Enhancing Federal Agency Peer Review

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Introduction

Peer review, the process of reviewing a piece of scientific research for accuracy and reliability, is widely but imperfectly used in government. It is typically used by government agencies to fulfil two primary purposes. First, an agency might use peer review for its own, internal benefit to ensure the validity of the science on which it relies. Second, peer review may be employed for the benefit of the public, to show that a study is dependable and/or publicize any shortcomings. Peer review can, therefore, be extremely valuable if implemented effectively. Unfortunately however, this is not always the case.

This white paper examines the use of peer review in federal agencies, points out important weaknesses in the current federal regulatory framework for peer review, and proposes a variety of ways in which peer review could be improved. Although the recommended improvements are discussed in terms of maximizing the value of peer review to the public, they would also have benefits for the agency making use of peer review.

The key change advocated for in this paper involves expanding disclosure of peer reviewers' conflicts of interest. Requiring universal disclosure of conflicts of interest would maximize transparency and thereby increase the accountability of peer review. Similar benefits could also be achieved through other reforms, including by expanding the scope of annual reporting on peer review, increasing public input in the process, clarifying the peer reviewer selection process, creating more specific guidelines for triggering peer review and the types of peer review required, and requiring (subject to exceptions) publication of peer review comments. These reforms are not explored in

detail in this paper, but rather are listed as ideas, with the hope that others may analyze them further. While the focus of this paper is the use of peer review by federal agencies, the problems and recommendations discussed herein are equally applicable to state governments, universities, and scientific journals.

The remainder of this paper is structured as follows: Section I provides a brief introduction to the topic, discussing what peer review is and its value, as well as the existing federal regulatory framework for peer review. The section uses the peer review process at the U.S. Environmental Protection Agency (EPA) as an example. Much of the discussion is, however, applicable to other federal agencies and the states. In Section I, we will see that peer review is utilized in an ad hoc manner, and where agency guidance does exist, it is plagued by vague or non-mandatory language. Based on these weaknesses, Section II outlines proposals for reform. Section III concludes.

I. Background

a. What is Peer Review?

Peer review is used by governments, corporations, universities, and other entities to ensure that the scientific data on which they rely is dependable and accurate. In a simplistic example, a federal regulation might cite a particular scientific study to support its findings. To ensure the study is accurate and based on sound science, the agency promulgating the regulation may engage one or a group of scientists to assess the study through peer review. Peer review can be conducted by an agency employee who is adequately insulated from the regulatory process; by another government employee

working in a different agency; or by an outside group or individual.[1] The remainder of this Section discusses how peer review is used in different contexts in government, using two examples from EPA as case studies.

b. EPA's Use of Peer Review

As mentioned above, peer review can be an invaluable tool in ensuring scientific determinations are accurate and well supported. Government agencies that deal with science are well aware of the value of peer review.[2] This section describes EPA's use of peer review in two specific places: its chemical risk assessment process and its review of hydrocarbon extraction. EPA was selected as, due to its large size and the scientific nature of its mandate, it uses peer review frequently and in a variety of contexts. The specific ways in which EPA executes peer review are controlled by government-wide mandates, as well as internal guidance, which will be discussed later in this paper. Here, we simply wish to illustrate the scope and effect of peer review in some specific situations.

i. Integrated Risk Information System

One place that EPA uses peer review is in its Integrated Risk Information System (IRIS). IRIS is a database operated by EPA that characterizes the human health hazards

[1] For an excellent summary of the importance and implications of peer review, see BIPARTISAN POLICY CENTER, *Improving the Use of Science in Regulatory Policy* 45–46 (Aug. 5, 2009), *available at* http://bipartisanpolicy.org/library/science-policy-project-final-report/. *See also* J.B. Ruhl & James Salzman, *In Defense of Regulatory Peer Review*, 84 WASH. UNIV. L. REV. 1 (2006).

[2] *See, e.g.*, U.S. ENVT'L PROT. AGENCY, *Peer Review Handbook* (4th Ed. October 2015), *available at* http://www2.epa.gov/sites/production/files/2015-09/documents/final_epa_peer_review_handbook-_4th_ed_091415_dummy_link.pdf (discussing the purpose and merits of peer review) [hereinafter EPA Peer Review Handbook].

associated with various environmental chemicals.[3] In IRIS, EPA produces reference values and cancer potency estimates for exposure to toxic substances, but the assessments are informational only; these assessments are not required by statute and are not judicially reviewable. The end result of this process is a reference value and accompanying Final Assessment, which is publicized on EPA's website.[4] IRIS assessments undergo independent external peer review as part of their standard review process.[5] The program also holds bimonthly public meetings so that its employees are exposed to a variety of points of view from outside the agency.[6]

ii. Hydraulic Fracturing

Another setting in which EPA has used peer review is in assessing the potential impact of hydraulic fracturing, or "fracking," in the oil and gas industry.[7] In its FY2010 Appropriations Committee Conference Report, Congress urged EPA to initiate research to determine the impact of fracking on drinking water resources. EPA designated this research as a "Highly Influential Scientific Assessment" (HISA). Research receiving this designation must undergo "meaningful and timely" peer review.[8]

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[3] U.S. ENVT'L PROT. AGENCY, *Basic Information about the Integrated Risk Identification System: Basic Information*, http://www2.epa.gov/iris/basic-information-about-integrated-risk-information-system#process.
[4] U.S. ENVT'L PROT. AGENCY, *IRIS Assessment*, http://www2.epa.gov/sites/production/files/2015-09/iris_process_figure_2015.jpg
[5] U.S. ENVT'L PROT. AGENCY, *Basic Information about the Integrated Risk Identification System: IRIS Process*, http://www2.epa.gov/iris/basic-information-about-integrated-risk-information-system#process.
[6] Louis D'amico, *Stengthening IRIS: Cultivating Broad Scientific Input*, http://blog.epa.gov/blog/2014/10/strengthening-iris-cultivating-broad-scientific-input/
[7] U.S. ENVT'L PROT. AGENCY, *EPA's Study of Hydraulic Fracturing and Its Potential Impact on Drinking Water Resources: Peer Review*, http://www2.epa.gov/hfstudy/peer-review.
[8] *Id.*

EPA's fracking study was comprised of numerous individual research projects, each of which faced peer review upon completion. In addition, the draft assessment report, completed in June of 2015, was submitted to EPA's Science Advisory Board (SAB) for peer review.[9]

c. Regulatory Framework

Peer review is an integral part of major policy decisions in EPA and in other agencies. But how is it utilized to ensure it is effective and rigorous? This subsection examines the statutory and regulatory framework that guides the use of peer review in federal agencies. While this paper focuses on EPA, many of the laws and regulations apply government-wide, so much of this discussion can be applied to other agencies.

i. Federal Legislation

A handful of federal laws can affect peer review. First, the Federal Advisory Committee Act (FACA) requires federal advisory committees to adhere to certain transparency and impartiality requirements. Although these requirements will not be explored here, it is important to note that peer review is sometimes conducted by federal advisory boards, and in such cases FACA would apply.[10] Federal Conflict of Interest requirements may also apply. These requirements bar federal employees from participating in a decision-making process in which they or a direct relative or spouse has

[9] U.S. ENVT'L PROT. AGENCY, *EPA's Study of Hydraulic Fracturing and Its Potential Impact on Drinking Water Resources: Peer Review*, http://yosemite.epa.gov/sab/sabproduct.nsf/fedrgstr_activites/HF%20Drinking%20Water%20Assessment?OpenDocument.

[10] EPA Peer Review Handbook, *supra* note 1, at 54–46 (observing that peer review conducted by federally chartered advisory boards "is always subject to FACA requirements").

a financial interest.[11] Finally, the Federal Privacy Act (FPA) may affect peer review to some extent. The FPA forbids federal agencies from revealing certain information about private citizens. For purposes of peer review, the FPA might prevent agencies using peer reviewers from revealing information such as the reviewer's specific comments or even their identity.[12]

In addition to the legislation, agencies' use of peer review is also subject to other instruments, including guidelines issued by the Office of Management and Budget (OMB).

ii. Office of Management and Budget's 2004 Information Quality Bulletin for Peer Review

Probably the most substantive guidance for agencies on peer review is a 2004 bulletin produced by OMB (OMB Bulletin).[13] The bulletin, which is binding on all federal agencies, requires "important scientific information" to be peer reviewed before the federal government publicizes it. Its goal is to increase the accuracy and reliability of scientific information on which the government relies.[14]

The OMB Bulletin has many valuable elements, but it lacks specificity and thus may not provide meaningful guidance to agencies. While some level of discretion is valuable—even necessary—since peer review may be used in a wide range of situations,

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[11] 18 U.S.C. § 208.
[12] 5 U.S.C. § 552a.
[13] OFF. MGMT. & BUDGET, *Memorandum for Heads of Departments and Agencies re: Issuance of OMB's "Final Information Quality Bulletin for Peer Review"* (December 16, 2004), https://www.whitehouse.gov/sites/default/files/omb/assets/omb/memoranda/fy2005/m05-03.pdf. This document is both a memorandum describing the bulletin and the bulletin itself. The bulletin itself appears at page thirty-five of the document, but since the memorandum provides valuable commentary, we cite to the memorandum.
[14] *Id.* at 2.

it is important that agencies be given some guidance on the exercise of that discretion. The OMB Bulletin, as summarized below, provides only vague guidance to agencies.

Take, for example, the guidance on when and what level of peer review is appropriate. The OMB Bulletin requires agencies to use peer review for "influential" agency actions,[15] and it creates a higher standard of peer review for "highly influential scientific assessments."[16] However, it admittedly leaves agencies "broad discretion" in determining whether a particular situation qualifies for either of these categories.[17] The Bulletin offers some specifics, including encouraging a benefit-cost perspective.[18] Most of its pronouncements are general, however. It articulates various common sense positions, for example stating that more complex problems will require more sophisticated peer review, observing that peer review is most valuable if employed early in the process, and noting that small groups of peer reviewers will generally work faster than large panels.

The OMB Bulletin also provides vague guidance on selection of peer reviewers. It suggests that while independence is a crucial characteristic, in some cases, "a broader view of independence" is required.[19] It does not offer any specifics. The Bulletin provides a fairly comprehensive conflict of interest requirement, based on the National Academy of Science's policy for committee selection, but provides only that agencies "should consider" publicly disclosing any conflicts of interest of peer reviewers, rather

[15] *Id.* at 2.
[16] *Id.* at 2, 23.
[17] *Id.* at 12.
[18] *Id.* at 12–13.
[19] *Id.* at 17.

than requiring such disclosure.[20] OMB's guidance could be more concrete here; and where it is concrete, it should do more to require transparency in the form of required conflicts disclosures.

Finally, public disclosure of peer review comments and public participation are also somewhat vague and unhelpful. Strangely, although the OMB Bulletin requires public disclosure of peer reviewers' identities, it does not require public attribution of specific comments[21]—something the public would undoubtedly find valuable, particularly where reviewers have conflicts of interest. To assess the impact of a particular reviewer's conflict in the decision making process, the public must have access to information about each reviewers' comments.

Moreover, while the OMB Bulletin acknowledges that public participation "can be important in shaping expert deliberations," it does not require or even encourage agencies to create a public participation mechanism, even for very important decisions.[22]

Thus, while the OMB Bulletin does provide some useful advice for agencies seeking to implement peer review, its requirements are largely silent on identifying how to ensure meaningful public oversight of agency peer review processes. As a result, agencies are, for the most part, left to craft their own rules and free to conduct peer review in nontransparent and inconsistent ways within their programs as discussed in more detail in the sections that follow.

[20] *Id.* at 19–20.
[21] *Id.* at 20.
[22] *Id.* at 21.

iii. Agency Guidance and Interpretations

EPA has created a comprehensive Peer Review Handbook. The handbook was first developed in 1998, and has been updated four times, with the latest edition published in October 2015.[23] It is not binding on EPA employees,[24] but naturally informs their use of peer review.

The EPA Handbook elaborates somewhat on OMB's requirement that all "influential" science must undergo peer review. The handbook sets out a list of factors for administrators to consider in determining whether a study is influential, such that it requires peer review, and specifies that when in doubt managers should choose to peer review.[25] It also articulates how employees should differentiate between "influential" and "highly influential" decisions by setting out a separate list of considerations.[26]

EPA's Handbook also provides some elaboration on what type of peer review is appropriate in a given situation. However, this elaboration does not substantively expand on the OMB Bulletin; instead it articulates some fairly obvious truisms like "[w]hen time and resources allow, panels are preferable," and "[w]ork products that are less complex, novel, or controversial, or have a lower impact might be subject to a less extensive, less resource-intensive review processes."[27] These guidelines would benefit from further elaboration.

Once a peer review manager determines peer review is appropriate, EPA's Handbook provides guidance for peer review planning. The Handbook provides detailed

[23] *See* EPA Peer Review Handbook, *supra* note 2.
[24] *Id.* at ii; App. A-5.
[25] *Id.* at 42–43.
[26] *Id.* at 43.
[27] *Id.* at 55.

information about developing the peer review charge, even including a flow chart and an example of successful charges.[28] It also offers guidance on selecting reviewers, emphasizing the importance of expertise, so as to ensure adequate review, and diversity, to achieve a broad spectrum of perspectives, where possible.[29]

The EPA handbook spells out conflict of interest requirements for peer reviewers who are regular government employees (RGEs) and special government employees (SGEs). Those requirements, which are highly complex, are effectively summarized for peer review managers. The document even provides a useful reference chart, cross-listing types of potential peer reviewers, against relevant ethics standards.[30] However, for peer review conducted by employees of outside organizations who are not commissioned as SGEs (to the extent that this occurs), the Handbook merely suggests peer review managers "should be thoroughly familiar" with conflict requirements, suggesting EPA does not have any of its own ethics requirements for these persons.[31]

Contracted peer review must also adhere to certain conflict of interest requirements.[32] While the EPA handbook articulates a handful of excellent suggestions for "contract-specific [conflict of interest disclosure] language," it merely proposes that peer review managers "advise [a contractor] to consider" the suggestions.[33] This leaves a significant hole for conflicts of interest for contractors and employees of outside organizations who are not subject to federal government conflict requirements.

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[28] *Id.* at 82–85; App. H.
[29] *Id.* at 70.
[30] *Id.* at 75–81.
[31] *Id.* at 63.
[32] *Id.* at 77; 48 CFR 1552.209-73 (requiring contractors to immediately notify EPA of any actual or potential conflict).
[33] *See* EPA Peer Review Handbook, *supra* note 2, at 61.

II. Recommendations

In light of the incomplete guidance for utilization of peer review, this section proposes several reforms that could improve the use of peer review. Our primary recommendation is that EPA—or OMB—require disclosure of conflicts of interest for all peer reviewers. This simple reform would yield a clear benefit, in the form of increased transparency in the use of science. Benefits would also result from other reforms, including:

1. Expanding the scope of the annual report required of each agency summarizing decisions made pursuant to peer review requirements;
2. Increasing public input in the peer review process;
3. Strengthening and clarifying the peer reviewer selection process;
4. Creating more specific guidelines for triggering peer review;
5. Creating more specific guidelines for the type of peer review required; and
6. Requiring publication of peer review comments as a default, with a simple and generous "opt-out" mechanism.

Each of these reforms could be implemented either by OMB or by EPA and other individual agencies. OMB implementation has the advantage of uniformity and broad clarity; however, reforms might not fit all agencies, or may suffer from unnecessary rigidity or a lack of clarity. Agency implementation would presumably be more nuanced and able to fit individual agencies' unique needs. Notably however, agency implementation could lead to a patchwork system, forcing scientists to learn multiple regulatory schemes if they act as peer reviewer for multiple agencies.

a. Conflicts of Interest Should Be Universally Disclosed

Our primary recommendation is that conflicts of interest for peer reviewers should be disclosed publicly as soon as an agency considers selecting that peer reviewer unless there are compelling reasons to withhold this information. FACA and federal

conflict of interest requirements mandate disclosure of conflicts of interest when the peer reviewer is a federal employee, as discussed above. These mandates do not, however, apply to other peer reviewers who are not federal employees. Moreover, even where they do apply, only internal disclosure, not public disclosure, is required. Thus, while the agency considering whether to assign the employee to a certain peer review or science advisory role will have access to the information, that information will not be disclosed to the public.[34]

Ideally, conflicts of interest should be publicly disclosed as early as possible in the peer review process. For example, where an agency publicizes a short list of potential peer reviewers for public comment, it should simultaneously publicize conflict of interest information, so that this information can be considered during the public comment process. If an agency does not use such a process, the agency should publish conflict of interest information as soon as the peer reviewer is selected. This way, the public can consider the reviewer's potential conflicts immediately, and can easily participate in the public comment process after the peer review process is completed. Finally, conflict of interest information should also be appended to any peer review and any agency action relying upon such peer review. This way, the public can understand any potential biases that may have affected the outcome.

Notwithstanding the benefits of expanded conflicts of interest disclosure, it should be noted that this reform could have the effect of discouraging scientists from participating in peer review if taken too far. For example, if agencies disclose a peer reviewer's financial investments as part of the process, fewer scientists might wish to

[34] *See supra* Part I(a).

take part in peer review. Similarly, disclosure of a peer reviewer's family's work history might discourage participation. But peer reviewers will, most likely, become accustomed to any disclosure requirements with the passage of time. The National Academies do not suffer from the lack of talented participants, and yet it employs similar procedures.[35] If OMB or another entity requires these disclosures from the entire federal government, as we recommend below, this will occur even more quickly.

One way to enhance disclosure would be for federal agencies to require all peer review candidates to submit a CV-style resume of conflicts that would be publicized.[36] To this end, we urge OMB to update its 2004 Bulletin to direct agencies to adopt such requirements. This would ensure that the requirements are implemented by all agencies uniformly, improving the reliability of science throughout the federal government and a creating a consistent climate for those scientists participating in the process. While some areas of reform may benefit from individual agency variation (for example, variation may be desirable for peer reviewer selection criteria, because different agencies may value expertise and diversity differently), there is no reason that disclosure of conflicts of interest should vary from agency to agency. Exceptions may be needed, but they should be construed narrowly and available only with written, publicly-accessible justification.

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[35] *See* BIPARTISAN POLICY CENTER, *supra* note 1 (generally touting the National Academies approach to conflict disclosures as a starting point for agencies).

[36] *See id.* at 21 ("An eventual goal would be to make it standard practice for scientists to have a public curriculum vitae (CV) that included all their relevant employment, research support, publications, speaking, testimony, etc. Such a CV would provide much of the information sought on government disclosure forms. Many scientists already post their CV on their websites, and standardizing and expanding this practice would be part of creating a culture of disclosure that would be responsive to, and relevant for more than requirements for service on government committees.").

In the absence of government-wide reform, we urge EPA and other federal agencies to implement internal guidance (like EPA's Peer Review Handbook) that would require public disclosure of conflicts of interest. The obvious weakness with this approach is that it will yield a patchwork system where some agencies disclose peer reviewers' conflicts while others do not. We encourage agencies, universities, and public interest groups to set a positive example by requiring or at least encouraging these disclosures from their own faculty and staff who serve as reviewers for federal agencies, perhaps in the form of a conflict CV as sketched above.

b. Further Recommendations

This section briefly describes a number of other proposals to improve federal agency use of peer review. These proposals are less fully developed than the comprehensive recommendation above, but could be a useful launch-pad for an interested advocate or administrator. We have ordered the proposals from simplest to most complex, and have attempted to flag the challenges associated with each.

i. Agencies Should Publish More Comprehensive Annual Reports

The OMB Bulletin requires each federal agency to publish an annual report detailing its use of peer review.[37] However, the OMB requirements are minimal. They state simply that agencies' reports "should" include:

> 1) the number of peer reviews conducted subject to the Bulletin (i.e., for influential scientific information and highly influential scientific assessments); 2) the number of times alternative procedures were invoked; 3) the number of times waivers or deferrals were invoked (and in the case of deferrals, the length of time elapsed between the deferral and the peer review); 4) any decision to appoint a reviewer pursuant to any exception to the applicable independence or conflict of interest standards of the Bulletin, including determinations by the Secretary or Deputy Secretary

[37] OMB Bulletin Memorandum at 30.

> pursuant to Section III (3) (c); 5) the number of peer review panels that were conducted in public and the number that allowed public comment; 6) the number of public comments provided on the agency's peer review plans; and 7) the number of peer reviewers that the agency used that were recommended by professional societies.[38]

The EPA's peer review guidance also addresses the information to be included in annual reports, but very nearly quotes the OMB bulletin verbatim.[39]

We believe that annual reporting is a useful tool for improving peer review and agency use of science generally. Current OMB and EPA guidance on the content of annual reports is inadequate, however. With the exception of item four, OMB's list is entirely administrative, compiling only numbers and frequencies of agency use of peer review. Item four is useful because it may help OMB track how agencies balance the importance of expertise or diversity against conflict of interest. Yet still more items should be reported in this trend. More specifically, agencies should describe in qualitative terms, but with examples and evidence, when and how they employed peer review across project areas and issues and how they ensured the public transparency of their peer review processes. This proposal should be fairly uncontroversial and simple to implement, because agencies are already required to create an annual report under the OMB Bulletin. This reform would simply require them to provide additional information in that report.

ii. Agencies Should Allow for More Frequent Public Input

In addition to increased transparency, as urged above, agencies should create more opportunities for public input throughout the peer review process. The OMB Bulletin encourages but does not require agencies to involve the public. For example, the

[38] *Id.*
[39] EPA Peer Review Handbook, *supra* note 2, at 96–97.

bulletin provides that agencies should establish a "workable process for public comment and involvement,"[40] requires agencies to consider requesting public nomination of peer reviewers,[41] and points out that agencies have the option to "solicit public comment before a panel of peer reviewers performs its work."[42] EPA's handbook does not create any requirements beyond those in OMB's bulletin.[43]

We believe agencies could do more to involve the public in peer review processes. For example, agencies could solicit public comments on a short list of reviewers before beginning peer review. Agencies could also invite public comment any time they use peer review, and ensure all comments are considered by the reviewer(s). And when agencies publish the results of peer review, they could invite public comment so the decision-makers can consider the public's perspective on the validity of the peer reviewers' comments.

Notwithstanding the above, as the OMB Bulletin and the EPA handbook both point out, while public comment can be valuable, agencies should not be forced to use it to such an extent that it burdens the administrative process.[44] To this end, an appropriate reform might be to require all agencies to incorporate at least one public participation mechanism in HISA actions, but allow them greater flexibility in determining how to involve the public in other proceedings. We encourage individual agencies to create, based on their unique administrative processes, special public participation requirements for certain types of actions within their realm. These mechanisms would be valuable in

[40] OMB Bulletin Memorandum at 13.
[41] *Id.* at 17.
[42] *Id.* at 21, 39–40.
[43] EPA Peer Review Handbook, *supra* note 2, at 86.
[44] OMB Bulletin Memorandum at 21.

ensuring the agency includes meaningful opportunities for public oversight of these important processes.

iii. Peer Reviewer Selection Criteria Should be Clarified

As sketched above, the OMB requirements and EPA guidelines for selecting peer reviewers are vague, which provides the potential for inconsistency and diminished accountability of agencies' peer review processes. One benefit of this approach is that it allows agencies and groups within agencies—which will naturally have differing priorities—flexibility in selecting peer reviewers. For example, some agencies may need a group of experts in a single discipline to review a narrow scientific finding. In contrast, some agencies may prioritize diversity of viewpoints and disciplines over concentrated expertise. Still, we believe agencies will benefit from more detailed guidance in this area. Because different agencies will have different needs when it comes to peer review, we recommend that individual agencies enhance their guidelines for selection processes for peer review rather than urging an OMB bulletin or some other government-wide reform.

iv. Peer Review Triggers Should be Clarified

The 2004 OMB Bulletin requires agencies to peer review "influential scientific information," defined as "information the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions."[45] EPA standards elaborate on this to some extent, but still instruct administrators to consider a list of factors.[46] This standard is very vague, however, and thus is susceptible to inconsistency. Therefore, the trigger for peer review should be

[45] OMB Bulletin Memorandum at 36.
[46] *See* EPA Peer Review Handbook, *supra* note 2, at 42–43.

clarified. For example, OMB and EPA could provide more thorough lists of factors that will trigger peer review, or provide a series of hypotheticals or examples that would trigger peer review for comparison.

v. The Type of Peer Review Required Should be Clarified

Similarly, OMB describes the bulletin as leaving agencies with "broad discretion in determining what type of peer review is appropriate."[47] We believe agencies should have some discretion to choose whether particular information should be peer reviewed by a panel, individual, etc. But we also believe agencies would benefit from more rigorous and transparent procedures. In this case, agency-specific guidance will be more useful than OMB-promulgated government-wide guidance, because different agencies have varied missions and use peer review in different ways. Agencies are perhaps best suited to create guidance or requirements for what type of peer review is appropriate in different circumstances. But EPA's guidance provides no further detail than OMB, which suggests that agencies do not currently have such guidance in place.

The OMB Bulletin encourages agencies "to approach this decision [as to the type of peer review] from a benefit-cost perspective."[48] While this lens can be useful in many cases, we caution against overreliance on that framework. One of the difficulties with benefit-cost analysis is quantification, and while it is probably easy to attach a number to the cost of peer review, quantifying the benefit—the potential of discovering the reliability of the information being reviewed—is inherently more difficult. Recognizing this, before relying too heavily on cost-benefit analysis, agencies should note factors affecting the potential value of peer review. For example, a particular study might be

[47] OMB Bulletin Memorandum at 12.
[48] *Id.* at 13.

especially well designed, conducted by a universally respected scientist, or overseen by a widely respected institution that has processes in place to check ends-oriented research practices. These features might indicate the value of peer review would be low. On the other hand, peer review would be more valuable in ensuring results and processes are not biased where the original science was sponsored by industry or an advocacy group with a stake in the outcome.[49] And naturally, in the case of clearly poorly designed studies, peer review could be highly valuable. Hinging peer review of cost-benefit outcomes misses and even distracts from these more relevant triggers.

vi. Agencies Should Publish All Peer Review Comments as the Default

Another reform would require publication of all peer review comments as a default and give peer reviewers the option to request that their comments not be published. This approach would allow the public to understand the impact that a particular peer reviewer (or peer review group) may have had on an administrative result. In fact, the publication of peer review comments is already established in some EPA programs, such as the setting of National Ambient Air Quality Standards (NAAQS) and in IRIS Assessments.

Combined with the conflict of interest disclosure detailed above, this reform would allow the public to more easily determine whether a potential conflict affected an agency action. Of course, the danger of such publication is that it could deter scientists from engaging in peer review for fear of arousing public controversy. This danger would likely be a hurdle in enacting any reform in this area. Thus, we would recommend

[49] *See* Jalees Rehman, *Can the Source of Funding for Medical Research Affect the Results?*, SCIENTIFIC AMERICAN GUEST BLOG (September 23, 2012) (discussing studies showing a correlation between studies sponsored by industry and results favorable to industry).

including some sort of opt-out mechanism, where a peer reviewer's comments would not be publicized if they had a legitimate reason. Even if most peer reviewers requested and received opt-out approval, merely changing the default would likely lead to increased publication and transparency for the public benefit.

III. Conclusion

Peer review is a tool with great potential. It can allow government agencies and other groups to determine the validity and dependability of scientific evidence, and while it can be costly, it can be extremely valuable if implemented effectively. But the way the federal government uses peer review today could be improved, particularly with respect to the consistency and public transparency of the processes. The recommendations proposed in this white paper—the main proposal to require conflict of interest disclosures, and our six smaller seed recommendations—would each improve the effectiveness or transparency of agency peer review. We urge administrators to consider our main proposal, and encourage advocates to turn our seed proposals into fully developed recommendations.