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- 031215 RegCheck comments on OMB peer review bulletin.pdf - Interests and Incentives in Peer Review _prefatory_.pdf

- RBB Presentation.pdf

Richard B. Belzer, Ph.D. President Belzer@RegulatoryCheckbook.org



December 15, 2003

Dr. John D. Graham Administrator Office of Information and Regulatory Affairs Office of Management and Budget Washington, DC 20503

Dear Dr. Graham:

I am writing in response to OMB's request for comment on its draft bulletin on peer review dated August 29, 2003. As you know, Regulatory Checkbook has been an active participant in the debate over information quality, including guidelines proposed an issued by OMB and selected federal agencies. Regulatory Checkbook is a nonpartisan, nonprofit organization whose mission is to encourage the best available science and economics in regulatory policy and decision making. These comments do not necessarily reflect the views of any interested party or stakeholder in any regulatory matter, and they have not been authorized, vetted or approved by any such interest.

Crafting constructive and insightful comments on OMB's draft peer review bulletin has been extremely challenging. The draft bulletin raises a number of legal, philosophical, and technical issues.

LEGAL ISSUES

It seems likely that some commenters will question the proposed bulletin's statutory basis in the Information Quality Law. Presumably, their arguments will allege that Congress did not authorize OMB to issue government-wide guidelines for peer review and that OMB's interpretation of the law is illegally overbroad. This argument suffers a debilitating logical weakness. Congress authorized OMB to establish government-wide guidelines for information quality. In those guidelines, OMB directed agencies to establish procedures for effective pre-dissemination review of covered information. OMB could have prescribed peer review as a uniform government-wide pre-dissemination review practice. That it chose not to do in 2002 does not seem to offer much support for the argument that it could not have done so, or the argument that it cannot do so now.

Some commenters also will object that OMB "interfering" in the procedures and practices of Executive branch agencies and independent commissions. "Interference" is merely a pejorative term for "management," and the management of federal agencies is a clearly established and uncontested function of OMB. With respect to independent commissions, the Information Quality Law amends or modifies the Paperwork Reduction Act, which explicitly covers independent commissions. Thus, although Congress was not explicit on the point, the most logical interpretation of the Information Quality Law is that it applies in the same manner as the PRA. Indeed, any other interpretation would be odd given this context. More importantly, because the draft bulletin is purely procedural there is nothing in the document that constrains in any way the exercise of statutory discretion in decision making at federal agencies. A debate about whether the agency or unitary theory of the Executive is constitutionally correct is therefore an immaterial diversion.

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PHILOSOPHICAL ISSUES

Policy neutrality in scientific peer review

A germane philosophical issue is whether peer review is an appropriate procedural device for "ensuring and maximizing" the quality of scientific information even if we presume that it could accomplish these objectives. Science and policy have become so intermingled, and in some cases inbred, in ostensibly scientific information. As scientific information takes on more and more policy elements, peer review is decreasingly legitimate because it delegates the authority for making policy decisions to external scientists who have no special expertise or political legitimacy as decision makers. Peer review is not a legitimate tool for resolving political problems that legislators or agency officials cannot resolve themselves. Abuse of peer review in this manner undermines the credibility of *all* peer review, by communicating uncertainty about whether scientific peer review is truly limited to its intended scope.

In its proposed Bulletin, OMB includes language that explicitly addresses this problem by requiring scientific peer review to be policy-neutral: "Peer reviews shall be asked to review scientific and technical matters, leaving policy determinations for the agency" (§3, p. 10). This language is welcome but it is not sufficient. It may be fine for agencies and institutions that do not already have active peer review programs and will be starting from scratch. In these cases, it establishes a baseline for the development of peer review programs and, in principle, it may deter agencies from designing peer review programs inappropriately. OMB's language seems inadequate, however, to deal with agencies and institutions that have active peer review programs but routinely ask reviewers to address policy matters or impose policy-driven constraints on scientific review. An obvious and commonplace example is an agency request that peer reviewers opine as to whether the agency's *interpretation* of the science is *reasonable* given a litany of so-called *science policy* defaults. As indicated below, one way to assist these agencies in making their peer review practices more compliant with the policy-neutrality criterion is to modify the Bulletin such that persuasive evidence of noncompliance is sufficient grounds for challenging the adequacy of pre-dissemination peer review.

A remedy for the circular logic in pre-dissemination review by dissemination

The stated purpose of the draft Bulletin is to foster more use of scientific peer review than agencies on their own have adopted to implement OMB's government-wide information quality guidelines. OMB had suggested but not required agencies to incorporate peer review. This draft Bulletin would convert that suggestion into a requirement for a small set of items that OMB terms "significant regulatory information."

Except in limited circumstances, however, external and independent peer review requires public dissemination of the very scientific information that needs to be reviewed *prior to dissemination*. It is logically inconsistent to disseminate scientific information for the purpose of pre-dissemination review, for the purpose of pre-dissemination review is to ensure and maximize information quality *prior to* dissemination. Struggle as we might, it is very hard to parse this language to avoid circularity.

When asked directly how to resolve this apparent logical inconsistency at the recent National Academy of Sciences' Science, Technology and Law workshop *Peer Review Standards for Regulatory Science And Technical Information* held on November 18, 2003, your response suggested that the solution was to perform a mix of individual letter reviews and interagency review might be a way to resolve this conundrum:

"...a lot of agency practices in peer review right now do not involve public dissemination of documents. They do involve sharing a document with individual technical experts, asking them to perform letter review, and then providing those, or in some cases, interagency review of documents." (Transcript at 29-30.)

This response is eminently reasonable, but it begs the question of what the draft Bulletin is supposed to accomplish. The language in the draft Bulletin appears to apply almost entirely to the last of these three

Page 3 December 15, 2003



review formats—formalized independent and external peer review. Moreover, the Bulletin focuses on the subset of scientific information most likely to be "significant regulatory information," and hence most likely to require formalized independent and external peer review. There is a place for letter reviews, such as very early in the process when threshold data quality questions can be addressed to avoid undue delays later. There also is a place for interagency review early in the process, such as when agencies may differ on basic questions of analytic methodology. But in neither case will these pre-dissemination review tools adequately ensure and maximize the quality of "significant regulatory information."

You also expressed a desire for comment on how to reconcile this conundrum:

"[W]e are open to public comment in the context of the draft bulletin about how OMB should weigh on the one hand, the need to provide an opportunity for public participation in information to peer reviewers as they discharge their work. But on the other hand, not having a lot of draft documents released publicly that aren't really of sufficient stature or haven't been well enough developed to justify that type of public dissemination. That's a difficult balance." (Transcript at 30).

In the interest of constructive engagement, we propose a remedy that would permit public *disclosure* of scientific information for the purpose of pre-dissemination peer review, but at the same time confront directly the reason why premature dissemination has become so problematic. Our remedy has two elements.

First, scientific information that is disclosed for the purpose of peer review of data quality should be as free as possible of policy content. For example, it is commonplace for health risk assessments to include a risk characterization that synthesizes scientific information into a summary statement about risk. Risk characterizations are vital, but they incorporate substantial policy judgments. The validity of these policy judgments often depends crucially on whether the underlying scientific information satisfies applicable information quality standards. Publishing the risk characterization *before* ensuring and maximizing the quality of underlying scientific information has the effect of placing a very large policy thumb on the scale. When agencies make policy decisions before information quality has been assured, peer reviewers may not take their charge seriously in the belief that their efforts are largely pro forma. Reviewers typically serve without compensation, so reviewers who are convinced that their work makes no difference are unlikely to be diligent in the task.

The premature public disclosure of agency policy positions, such as in a risk characterization, also makes it exceptionally difficult for an agency to reconsider when peer review shows that underlying scientific information fails to satisfy applicable information quality standards. Instead of allowing the best scientific information to inform policy choice, an agency may feel compelled to defend substandard scientific information to avoid having to revisit its policy choice.

In sum, information quality should be ensured and maximized *before* policy decisions or preferences are disclosed. This requires the removal of policy content from scientific documents so that peer review can focus solely on scientific information. A recent example of this peer review model is the Perchlorate State-of-the-Science Symposium conducted by the University of Nebraska Medical Center September 29—October 1, 2003. Four groups of independent and external experts reviewed the primary scientific documents underlying an important and controversial health risk assessment. Authors of these studies were asked to present the results of their work in a public setting and were subjected to rigorous questioning by both experts and attendees. Derivative risk assessments prepared by both government agencies and private parties were not the subject of peer review, not were important policy questions such as what should be established as a "safe" exposure level. The final reports of the four expert panels have not yet been published, but it seems clear that much of the controversy surrounding the characterization of perchlorate health risks could have been avoided if a peer review of this type had been performed before the agency announced its policy positions.¹

¹ More information about the Perchlorate State-of-the-Science Symposium can be found on the event's website: <u>www.perchloratesymposium.com</u>. It should also be noted that the planning committee for the

Page 4 December 15, 2003



Second, scientific information distributed for the purpose of external and independent peer review should be more clearly characterized as not yet satisfying applicable information quality standards. It is common practice to print boilerplate disclaimers in draft documents. The purpose of printing disclaimers is to deter readers from interpreting draft documents as implicitly representing agency views. These disclaimers are notoriously ineffective, however. There are numerous instances in which federal or state regulatory agencies have relied upon external review draft risk assessments as the scientific foundation for policy or regulatory decision making. Sometimes this occurs in the realm of remedial action because applicable laws and regulations give regulatory agencies unfettered discretion to rely on virtually any source of information irrespective of its status or quality. Review under the Administrative Procedure Act is limited, and more importantly, delayed until the remedy is completed. By that time it is too late, as resources have already been expended and they cannot be recovered.

We have a proposed remedy to the "difficult balance" between "the need to provide an opportunity for public participation" and "not having a lot of draft documents released publicly that aren't really of sufficient stature." Our proposal requires amending the definition of "dissemination" to exclude information *distributed* for external, independent peer review, provided that the distributing agency include a bullet-proof disclaimer at the bottom of every page. We suggest the following language:

THIS INFORMATION IS DISTRIBUTED SOLELY FOR THE PURPOSE OF PRE-DISSEMINATION PEER REVIEW UNDER APPLICABLE INFORMATION QUALITY GUIDELINES AND OMB PEER REVIEW BULLETIN XXX. ANY OTHER USE INCLUDING, BUT NOT LIMITED TO, SUPPORTING A POLICY OR REGULATORY ACTION IS A VIOLATION OF FEDERAL LAW.

This disclaimer language makes clear that information *distributed* for peer review has *not been disseminated*, as that term is defined. Also, and more to the point, it makes clear that information *distributed* for external peer review can not be used prematurely for a regulatory or other policy purpose. Federal and state regulators would be hard-pressed to ignore this language. Later in this letter we provide suggestions concerning how to further reduce this problem by removing policy content from these documents.

Compliance with the scope of the Bulletin

OMB's draft Bulletin includes no transparent mechanisms for enforcement. Without enforcement mechanisms, however, it seems guaranteed to fail. Two types of enforcement tools are needed. In this section we describe the need for compliance mechanisms related to the threshold question of *whether* peer review will be conducted. In the next section, we deal with the problem of ensuring that an external and independent peer review *actually adheres* to the principles and practices set forth in the Bulletin.

The Bulletin needs devices other than OMB jawboning to ensure that agencies actually subject to peer review those informational documents or action within the scope of the Bulletin. OMB resources are scarce and would be even more severely taxed if OMB staff must bear the burden of jawboning agency adherence. Also, OMB staff will sometimes be constrained by Administration policy. In cases where the Administration has taken a policy position, peer review of otherwise covered scientific information might be discouraged because of the risk that independent scientists would judge the information underlying inadequate and thereby undermine the policy. Nevertheless, a consistent set of rules applied consistently to all covered actions is essential to rebut charges of politically motivated or partisan hypocrisy.

A number of possible tools present themselves. For example, peer review ought to be required in any case where a federal agency informs OMB in writing that it believes scientific information about to be disseminated by a sister agency ought to be deemed "significant regulatory information." OMB could strive to

Symposium explicitly incorporated both OMB's information quality guidelines and OMB's draft peer review Bulletin in its structure, panel selection, and charge to reviewers.

Page 5 December 15, 2003



resolve differences using interagency review, but at the end of the day external and independent peer review ought to be required if the petitioning agency insists on it. Agencies are very unlikely to abuse this privilege because of concerns about retaliation. Budgetary concerns can be ameliorated by requiring the petitioning agency to share the cost of the review, as well as participate in its oversight.

Another example of a useful enforcement procedure is to amend OMB's information quality guidelines to explicitly permit affected persons to petition an agency for independent and external peer review as part of the pre-dissemination process. Petitions should clearly state the scientific information at issue, and propose a specific peer review model that adheres to the OMB Bulletin, including such matters as venue, panel selection and charge. An open and transparent process would enable all parties, including those not party to the petition, to intervene. Making the scope, scale and mechanics of peer review a matter of public record dramatically enhances the public legitimacy of peer review. Again, budgetary concerns could be ameliorated by requiring the affected person (and perhaps intervenors, as well) to share the cost of the review, as well as participate in its oversight.

Adherence to OMB peer review criteria

OMB's proposed criteria for peer review are generally sound and, if complied with, would enhance the quality of peer review. Furthermore, OMB's criteria should not be overly controversial because they mimic the criteria established by the National Academy of Sciences for reviews it performs on contract to federal agencies. The Academies have similar criteria for the selection of peer reviewers, conflicts of interest, and procedure. The OMB criteria expand upon the NAS criteria in an important way, by clearly specifying that "agency entanglements" must be given the same level of scrutiny as private financial interests. The Academy may take these concerns into account but it does not do so routinely. Many NAS peer review panels have members who have deep entanglements with sponsoring agencies.

OMB's criteria are also narrower than those of the NAS. Most notable is the explicit proscription of peer reviewers to consider policy matters. NAS does not have such a constraint, and indeed, NAS peer reviews systematically include policy issues within their charge. Adhering to OMB's language could return the National Academies to their core mission where they have access to unrivaled expertise—the resolution of *scientific* controversies, not policy disputes.

OMB should amend the Bulletin to explicitly provide for enforcement mechanisms that make agencies highly motivated to fully comply with the final peer review criteria, not just the requirement that they conduct peer review. Annual reports on peer review activities are not enough. There is no way to ensure that these reports will be adequately transparent such that departures from OMB's criteria are detectable. Further, annual reports of past peer review activity are too late to influence agencies' decisions concerning their extent of compliance.

An example of a timely, self-enforcing mechanism would be an expansion of the public comment process to enable affected persons to challenge proposed peer reviews for failing to adhere to OMB's criteria. Challenges should include persuasive evidence of a material discrepancy, based on whatever information the sponsoring agency discloses, and a proposed remedy. These challenges should be directed to the sponsoring agency before proceeding. An agency may choose whether or not to accommodate the challenge, but with the knowledge that non-adherence to OMB's criteria could be grounds for a subsequent error correction petition alleging failure to perform an adequate pre-dissemination review. The objective is to get problems out in the open early so that disputes about the adequacy of peer review can be resolved beforehand.

Early resolution of scientific controversy is essential for an expanded emphasis on peer review to be effective and not delay the regulatory process. Agencies should be encouraged to sponsor short, tightly focused peer reviews well before they have an inkling of what policy they might be inclined to adopt. Agencies also should abandon the practice of subjecting only completed, comprehensive documents to external peer review. These documents deal with too many scientific issues for even a relatively large panel of reviewers to address. Page 6 December 15, 2003



When they uncover significant faults the agency may be compelled to start over. This is the reason why peer review delays public decision making, not the use of peer review per se.

TECHNICAL ISSUES

Peer review is generally a good thing, and in the preamble to the draft Bulletin OMB notes support for peer review from a diverse array of interests and individuals. There is a serious risk, however, that peer review could become the latest Big Thing whose actual accomplishments are dwarfed by expectations.

Analyzing the draft Bulletin reveals a number of questions that may need to be addressed before the document is finalized. These questions cut to the heart of whether the Bulletin will achieve its objective of ensuring and maximizing the quality of information disseminated by the federal government.

What is the problem peer review is supposed to solve?

OMB proposes to expand the use of a model of peer review that is borrowed from the world of scholarship. But the practice of peer review in scholarly settings is fundamentally different than government peer review. Scholarly peer review, such as for an academic journal, serves a very narrow purpose—allocating scarce pages to the most "worthy" submissions given the editorial objectives of the journal. In contrast, the purpose of government peer review is to ascertain what constitutes the best, policy-neutral (i.e., "objective") science.

What presumption ought to apply to peer-reviewed scientific literature?

Scholarly journals may achieve objectivity in isolated cases, but as a generally rule they do not. Peerreviewed scientific information published in scholarly journals therefore deserves only a weak rebuttable presumption of objectivity. The presumption should not hold if the journal did not base its publication decisions on objectivity, as that term is defined in OMB's information quality guidelines, or if the journal has an ideological foundation.

Ironically, OMB's draft Bulletin can be read to imply that publication in any peer-reviewed journal has been subjected to "adequate" peer review:

Agencies need not, however, have peer review conducted on studies that have already been subjected to adequate independent peer review. For purposes of this Bulletin, peer review undertaken by a scientific journal may generally be presumed to be adequate. (§2, p. 9)

OMB should be careful to avoid this step backward. Scholarly peer review is fundamentally different than governmental peer review. It is wholly inappropriate to assume that an article that met a journal editor's standards also satisfies OMB's information quality guidelines, particularly the standard of objectivity. As long as ensuring objectivity is the primary purpose of governmental peer review, academic peer review will be inadequate.

Why is there so much cognitive dissonance between scholarly and governmental peer review?

As indicated above, scholarly and governmental peer reviews have fundamentally different objectives. Yet, it is scholars who are recruited to serve as governmental peer reviewers. It is not obvious that they are well -equipped to perform this very different function. This and other sources of dissonance between scholarly and government peer review are discussed in greater detail in a paper prepared for the Society of Risk Analysis Page 7 December 15, 2003



Forum on Peer Review,² which was held May 28, 2002—more than a year before OMB proposed its draft Bulletin. A copy of this paper is enclosed.

Several important differences have been noted between scholarly and governmental peer review in addition to conflicting objectives. Examples include differences in ownership of the process, different reviewer selection procedures and review procedures, and compensation of reviewers. In the governmental setting a great deal of attention has been devoted to the matter of conflict of interest, something that rarely applies to scholarly peer review. Conflict of interest traditionally meant the abuse of official powers to benefit personal financial interests. But this was difficult or impossible to observe, so perceived conflict—the mere *capacity* to abuse official powers—became an attractive proxy. Although perceptions are always in the eye of the beholder, perceived conflict of interest has the advantage of being easy to observe. Soon, perceived conflict superceded actual conflict as a basis for challenging peer reviewers.

In the presentation accompanying the enclosed paper a distinction was made between *conflict* and *coincidence* of interest. The argument was advanced that true conflicts of interest are rare, and that coincidence of interest is more worrisome. Coincidence of interest may be financial, such as when peer reviewers are dependent on a funding from the sponsor of the review. Intellectual coincidence of interest with the agency sponsor is especially debilitating because it undermines scientific rigor. Obviously, coincidence of policy views with a sponsoring agency is similarly detrimental. A copy of this presentation also is attached.³

Coincidence of interest can be more insidious than conflict of interest. It arises when a reviewer lacks effective independence from the sponsor of the peer review on non-financial matters. For example, the author of a study on which an agency relies heavily has a coincidence of interest with the agency and should not serve as a peer reviewer of the agency's work. The same goes for the author of a study that contradicts an agency's interpretation. It is best to exclude from the ranks of peer reviewer any candidate who has staked out a position on the scientific issue at hand.

Can scholars selected for government peer review competently apply OMB's information quality guidelines?

Few academic peer reviewers know anything about OMB's information quality guidelines, much less how to interpret them. Merely providing peer reviewers with these guidelines, and directing them to be applied, is highly unlikely to succeed.

Relationships between reviewer and reviewee are also fundamentally different in the two settings. Most authors of journal papers are supplicants. Governmental peer review is closer to a consultant-client relationship. Quoting from the enclosed paper:

Government peer review is so different it ought not be called by the same name. The revieweeagency is not a supplicant but a client. In many cases, the reviewee-agency directly selects the peer reviewers. In other cases a firewall of uncertain temperature resistance separates the reviewee from those who formally select the reviewers. Typically, the reviewee-agency retains the authority to veto selections made by others, which is almost equivalent to enjoying the power to select. Revieweeagencies write the charge, fund and staff the process, control the flow of information, and manage the discussion agenda if the panel chairman lacks a firm hand.

² Belzer, RB, "Interests and Incentives in Peer Review," Prefatory Remarks for the Society for Risk Analysis Forum on Peer Review, May 29, 2002.

³ Belzer, RB, "Interests and Incentives in Government Peer Review," PowerPoint presentation delivered at the Society for Risk Analysis Forum on Peer Review, May 29, 2002.

Page 8 December 15, 2003



For governmental peer review to mimic the scholarly setting from which it was borrowed peer reviewers need the same powers as scholarly peer reviewers. This means the power to decide that the information they have been asked to review is not the best available, policy-neutral scientific information. In the governmental setting, of course, this power cannot be wielded anonymously. Along with the authority to review is a requirement to take responsibility for one's review.

Conflict of interest and bias appear to be confused

The criteria set forth on the selection of peer reviewers appear to confuse conflict of interest and bias. They are not the same thing. As indicated above, conflict of interest usually means private financial interest in the outcome of a peer review. OMB has leveled the playing field by applying analogous criteria to what it calls "agency entanglements." Bias is different, however. Bias is the existence of a predetermined position that is impervious to contrary evidence. Most people believe that the earth is spherical; flat-earthers are biased not because they believe the earth is flat but because their views are impervious to contrary evidence. Bias may be manifest as much through a conflict as a coincidence of interest, or it can occur without any apparent conflict or coincidence of interest. Construed this way, bias is something to be avoided, not merely balanced, because bias undermines the credibility of the review. Interests should be managed based on the role peer reviewers are expected to perform. An expert can be a peer in one setting but a stakeholder in another

Selection of peer reviewers

OMB's draft Bulletin would permit agencies to continue to select their own peer reviewers. We believe this is a mistake, for it compromises the perception of independence. We suggest an alternative approach that would be incontestably fair. First, through a public process agency sponsors should solicit recommendations in each specialty that is needed to review a specific scientific issue. Second, these candidates should be vetted for financial conflicts, agency entanglements, and coincidence of interest, and contacted to determine availability and willingness to serve. Third, from each list of candidates who pass these tests, the actual members of the panel should be selected by random draw. Where multiple parties jointly sponsor a single peer review, they should have the privilege of developing their own lists of qualified peer reviewers in proportion to their share of the funding and using the same lottery procedure to select members from the list.

PUBLIC PARTICIPATION

Section 4(a) of OMB's draft Bulletin is inscrutable on the matter of public participation. The text does not require or encourage it, and indeed it reads more like a road map directing agencies how to avoid it:

When considering selection of an outside panel of peer reviewers for regulatory information subject to the requirements of this Bulletin, an agency should assess the treatment of such a panel under the Federal Advisory Committee Act, and may retain a firm to oversee the peer review process with instructions to comply with principles consistent with those set forth in this Bulletin. See Byrd v. EPA, 174 F.3d 239 (D.C. Cir. 1999) (holding that peer review panels selected and supervised by outside consultants are not governed by the Federal Advisory Committee Act, 5 U.S.C.S. App. II §§ 1-15). (p. 12.)

This approach is ill-advised. Public participation is essential for peer review to be legitimate, and OMB should go out of its way to encourage it.

* * *

Page 9 December 15, 2003



Thank you for the extended opportunity to comment on the OMB's draft peer review Bulletin. The draft represents a good start toward enhancing the effectiveness of agencies' pre-dissemination review programs. We hope the suggestions made here will aid OMB as it works to revise the Bulletin for final promulgation.

Richard B. Belzer, Ph.D. President

Enclosures (2)

REGULATORYCHECKBOOK.ORG

Interests and Incentives in Peer Review

Prefatory Remarks for the Society for Risk Analysis Forum on Peer Review May 29, 2002 Arlington, VA

> Richard B. Belzer President Regulatory Checkbook Washington, DC RegulatoryCheckbook.org 202.898.2050

Some (but not all) of the complaints that have been leveled against government peer review reflect legitimate problems with its implementation by federal agencies. Others, however, actually speak to designed-in features and thus are not appropriately construed as "faults" or "errors." Still others bemoan phenomena that are simply not reducible unless and until a race of scientists can be created whose members lack all human qualities.

In this presentation I will deconstruct government peer review not to complain or criticize it, but rather to identify those salient features that are the source of our collective misery. My analytical approach is positive (i.e., descriptive) economics rather than moral philosophy. Government peer review performs much the way one should expect it to perform given the interests of the people, institutions and issues involved. Improving its performance requires that we have fundamental clarity about three things: first, what we expect peer review to accomplish; second, whether we are all agreed that these objectives are so reasonable and appropriate that we are willing to commit ourselves ex ante to peer review as a process-based management approach; and third, whether we can design a peer review system that imparts behavioral incentives that are consistent with both objectives and this commitment to process.

IS PEER REVIEW THE RIGHT TOOL FOR THE PROBLEM?

The answer clearly depends on what we are trying to accomplish, and much disagreement about peer review arises from lacking a shared consensus on goals and objectives. Unlike many others who seek to achieve a meeting of the minds on this matter, I do not believe that true agreement is possible. The interests of parties interested in peer review are too divergent, discordant and conflicted to reach any genuine consensus. Even if all the relevant players were here at this meeting and a common written statement could be agreed upon today, consensus would begin to unravel before the first signatory left the room.

Peer review is a tool borrowed from academic and scholarly settings. For many of us, our first real introduction to "peer review" occurred during the writing and defending of our doctoral dissertations. We had committees of reviewers led by autocratic chairmen – benign autocrats, of course, if they are still alive and we want to remain on speaking terms. We chose the members of our committees and tried very hard to please and persuade them, for they held all the cards. We were not finished until our "peer reviewers" said we were.

Subsequently most of us began applying for grants and shopping our scholarly wares in front of journal editors.¹ We promised whatever grantors said they wanted and accommodated any tomfool things an editor demanded in order to get manuscripts accepted. Grantors and editors were the autocrats, but peer reviewers were anonymous and accountable only to the grantors and editors for whom they toiled. For some of us, the path to publication was eased by prior success and perhaps rewards for service as peer reviewers and on editorial boards.

The fundamental question raised by journal editors is, "Does this body of work deserve to be published given the limited number of pages available and the quality of competing manuscripts?" It is not that different from our dissertation committee's fundamental question: "Does this thesis candidate's work meet appropriate quality standards for our institution and program?"

At no point during that debate does scholarly peer review ask, "Is this manuscript essentially correct in all its data, methods, inferences and conclusions?" That's a matter for Science to figure out, and Science takes its own sweet time. But this is precisely the fundamental question asked by governmental peer review. Little attention is given to whether a document ought to be published, because the reviewee-agency doesn't need peer reviewers' permission to publish and isn't constrained by page limitations.

Additional problems arise to the extent that hidden objectives dominate. A revieweeagency might care about the state of scientific knowledge or the fundamental truthfulness of the document reviewed. It also might not. It might care more about whether science can justify what it wants to say and do. It also might be keenly interested in whether the responsibility for controversial or unpleasant policy decisions can be implicitly delegated to others, such as Scientists.

DIFFERENCES IN THE RELATIONSHIP BETWEEN REVIEWEE AND REVIEWER

In academic and scholarly settings, the reviewee is best understood as a supplicant. The thesis chairman is superior to other committee members who are superior to the

¹ I myself did not follow this track, accepting a position as staff economist in the Office of Information and Regulatory Affairs at the Office of Management and Budget. I did not apply for grants because federal regulatory agencies kept me supplied with work peer reviewing draft regulations and regulatory impact analyses. I did not seek publication of my work because the working motto there was "publish *and* perish."

candidate. Power rests predominantly with the chairman, who along with other committee members perform functions that are part of their normal academic responsibilities. There are no deadlines. The process is private but the reviewers are known exactly. Nothing can force these people to be cooperative, complacent, speedy, encouraging, supportive or polite. Chocolate chip cookies sometimes help.

The authors of manuscripts submitted to scholarly journals face a similar (but not identical) relationship. They are still supplicants. Editors obtain peer reviewers through a variety of means, but authors do not select them and they remain anonymous.² They can (and sometimes literally do) take forever to complete a review. There are very strict deadlines that nobody pays real attention to. All power rests with editors.

Government peer review is so different it ought not be called by the same name. The reviewee-agency is not a supplicant but a client. In many cases, the reviewee-agency directly selects the peer reviewers. In other cases a firewall of uncertain temperature resistance separates the reviewee from those who formally select the reviewers. Typically, the reviewee-agency retains the authority to veto selections made by others, which is almost equivalent to enjoying the power to select. Reviewee-agencies write the charge, fund and staff the process, control the flow of information, and manage the discussion agenda if the panel chairman lacks a firm hand.

Government peer reviewers have deadlines. They are publicly known and are supposed to do their work in a fishbowl. Frequently the staff of the reviewee-agency gets an early and private peek at the peer reviewers' work. This would be considered an unethical practice in scholarly peer review.

THE DOMINANT STRUCTURAL PARADIGM FOR GOVERNMENT PEER REVIEW

In theory, government peer review is supposed to have a stack of certain attributes. It is supposed to be external to the reviewee-agency and independent from it, comprised of members who are expert in those scientific disciplines relevant to the task at hand, free of conflicts of interest that could undermine their impartiality, focused on science, transparent to public observation and scrutiny, and intellectually vigorous. A succinct version of this structure can be found in OMB's guidance to agencies on Executive Order 12866 implementation issued on September 20, 2001. Federal agencies that follow peer review processes containing these attributes are said to gain deference when their work is ultimately reviewed by my former colleagues at OMB.

External and independent. It is too early to say whether OMB actually will confer that deference, though my view is that it won't have any option. The problem is that there is a substantial discrepancy between theory and practice on the matter of whether government

² Anonymity tends to become asymmetrical as scholars become more specialized. Authorship cannot be disguised in many cases because the identity of those working on specific issues or projects is widely known. Peer reviewers can retain anonymity by writing their reviews carefully.

peer review structures actually have these attributes. "External" and "independent" are not synonyms. Only employees of the reviewee-agency are excluded from service on an "external" peer review panel. While this surely makes sense, it is not a particularly demanding requirement. "Independence" is far more difficult to achieve. Some peer reviewers are only nominally independent (or, for that matter, nominally external) because their employers depend critically on financial support, grants and contracts from the reviewee-agency. Typically, "independence" is presumed to include only a financial margin when *intellectual* independence may be much more relevant. An external peer reviewer who is fully concordant with a reviewee-agency's policy views, for example, offers precious little true independence.

Independence is always constrained insofar as peer reviewers are explicitly or implicitly selected by the reviewee-agency, which should not be expected to aggressively search for and appoint its critics. In many instances, that is precisely what a grantor or journal editor might do to ensure that a highly controversial proposal or manuscript receives the most rigorous of reviews. Reviewee-agencies should be expected to avoid such peer reviewers to the maximum extent possible.

Less well understood is the problem associated one-time versus repeated transactions. A peer reviewer who is professionally flattered by being selected but knows in advance that she will not be asked to serve again is more inclined to act like a juror in a civil trial. This probably enhances objectivity because it removes from the equation any sense that discretion might be rewarded by a return engagement. Conversely, a peer reviewer who earnestly desires to return will be sorely tempted to pull his punches.

This is an ironic twist on the longstanding notion in economics that efficiency and fair dealing are enhanced by repeated transactions. These are memorialized in the adage "the customer is always right." Sellers strive to keep customers happy by promising to resolve problems even if they are fully customers' own fault. Markets with repeat transactions stimulate socially desirable strategic behavior. Markets dominated by one-time or rare transactions (e.g., buying a rebuilt automobile motor, hosting weddings and funerals) are the most prone to fraud and other shady dealing. That is not necessarily the case in government peer review, where strategic behavior on the part of reviewee-agencies and peer reviewers may diminish the quality of peer review. The prospect of a future relationship can motivate a peer reviewer to accommodate the reviewee-agency's interests.

<u>Expertise</u>. The presence of expertise on government peer review panels is rarely a problem, but oftentimes the expertise of the members is poorly matched to the issue at hand. This may occur for any number of reasons. The "most expert" candidates may be unavailable or unwilling to serve. Those selecting the panel may not fully understand what is needed, or the panel itself may discover that it lacks expertise that it didn't know it would need. Peer reviewers (especially economists!) may be unenthusiastic about serving for nominal pay and maximal headaches. It is still the case that you get what you pay for, so the absence of financial compensation has to be made up elsewhere – in

prestige, in repeat engagements, or perhaps in private access in the halls of the revieweeagency.

In adequate or poorly targeted expertise also may be the product of strategic behavior on the part of the reviewee-agency (or other party with authority to select members). A gap in expertise may be intended if the panel selector -agency wants to skirt a particularly difficult issue. Frequently, there is but one expert in any specific and important issue on a panel. The absence of expertise overlaps creates the potential for substantially diminished intellectual vigor, as members defer to each other in areas where they perceive another panelist having superior knowledge. (Deferring to other members also may motivate them to defer to you.)

A relatively new phenomenon that threatens to severely undermine expertise (as well as several other desirable attributes) is the selection of peer reviewers because of the stakeholders they represent rather than the expertise they bring. My view is a stark one: stakeholders belong on policy advisory committees but not on peer review panels.³ If peer review panels are slowly transformed into stakeholder groups, then science will be a sure casualty.

<u>Conflicts of interest</u>. Our infatuation with conflict-of-interest seems to be legalistic, misapplied and ultimately self-defeating. As constructed in law, conflict-of-interest has almost nothing to do with improper or unethical conduct (which is generally unobservable) and everything to do with appearances (which can be readily observed at any level of abstraction one might choose). Thus, a peer reviewer may be considered "conflicted" not because of anything she did or said, or because of any hint of partiality in her scientific analysis, but because she is *affiliated* with an organization that has a financial interest in the outcome.

Moreover, this tenuous definition of conflict is almost always limited to for-profit financial interests. University professors are exempt because their employers are nonprofits and their financial interests, however memorable, are laundered through their universities' sponsored research programs. Noneducational nonprofits (such as mine) are presumptively free of conflicts because nonprofit status confers a presumption of social beneficence to which no for-profit enterprise is entitled irrespective of the relative social value of their work to mine. The unalterable fact is that almost all nonprofits (including mine) attract funds because of what we say and do, and our choice of what to say and do influences whom is interested in contributing. The only nonprofits that are free of this *conflict* of interest are the endowed foundations whose financial statements are totally unaffected by the speech and conduct of their leaders. Ironically, foundations are oftentimes bastions of extremely intense and luridly corrupting interest if their employees are permitted to serve on peer review panels.

³ This does not speak to individuals as much as it does to the relationship between an individual and the problem at hand. I consider myself an impartial peer reviewer on matters related to whether a specific benefit-cost methodology is appropriate applied in a specific risk analysis issue. However, I am a stakeholder if the question is whether benefit-cost analysis *ought* to be applied. On that margin I have a fixed and possibly unchangeably biased view.

Conventional discourse on conflict-of-interest is limited to financial matters, which in the case of scientific peer review may actually be relatively unimportant. The critical kind of interest that matters in peer review is *intellectual* interest, and *conflicts* of intellectual interest are generally desirable. It is only through conflicts of intellectual interest that peer review can sort out competing viewpoints and provide practical utility to the public. A peer review panel that lacks conflicts of intellectual interest is a stultifying enterprise whose primary output is likely to be mere conformity to common dogma.

One final note on conflict of interest: too much attention seems to be devoted to what economists call *inframarginal* concerns. For example, an expert who is employed in a scientific capacity by a giant, multinational company can have but a trivial effect on his share of the company's success or failure through service on a government peer review panel. In contrast, an otherwise identical expert who is a self-employed consultant can find her firm thrives or dies depending on her service as a peer reviewer. In the case of the scientist working for the giant company, all his efforts lie below the margin because they have no detectable effect on his livelihood. In the case of the self-employed consultant, however, virtually anything she does influences the fortunes of her company.

THERE IS MUCH MORE THAN SCIENCE AT STAKE IN GOVERNMENT PEER REVIEW

It is a remarkably resilient conceit that government peer review is about Science. It is not. It is about policy. If it weren't about policy we wouldn't care so much. So, when agency officials say that they are just following the advice of Scientists or they really want the input of Scientists before making a controversial decision, it is okay to laugh.

Sometimes science illuminates alternative policy choices and makes decisions easier or less controversial. Sometimes. More often, it seems, science is used as a means toward policy ends. The tool of peer review is abused when reviewee-agencies seek to convert policy disputes into scientific arcana. This tactic misleads the public and diminishes the reputation of scientific enterprise. It is especially disturbing to see agency officials abdicate their responsibility for making decisions by enlisting a peer review panel to provide scientific cover.

Scientists are (mostly) human. When invited to opine on policy matters, scientists are generally inclined to do so with the same regularity and intensity of others. When tempted to craft public policy under the guise of Science, many scientists will fall prey to the lures of self-importance and opportunity. While scientists have no special expertise in policy matters, their voices gain in relative strength when they become policy or decision makers.

<u>Transparency</u>. Academic and scholarly peer review – the setting from which this tool was adapted for government use – is notoriously opaque. Peer reviewers have been known to invent scientific objections to papers they simply didn't understand. In contrast, government peer review is supposed to be fully transparent. The academics and scholars who are brought in to be government peer reviewers are not at all accustomed to

conducting peer review in a fishbowl. Some handle it with equanimity; some grandstand; others withdraw into scholarly shells.

Much of the work of government peer reviewers cannot be done in public, of course. There is too little time; the settings are not conducive to rigorous analysis and scholarly reflection; and difficult and delicate questions that can be resolved responsibly in private may never be raised if all communications had to be public. This means government peer review is knowingly and perhaps purposefully schizophrenic. It is only as transparent as law, custom or public demands require.

<u>Vigor</u>. If vigorous effort and examination is an essential attribute of government peer review, it is rather amazing how many obstacles lay in the way. First, government peer review systems are designed to maximize collegiality and consensus. These attributes are consistent with satisfying a client reviewee-agency but they are foreign to scholarly peer review whence the peer review model came. Second, peer review tasks are often so complex that there is little or no overlap among reviewers in relevant expertise. Lack of overlap reduces effective expertise to one (or perhaps two) members on any issue. That makes a panel – even a large one – less of a panel and more a collection of individual experts. This is not a formula for vigorous intellectual discourse. Third, government peer review systems tend to provide a dominant role for the reviewee-agency. If the subject of the peer review controls panel selection, writes the charge, sets the schedule for meeting and report deadlines, staffs the panel, manages document flow, and many times actually runs the meetings, the resulting peer review cannot be expected to be vigorous.

REMEDIES

Government peer review is designed and operated to achieve conflicting goals under trying conditions with personnel who may not be properly equipped to do a job they were asked to do that might well be different its actual purpose. It's no wonder we have problems.

Identifying effective remedies depends first on reestablishing clarity of purpose for government peer review. This means drawing clear distinctions between stated and revealed objectives, and designing reforms that penalize gaps and reward transparent coincidence. The interests (whether conflicting or coincident) of all interested parties then must be properly understood without euphemism or favor, because understanding these interests is essential for designing a system that has incentives which encourage the cultivation of desirable process attributes. The final step is to identify these specific process reforms and suggest how any why they would bring government peer review closer to its aspirations.

During the Forum, I will identify and elaborate on a number of specific proposals. These proposals include structural changes to overcome inherent structural flaws, and functional changes to overcome dysfunctional behavior. I will elaborate at length on the fundamental problem of conflict-of-interest – not the exhibition of actual bias and partiality by government peer reviewers, but the unhealthy fixation on legalistic rules and perceived conflicts that capture only a small portion of real problems and tend to do so rather badly. Unless this particular problem is addressed, government peer review appears to be well on the way to becoming fatally bollixed in useless, paralyzing procedure.

Interests and Incentives in Government Peer Review

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Why Are There Problems in Government Peer Review?

- Performs as expected given interests of people, institutions and issues involved
 Improving performance requires clarity about
 What do we expect peer review to accomplish?
 Are we so convinced of these objectives that we are willing to commit ex ante to peer review outcomes?
 - Can we design a system with incentives that are compatible with objectives and process commitment?

Sources of Problems

Ownership
Objectives
Selection Issues
Procedures
Compensation

Interests

 conflict vs. coincidence
 Reviewers

 Accountability

Ownership

Scholarly Setting

Reviewee

- Graduate student supplicant
- Scholar supplicant

Owner

- Reviewee? Chairman?
- Grantor or editor

EIPs

- Reviewee's competitors
- No participation

Government Setting Reviewee Agency/Client

Owner • Agency/Client

EIPs
 Policy targets
 Token participation

Objectives

Scholarly Setting Supervisory

 Determine threshold competence

Peer

- Does this work deserve to be funded?
- Does this work deserve to be published?

Government Setting

- Is the product correct?
- Does the product meet owner/client needs?
 - Correct enough to guide policy- and decisionmaking?
 - Correct enough to support preferred policies and decisions?

How Owner/Clients Can Interfere: Auto Mechanics Example

Mechanic says I need major engine work I am not expert on cars Hire peer review panel: 10 best mechanics "Science" charge: Is my mechanic right? "Policy" charge: Should I fix or sell? All mechanics have views on fix or sell They are liberal with advice May be easier to answer policy charge Consensus on policy charge says nothing about science

Selection Issues

Scholarly Setting
Supervisory

Owner selects
Owner ≠ reviewer

Peer

Owner selects
Owner selects
Owner ≠ reviewer

Government Setting Supervisory Not applicable BRAC model Peer Owner selects Owner = reviewee = client

Procedures

Scholarly Setting Process management Owner control Communication None if anonymous Otherwise informal **Group Dynamics** Chair domination None if anonymous Iteration Owner ≠ reviewee ■ ∴ COI not likely

Government Setting Process management Owner control Communication Scripted Deferential **Group Dynamics** Depends on chair Highly idiosyncratic Iteration Owner = reviewer = client .:. COI likely _

Compensation

Scholarly Setting
Financial: none
Intellectual: possible
Prestige: minimal
Other: chits earned with grantor, editor

Government Setting
Financial: nominal
Intellectual: significant
Prestige: substantial
Other: agency access, policy role

Repeated Transactions

Markets

- Build relationships
- Reduce uncertainty
- Enforce contracts
- Reduce strategic behavior
- One-time transactions
- Weddings, used cars, aluminum siding, funerals

Peer Review

- Build relationships
- Reduce uncertainty
- Better grantsmanship
- Increase strategic behavior

One-time transactions

Juries

Conflict of Interest: Origins

Abuse of official powers to benefit personal financial interests Difficult or impossible to observe Perceived COI used as proxy Easy to observe COI is defined in the eye of the beholder Poorly correlated with real COI Perceived COI becomes real COI

Conflict of Interest: Application I

<u>Real</u>

Use of nonscientific criteria to evaluate science

 Exclude nonscientists, lobbyists, activists
 Verify absence of COI by quality of product

Perceived

- For-profit financial interest in decisions based on document
 - Exclude scientists with perceived COI
- Assume absence of COI by conformity with process

Conflict of Interest: Application II

Perceived COI

For-profit financial interest in decisions based on document
Exclude scientists with perceived COI
Assume absence of COI by conformity with process

<u>Consequences</u>

- Non-profit financial interests okay; they dominate
- Less perceived COIMore real COI
- Process displaces substance

Coincidence of Interest

More troubling than perceived COI Financial **Reviewer-agency funding undermines** independence Intellectual Conformity undermines scientific rigor Reviewer dominance Policy Conformity undermines policy-analytic rigor

Accountability

Owner/client Interest Information or affirmation is critical question Reviewer Interest Avoid embarrassment (confine to specialty) Get along with others, satisfy the client Achieve both by consensus reporting Group products reduce workload, dilute responsibility

Why Government Peer Review Causes Cognitive Dissonance

Mismatched capacities and responsibilities **Scientist** \rightarrow stakeholder ■ Science \rightarrow policy Desirable polar cases Stakeholders do policy Scientists do science Undesirable polar cases Stakeholders do science Scientists do policy





Why Government Peer Review Causes Cognitive Dissonance











The Perfect Peer Reviewer

Can't be influenced by interests, outcomes or unexpected events The rules are set out in advance Sticks to the rules Despised but essential Don't know what they will decide Can't play the game without them



Norman Rockwell's "Tough Call" Dodgers' vs. Pirates, Ebbets Field. *Saturday Evening Post* cover April 23, 1949.

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Standard Process Remedies

External
 Independent
 Select based on expertise
 Disclose potential COIs

 Private/public financial
 Technical/policy views

OpenRigorous

Low standard

- Ownership problems
- Stakeholder balance
- Drunk-and-lamppost problem
 - Private financial only
 - Coincident views
- Token public participation
 Rigor ≠ weight of tome

Alternative Remedies: I

Ownership: Separate from reviewee Government council (e.g., OSTP) External auditor **Objectives:** Distinguish science from policy Reserve peer review for science Limit scope of review to fundamental science questions Agencies: don't ask

Reviewers: don't cooperate

Alternative Remedies: II

Selection Issues: Separate from reviewee Build reviewer pool, select panelists by lottery Larger the pool, lower the risks Procedures: Incentive-compatibility Open process to views other than reviewee's Deter artificial consensus via final-offer arbitration Obtain accountability via individual, majority/minority reports Managing interests: Role-based, not status-based Expert can be a peer in one setting but a stakeholder in another Defines roles before choosing reviewers



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