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To: Mabel E. Echols OMB\_Peer\_Review/OMB/EOP@EOP

cc:

Subject: Comments from CPR on OMB's Proposed Peer Review Bulletin

<<OMB.peerreviewcomments12.07.03..PDF>>

Dear Dr. Schwab,

Please find attached comments on OMB's Proposed Peer Review Bulletin from the Center for Progressive Regulation. Please disregard an earlier attempt to email you these comments because I erroneously attached the wrong version. (I withdrew this email but I don't know if it was delivered.) The correct version is dated Dec. 7, 2003.

Thank you for this opportunity to comment.

Sid Shapiro

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December 7, 2003

Dr. Margo Schwab  
Office of Information and Regulatory Affairs  
Office of Management and Budget  
725 17<sup>th</sup> Street, N.W.  
New Executive Office Bldg., Room 10201  
Washington, D.C.

**Re: Proposed Bulletin on Peer Review and Information Quality**

Dear Dr. Schwab:

OMB has proposed a Bulletin that would supplement existing procedures under the Information Quality Act (IQA)<sup>1</sup> by requiring peer review of regulatory information and by specifying the procedures under which that review would take place.<sup>2</sup> OMB has also proposed to become intimately involved in the resolution of information quality complaints.<sup>3</sup> The scope of matters covered Bulletin is overbroad and therefore exceeds OMB's legal authority. For the same reasons, the Bulletin will result in duplicative and costly peer review. In its preoccupation with agency-funded scientists, and its omission of comparable rules for industry scientists, the Bulletin will not accomplish the most important reform that could justify its issuance: ensuring that peer review is balanced for bias and therefore is not dominated by regulated industries to the extent it is today.

The Center for Progressive Regulation (CPR) appreciates the opportunity to comment on these proposals. CPR is an organization of academics specializing in the legal, economic, and scientific issues that surround health, safety, and environmental regulation. As our website indicates, [www.progressiveregulation.org](http://www.progressiveregulation.org), CPR's mission is to advance the public's understanding of the issues addressed by the country's health, safety and environmental laws and to make the nation's response to health, safety, and environmental threats as effective as possible. The Center is committed to developing and sharing knowledge and information, with the ultimate aim of preserving the fundamental value of the life and health of human beings and the natural environment. CPR circulates academic papers, studies, and other analyses that

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<sup>1</sup> Treasury and General Appropriations Act for Fiscal Year 2001, Pub. L. No. 106, § 515 (2001).

<sup>2</sup> Proposed Bulletin on Peer Review and Information Quality, 68 Fed. Reg. 54023 (2003).

<sup>3</sup> Id.

promote public policy based on the multiple social values that motivated the enactment of our nation's health, safety and environmental laws. CPR seeks to inform the public about scholarship that envisions government as an arena where members of society choose and preserve their collective values. We reject the idea that government's only function is to increase the economic efficiency of private markets.

The Center also seeks to provoke debate on how the government's authority and resources may best be used to preserve collective values and to hold accountable those who ignore or trivialize them. We seek to inform the public about ideas to expand and strengthen public decision-making by facilitating the participation of groups representing the public interest that must struggle with limited information and access to technical expertise.

### SUMMARY

OMB proposes mandatory peer review even though the IQA says nothing about peer review and contains no directive that agencies must use it before disseminating information. Moreover, OMB proposes to require peer review even though Congress rejected legislation mandating similar peer review procedures just a few years ago.<sup>4</sup> In light of the lack of statutory authority for its proposal, OMB seeks to justify its peer review requirements by noting that scientists and government officials have recognized the importance of peer review in regulatory processes.<sup>5</sup> There is a difference, however, between recognizing in the abstract that peer review can aid regulatory decision-making and developing specific proposals for making peer review useful. When OMB fills in the details, it fails to limit peer review to circumstances where it is best utilized, and it does not provide for an accountable and balanced peer review process in those circumstances.

More specifically, CPR asks that OMB consider the following objections to its proposal:

- OMB's assertion of jurisdiction to require agencies to use peer review regarding the dissemination of information is doubtful. Even if OMB has authority to require peer review for information that the government disseminates in reports and on the Web, it lacks the authority to require peer review in rulemaking because the IQA does not apply to rulemaking. OMB should delete the requirement that agencies undertake peer review with respect to scientific information that is already subject to extensive notice and comment in the context of a rulemaking covered by the Administrative Procedure Act (APA).
- OMB fails to target peer review to those situations in which it might be most useful. In light of the considerable costs of peer review, OMB should limit peer review to circumstances in which the information to be disseminated sets a new precedent or is reasonably controvertible.
- OMB's effort to avoid the Federal Advisory Committee Act (FACA) does not serve its purpose of increasing public confidence in the information that government disseminates.

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<sup>4</sup> See, e.g., H.R. 9 (1995).

<sup>5</sup> Proposed Bulletin, *supra* note 2, at 54024.

Contrary to OMB's legal analysis, FACA would apply to any peer review committee mandated by an OMB Bulletin. Even when FACA does not legally apply, OMB should require that agencies comply with the requirements in FACA for balanced peer review committees and a public peer review process when agencies seek peer review of especially significant information.

- OMB's assumption that scientists who receive public funding are more likely to be biased than scientists who receive industry funding is simply wrong, and its plan for appointing scientists with offsetting biases is unworkable. To address potential bias, OMB should require peer review committees to be "fairly balanced," as FACA requires, and should require public disclosures by scientists undertaking peer review of their historical affiliations and sources of research funding. OMB should make explicit its intent to leave in place federal laws and regulations that bar the participation of scientists with demonstrable financial "conflicts of interest," and should encourage agencies to disclose any waivers granted such reviewers.
- OMB rightfully rejected the centralized appointment of peer reviewers, although the reasons expressed by OMB for doing so significantly understate the difficulty of such a process, including the lack of coordination and accountability.
- OMB's decision to exempt information disseminated in adjudication and permit proceedings from its peer review procedures lacks any apparent justification, raising the suspicion that OMB's exemption is based on the fact that the information disseminated in adjudications and permit proceedings is largely information submitted by industry. OMB should require peer review of such studies under the circumstances recommended above.
- OMB's proposal to review each and every request for information correction creates the potential for backroom deals between OMB and the complaining party or other interested parties. To ensure accountability, OMB should issue a concise written explanation for public disclosure indicating that it recommended that an agency modify existing information in light of a complaint, and it should reveal for public disclosure any written communications, and a summary of any oral communications, pertaining to the substance of an information quality complaint received from members of Congress or their staffs or from persons outside of government.

#### **AUTHORITY TO REQUIRE PEER REVIEW**

OMB claims the IQA provides authority for its Bulletin, but the text of the Act does not support this claim. The Act does not explicitly require, or even authorize, peer review. Moreover, although the Act imposes a number of duties on OMB, Congress did not include among these duties setting up guidelines for peer review. Further, Congress explicitly rejected the imposition of peer review a few years ago after due consideration and debate,<sup>6</sup> and it is difficult to believe that Congress changed its mind when it passed the IQA. After all, the IQA was a rider hidden in an appropriations bill that no one in Congress other than the sponsor knew was there.

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<sup>6</sup> Note 4 & accompanying text.

Moreover, OMB cannot claim other sections of the Paperwork Reduction Act (PRA) as authority for requiring peer review. Although the Act was passed in 1980, OMB has never previously interpreted PRA to authorize the imposition of peer review, and the fact that Congress has several times considered legislation that would expressly require peer review confirms that OMB lacks this power. Although PRA gives OMB authority to “develop and oversee the implementation of policies, principles, and standards to apply to Federal agency dissemination of public information ...,”<sup>7</sup> this authority extends only to overseeing how the government “manages” the information that it collects.<sup>8</sup>

Even if the courts hold that OMB can impose a peer review requirement on agencies, this authority does not extend to the dissemination of information in rulemaking because the IQA simply does not apply to rulemaking. Congress indicated that the IQA does not apply to rulemaking when it required that agencies create a new “administrative mechanism” to hear and resolve complaints about information quality.<sup>9</sup> This means Congress intended the rider to apply to contexts where the dissemination of information is not already subject to an administrative mechanism to correct problems. This would not include rulemaking because such a process already exists in rulemaking. Since setting up another process would be superfluous or redundant, it has to be assumed that Congress had no such intention.<sup>10</sup>

#### SCOPE OF PEER REVIEW

While peer review has a role to play in the regulatory process, OMB’s proposal for peer review is too broad in light of the potential benefits that it is likely to generate. OMB errs in assuming that peer review is appropriate or even necessary for all “significant” information because it is likely to have or will have a substantial impact on public policy or private initiatives.<sup>11</sup> Although information may have such an impact, it does not follow that the information is likely to be unreliable or that peer review is necessary to ensure its objectivity. OMB should therefore limit peer review to circumstances where the information to be disseminated sets a new precedent or is reasonably controvertible.<sup>12</sup> In any other circumstance, peer review is wasteful and will unnecessarily delay the dissemination of important information.

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<sup>7</sup> 44 U.S.C. §§3504(d)(1).

<sup>8</sup> See OMB Circular No. A-130 Revised (“The PRA establishes a broad mandate for agencies to perform their information resources management activities in an efficient, effective, and economical manner.”), available at <http://www.whitehouse.gov/omb/circulars/a130/a130trans4.html#8>.

<sup>9</sup> Information Quality Act, *supra* note 1, §515(b)(2).

<sup>10</sup> The background of the Act also confirms that Congress intended the Act to apply outside the context of rulemaking. Prior to enactment of the Information Quality Act, there was a discussion and debate over how to provide for public input before agencies produce reports or put information on their web sites. See, e.g., 23 Administrative & Regulatory Law News #3 (Spring 2000), at 10 (describing program held by the ABA on the dissemination of reports and information on the Web); White Paper From Industry Coalition to EPA Over Concerns Over Information Programs Submitted May 4, 1999, Daily Env. Rep. (May 4, 1999), at E-1 (discussing the dissemination of reports and information on the Web). There was no discussion, however, of the need to provide mechanisms to improve information quality in the context of rulemaking.

<sup>11</sup> Proposed Bulletin, *supra* note 2, at 54028, §§1-2.

<sup>12</sup> This argument is supported by a formal policy position of the American Bar Association concerning risk assessment. The ABA has recommended that the “nature, significance, and complexity” of a risk assessment should determine “when” agencies use peer review, as well as determining the “nature and scope” of peer review. ABA Resolution on Risk Assessment (October 1999), available at <http://www.abanet.org/adminlaw/risk02.pdf>. The report accompanying the recommendation, which was not officially adopted by the ABA, explains that peer review

OMB partially concedes this point. Regarding “significant” information, it permits agencies to “select an appropriate peer review mechanism based on the novelty and complexity of the science to be reviewed, the benefit and cost implications, and any controversy regarding the science.”<sup>13</sup> The government, however, distributes a wide variety of information, much of which occurs outside of the context of rulemaking, for which peer review may be unnecessary, even though the information has not been previously subjected to peer review. While OMB’s flexibility regarding such information may minimize the government’s burden in individual situations, the collective time and expense to the government of having universal peer review for significant information is likely to be substantial. Moreover, agencies are not permitted to vary the additional procedures they must use concerning “especially significant” regulatory information,<sup>14</sup> regardless whether the additional procedures are useful and necessary.

## FACA

OMB suggests to agencies that they can avoid complying with the Federal Advisory Committee Act (FACA) when they undertake peer review. Congress passed FACA “in large part to promote good-government values such as openness, accountability, and balance of viewpoints.”<sup>15</sup> Because these values are vital to ensuring the legitimacy of peer review, OMB should require that agencies conduct peer review of “especially significant information” under FACA.

FACA offers two essential protections necessary to legitimize peer review. First, it mandates a peer review process that is open to the public.<sup>16</sup> OMB does require that an agency provide an opportunity for public comment and that such comments should be furnished to peer reviewers in sufficient time that they can take the comments into account.<sup>17</sup> OMB presumably intends that the comments also be made public, although it does not explicitly so provide. OMB also provides that the report of the peer reviewers and the agency’s responses to that report be made public.<sup>18</sup> It is difficult to see why the public should trust a peer review process that operates behind a veil of secrecy. If OMB’s goal is to increase public confidence in the information that

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should be “limited to situations in which it is most likely to improve the analysis, such as complex or novel problems, or add authority, such as highly controversial situations.” American Bar Association, Section of Administrative Law and Regulatory Practice, Report (August 1999), at 9, available at <http://www.abanet.org/adminlaw/risk02.pdf>.

<sup>13</sup> Proposed Bulletin, *supra* note 2, at 54028, §2.

<sup>14</sup> *Id.* at 54028, §3.

<sup>15</sup> Steven P. Croley, *Practical Guidance on the Applicability of the Federal Advisory Committee Act*, 10 AD. L.J. 111, 117 (1996); see also Jay S. Bybee, *Advising the President: Separation of Powers and the Federal Advisory Committee Act*, 104 YALE L.J. 51, 73 (1994) (noting that Congressional hearings on FACA “focused on the non-representative nature of the advisory committees, and the need to open their proceedings and reports to the President).

<sup>16</sup> FACA requires that peer review minutes are open to the public, 5 U.S.C. App. II §10(a)(1), interested persons are entitled to “attend, appear before, or file statements with any advisory committee,” *id.* §10(a)(3), detailed minutes must be kept, *id.* §10(c), and any records or documents made available to the committee be made available to the public unless the records can be withheld according to one of the exceptions for public disclosure under the Freedom of Information Act (FOIA), *id.* §10(b). An agency can close a meeting only if it determines that one of the exceptions to the Sunshine Act applies. *Id.* §10(d).

<sup>17</sup> Proposed Bulletin, *supra* note 2, at 54029, §3.

<sup>18</sup> *Id.*

the government disseminates, closing the peer review meetings and hiding peer review documents does not serve its purpose.

Second, FACA requires agencies to ensure that their advisory committees are “fairly balanced in its membership in terms of the points of view represented and the functions to be performed.”<sup>19</sup> This safeguard is important because it recognizes that peer review inevitably involves matters of judgment about which reasonable scientists can disagree. This is the situation for two reasons. First, although OMB correctly asks that agencies refer only “scientific and technical matters to agencies, leaving policy determinations for the agency,” it is virtually impossible to separate scientific and policy issues.<sup>20</sup> Second, even within the realm of “scientific issues,” peer reviews will confront issues for which there are no objective answers, requiring them to use their best judgment.<sup>21</sup> Furthermore, allowing an agency to pick peer reviewers without regard to balance invites an agency to tilt peer review to its preferred outcome. This has long been a problem with peer review,<sup>22</sup> and OMB’s failure to require the use of FACA will continue the problem.

OMB seeks to avoid FACA by authorizing agencies to “direct peer reviewers of regulatory information – individually or in a group – to issue a final report detailing the nature of their review and their findings and conclusions.”<sup>23</sup> Although FACA may not apply to convening a number of people to obtain the advice of each individually (rather than collectively),<sup>24</sup> individual review is a bad idea. The advantage of conducting peer review by committee is that “each committee member has the opportunity to observe the demeanor of the others and to challenge their evaluations.”<sup>25</sup> As a result, “bringing all reviewers together to discuss their opinions can be a powerful shield against favoritism and animus.”<sup>26</sup> This shield becomes even more important if OMB succeeds in closing peer review meetings to the public by permitting agencies to avoid FACA by hiring contractors to conduct the peer review.

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<sup>19</sup> 41 C.F.R. §102-3.30(c) (2003).

<sup>20</sup> See Wendy E. Wagner, *Congress, Science, and Environmental Policy*, 1999 U. ILL. L. REV. 181, 214 (1999) (“Although these advisory panels have proved helpful in ensuring that the agencies use positive scientific knowledge accurately, these panels often find themselves reviewing the agency’s policy choices under the auspices of peer review.”); Joel Yellin, *Science, Technology, and Administrative Government: Institutional Designs for Environmental Decisionmaking*, 92 YALE L.J. 1300, 1305-06 (1983) (“If it were possible to separate the technical from the political, ethical, and legal, ... environmental decisions could be made in a simple two step process. ... The history of unsuccessful attempts to distinguish fact from law suggests that separation may be an unattainable goal.”)

<sup>21</sup> See Holly Doremus, *Listing Decisions Under the Endangered Species Act: Why Better Science Isn’t Always Better Policy*, 75 WASH. U.L.Q. 1029, 1064 (1997) (Reliance on science must, by necessity, include reliance on some hunches.)

<sup>22</sup> See Bybee, *supra* note 15, at 58-59 (discussing the uses and abuses of advisory committees); THOMAS O. MCGARITY & SIDNEY A. SHAPIRO, *WORKERS AT RISK: THE FAILED PROMISE OF THE OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION* 196 (1993) (discussing the potential of stacking advisory committees to obtain an agency-favored preordained outcome).

<sup>23</sup> Proposed Bulletin, *supra* note 2, at 54027, §3. This interpretation is open to challenge. See Steven P. Croley & William F. Funk, *The Federal Advisory Committee Act and Good Government*, 14 YALE J. REG. 451, 472-78 (1997) (questioning the conclusion that FACA does not apply to individual reviewers).

<sup>24</sup> 41 C.F.R. §102-3.40(e) (2003).

<sup>25</sup> Thomas O. McGarity, *Peer Review in Awarding Federal Grants in the Arts and Sciences*, 9 HIGH TECHN. L.J. 1, 64 (1994).

<sup>26</sup> *Id.*

Based on *Byrd v. EPA*,<sup>27</sup> OMB also claims that an agency can avoid complying with FACA if it hires a contractor or consultant, who in turn organizes the peer review.<sup>28</sup> In *Byrd*, the Environmental Protection Agency (EPA) hired a private contractor to select and manage a peer review panel and submit a report to the agency.<sup>29</sup> A majority of the panel held that FACA did not apply because, although EPA had reserved authority to control the contractor's choice of peer reviewers, it did not exercise this power. In their words, the decision was based "on what EPA in fact did, rather than on what it could have done."<sup>30</sup>

The *Byrd* case has not been followed by any other circuit. More importantly, it does not help OMB because OMB requires agencies to ensure that peer review of especially significant regulatory information meets a number of requirements, including that peer reviewers "shall be selected primarily on the basis of necessary scientific and technical expertise."<sup>31</sup> In order to meet this requirement, agencies must actively review the choice of peer reviewers by a contractor and veto any peer reviewer that does not meet this condition. Likewise, agencies have a legal duty to ensure that the other conditions that OMB has established for peer review of especially significant information are met. Thus, unlike the situation in *Byrd*, an agency will have to control the peer review process, which EPA did not do in *Byrd*, according to the majority opinion.

Of course, it is not necessary for OMB to require the formal use of FACA, although that would be a good idea, in order to ensure an open peer review process and balanced peer review. OMB could simply require agencies to comply with the fair balance and open government provisions of FACA without formally chartering peer review committees.

### CONFLICTS OF INTEREST VERSUS BIAS

A fundamental flaw in the proposed Bulletin is its failure to distinguish between conflicts of interest that disqualify prospective scientists from serving on peer review panels under existing law and the bias that scientists may exhibit when they have formulated a position on a scientific issue through their work in the same or related areas. A full range of statutory and regulatory requirements, most notably the Ethics in Government Act,<sup>32</sup> bar scientists who have a direct financial interest in the outcome of an administrative decision from serving on government peer review panels established to review scientific studies that affect such deliberations. Agencies may waive these requirements, but must go through a formal process to do so. The proposed Bulletin uses the phrase "real or perceived conflicts of interest" but does not otherwise recognize

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<sup>27</sup> 174 F.3d 239 (D.C. Cir. 1999).

<sup>28</sup> Proposed Bulletin, *supra* note 2, at 54028, §4a.

<sup>29</sup> 174 F.3d at 241.

<sup>30</sup> *Id.* at 247. In his dissent, Judge Williams held that FACA applied because the panel was "so closely" controlled "in membership and purpose." *Id.* at 249. For Judge Williams, the key was EPA's "veto power," and the fact that "it was not used" did not matter because EPA might "exercise it in future applications" and "the contractor was and is quite likely to take the fact of the veto into account in its selection decisions." *Id.*

<sup>31</sup> Proposed Bulletin, *supra* note 2, at 54027. Further, the proposed guidelines require an agency to "provide to peer reviewers an explicit written charge statement describing the purpose and scope of the review." *Id.* at 54028. In addition, the "agency shall provide an opportunity [for public comment]," and it "shall direct peer reviewers ... to issue a final report," and OMB specifies the specific nature of the report. *Id.*

<sup>32</sup> 5 U.S.C. §§ 201 et. seq.

that this term has a legal meaning under existing law.<sup>33</sup> It should be revised to make explicit OMB's recognition that existing legal requirements regarding conflicts of interest remain in force with respect to any peer review panels established under the Bulletin.

Even if scientists possess indirect financial interests (e.g., continued employment with a broadly-based industry trade association) that are not covered by federal conflict of interest rules, such interests may lead to an appearance that they are biased with respect to the outcome of a peer review. Despite its apparently exhaustive review of prominent literature on peer review, including reports by the General Accounting Office (GAO) and the EPA Inspector General, OMB conspicuously omits a recent GAO report documenting EPA's persistent tendency to ignore such financial interests in assembling peer review panels, with the result that scientists who were paid by manufacturers of chemicals under consideration by the EPA Science Advisory Board were actually permitted to serve on such panels.<sup>34</sup> To remedy its apparent insensitivity to this important problem, OMB should consider describing these interests without reference to the legal term of art "conflict of interest," while simultaneously strengthening its exhortations to agencies to avoid choosing such compromised candidates.

OMB advises agencies to consider disqualifying scientists who have or may do research supported by the government,<sup>35</sup> but it does not recommend a parallel rule to disqualify a scientist who has received, or is attempting to receive, research funding from regulated industries.<sup>36</sup> OMB, however, has the situation exactly backwards. If anything, agencies should exhibit more care in their selection of scientists whose research is funded by industry.

OMB is concerned that scientists funded by agencies, or who would seek such funding, could feel pressured to bend their advice to an agency in order to secure present or future funding. Public financing of science, however, occurs under procedures that protect and promote the independence of the scientists doing the research. By comparison, private research occurs under conditions that make it more likely that scientists will lose their funding if they do not produce results that are satisfactory to the industrial source of funding.<sup>37</sup>

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<sup>33</sup> Proposed Bulletin, *supra* note 2, at 54027, § 2.

<sup>34</sup> GENERAL ACCOUNTING OFFICE, EPA'S SCIENCE ADVISORY BOARD: IMPROVED PROCEDURES NEEDED TO ENSURE INDEPENDENCE AND BALANCE 18 (2001) (Report No. GAO-01-536) (describing the impropriety of EPA's appointment of industry-dominated panels) [GAO EPA Report].

<sup>35</sup> *Id.*

<sup>36</sup> OMB apparently does not think that latter situation is a problem unless a scientist has an actual financial interest in the outcome of the study. Proposed Bulletin, *supra* note 2, at 54024. Perhaps OMB anticipates that scientists who undertake research funded by industry will also have a financial stake in the outcome of the research. While this is a growing problem, not all industry-funded scientists are in this situation. OMB's position on this issue, however, is not entirely clear. In its proposed rules, OMB lists as possibly disqualifying the receipt of "substantial funding" from an agency or the application for such funding from an agency. *Id.* at 54027. There is no similar proposed disqualification for scientists who receive, or are seeking to receive, funding from industry, although OMB does propose that agencies consider as potentially disqualifying that a person has "financial interests in the matter at issue." *Id.* OMB's preamble informally defines "financial interest in the subject matter" as "(e.g., ties to a regulated business)." *Id.* at 54024. This seems to suggest an implicit acknowledgment by OMB that ties to a regulated business should be a negative factor in the selection process.

<sup>37</sup> Professor Sheldon Krinsky explains:

When government funds basic science, it does not have a vested interest in a particular outcome. Given the transparency of the funding and the peer-review process, government agencies have to be very careful

Finally, OMB proposes that an agency can appoint a “biased” reviewer if necessary to gain needed expertise if it appoints someone who has a contrary bias.<sup>38</sup> This proposal reflects OMB’s assumption that agencies can generally create a neutral peer review process, which is not actually possible in light of the factors discussed earlier. Moreover, it is unlikely that an agency can match up offsetting biases in the manner that OMB anticipates. What type of person, for example, has a “contrary bias” to a person who has an unrelated contract with the agency? The general prophylactic of requiring a “broadly representative” and “fairly balanced” review group is a more effective protection against biased peer review outcomes and is more manageable.

### DISCLOSURE OF AFFILIATIONS

OMB requires that a peer review report shall “disclose the names, organizational affiliations, and qualifications of all peer reviewers, as well as any current or previous involvement by a peer reviewer with the agency or issue under peer review consideration.”<sup>39</sup> Once again OMB draws a distinction between agency and industry affiliation that is unwarranted. Whereas a peer review report must disclose the involvement of peer reviewers with an agency, there is no similar disclosure requirement for scientists who are involved with the regulated industry. Further, although OMB suggests that an agency may wish to require peer reviewers to disclose “sources of personal or institutional funding,”<sup>40</sup> it is not clear whether OMB is referring to industry funding of research.

OMB should require that a peer review report disclose the historical affiliations of peer reviewers (both agency and industry related) and the sources of funding that a scientist has received. As the General Accounting Office (GAO) has observed, this approach gives the public information that can be used to evaluate the legitimacy of the advice being received because it indicates the degree of balance that the agency has obtained in its appointment of peer reviewers.<sup>41</sup> Moreover, this approach permits an agency to hear from a diverse group of scientists and not disqualify certain scientists because of their previous sources of funding, while assuring the public of the legitimacy of the peer evaluation process.<sup>42</sup> Finally, an agency should gather this information at

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of not appearing to tease out or share scientific results that meet a political perspective, even in areas of applied research....

Private funded science is not transparent. There are unstated agendas. Many scientists who are funded by private companies understand what results would please the company and what results would benefit the company’s bottom line. If a scientist is tethered to a company’s research program, then the company is likely pleased with the outcome of the research and therefore would benefit by continuing to fund it. It is not unusual for investigators to internalize the interests of the company....

SHELDON KRIMSKY, SCIENCE IN THE PRIVATE INTEREST: HAS THE LURE OF PROFITS CORRUPTED BIOMEDICAL RESEARCH? 143-44 (2003).

<sup>38</sup> Proposed Bulletin, *supra* note 2, at 54027, §3,

<sup>39</sup> *Id.* at 54028, §3.

<sup>40</sup> *Id.*

<sup>41</sup> GAO Report, *supra* note 34, at 18.

<sup>42</sup> Disclosures might implicate some protections under the Privacy Act, but the Act permits individuals to waive any privacy protections that they might have. See 5 U.S.C. § 552a(b) (permitting written waivers). It is reasonable for an agency to require such waivers as a condition of serving as a peer reviewer.

the beginning of the peer review process when the agency can use it to ensure that peer review is a balanced process.<sup>43</sup>

### CENTRALIZED APPOINTMENT OF REVIEWERS

In its proposed guidelines, OMB declines to propose the centralized appointment of reviewers because it “could be unduly inefficient and raise other concerns.”<sup>44</sup> OMB understates the difficulties with centralized appointment of reviewers.

First, OMB does not suggest what entity might serve this function, but it is clear that the selection of OMB for this function is unlikely to “lend the appearance of greater integrity to the peer review process.” There has been significant concern over the years concerning the accountability of presidential supervision of rulemaking,<sup>45</sup> and OMB’s control over peer review would raise the same legitimate concerns.

Second, putting an entity in charge of peer review which has no responsibility for the implementation of a statutory scheme invites the appointing agency to pursue its own political and substantive agenda, regardless of whether it is appropriate for the implementation of the statutory scheme.<sup>46</sup> The risk that a centralized agency would pursue its own agenda is particularly acute to the extent that it is not publicly accountable for its actions. Yet, as indicated above, there is no assurance that the agency that appoints the peer reviewers, whether it is OMB or some other entity, will do so in an accountable way. The lack of accountability invites capture by vested interests. This is particularly a problem because OMB fails to require that peer review be a balanced process.

Finally, peer review is less likely to inform and improve regulatory decision-making when agency employees regard it as a bureaucratic burden imposed on an agency rather than a tool for improving the quality of decision-making.<sup>47</sup> Agency personnel are more likely to regard peer review as a bureaucratic requirement, as opposed to an integral part of the agency’s decision-making process, when it is imposed on the agency by OMB and implemented by another entity, be it OMB or some other agency.

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<sup>43</sup> See GAO Report, *supra* note 34, at 20 (recommending that EPA collect background information about potential peer reviewers before their appointment to a peer review committee).

<sup>44</sup> *Id.*

<sup>45</sup> See, e.g., GLEN ROBINSON, *AMERICAN BUREAUCRACY: PUBLIC CHOICE & PUBLIC LAW* 102 (1991), Sidney A. Shapiro, *Presidential Oversight and the Deterioration of Regulatory Policy*, 46 AD. L. REV. 1, 21-23 (1994) (discussing the debate of White House accountability in rulemaking oversight).

<sup>46</sup> This is what happened when Congress located the Occupational Safety and Health Administration (OSHA) and the National Institute of Occupational Health (NIOSH) in two different cabinet departments. Although Congress created NIOSH to serve as the scientific arm of OSHA, NIOSH at times has pursued this mission according to its agenda and has not always pursued projects helpful or appropriate to OSHA. Sidney A. Shapiro & Thomas O. McGarity, *Reorienting OSHA: Regulatory Alternatives and Legislative Reform*, 6 YALE J. ON REG. 1, 57-59 (1989).

<sup>47</sup> According to the National Academy report, peer review “must become accepted as part of the agency’s culture, not merely a bureaucratic requirement.” National Academy of Sciences, *Strengthening Science as the US Environmental Protection Agency: Research Management and Peer Review Practices* 115 (2000). Professor Lars Noah makes a similar point when he observes that peer review works best when it is peer reviewers interact with agency scientists in an ongoing dialogue. Lars Noah, *Scientific “Republicanism”: Expert Peer Review and the Question for Regulatory Deliberation*, 49 EMORY L.J. 1033, 1059-60 (2000)

## UNEQUAL TREATMENT OF INDUSTRY INFORMATION

The proposed Bulletin seeks to assure the objectivity of information disseminated by the government by subjecting it to peer review, but the Bulletin exempts an important category of information generated by industry from this procedure. According to the proposal, “agencies need not have peer review conducted on significant regulatory information that ... is disseminated in the course of an individual agency adjudication or proceeding on a permit application.”<sup>48</sup> The lack of any apparent justification for these exceptions leads to the conclusion that OMB is protecting industry information from peer review.

OMB presumably exempted information disseminated in adjudications because its Information Quality Guidelines exempted adjudication from the Act altogether,<sup>49</sup> but it is not clear why information disseminated in adjudication is not subject to the Act. Maybe OMB believed that the adjudicatory process is sufficient to vet the accuracy of the information involved, but there are two difficulties with this position. First, the procedures in an adjudication vary widely depending on whether the adjudication is formal or not, and if not, what procedures are required by the statutory mandate under which the agency is operating.<sup>50</sup> Many informal adjudications are conducted with no procedures whatsoever. Second, if this is OMB’s position, it is difficult to understand why OMB does not also exempt information disseminated in a rulemaking because the procedures are adequate to vet the information that is disseminated.

OMB also offers no reason why it exempts information disseminated in a proceeding on a permit application. Since these proceedings involve adjudication, OMB’s exemption might have been based on the prior reason. Or OMB may have concluded that permit applications were not important enough to deserve peer review. But OMB subjects other types of significant regulatory information to peer review, and there is no indication by OMB why information disseminated in a permit proceeding, if it is significant regulatory information, should not be subject to peer review.

OMB’s exemption for permit proceedings may be an attempt to protect propriety or trade secret industry information, but this is an invalid reason for not subjecting this information to peer review. An agency can follow the practice of FDA, which regularly protects such information and still subjects it to peer review.<sup>51</sup>

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<sup>48</sup> Proposed Bulletin, *supra* note 2, at 54027, §2.

<sup>49</sup> In the Guidelines, OMB defines “dissemination” as not including “distribution ... limited to adjudicative processes. Office of Management and Budget, Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility and Integrity of Information Disseminated By Federal Agencies, 67 Fed. Reg. 8452, 8460 (2002).

<sup>50</sup> See RICHARD J. PIERCE, SIDNEY A. SHAPIRO & PAUL R. VERKUIL, ADMINISTRATIVE LAW & PROCEDURE §§ 6.4.3, 6.4.10 (3d ed. 1999) (explaining the variability of procedures used in adjudication).

<sup>51</sup> FDA advisory committees are composed of scientists who are hired as special government employees, which makes it possible for FDA to reveal the information to them and which imposes on the scientists a legal obligation to keep the information confidential. See 21 C.F.R. §14.80 (members of FDA advisory committees serve as special government employees).

The lack of any apparent justification for these exceptions leads one to the suspicion that OMB's exemption is based on the fact that the information disseminated in adjudications and permit proceedings is largely information that is submitted by regulated industries. But there is no apparent reason why industry information should be exempted from peer review, except when the nature of the information does not warrant the cost and delay created by peer review. As noted earlier, peer review should be reserved for the dissemination of information that sets a new precedent or is reasonably controvertible. If industry information meets this test, it is not possible to distinguish it from information that arises in other contexts.

OMB's solicitude for industry information is particularly puzzling because such information is usually not subjected to the same level of scrutiny as information that is the result of public funding.<sup>52</sup> Moreover, since industry often regards information submitted to agencies to obtain permits or licenses as propriety or trade secret, it is far more likely to have received little or no independent scrutiny than information produced by scientists as the result of public funding.

### OMB AND CORRECTION REQUESTS

OMB's proposed Bulletin ends with a proposal that agencies provide to it within seven days a copy of each non-frivolous request for information quality correction unless the agency posts the complaint on its web site, and that an agency consult with OMB before it responds to the complaint.<sup>53</sup> In light of the public interest in the outcome of complaints concerning "especially significant regulatory information," it is important that OMB be accountable for its participation in the resolution of information quality complaints, but OMB has proposed nothing in the way of accountability procedures.

OMB should take two steps to promote accountability concerning complaints about "especially significant regulatory information." It should issue a concise written explanation for public disclosure indicating that it recommended that an agency modify existing information in light of a complaint, and it should reveal for public disclosure any written communications, and a summary of any oral communications, pertaining to the substance of an information quality complaint from members of Congress or their staffs or from persons outside of the government.<sup>54</sup>

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<sup>52</sup> For example, regarding privately funded research in the life sciences, empirical studies have found a "greater secrecy among colleagues, a significant failure of scientific exchange in the community, and a pattern of delayed publication." KRIMSKY, *supra* note 37, at 84.

<sup>53</sup> §7, Proposed Bulletin, *supra* note 2, at 54029.

<sup>54</sup> These recommendations reflect a formal policy adopted by the American Bar Association concerning the accountability of White House oversight in the context of rulemaking. See Recommendation on Presidential Oversight (Feb. 1993), available at <http://www.abanet.org/adminlaw/policy.html>, The ABA has recommended that government entities designated by the President to engage in a continuing process of oversight of the rulemaking process should issue a written explanation of changes it has requested agencies to make in proposed and final rules. The ABA has also recommended that the entity reveal conduit communications that it has received concerning the matter it is reviewing from members of Congress, their staffs, or from persons outside of the government concerning such proposed or final rules. The former Administrative Conference of the United States (ACUS) has made a similar recommendation of. Presidential Review of Agency Rulemaking (Recommendation 88-9), 1 C.F.R. §305.88-9 (1992).

Sincerely yours,

Sidney A. Shapiro  
Board Member and Treasurer