

This raises several questions.

1. Given that either the agency or the OIRA Administrator can make this determination, what happens if they disagree?
2. When in the regulatory process will the determination take place?

3. What will happen if an agency determines that a study is not “highly influential” but as OIRA is reviewing a rule under Executive Order 12866, OIRA decides that the study is subject to the guidelines? Will the agency have to suspend work on the rule and subject the study to peer review?

4. In the above scenario, can the agency argue that the dissemination is “time sensitive” under VIII (4) of the bulletin, thus effectively overriding the OIRA Administrator’s decision that the study is highly influential?

I suggest that OIRA attempt to outline a more objective set of criteria upon which the determination of whether something is highly influential can be made. Absent such a set of criteria, many of the gains in agency discretion discussed above could be rendered meaningless. One possibility for objective criteria is to rely solely upon criteria based on the economic impact of the regulation. I also suggest that OIRA outline a process by which the highly influential determination will be made. Without such a process, these determinations will be made on an ad hoc basis and unnecessary and untimely delays in the regulatory process will result.

Conclusion

The public comments on the proposed guidelines have clearly had an impact. OMB should be praised both for revising the guidelines in light of these comments and for allowing the public a further opportunity to comment. As noted above, questions still remain about the need for the peer review guidelines. It is unlikely that the benefits that will result from their adoption will outweigh the costs associated with the delays in the regulatory process.

That said; the likely costs of the bulletin have been significantly reduced by the changes from the initial proposal. If OMB does decide to finalize the bulletin, I strongly recommend the following changes in order to maximize the probability that peer review will have beneficial effects upon the regulatory process:

- Make further changes to increase the amount of discretion for regulatory agencies, most importantly allow agencies to protect the anonymity of peer reviewers if they deem it to be appropriate.
- Outline specifically how it will be determined whether a scientific assessment is influential or highly influential.
- OMB should commit to a review of how these guidelines have worked in practice after they have been in effect for a relatively short period of time and should arrange for outside parties to conduct this review.