

environmental science will be stuck in a holding pattern, producing only small and disconnected pockets of basic and applied research. Unjustified attacks on high-quality regulatory science, as documented elsewhere in this book, serve only to exacerbate such problems. To reform this state of affairs, Professor Applegate develops threshold principles for determining when the private sector should address research needs and when government investment and supervision are crucial.



## Politicizing Peer Review: The Scientific Perspective

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### The Role of Peer Review

Peer review, or independent review by experts, is an important but limited mechanism for quality control within the scientific enterprise. While it has many manifestations, peer review generally involves a review of materials by experts who are thought to have adequate knowledge and technical expertise to judge the material's quality, while being sufficiently impartial and disinterested to provide judgment free of conflict of interest.<sup>1</sup>

Peer review plays an important role in the production and shaping of the scientific knowledge that is the product of the current scientific enterprise. This enterprise is one in which, at least in theory, scientists are constantly evaluating and building upon each other's works through a continual system of experimentation, publication, dissemination, replication, and further experimentation. Peer review may be performed in at least two aspects of this process: in the decision-making processes of agencies and institutions that provide financial support for scientific research, and in the editorial prepublication assessment of manuscripts submitted to scientific journals (often called "refereeing"). There is significant competition both for space in prestigious journals and limited research funds, and peer review plays a pivotal role in allocation of both of these highly valued resources.

Beyond these two models of peer review, in recent years there has been a growing interest in a new, distinct function for peer review: an evaluation of analytical and synthetic documents prepared by governmental agencies,

1 U.S. General Accounting Office, *Federal Research: Peer Review Practices at Federal Science Agencies Vary* (Washington, DC: Government Printing Office, 1999) (available at <http://www.gao.gov/archive/1999/rc99099.pdf>).

often in support of regulatory programs. This is being driven in part by opponents of the environmental and public health protections that require significant corporate expenditures or even limit production of particularly toxic materials. These increasingly fervent calls for peer review in regulatory science were evidently heard in the White House, which, in the later part of President George W. Bush's first term, began an effort to require peer review of most reports and documents produced by federal agencies.

The official adoption of uniform peer review requirements by all federal agencies is a mechanism by which corporate interests can question the science underlying not just regulation but virtually any "information" disseminated by federal agencies. This development has the potential to impede the implementation of programs that protect public health and the environment. While peer review will no doubt be useful in some cases, it is increasingly being invoked in a way that is likely to magnify the ability of parties with a financial interest in the outcome to intervene successfully in the process, to the detriment of the public good. Further, when peer review of regulatory documents is applied in a way that impedes the dissemination of study results, it becomes a tool for stifling rather than improving science.

To provide a context for discussion of peer review of regulatory science, this chapter first examines very briefly the historical development of peer review and then reviews the function of peer review of editorial and program evaluation. Following these explanations, the chapter focuses on the debate over the application of peer review to regulatory science, with particular attention to the Bush Administration's imposition of a federal government-wide mandatory peer review program in 2005. My goal is to present a scientist's perspective on these developments, while Professor Sidney Shapiro presents the legal perspective in the next chapter.

### A Brief History of Peer Review

The antecedents of prepublication editorial peer review appear to date from the middle of the seventeenth century, with the publication of the journal *Philosophical Transactions*. The initial authorization for its publication, by the Council of the Royal Society of London, included the order that it be "first reviewed by some members" of the Council.<sup>2</sup> A century later,

*Philosophical Transactions* became the official publication of the Royal Society; it is the oldest scientific journal in continuous publication.<sup>3</sup> In 1752, the Society established a "Committee on Papers," to review all articles considered for publication.<sup>4</sup> For centuries, such prepublication review appears to have been the exception rather than the rule in scientific publishing. While casual refereeing of individual journal submissions occurred in the nineteenth and early-twentieth century, the widespread acceptance of editorial peer review as an integral part of development of scientific knowledge is a relatively new development, starting in the middle of the twentieth century.

A review of this history by John Burnham, a professor of history and psychiatry at Ohio State University, suggests that the institutionalization of peer review practices by editors was not initially the result of a generalized recognition of the intrinsic value of this mechanism. Rather, the imposition of peer review was a reflection of the needs of editors, scientists, or physicians themselves "either to handle new problems in the numbers of articles submitted or to meet the demands for expert authority and objectivity in an increasingly specialized world."<sup>5</sup> As a result, the institutionalization of editorial peer review occurred in an idiosyncratic and haphazard manner, without the recognition of a single predominant model.

Editorial peer review appears to have developed independently of peer review procedures used to determine funding allocations. In the United States, the use of a formal peer review procedure to consider applications for support of research began in the early part of the twentieth century; by 1937 it was already established in the authorizing legislation of the National Cancer Institute. The diffusion and acceptance of peer review for funding, in contrast to that of editorial peer review, reflected a shared recognition of the value of this process within the scientific community.<sup>6</sup>

Peer review, as a process fundamental to the functioning of the scientific enterprise, is often the subject of superlative description. In an oft-cited

<sup>3</sup> For a brief history of the Royal Society, see the Royal Society, "Brief History of the Society," the Royal Society, <http://www.royalsoc.ac.uk/page.asp?id=2176>.

<sup>4</sup> David A. Kronick, "Peer Review in 18th-Century Scientific Journalism," *Journal of the American Medical Association* 263, no. 10 (1990): 1321.

<sup>5</sup> John C. Burnham, "The Evolution of Editorial Peer Review," *Journal of the American Medical Association* 263, no. 10 (1990): 1323.

<sup>6</sup> *Ibid.*, 1326.

<sup>2</sup> Harriet A. Zuckerman and Robert K. Merton, "Patterns of Evaluation in Science: Institutionalization, Structure and Functions of the Referee System," *Minerva* 9, no. 1 (1971): 65-9.

1971 paper, Harriet Zuckerman and Robert Merton asserted that despite its flaws,

... the system of monitoring scientific work before it enters into the archives of science means that much of the time scientists can build upon the work of others with a degree of warranted confidence. It is in this sense that the structure of authority in science, in which the referee system occupies a central place, provides an institutional basis for the comparative reliability and cumulation of knowledge.<sup>7</sup>

More recently, two editors of the *New England Journal of Medicine* called peer review "indispensable for the progress of biomedical science."<sup>8</sup> The Royal Society, Britain's national academy of sciences, opined that "peer review is to the running of the scientific enterprise what democracy is to the running of the country."<sup>9</sup>

### Refereeing or Editorial Peer Review

#### Framework for the Peer Review Process

Perhaps the best-known type of scientific peer review is prepublication assessment by independent experts of manuscripts describing scientific research. This editorial peer review plays an important role in determining and shaping what many scientific journals publish. Generally, authors submit papers for consideration by editors or editorial boards, who send the manuscripts to other scientists, often called referees, who provide feedback and advice to the editors and the manuscripts' authors. Editors usually ask the referees to evaluate a paper's quality in terms of its reliability, originality, relevance, and appropriateness to the journal.<sup>10</sup> The editors may use that information to request that the authors modify (and, they hope, improve) the original paper, and to decide whether to publish the revised paper. The publication decision generally rests solely in the hands of the editor or editorial board, who retains discretion to accept or reject the advice of the

<sup>7</sup> Zuckerman and Merton, 99-100.

<sup>8</sup> Jerome P. Kassirer and Edward W. Campion, "Peer Review: Cnide and Understudied, But Inispensable," *Journal of the American Medical Association* 272, no. 2 (1994): 96-7.

<sup>9</sup> The Royal Society, "Brief History of the Society."

<sup>10</sup> Sandra Goldberg-Wood, "Evidence on Peer Review: Scientific Quality Control or Smoke-screen?" *British Medical Journal* 318, no. 7175 (1999): 44.

independent referees. Editors of scientific journals have traditionally been able to shape the specific rules and applications of the peer review system and use this manuscript management system to fit their needs. As a result, there is much heterogeneity in the charges given to reviewers.<sup>11</sup>

There is also variation in the use of anonymity in the peer review process. Some journals employ a system in which the reviewers know the names and affiliations of the authors; other journals blind the referees to the identity of the authors, although it is sometimes possible for knowledgeable reviewers to guess the identity of one or more authors of a paper from reading the material under review. For the most part, only the journal editors know the identity of the referees, although a list of all reviewers is often published annually, to thank the reviewers who are not otherwise remunerated for their work. The anonymity of the reviewers presumably allows them to provide critical feedback without risking the personal or professional wrath of the authors being critiqued. However, there are little hard data on the value of anonymity in peer review, and there appears to be growing interest in altering or abandoning it.<sup>12</sup>

#### Limitations of Editorial Peer Review

The limitations to peer review as a mechanism for quality control are widely recognized within the scientific community. Among those most critical of the peer review system are editors of the leading biomedical journals, scientists who are intimately involved in its use.<sup>13</sup> Richard Smith, the editor of the *British Medical Journal*, has written:

The problem with peer review is that we have good evidence on its deficiencies and poor evidence on its benefits. We know that it is expensive, slow, prone to bias, open to abuse, possibly anti-innovatory, and unable to detect fraud. We also know that the published papers that emerge from the process are often grossly deficient.<sup>14</sup>

<sup>11</sup> Stephen Lock, *A Difficult Balance: Editorial Peer Review in Medicine* (London: Nuffield Provincial Hospitals Trust, 1985).

<sup>12</sup> Richard Smith, "Opening Up BMJ Peer Review," *British Medical Journal* 318, no. 7175 (1999): 4-5.

<sup>13</sup> Kassirer and Campion, Lock.

<sup>14</sup> Robin Smith, "Peer Review: Reform or Revolution," *British Medical Journal* 315, no. 7111 (1997): 759.

Perhaps the most widely recognized failing of peer review is its inability to ensure the identification of high-quality work. The list of important scientific papers that were initially rejected by peer-reviewed journals goes back at least as far as the editor of *Philosophical Transactions*'s 1796 rejection of Edward Jenner's report of the first vaccination against smallpox.<sup>15</sup>

Nor is peer review a tool for ensuring honesty or for detecting fraud in science. In submitting a manuscript for consideration for publication, authors assert, either implicitly or, with increasing frequency, explicitly through signed testimonials, that they have personally conducted the work (that is, the experiment or analysis) presented in the article. For the most part, referees do not request additional material, examining only the manuscript that is provided by the authors; the system operates on an assumption of honesty and trust. It is widely understood among scientists that peer review is not a defense against data fabrication, since a scientist intent on fraud would likely be able to falsify results in a way undetectable to a manuscript's reader.<sup>16</sup> Peer review is also not particularly effective in identifying poor laboratory practices, or mistakes in computation associated with incorrect results.

Bias and conflict of interest among reviewers may be problematic in editorial peer review. In theory, conflicts of interest can be overcome in pre-publication peer review since final publication decisions generally rest with the editor. Many journals, especially in the biomedical sciences, require referees to provide conflict-of-interest disclosures.<sup>17</sup> In selecting papers to publish, editors are therefore able to evaluate and discount the views of referees who have conflicts that are reflected in their commentary.

Referee bias is a more subtle and difficult issue to resolve. In those systems in which the authors of a manuscript are identified, academic status, scientific discipline, institution, gender, or other characteristics of

the author or authors may influence referees, consciously or not.<sup>18</sup> Editors may or may not be able to discern such bias and it is generally not easily identified.

Although editorial peer review holds an important position in the system of production of scientific knowledge, there is a dearth of empirical research of its impact on the quality of scientific research. One recent review of peer review as practiced by biomedical journals found little agreement about how to measure either its effects or processes.<sup>19</sup> A second review could identify only a few well-designed studies, and the results of these were for the most part ambiguous or inconclusive, leading the authors to conclude that "editorial peer review, although widely used, is largely untested and its effects uncertain."<sup>20</sup>

While peer review has been blamed for the increased probability that studies with positive results will be published, this problem does not appear to be a result of inequities in the peer review process itself. Authors and sponsors may be more likely to submit positive studies for publication.<sup>21</sup> Moreover, recent analyses actually found no difference in the time to publication between positive and negative studies. This also suggests that the peer review process may not be imposing added impediments to the publication of negative studies.<sup>22</sup>

### Research Evaluation or Peer Review for Funding Allocations

Peer review is widely used in evaluating the progress and performance of research programs, particularly those operated or funded by federal

<sup>15</sup> Lock, 26-9.

<sup>19</sup> Tom Jefferson et al., "Measuring the Quality of Editorial Peer Review," *Journal of the American Medical Association* 287, no. 21 (2002): 2786-90.

<sup>20</sup> Tom Jefferson et al., "Effects of Editorial Peer Review: A Systematic Review," *Journal of the American Medical Association* 287, no. 21 (2002): 2784.

<sup>21</sup> Philippa J. Easterbrook et al., "Publication Bias in Clinical Research," *Lancet* 337, no. 8746 (1991): 867-72; Anastasia L. Misakian and Lisa A. Bero, "Publication Bias and Research on Passive Smoking: Comparison of Published and Unpublished Studies," *Journal of the American Medical Association* 286, no. 3 (1998): 250-253; Jerome M. Stern and R. John Simes, "Publication Bias: Evidence of Delayed Publication in a Cohort Study of Clinical Research Projects," *British Medical Journal* 315, no. 7109 (1997): 640-5.

<sup>22</sup> Carin M. Olson et al., "Publication Bias in Editorial Decision Making," *Journal of the American Medical Association* 287, no. 21 (2002): 2835-8.

<sup>15</sup> Joshua S. Gans and George B. Shepherd, "How Are the Mighty Fallen: Rejected Classic Articles by Leading Economists," *Journal of Economic Perspectives* 8, no. 1 (1994): 165-79; Lock, 2.

<sup>16</sup> It appears that in most cases in which fraud is actually detected, the detection occurs after publication. At that point, the article is generally retracted, either by the author or the editors.

<sup>17</sup> Frank Davidoff et al., "Sponsorship, Authorship and Accountability," *Journal of the American Medical Association* 286, no. 10 (2001): 1232-3; Drummond Rennie et al., "Conflicts of Interest in the Publication of Science," *Journal of the American Medical Association* 266, no. 2 (1991): 266-7.

agencies. In a review of the peer review practices at federal science agencies, the U.S. General Accounting Office (now called the Government Accountability Office) found that while there is no uniform federal peer review policy or even definition, the agencies sampled all used some type of program evaluation process involving assessment by independent experts.<sup>23</sup> The science community generally supports this approach. In 1999, for example, the Committee on Science, Engineering, and Public Policy, a collaborative effort of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine, recommended that "Federal agencies should use expert review to assess the quality of research they support, the relevance of that research to their mission, and the leadership of the research."<sup>24</sup>

Most government agencies also employ some type of peer review structures to assist in funding decisions.<sup>25</sup> Grant-making peer review is similar to editorial peer review in how its resources are allocated. In both cases, scientists are competing for scarce resources — pages in a scientific journal or funds from an agency. Yet the two processes also differ in several key respects.

For the most part, the identities of researchers are known to the reviewers, while reviewer identities are not (although membership on a federal review panel is public information). Peer reviews of funding applications rarely have the iterative quality of editorial peer review, in which authors are offered and re-offered the opportunity to refine their manuscript until a point at which the paper is either accepted for publication rejected, or withdrawn. In reviewing funding proposals, competing applications are evaluated and scored, with the superior proposals generally being selected for funding by the sponsoring agencies. In contrast to the ultimate power of editors to accept or reject the advice of editorial peer reviewers, agency funders have little discretion to diverge from the rankings of the evaluators.

Given the explicit financial implications of decisions by research reviewers, it is widely understood that conflict of interest concerns must be addressed in the choice of reviewers. In the review of competitive funding

<sup>23</sup> U.S. General Accounting Office, *Federal Research*.

<sup>24</sup> Committee on Science, Engineering, and Public Policy (COSEPP), *Evaluating Federal Research Programs: Research and the Government Performance and Results Act* (Washington, DC: National Academy Press, 2000).

<sup>25</sup> U.S. General Accounting Office, *Federal Research*.

applications, at least as practiced by the U.S. National Institutes of Health, members of review panels with financial, institutional, or personal conflicts of interest are generally barred from reviewing individual proposals.<sup>26</sup>

### Peer Review of Regulatory Science

#### The Rise of Policy-Based Peer Review

The application of peer review to the science involved in regulatory decision making is a relatively new and controversial phenomenon. As regulatory agencies are called upon to make decisions and issue rules on the basis of increasingly complex science, they have developed quality assurance programs that share characteristics with the two types of peer review previously described. Given the scientific community's traditional reliance on peer review in determining which studies are published in scientific journals and which research proposals are supported by funding agencies, the application of some form of peer review to regulatory science seems reasonable at first glance. Shouldn't the scientists' own system be employed to distinguish good science from bad science in the regulatory context? This argument has been raised with some frequency over the last few decades, especially in Congress, where critics of the regulatory system regularly introduce legislation requiring use of peer review in agency science.

In her seminal work *The Fifth Branch: Science Advisors as Policymakers*, Professor Sheila Jasanoff recounts examples from the 1970s in which government agencies issued alarming warnings regarding the potential impacts of environmental exposures, including nitrates in food, the dioxin-contaminated herbicide 2,4,5-T, and Love Canal. Critics of government's regulatory decisions disputed the agencies' analyses, disparaging the scientific competence and performance of the agencies. Since then, according to Jasanoff, the call for peer review is a refrain heard often from corporate interests that feel that regulatory policy makers have not adequately separated "good" science from "bad" science, and that policy makers have exercised their sizable regulatory discretion to formulate science policies

<sup>26</sup> National Institutes of Health, "Review Procedures for Scientific Review Group Meetings" (available at <http://www.csr.nih.gov/guidelines/proc.pdf>).

that do not adhere to the standards used by the scientific community to evaluate evidence.<sup>27</sup>

Two political scientists, Stuart Shapiro and David Guston, describe regulatory peer review as an administrative procedure used by the president to exert political control over the burgeoning expert bureaucracy. This exercise of power occurs primarily as an executive branch initiative because congressional supporters of "regulatory reform" have been largely unsuccessful in passing legislation to alter the basic functioning of the regulatory agencies.<sup>28</sup>

As Professor Jasanoff has noted, regulatory science has many characteristics that are different from those of "investigator-initiated" or "curiosity-driven" science, which is judged in peer review systems (both editorial and resource-allocation) for its originality and significance. In contrast, regulatory science is rarely innovative; although it may involve generation of new knowledge, it is generally designed to answer questions specific to regulatory requirements. Jasanoff further distinguishes science used in the policy process from research science:

The efficacy of regulatory science depends in part on its capacity to provide timely answers to pressing policy questions or, put differently, to produce "serviceable truths." Research science operates under no comparable time pressures; in principle, it can wait indefinitely to produce results. Accordingly, the meanings of reliability and "doing well" are legitimately different for regulatory and research science. The reliability of regulatory science cannot and should not necessarily be measured according to the same criteria as the reliability of research science. Correspondingly, the procedures used to ensure reliability may reasonably differ from the one scientific context to the other.<sup>29</sup>

Unless peer review is structured in a manner that recognizes the context in which regulatory science is used, it can become unnecessary and

cumbersome, and thus undermine agency functioning. In a comment on a Bush Administration government-wide peer review proposal discussed later in this chapter, Shapiro and Guston explain:

Any individual peer reviewer will have the potential power to derail a rule-making effort by providing a negative peer review. This is not the case in academic peer review, where editors and program managers are free to ignore negative reviews of articles or proposals. The context of regulatory peer review is very different however. It is very easy to envision a court using a negative peer review as evidence that an agency was arbitrary and capricious in promulgating a regulation. It is also very easy to envision political actors hostile to a regulation using a negative peer review to attempt to derail regulatory initiatives for purely political reasons.

And such negative peer reviews need not (and indeed are likely not to) come from peer reviewers with particular anti-regulatory agendas. . . . [D]isagreement in the sciences is common. Disagreement in economics is rampant. It is unlikely that very many analyses that agencies submit for regulatory peer review will result in unanimous endorsement. Such a lack of consensus, which is useful in the academic setting may provide a deathblow for regulatory efforts in the policymaking setting. This may be true even for regulations with large net benefits.<sup>30</sup>

In summary, independent review by experts of the documents and reports used in regulatory science shares some characteristics with but is also quite different from the peer review processes used for editorial decision making or research or program funding. Although peer review of regulatory science can help improve the quality of these documents, it can also be applied in a way that is antithetical to the outcome for which it is being invoked: to utilize the best available science to protect the public good.

### Peer Review at the Environmental Protection Agency

The Environmental Protection Agency (EPA) has regulatory needs that require research involving an extraordinarily wide range of scientific and

27. Sheila Jasanoff, *The Fifth Branch: Science Advisers as Policymakers* (Cambridge, MA: Harvard University Press, 1999).

28. David H. Guston and Stuart Shapiro, "Procedural Control of the Bureaucracy, Peer Review, and Epistemic Drift" (paper presented at the annual meeting for the Association of Public Policy Analysis and Management, Atlanta, GA, October 29, 2004), 24 (available at [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=631161](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=631161)).

29. Comment on Office of Management and Budget (OMB) Proposed Bulletin on Peer Review and Information Quality from Sheila Jasanoff, Harvard University, to Mabel Echols, OMB Peer Review 2 (December 16, 2003) (available at <http://www.whitehouse.gov/omb/inforeg/2003/q1/159.pdf>).

30. Comments on the Office of Management and Budget's Proposed Bulletin on Peer Review and Information Quality from Stuart Shapiro and David Guston, Rutgers University, to Mabel Echols, OMB Peer Review 3 (December 12, 2003) (available at <http://www.whitehouse.gov/omb/inforeg/2003/q1/187.pdf>).

technological disciplines, and it has become the federal regulatory agency with the most well-known engagement in the peer review process. The EPA is charged with developing environmental safeguards in areas in which there is much uncertainty and disagreement, often relying on complex mathematical models that may predict risk, exposure, emissions, and costs. The variables involved in the design and use of these models are often the subjects of great debate.

Since the regulatory and financial implications of EPA's research are so huge, it is not surprising that heated disputes have erupted over the nature and quality of EPA science. Polluters and producers of hazardous products have often expressed their displeasure at various EPA activities (that is, regulations and the risk assessments upon which they are based), claiming that the science at EPA was biased or otherwise questionable. In many instances, these parties have called for peer review, or better peer review, of the EPA documents in question.

In responding to these concerns, both the EPA and the National Academy of Sciences (NAS) have convened several groups of experts to evaluate the quality of science at the Agency. Congress first mandated peer review at EPA through the 1978 authorization of the Science Advisory Board, whose mandate is to review "the quality and relevance of the scientific and technical information being used or proposed as the basis for Agency regulations."<sup>31</sup> In 1992, the EPA appointed a committee of independent academic scientists, who issued the report *Safeguarding the Future: Credible Science, Credible Decisions*. After reviewing the production and evaluation of science at the EPA, these observers recommended that:

Quality assurance and peer review should be applied to the planning and results of all scientific and technical efforts to obtain data used for guidance and decisions at EPA, including such efforts in the program and regional offices. Such a requirement is essential if EPA is to be perceived as a credible, unbiased source of environmental and health information, both in the United States and throughout the world.<sup>32</sup>

<sup>31</sup> U.S. Environmental Protection Agency, "EPA Science Advisory Board," U.S. Environmental Protection Agency, <http://www.epa.gov/sab>.

<sup>32</sup> U.S. Environmental Protection Agency, *Safeguarding the Future: Credible Science, Credible Decisions: The Report of the Expert Panel on the Role of Science at EPA* (Washington, DC: U.S. Environmental Protection Agency, 1992).

Since the first Bush Administration, EPA policy has required that major scientific and technical work products related to agency decisions should be peer-reviewed, with independent or external peer review required for those documents supporting the most important decisions. In 1998, Carol Browner, EPA Administrator under President Clinton, issued a detailed handbook (revised and reissued in 2000) to ensure uniform implementation of the peer review policy.<sup>33</sup> As specified in the procedures outlined in the EPA handbook, only a relatively small portion of all documents that the agency produces are peer-reviewed. This policy was reviewed by an NAS panel, which, in its report *Strengthening Science at the U.S. Environmental Protection Agency*, congratulated EPA on its peer review practices.<sup>34</sup>

According to this policy, EPA scientific and technical work products that are considered candidates for peer review are those that are used to support a regulatory program or policy position and that meet certain additional criteria, the first of which is that the work product "establishes a significant precedent, model, or methodology." This policy recognizes that many of the studies and reviews used to support regulatory activity are not novel, but rather summaries and recapitulations of work that has already been subjected to other quality assurance processes and therefore does not require additional review.<sup>35</sup>

### Peer Review in the Second Bush Administration: Code Red in the Science Community

The deliberative process through which the EPA developed and implemented this program stands in stark contrast to an effort by the White House Office of Management and Budget (OMB) in the later part of the first term of President George W. Bush to compel all federal agencies to subject a tremendous proportion of their reports and documents to peer review. While similar in some ways to the EPA peer review system, this

<sup>33</sup> U.S. Environmental Protection Agency, Science Policy Council, *Peer Review Handbook* (Washington, DC: U.S. Environmental Protection Agency, 1998); U.S. Environmental Protection Agency, Office of Science Policy, *Science Policy Council Handbook: Peer Review* (Washington, DC: U.S. Environmental Protection Agency, 2nd ed., 2000).

<sup>34</sup> National Research Council, *Strengthening Science at the U.S. Environmental Protection Agency* (Washington, DC: National Academy Press, 2000), 19.

<sup>35</sup> U.S. Environmental Protection Agency, *Science Policy Council Handbook*, 26-7.

One particularly troubling aspect of OMB's plan was the notably unbalanced or asymmetrical conflict-of-interest provision. Applying the untested hypothesis that financial support from an agency compromises the independent judgment of academic scientists, the proposal barred all scientists with a financial tie to an agency from participating in the review of agency documents. Because the proposal would exclude those scientists whose research is funded by the agency involved, many of the nation's leading academic experts could not be utilized. At the same time, the proposal did not equally preclude industry-employed scientists from appointment to the panels.<sup>39</sup>

Certain categories of information were exempt from the proposal's requirements, including documents relating to national defense or foreign affairs. All permits and licenses were also exempted so that, for example, peer review was not required of studies submitted by a manufacturer to demonstrate the safety of a new pesticide. In all, this suggested that OMB had targeted agencies with missions to protect the public's safety, health, and environment.

Interestingly, the initial attempt by OMB in August 2003 to impose governmentwide peer review requirements was met with opposition not only from the environmental and public interest communities but also from an unexpected source: institutions and organizations representing mainstream science. Much of this opposition solidified at a November 2003 workshop convened at OMB's request by the NAS Science, Technology, and Law program. The workshop began with an address by Dr. Graham, who explained that the proposal was a "major priority" for the Bush Administration, asserting that peer review would improve the quality of regulations and information.<sup>40</sup>

In response, speaker after speaker, all invited as experts in regulatory sciences by the NAS, warned that the OMB proposal would lead to increased costs and delays in disseminating information to the public and in promulgating health, safety, environmental, and other regulations, while potentially damaging the existing system of peer review. Many of the speakers challenged OMB to identify a single report or regulation that would have

<sup>39</sup> *Ibid.*, 54-027-54-028; Anthony Robbins, "Science for Special Interests," *Boston Globe*, Dec. 7, 2003, Op-Ed sec.

<sup>40</sup> Graham, 16.

initiative was far more sweeping, requiring that a huge quantity of federal "information" — including reports, pamphlets, web pages, perhaps even statements by federal officials — be subject to new levels of review before dissemination. The proposal went through two public comment periods, in which many individuals and organizations in the scientific as well as business communities voiced their opinions on the matter. The final formal policy was issued in December 2004.

OMB's "Peer Review and Information Quality" guidance for agencies was first proposed in August 2003.<sup>36</sup> The proposal was overtly aimed at what some critics of federal regulatory authority call "regulation by information." In explaining the proposal, Dr. John Graham, director of OMB's Office of Information and Regulatory Affairs (OIRA) and the signatory of the peer review proposal, asserted "that release of governmental information that has important impacts on the private sector, is in itself in some ways, a form of regulation."<sup>37</sup>

Under the initial proposal, all covered information issued by an agency would undergo some form of peer review; covered information that might influence a major regulation, or that could have a "substantial impact" on public policies or private sector decisions with a possible impact of more than \$100 million annually, would be put through a cumbersome process during which experts independent of the agency review the information. The proposal required that agency-generated information undergo multiple time-consuming reviews before release. Moreover, the information (reports, web pages, and so on) would first have to be published in draft form and disseminated for public comment, after which it would be sent to a peer review panel, along with the public comments. The agency would then issue a formal response to the peer reviewers' comments before the information could be redisseminated.<sup>38</sup> It was reasonable to conclude that application of this process could delay dissemination of information important in protecting that public's health and environment.

<sup>36</sup> Proposed Bulletin on Peer Review and Information Quality, 68 Fed. Reg. 54-023-54-029 (Sept. 15, 2003).

<sup>37</sup> John Graham, Statement at the Workshop on Peer Review Standards for Regulatory Science and Technical Information, Hosted by the National Academies, the National Research Council, Global and Policy Affairs Division, Science, Technology, and Law Program, Nov. 18, 2003, 16 (available at <http://www7.nationalacademies.org/all/Peer-Review-Transcript.pdf>).

<sup>38</sup> Proposed Bulletin on Peer Review and Information Quality, 68 Fed. Reg. 54-023-54-029 (Sept. 15, 2003).

been improved had the proposed peer review system been in place. Following the NAS meeting, the American Association of Medical Colleges, representing the nation's schools of medicine, and the Federation of American Societies for Experimental Biology, a federation of twenty-two scientific societies, sent a scathing letter of opposition to the White House, as did the Council on Government Relations, representing more than 150 leading U.S. research universities. Both the American Association for the Advancement of Sciences<sup>41</sup> (AAAS) and the American Public Health Association<sup>42</sup> passed resolutions at their annual meetings opposing the peer review guidelines. This response by the scientific community was surprising to many. Traditionally, the organizations that represent mainstream scientists and their research institutions have focused their Washington political efforts on research funding, avoiding involvement in policy fights that might be perceived as partisan.

The widespread opposition among mainstream scientists can be seen in a powerful editorial that Donald Kennedy wrote in *Science* magazine. Dr. Kennedy, who also wrote the prologue to this book, is a giant in the scientific community, having held major posts in academia (president of Stanford University) and government (commissioner of the Food and Drug Administration), before becoming editor of *Science*, the AAAS's weekly journal. In the editorial, Dr. Kennedy remarked that calling OMB's proposed process peer review "seems strange to us here."<sup>43</sup>

Perhaps most notable reaction, however, was the harsh language used by Bruce Alberts, at the time president of NAS. As the nation's preeminent scientific organization, the NAS chooses its battles carefully and rarely joins the open opposition to major White House initiatives. Dr. Alberts described OMB's peer review model as "highly prescriptive," and warned Dr. Graham that "if enacted in its present form [the model] is likely to be counterproductive." It is possible that the NAS's response was prompted by concern that this new approach could require government-sponsored NAS

<sup>41</sup> American Association for the Advancement of Science, AAAS Resolution: On the OMB Proposed Peer Review Bulletin, American Association for the Advancement of Science, [http://archives.aaas.org/docs/resolutions.php?doc\\_id=434](http://archives.aaas.org/docs/resolutions.php?doc_id=434)

<sup>42</sup> American Public Health Association, "Late Breaker Resolution: Threats to Public Health Science," American Public Health Association, <http://www.apha.org/legislative/policy/2003/LB-03-01.pdf>

<sup>43</sup> Donald Kennedy, "Disclosure and Disinterest," *Science* 303, no. 5654 (2004): 15.

reports to undergo additional agency-administered peer review, a requirement that would undermine the NAS's position as the final authority on the interpretation of science.

From the tone of the comments by scientists at the meeting and subsequently, it seems that the proposal evoked an almost visceral response among scientists whose work is used by regulatory agencies. The White House was providing an opportunity for interests who are discomfited by the results of these scientists' studies to "stack the deck" in order to disparage or diminish the importance of their work. This concern was also evident in Dr. Kennedy's *Science* editorial, which expressed that the proposed system would contribute to the erosion of public trust in the work of scientists.<sup>44</sup>

In contrast, the proposal had the strong support of most of the major trade associations—the U.S. Chamber of Commerce, the National Association of Manufacturers, the American Chemistry Council—a plus a host of minor ones (such as the California Avocado Commission, the Council of Industrial Boiler Owners, and the National Funeral Directors Association). Many of these groups wanted the proposal to go even further, eliminating any connection with traditional scientific peer review.<sup>45</sup>

These arguments seem to prove that the trade associations do not actually desire high-quality peer review (after all, NAS reports are peer-reviewed by some of the country's leading scientists), but rather seek to delay or prevent dissemination of information about which they disagree. Given this objective, it is logical that they should discard peer review in which journal editors, rather than the White House, select the peers.

Not all trade associations supported White House control of agency peer review systems. The comments filed by the drug industry suggest it is clearly comfortable (perhaps too comfortable) with its regulators at the FDA. Criticizing OMB with unusually direct language, the Pharmaceutical Research and Manufacturers of America asserted that the proposed requirements "would contribute little value and would add to the time and expense of a gatekeeper function that has historically been criticized for obstruction and delay."<sup>46</sup>

<sup>44</sup> *Ibid.*

<sup>45</sup> Office of Management and Budget, 2003 Public Comments on Peer Review. Available at <http://www.whitehouse.gov/omb/inforg/2003/q/q4-list.html>. Access verified May 26, 2005.

<sup>46</sup> Comments on Proposed Bulletin on Peer Review and Information Quality from Erika King, Assistant General Counsel, Pharmaceutical Manufacturers of America, to Margo Schwab,

In a victory for the science community, the final version of the peer review requirements, issued in December 2004, was significantly modified to address several of the community's concerns. Perhaps the most significant revision involved the conflict-of-interest provisions, which now allow scientists who have grant funding from agencies to participate in peer review panels. OMB has also deferred to the NAS in several areas; NAS panel reports are now presumed not to require additional peer review, and OMB requires agencies to adopt the NAS policy for dealing with conflict of interest in the selection of nongovernment employee members of peer review committees.<sup>47</sup>

While other modifications make the peer review requirements somewhat less onerous for agencies (for example, the level that triggers the most cumbersome and time-consuming level of peer review was raised from \$100 million to \$500 million), the fundamental issue raised by scientists at the initial NAS workshop remained: OMB failed to establish the need for a single governmentwide peer review policy. The final bulletin provides little evidence with which to question the initial conclusion of many observers: that the new requirements are a poorly camouflaged attempt to introduce delays into already slow regulatory processes, and further hamper government activities aimed at protecting the public health and environment.<sup>48</sup>

## Conclusion

Over the last few decades, polluters and manufacturers of other dangerous materials have increasingly adopted the strategy of manufacturing uncertainty in the face of proposed government action. In virtually every instance in which a federal regulatory agency proposes protecting the public's health by reducing the allowable exposure to a toxic product, the

Office of Management and Budget, Office of Information and Regulatory Affairs (Dec. 15, 2003) (available at <http://www.whitehouse.gov/omb/infoereg/2003/q/n8.pdf>).

47. Memorandum from Joshua B. Bolten, Director, Office of Management and Budget, to the Heads of Executive Departments and Agencies, "Issuance of OMB's Final Information Quality Bulletin for Peer Review" (Dec. 16, 2004) (available at <http://www.whitehouse.gov/omb/memoranda/2005/m05-03.pdf>).

48. OMB Watch, "OMB Watch Analysis on Final Peer Review Bulletin," OMB Watch, <http://www.ombwatch.org/article/articleview/2594/1/2327?topicID=3>.

regulated industry hires scientists to dispute the science on which the proposal is based.<sup>49</sup>

New mandates for peer review in regulatory science appear to be an additional component in the strategy that enables producers of hazardous products and pollution to delay formal regulation, and avoid compensating their victims. While independent review by impartial experts may help improve the quality of regulatory science, the improvident imposition of ill-fitting peer review structures and approaches might needlessly impede the work of government agencies and delay programs needed to protect the public's health and environment. In contrast to refereeing and program evaluation, regulatory peer review is invoked not to assist in the allocation of scarce resources but primarily as a procedural mechanism to control information dissemination. As a result, it seems likely that the newly implemented federal peer review requirements, while less onerous than those originally proposed, will provide new and convenient opportunities for special interests to promote an antiregulatory agenda.

49. David Michaels, "Doubt Is Their Product," *Scientific American* 292, no. 6 (2005): 96-101; David Michaels and Celeste Monforton, "Manufacturing Uncertainty: Contested Science and the Protection of the Public's Health and Environment," *American Journal of Public Health* 10 (forthcoming).