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OMB's Dubious Peer Review Procedures

by Sidney A. Shapiro

The Office of Management and Budget (OMB) has recently proposed a bulletin that would supplement existing procedures under the Information Quality Act by requiring peer review of regulatory information and by specifying the procedures under which that review would take place.[1] OMB has also proposed to become intimately involved in the resolution of information quality complaints.[2] OMB's proposals would continue its previous efforts to build almost out of whole cloth a procedural apparatus that is likely to stifle the government's efforts to provide useful information to the public about their safety and health risks and about risks to the environment.

The Information Quality Act, formerly referred to by OMB as the Data Quality Act, is a two paragraph rider that Rep. Jo Ann Emerson (R-Mo.) slipped into a 2001 appropriations bill without legislative hearings, committee review, or debate.[3] As far as can be determined, few, if any, other members of the U.S. Congress knew of the appropriations rider at the time they voted for it. In February 2002, OMB issued instructions telling agencies how to implement the legislation.[4] After seeking public input, agencies adopted permanent procedures to implement the rider in October 2002.[5]

Ensuring high-quality information is a worthy goal, but procedural requirements have an important side effect—they slow down the government's capacity to act and, if they are sufficiently burdensome, they can bring government to a standstill. As a result, the benefits of imposing additional procedures have to be balanced against the consequences to the public of delaying agency action. As Roger C. Cramton reminded us years ago, the potential benefits of administrative procedure—fairness and accuracy—must be balanced against the "efficient disposition of agency business."[6] In this context, the goal of ensuring the quality of information has to be reconciled with the substantive mission of an agency and the role of disseminated data in the implementation of that mission. Unfortunately, Congress gave little indication of how these competing goals were to be reconciled. It defined none of the key terms of the rider, and left no legislative history. This failure has left OMB free to attempt to fill the legislative void with its own views as to how to balance regulatory delay with promoting the quality of information.

OMB's proposed peer review guidelines illustrate how OMB has built an ambitious procedural edifice on the vague and ambiguous foundation of the Information Quality Act according to its own policy objectives. OMB proposes mandatory peer review even though the Information Quality Act 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.[7] Finally, as will be developed below,[8] OMB exempts peer review from the procedures mandated by the Federal Advisory Committee Act (FACA),[9] which Congress established to ensure the government seeks outside advice in a manner that is accountable to the public, in favor of its own procedures, which will decrease the accountability of the peer review process as compared to FACA.

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.[10] There is a difference, however, between recognizing in the abstract that peer review can aid regulatory decisionmaking 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, it does not provide for an accountable and balanced peer review process in those circumstances, and it creates the potential for unaccountable OMB interference in the resolution of information quality complaints.

Authority to Require Peer Review

OMB bases its requirements for peer review on the Information Quality Act, but there are two difficulties with this assertion. As mentioned earlier, the Act does not explicitly re-

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1. Proposed Bulletin on Peer Review and Information Quality, 68 Fed. Reg. 54023 (Sept. 15, 2003) [hereinafter Proposed Bulletin].
2. *Id*.
3. Treasury and General Government Appropriations Act for Fiscal Year 2001, Pub. L. No. 106, §515 (2001) [hereinafter Information Quality Act].
4. OMB, Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies, 67 Fed. Reg. 8452, 8460 (Feb. 22, 2002) [hereinafter Information Quality Guidelines].
5. *See, e.g.*, Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Department of Labor, 67 Fed. Reg. 61669 (Oct. 1, 2002); U.S. Department of Commerce, Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Disseminated Information, 67 Fed. Reg. 62685 (Oct. 8, 2002); Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency, 67 Fed. Reg. 63657 (Oct. 15, 2002).
6. Roger C. Cramton, *A Comment on Trial-Type Hearings in Nuclear Power Plant Siting*, 58 Va. L. Rev. 585, 591 (1972).
7. *See, e.g.*, H.R. 9, 102d Cong. (1995).
8. *See infra* note 26 and accompanying text.
9. 5 U.S.C. app. II, §§1-14.
10. Proposed Bulletin, *supra* note 1, at 54024.

quire, 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,[11] which makes it difficult to conclude that Congress changed its mind in a rider hidden in an appropriations bill that no one in Congress (except the sponsor) appears to have known was there. In short, there is a strong case that Congress did not authorize OMB to impose peer review on agencies.

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 Information Quality Act simply does not apply to rulemaking.[12] In the Information Quality Act, Congress required OMB and agencies to issue "guidelines" concerning the "quality, utility, and integrity of information" *disseminated* by federal agencies . . . ,"[13] but Congress failed to define the word "disseminated." OMB has defined the term as "agency initiated or sponsored distribution of information to the public."[14] The better reading of the law is that, while the legislation applies to information in government reports and information posted on the Internet, it does not apply to data relied upon in rulemaking.

The difficulty with OMB's interpretation is that it ignores that portion of the Act that requires agencies to create a new "administrative mechanism" to hear and resolve complaints about data quality.[15] 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.[16] This would not include rulemaking because such a process already exists in rulemaking. Indeed, the rulemaking process provides more stringent procedures regarding the vetting of data than the appropriations rider. Agencies are required under prevailing interpretations of the Administrative Procedure Act (APA) to reveal the scientific basis for any proposed rule, to solicit comments, and to respond to the comments that are received when a final rule is adopted.[17] Thus, not only is there an obligation for transparent disclosure of scientific information, but the courts will enforce an agency's obligation to respond to comments about any significant potential problems with any such information. Since setting up another process would be superfluous or redundant, it has to be assumed that Congress had no such intention.[18]

Moreover, the rulemaking procedures used to vet information have worked quite well over the years. The academic literature indicates that there are very few instances where agencies may have relied on unreliable science among the thousands of public health and safety regulations promulgated annually. As Wendy E. Wagner has found:

> After more than [30] years of vigorous public health and safety regulation, it seems almost inevitable that an agency will rely on a scientific study that ultimately proved unreliable. Yet in spite of the thousands of public health and safety regulations promulgated annually, there are surprisingly few instances where unreliable science has been used. . . . If one subtracts from the studies where industry or independent contractors fabricated data in order to support their application for a license under [the Toxic Substances Control Act (TSCA), the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), or the Federal Food, Drug, and Cosmetic Act (FFDCA)], then the examples of regulatory bad science is winnowed down to a few, virtually all of which are contested.[19]

In light of this record, there is no reason to suppose that Congress intended to add to the procedural requirements that agencies must undertake in rulemaking when it passed the Information Quality Act.

In summary, OMB's assertion of jurisdiction to require agencies to use some form of peer review regarding the dissemination of information is doubtful. Even if OMB has such authority regarding information disseminated in reports and on the Internet, it cannot impose peer review in rulemaking because the Act does not apply to rulemaking.

Scope of Peer Review

While peer review has a role to play in the regulatory process, OMB's proposal does not do an adequate job of weighing the benefits of peer review with the impact of peer review on an agency's substantive mission and the role of disseminated information in the implementation of that mission. OMB's proposal for peer review is too broad in light of the potential benefits that it is likely to generate.

OMB seeks to require agencies to conduct "appropriate and scientifically rigorous peer review" on all "significant" regulatory information that an agency intends to dissemi-

11. *See supra* note 7 and accompanying text.
12. I have developed this argument in more detail at Sidney A. Shapiro, *Data Quality and Environmental Protection: The Perils of Reform by Appropriations Rider*, 27 Wm. & Mary Envtl. L. & Pol'y Rev. (forthcoming 2003).
13. Information Quality Act, *supra* note 3, §515(a) (emphasis added).
14. Information Quality Guidelines, *supra* note 4, at 8460.
15. Information Quality Act, *supra* note 3, §515(b)(2).
16. I am discussing a hypothetical congressional intent since, as mentioned earlier, there is no evidence that anyone in Congress knew about the Information Quality Act at the time it was passed except its sponsor.
17. *See* Richard J. Pierce et al., Administrative Law and Procedure §6.4.6 (3d ed. 1999).
18. Moreover, while OMB's definition of "dissemination" is consistent with one "common use" of that term, that is not the only common meaning of the term. Dictionary definitions emphasize that dissemination involves efforts to engage in the "widespread" distribution of information. *See, e.g.*, Cambridge International Dictionary of English, *at* http://dictionary.cambridge.org/default.asp (last visited Nov. 19, 2003) (the act of "dissemination" means "to spread or give out something, especially news, information, ideas, etc., to a lot of people"). This latter definition suggests the Information Quality Act only applies when agencies are actively engaged in trying to bring information to the attention of the public, as in a report or website. This is different than making information available to people who would like to seek it out, which is what occurs during rulemaking.

    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 websites. *See, e.g.*, Admin. & Reg. L. News, Spring 2000, at 10 (describing program held by the ABA on the dissemination of reports and information on the Internet); White Paper From Industry Coalition to EPA Over Concerns Over Information Programs Submitted May 4, 1999, Daily Env't Rep. (BNA), May 4, 1999, at E-1 (discussing the dissemination of reports and information on the Internet). There was no discussion, however, of the need to provide mechanisms to improve data quality in the context of rulemaking.
19. Wendy E. Wagner, *"Bad Science" Fiction: The Imaginary Crisis in Public Health and Environmental Regulation*, 66 Law & Contemp. Probs. 63-133 (2003).

nate, which is defined as any information that satisfies the "influential test" in OMB's Information Quality Guidelines.[20] The Information Quality Guidelines define "influential" information as any information that an agency can "reasonably determine" "will have or does have a clear and substantial impact on important public policies or important private sector initiatives."[21] OMB proposes additional peer review requirements for "especially significant regulatory information," which is information that is disseminated in support of a "major regulatory action," has a possible impact of $100 million or more, or is determined by the Administrator of OMB to be of "significant interagency interest" or "relevant to an Administration policy priority."[22]

OMB errs, however, in assuming that peer review is appropriate or even necessary because information is likely to have or will have a substantial impact on public policy or private initiatives. 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. In any other circumstance, peer review is wasteful and will unnecessarily delay the dissemination of important information.

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."[23] 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, regardless whether the additional procedures are useful and necessary.

This position is supported by a formal policy position of the American Bar Association (ABA) 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.[24] The report accompanying the recommendation, which was not officially adopted by the ABA, explains that peer review 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."[25]

20. Proposed Bulletin, *supra* note 1, at 54027.
21. Information Quality Guidelines, *supra* note 4, at 8460.
22. *Id*.
23. Proposed Bulletin, *supra* note 1, at 54027.
24. ABA, Resolution on Risk Assessment (1999), *available at* http://www.abanet.org/adminlaw/risk02.pdf (last visited Nov. 19, 2003).
25. ABA, Section of Administrative Law and Regulatory Practice Report 9 (1999), *available at* http://www.abanet.org/adminlaw/risk02.pdf (last visited Nov. 19, 2003).

FACA

Having decided that the Information Quality Act and peer review applies to the dissemination of information in rulemaking, as well as to reports and websites, OMB invents its own accountability procedures rather than ordering agencies to comply with 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."[26] 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.

OMB does require agencies follow several procedures that promote accountability in the peer review of "especially significant regulatory information."[27] These procedures fall short of the protections guaranteed by FACA, however, in two important ways.

First, FACA mandates a broader set of procedures to ensure the accountability of the process than OMB contemplates. FACA requires that peer review meetings are open to the public,[28] interested persons are entitled to "attend, appear before, or file statements with any advisory committee,"[29] detailed minutes must be kept,[30] 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).[31] An agency can close a meeting only if it determines that one of the exceptions to the Sunshine Act applies.[32]

By comparison, OMB's proposal contains none of these requirements. OMB does require that an agency provide an opportunity for public comment and that such comments

26. Steven P. Croley, *Practical Guidance on the Applicability of the Federal Advisory Committee Act*, 10 Admin. 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").
27. OMB requires that agencies provide an explicit, written charge describing the purpose and scope of review, that there is an opportunity for the public to comment, that peer reviewers issue a final written report, and that agencies respond to the final report indicating where they agree and disagree. Proposed Bulletin, *supra* note 1, at 54028.
28. 5 U.S.C. app. II, §10(a)(1).
29. *Id*. §10(a)(3).
30. *Id*. §10(c).
31. *Id*. §10(b).
32. *Id*. §10(d). The exceptions to the Sunshine Act are found at 5 U.S.C. §552b(c). The Sunshine Act contains exemptions to protect trade secrets and proprietary information, *id*. §552b(c)(4), and personal information the disclosure of which would constitute a "clearly unwarranted invasion of personal privacy," *id*. §552b(c)(6), which grant-giving agencies apparently have used to close peer review meetings to review grant applications. *See* Steven P. Croley & William F. Funk, *The Federal Advisory Committee Act and Good Government*, 14 Yale J. on Reg. 451, 507 (1997). However, Profs. Steven P. Croley and William F. Funk endorse Prof. Thomas O. McGarity's conclusion that "[w]hile the case for closing peer-review panel meetings to the public under FACA is plausible, it is not especially compelling." *Id*. at 511 (citing Thomas O. McGarity, *Peer Review in Awarding Federal Grants in the Arts and Sciences*, 9 High Tech. L.J. 1, 71 (1994)). The extent to which these exemptions might apply outside the context of peer review of grant applications is unknown, but there would appear to be less reason to close meetings to protect personal privacy since the review would be on completed research and not uncompleted research.

should be furnished to peer reviewers in sufficient time that they can take the comments into account.[33] 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.[34] 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 the government disseminates, closing the peer review meetings and hiding peer review documents does not serve its purpose.

Some commentators have argued that peer review should occur outside of FACA to facilitate the process and because there is less need for open meetings concerning scientific peer review than in other contexts because only scientific issues are involved.[35] An open process ensures that peer reviewers are more careful to take well-supported positions. As Prof. Thomas O. McGarity notes: "Open meetings allow outsiders to observe any overt bias in the decisionmaking process."[36] This advantage, which is crucial to establishing the legitimacy of peer review, would seem to far outweigh the disadvantage of any loss in candor. Moreover, it is difficult, if not impossible, to limit peer review to scientific issues.[37] Finally, it is worth noting that the argument that secrecy is necessary for candor was rejected as a common-law privilege and First Amendment defense to an Equal Employment Opportunity Commission subpoena seeking tenure review materials by outside evaluators.[38]

Second, the General Services Administration's (GSA's) regulations implementing FACA require 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."[39] 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.[40] 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. As Prof. Holly D. Doremus observes:

> Because no theory is ever proven to an absolute certainty, no bright line separates hunches from established scientific knowledge. Every scientific conclusion or opinion is to some degree a hunch. Although opinions can be evaluated on the basis of the strength of the data supporting them, no quantitative difference distinguishes knowledge from guesswork. Reliance on science must, by necessity, include reliance on some hunches.[41]

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,[42] and OMB's failure to require the use of FACA will continue the problem.

One way that OMB seeks to avoid FACA is 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.'"[43] According to GSA regulations interpreting FACA, convening a number of people to obtain the advice of each individually (rather than collectively) does not establish an advisory committee.[44] Besides avoiding FACA, OMB's decision to permit peer review by individuals, rather than by a committee, decreases accountability in a second important way. 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."[45] As a result, "bringing all reviewers together to discuss their opinions can be a powerful shield against favoritism and animus."[46] 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.

The other way that OMB seeks to avoid FACA is to permit agencies to hire an outside contractor to oversee the peer review process. OMB claims that an agency can avoid complying with FACA if it hires a contractor or consultant, who in turn organizes the peer review,[47] but this does not appear to be correct. FACA defines "advisory committee" as "any committee . . . which is *established or utilized* by one or more agencies, in the interest of obtaining advice or recommendations."[48] According to the U.S. Supreme Court, an advisory panel is "established" by an agency only if the

33. Proposed Bulletin, *supra* note 1, §3, at 54029.

34. *Id*.

35. *See, e.g.*, Lars Noah, *Scientific "Republicanism": Expert Peer Review and the Quest for Regulatory Deliberation*, 49 Emory L.J. 1033, 1064 (2000) (arguing that FACA should not apply to peer review for these reasons).

36. McGarity, *supra* note 32, at 64.

37. *See infra* notes 40-41 and accompanying text.

38. University of Pennsylvania v. Equal Employment Opportunity Comm'n, 493 U.S. 182 (1990).

39. 41 C.F.R. §102-3.30(c) (2003). The obligation of fair balance arises under §5(c) of FACA, 5 U.S.C. app. II, §5(c), although the requirement is somewhat convoluted. For an explanation, see Croley & Funk, *supra* note 32, at 449-500.

40. *See* Wendy E. Wagner, *Congress, Science, and Environmental Policy*, 1999 U. Ill. L. Rev. 181, 214 ("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.").

41. Holly D. Doremus, *Listing Decisions Under the Endangered Species Act: Why Better Science Isn't Always Better Policy*, 75 Wash. U. L.Q. 1029, 1064 (1997).

42. *See* Bybee, *supra* note 26, 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).

43. Proposed Bulletin, *supra* note 1, §3, at 54027. This interpretation is open to challenge. *See* Croley & Funk, *supra* note 32, at 472-78 (raising questions about the GSA interpretation).

44. 41 C.F.R. §102-3.40(e) (2003).

45. McGarity, *supra* note 32, at 64.

46. *Id*.

47. Proposed Bulletin, *supra* note 1, §4a, at 54028.

48. 5 U.S.C. app. II, §3(2).

agency actually forms the panel,[49] and a panel is "utilized" by an agency only if it is "so closely tied to an agency as to be amendable to 'strict management' by agency officials"[50] Although the courts narrowly construe the term "utilize" (the test is not satisfied, for example, by the agency's participation in the process or even its "significant influence" over it),[51] the test appears to be met in the context of OMB's proposed peer review process.

OMB's analysis that FACA does not apply is based on *Byrd v. U.S. Environmental Protection Agency*,[52] in which the U.S. Environmental Protection Agency (EPA) hired a private contractor to select and manage a peer review panel and submit a report to the agency.[53] The plaintiff alleged that EPA "strictly managed" the peer review process because, among other controls, it had authority to approve the composition of the panel, to deliver a charge to the panel, and to make written comments on the draft report.[54] A majority of the panel interpreted the utilization test as requiring "'something along the lines of *actual management or control* of the advisory committee,'"[55] and it held that FACA did not apply because EPA chose not to exercise the control that it reserved for itself over the panel. In their words, the decision was based "on what EPA in fact did, rather than on what it could have done."[56] In his dissent, Judge Stephen F. Williams held that EPA established the committee. Since an agency establishes a committee "if it has real control over its personnel and subject matter at its inception,"[57] Judge Williams held that FACA applied because the panel was "so closely" controlled "in membership and purpose."[58] 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."[59]

The *Byrd* case does not help OMB because agencies will be legally responsible for complying with the peer review procedures contained in the final bulletin.[60] For example, the proposed guidelines require that peer reviewers "shall be selected primarily on the basis of necessary scientific and technical expertise."[61] 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. 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."[62] In addition, the "agency shall provide an opportunity [for public comment],"[63] and it "shall direct peer reviewers . . . to issue a final report," and OMB specifies the specific nature of the report.[64] Thus, unlike the situation in *Byrd*, an agency will have to exercise its authority to control the peer review process, which EPA did not do in *Byrd*, according to the majority.

Of course, it is not necessary for OMB to require the use of FACA, although that would be a good idea, in order to ensure balanced peer review. When the U.S. Senate considered mandating peer review, S. 746 did exempt the process from FACA, but the legislation also specifically required that panels, expert bodies, or other formal or informal devices used to conduct peer review be "broadly representative."[65] Likewise, it is not necessary for OMB to require the use of FACA to have a more open peer review process. OMB could simply require agencies to comply with all of the open government provisions of FACA, described earlier,[66] without formerly chartering peer review committees.

Nevertheless, agency experience indicates that use of FACA for legitimizing peer review indicates that compliance is feasible. Peer review at the Food and Drug Administration (FDA) and EPA has long taken place under FACA.[67] Moreover, OMB could limit the application of FACA to peer review of "especially significant regulatory information," which should lessen the burden on an agency. This is the category of information for which OMB already requires additional procedures.[68] In addition, according to the previous argument, agencies would only use peer review in this context when there are novel or complex questions to be resolved, which is exactly the circumstances in which it is necessary to legitimize peer review by use of FACA. Finally, the White House can make the FACA process more efficient by speeding up the process of chartering advisory committees.[69]

Conflicts of Interest

OMB proposes that peer reviewers should "be selected primarily on the basis of necessary scientific and technical expertise," and it asks agencies to strive to "appoint experts who, in addition to possessing the necessary scientific and expertise, are independent of the agency, do not possess real or perceived conflicts of interest, and are capable of approaching the subject matter in an open-minded and unbiased manner."[70] OMB proposes that factors relevant to whether a scientist meets the previous criteria include

49. Public Citizen v. Department of Justice, 491 U.S. 440, 452, 456-57 (1989).
50. *Id*. at 457-58.
51. *See* Washington Legal Found. v. U.S. Sentencing Comm'n, 17 F.3d 1446, 1451, 25 ELR 21189, 21191 (D.C. Cir. 1994).
52. 174 F.3d 239, 29 ELR 21150 (D.C. Cir. 1999).
53. *Id*. at 241.
54. *Id*. at 247.
55. *Id*. (quoting Animal Legal Defense Fund v. Shalala, 104 F.3d 424, 430 (D.C. Cir. 1997)) (emphasis in original).
56. *Id*. at 247.
57. *Id*. at 249 (quoting Food Chem. News v. Young, 900 F.2d 238, 333 (D.C. Cir. 1990)).
58. *Id*. at 249.
59. *Id*.
60. I am grateful to Professor Funk for suggesting this argument.
61. Proposed Bulletin, *supra* note 1, at 54027.
62. *Id*. at 54028.
63. *Id*.
64. *Id*.
65. S. 746, 106th Cong. §625(b)(1)(A) (1999).
66. *See supra* notes 28-32 and accompanying text.
67. EPA and the FDA use standing committees for purposes of peer review. The major administrative difficulty with ad hoc advisory committees concerns obtaining a charter for them. OMB, however, is in a position to reduce any such delays because FACA authorizes the president to charter such committees. 5 U.S.C. app. II, §9(a)(1).
68. *See supra* note 22 and accompanying text (mandate of additional procedures).
69. *See* Croley & Funk, *supra* note 32, at 493-95 (describing paperwork requirements associated with notice and chartering of advisory committees, and limitations on the creation of committees created by Executive Orders).
70. Proposed Bulletin, *supra* note 1, §3, at 54027.

whether the individual has "in recent years, advocated a position on the *specific* matter at issue," is "currently receiving or seeking substantial [financial] funding from the agency through a contract or research grant (either directly or indirectly through another entity, such as a university)," or who has "conducted multiple peer reviews for the same agency in recent years, or has conducted a peer review for the same agency on the same *specific* matter in recent years."[71]

While OMB advises agencies to disqualify scientists who have or may do research supported by the government, it does not recommend a parallel rule to disqualify a scientist who has received, or is attempting to receive, research funding from regulated industries. 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.[72] OMB observes:

> Unless the peer review is conducted with genuine independence and objectivity, this can create at least the appearance of a conflict-of-interest. For example, it might be thought that scientists employed *or funded* by an agency could feel pressured to support what they perceive to be the agency's regulatory position, first in developing the science, and then in peer reviewing it. Scientists with a financial interest in the subject matter of a study[,] e.g., ties to a regulated business[,] face a similar issue.[73]

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 loose their funding if they do not produce results that are satisfactory to the industrial source of funding. Prof. Sheldon Krimsky 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 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. . . .[74]

Further, by recommending the disqualification of scientists who do (or would do) research for the government, but not scientists who do research for industry, OMB's recommendations make it more difficult for agencies to establish peer review that is "broadly representative," as FACA requires and as S. 746 would have required. S. 746, by comparison, explicitly established that the "status of a person as a contractor or grantee of the agency conducting the peer review shall not, in and of itself, exclude such person from serving as a peer reviewer for such agency because of the requirement [that peer reviewers be independent]."[75]

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.[76] 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.[77] It is not clear how an agency can match up offsetting biases in the manner that OMB anticipates. For example, what is the "contrary bias" to a person who has an unrelated contract with the agency? It seems clear that the general prophylactic of requiring a "broadly representative" and "fairly balanced" review group would serve the same ends and be 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."[78] OMB also requires that agencies adopt guidelines for peer review and that such guidelines indicate "the types of information regarding peer reviewers that should be publicly disclosed in addition to [the information that OMB requires to be disclosed]."[79] OMB suggests to agencies, but does not require, that agencies disclose such information as "prior service as an expert witness, sources of personal or institutional funding, and/or other matters

71. *Id*. (emphasis added).

72. 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.

73. Proposed Bulletin, *supra* note 1, at 54024 (emphasis added). 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.

74. Sheldon Krimsky, Science in the Private Interest: Has The Lure of Profits Corrupted Biomedical Research? 143-44 (2003).

75. *See* S. 746, 106th Cong. §625(g). OMB proposes: "If it is necessary to select a reviewer who is or appears to be biased in order to obtain a panel with appropriate expertise, the agency shall ensure that another reviewer with a contrary bias is appointed to balance the panel." Proposed Bulletin, *supra* note 1, §3, at 54027-28. This proposal, however, is responsive to the previous concern only if OMB recognizes industry funding as raising the same problems of bias as government funding of scientists. Otherwise, an agency would find itself in this position only if there were not a sufficient number of scientists with the relevant expertise among the scientists who had or were receiving funding from industry.

76. Proposed Bulletin, *supra* note 1, §3, at 54027.

77. *See supra* notes 40-41 and accompanying text.

78. Proposed Bulletin, *supra* note 1, §3, at 54028.

79. Proposed Bulletin, *supra* note 1, §4b, at 54028.

that might suggest a possible conflict of interest or appearance of a conflict of interest. . . ."[80]

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," 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 U.S. 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.[81] 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.[82] Finally, an agency should gather this information at the beginning of the peer review process when the agency can use it to ensure that peer review is a balanced process.[83]

Centralized Appointment of Reviewers

In its proposed guidelines, OMB notes that "some observers may favor a system whereby a centralized body would appoint peer reviewers or supervise the details of the peer review process," but it declines to propose such a system.[84] OMB, however, notes that it is "arguable that an entity outside of the agency should select the peer reviewers and perhaps even supervise the peer review process."[85] OMB observes that this approach "might lend the appearance of greater integrity to the peer review process, but could be unduly inefficient and raise other concerns."[86] 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.[87] This should be no surprise because

> one should not suppose that, individually or collectively, these interveners are simply representatives of the president. In fact, these executive interveners are themselves part of the administrative bureaucracy and, as such, present the same type of monitoring and control problems . . . as the agencies that they seek to influence.[88]

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. This is what happened when Congress located the Occupational Safety and Health Administration (OSHA) and the National Institute of Occupational Safety and 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.[89]

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 I 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.[90]

Third, there is a more efficient and responsible way to ensure the integrity of the peer review process. As discussed earlier, OMB should require agencies to utilize FACA for the appointment of peer reviewers.[91] Since Congress created FACA to address the very concerns that OMB addresses,[92] there is no need to invent another accountability process for obtaining scientific advice. Moreover, Congress considered it important that agencies retain authority over the advisory committee process as part of ensuring the legitimacy of seeking outside review.[93]

Finally, peer review is less likely to inform and improve regulatory decisionmaking when agency employees regard it as a bureaucratic burden imposed on an agency rather than a tool for improving the quality of decisionmaking. According to the National Academy of Sciences' report, peer review "must become accepted as part of the agency's culture,

80. *Id*.

81. U.S. GAO, EPA's Science Advisory Board: Improved Procedures Needed to Ensure Independence and Balance 18 (2001) (GAO-01-536).

82. 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.

83. *See* U.S. GAO, *supra* note 81, at 20 (recommending that EPA collect background information about potential peer reviewers before their appointment to a peer review committee).

84. Proposed Bulletin, *supra* note 1, at 54027.

85. *Id*.

86. *Id*.

87. *See, e.g.*, Sidney A. Shapiro, *Presidential Oversight and the Deterioration of Regulatory Policy*, 46 Admin. L. Rev. 1, 21-23 (1994) (discussing the debate of White House accountability in rulemaking oversight).

88. Glen Robinson, American Bureaucracy: Public Choice and Public Law 102 (1991)

89. Sidney A. Shapiro & Thomas O. McGarity, *Reorienting OSHA: Regulatory Alternatives and Legislative Reform*, 6 Yale J. on Reg. 1, 57-59 (1989).

90. *See supra* notes 27, 39 and accompanying text.

91. *See supra* note 26 and accompanying text.

92. *Id*.

93. FACA ensures that an agency retains its authority over committee meetings by requiring the agency to designate an employee to attend each meeting and have the authority to terminate the meeting when he or she determines that it is in the public interest to do so. 5 U.S.C. app. II, §10(e). Moreover, only the agency has the authority to call meetings and approve the agenda. *Id*. §10(f).

not merely a bureaucratic requirement."[94] Prof. Lars Noah makes a similar point when he observes that peer review works best when it is peer reviewers who interact with agency scientists in an ongoing dialogue.[95] Agency personal are more likely to regard peer review as a bureaucratic requirement, as opposed to an integral part of the agency's decisionmaking process, when it is imposed on the agency by OMB and implemented by an another entity, be it OMB or some other agency.

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."[96] 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 an adjudication because its Information Quality Guidelines exempted adjudication from the Act all together,[97] but it is not clear why information disseminated in an 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.[98] 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. Indeed, as noted earlier,[99] rulemaking involves procedures to vet information that are more stringent than those required by the Information Quality Act.[100]

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. 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.[101]

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.[102] 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. 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."[103] 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 that information produced by scientists as the result of public funding.

OMB and Correction Requests

OMB's proposed bulletin ends with a proposal regarding the management of the correction process under the Information Quality Act. OMB proposes that agencies provide to it within seven days a copy of each non-frivolous request for information quality correction request, and that an agency need not provide a copy if it posts the request on its website. OMB further proposes that an agency provide it with a copy of its response and consult with OMB before the response is issued.[104]

As noted earlier, there has been concern over the years regarding the accountability of presidential supervision of rulemaking.[105] OMB has responded to these concerns by adopting procedures that make its oversight process more

94. National Academy of Sciences, Strengthening Science at the U.S. Environmental Protection Agency: Research-Management and Peer-Review Practices 115 (2000).

95. Noah, *supra* note 35, at 1059-60.

96. Proposed Bulletin, *supra* note 1, §2, at 54027.

97. In the guidelines, OMB defines "dissemination" as not including "distribution . . . limited to adjudicative processes." Information Quality Guidelines, *supra* note 4, §V8, at 8460.

98. *See* Pierce et al., *supra* note 17, §§6.4.3, 6.4.10 (explaining the variability of procedures used in adjudication).

99. *See supra* note 17 and accompanying text.

100. This is the basis for the earlier argument that Congress did not include rulemaking within the scope of the Information Quality Act. *See supra* notes 12-18 and accompanying text. Although OMB does not agree with this interpretation, it is still free to exempt rulemaking from the Act, as it has done for adjudication.

101. *See* 21 C.F.R. §14.80 (members of FDA advisory committees serve as special government employees).

102. *See supra* notes 23-25 and accompanying text.

103. Krimsky, *supra* note 74, at 84.

104. Proposed Bulletin, *supra* note 1, §7, at 54029.

105. *See supra* notes 87-88 and accompanying text.

transparent.[106] OMB's request that agencies consult it before information quality complaints are resolved appears to raise the same concerns and requires a similar response. Nevertheless, OMB has proposed nothing in the way of accountability procedures for its oversight. Under OMB's proposed process, it can make decisions concerning the public availability of regulatory information without any acknowledgment of its role. Further, OMB may make such decisions on the basis on information and lobbying that is unknown to the public or even the agency that received the correction request.

OMB should take two steps to promote accountability concerning complaints about "especially significant regulatory information." 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. OMB should also 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.

These recommendations reflect a formal policy position of the ABA concerning OMB oversight in the context of rulemaking[107] and a similar recommendation of the former Administrative Conference of the United States (ACUS).[108] 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.

In light of the public interest in the outcome of complaints concerning "especially significant regulatory information," it is important to have the same accountability process. If OMB decides how to resolve data quality complaints behind closed doors and in response to ex parte contacts from interested parties, it is difficult to see how the public will have greater trust in the government and its information.

Conclusion

OMB has recently proposed a bulletin that would require universal peer review for significant regulatory information and that would place OMB in the middle of resolving information quality complaints. The proposal is dubious on several grounds. OMB has proposed an ambitious program of peer review without sufficient regard for the impact of its proposal on the efficient disposition of agency business or for the transparency and accountability of the process. Moreover, OMB's legal basis for requiring peer review is highly questionable. Finally, its proposal to supervise the resolution of information quality complaints puts OMB in the position of influencing the outcome of those disputes with no accountability whatsoever.

Although OMB seeks to justify its proposals as necessary to implement the Information Quality Act, never has so much been made out of so little. OMB seeks to build a major regulatory regime on the basis of a vacuous rider snuck into an appropriations bill at the last moment and passed with no hearings or debate, let alone any awareness by members of Congress of its terms. The courts should not assist this antidemocratic process by interpreting the legislation as authorizing OMB to impose universal peer review, particularly since Congress has previously expressly rejected such proposals. The courts should also reject the application of the Information Quality Act to rulemaking as inconsistent with the specific language of the rider.

Peer review has a useful role to play in promoting the quality of government information. In light of the delay and cost involved, however, OMB should restrict the use of peer review to instances where information is unlikely to be unreliable or where it is necessary to ensure objectivity. Instead, OMB would require the use of peer review regardless of whether there was some question about the reliability of the information that would be subject to review. OMB also inexplicably exempts important categories of industry information from peer review, although such information is often more unreliable than information produced by government grants.

OMB recognizes the importance of accountability in a peer review process, but instead of requiring agencies to comply with FACA, which Congress established for this very purpose, OMB invents its own accountability procedures, which fall far short of the protections offered by FACA. OMB does not require agencies to comply with any of the open government requirements contained in FACA including the requirement that peer review panels be "fairly balanced." Moreover, OMB proposes that agencies screen potential peer reviewers for bias, but apparently only sees a problem with scientists who receive or have received government funding. If anything, agencies should take more care in their selection of scientists who receive industry funding, which creates a greater potential of bias than public funding.

Finally, OMB toys with the idea of running the peer review process itself, instead of having agencies manage the process, and it proposes to intervene in the resolution of information quality complaints. It is not in OMB's contemplation, however, that it be accountable or transparent when it takes these actions. Either or both actions would place OMB in the position of making important decisions about the government's dissemination of information without any paper trail concerning its actions. This is hardly the stuff of democratic government.

106. *See, e.g.*, Memorandum from John D. Graham, to Office of Information and Regulatory Affairs Staff (Oct. 18, 2001) (establishing disclosure policies for regulatory review), *available at* http://www.whitehouse.gov/omb/inforeg/oira_disclosure_memo-b.html (last visited Nov. 20, 2003).

107. ABA, Recommendation on Presidential Oversight (1993), *available at* http://www.abanet.org/adminlaw/policy.html (last visited Nov. 20, 2003).

108. Presidential Review of Agency Rulemaking (Recommendation 88-9), 1 C.F.R. §305.88-9 (1992).