

## RESPONSE

### Comment on *In Defense of Regulatory Peer Review*

by Rick E. Melberth and Gary D. Bass

In their article, *In Defense of Regulatory Peer Review*,<sup>1</sup> J.B. Ruhl and James Salzman have made a valuable contribution to the politically charged debate over regulatory peer review. Their proposal for a mechanism to provide empirical data about whether agencies would benefit from peer review helps lift the debate from the realm of arguing over “sound science.” They correctly identify the need for information collection to determine the scope of the problem before proposing the notion that regulatory peer review is the solution.

It hardly seems controversial to suggest that research used for regulatory decisionmaking be peer-reviewed, but the devil is always in the details. For 25 years, the nonprofit organization OMB Watch has tracked and documented increasingly prescriptive executive branch policies over agency regulatory decisions.<sup>2</sup> These policies have marginalized and/or reduced the importance of science (and social considerations) in agency decisionmaking in favor of economic considerations, culminating in today’s open attacks on science: disputing and falsifying scientific evidence; introducing scientific “uncertainty” as justification for avoiding or delaying rulemakings; delaying or suppressing scientific findings; and censoring and intimidating government scientists.<sup>3</sup>

This environment has increased our skepticism about the value of using tools like peer review, at least as it has been imposed on agencies through the Office of Management and Budget’s (OMB’s) *Final Information Quality Bulletin for Peer Review*.<sup>4</sup> The authors of *In Defense of Regulatory Peer Review* describe the academic environment in which this debate about regulatory peer review currently takes place. We have to see this debate in the political context of the great influence exerted by OMB’s Office of Information and Regulatory Affairs (OIRA) over what information is even allowable in the regulatory decisionmaking process and how that information is developed and analyzed.

To their credit, the authors have thought hard about how to remove peer review from this unwinnable debate over sound science. They propose using it as a diagnostic tool because “[n]either advocates nor critics of regulatory peer review can intelligently assess the merits of requiring it . . . without first having a clear sense of whether none, a few, or

many of these decisions would benefit from peer review.”<sup>5</sup> We could not agree more, because the costs both to agencies in terms of resources, and to the public in terms of potential improvements in health and safety, of unnecessary peer review processes can be steep.

The authors base much of their analysis on first-hand experience with the Klamath Committee, a peer review process established by the National Research Council (NRC) to review the decision to close the floodgates of an irrigation ditch in Oregon in order to protect endangered fish. The Klamath Committee work was reportedly the basis for changing the government’s decision on the floodgates, but the authors note that regulatory action may still be justified, even when the science is not conclusive. “The Klamath Committee, it is worth noting, never condemned the federal government’s decision to close the floodgates, acknowledging that the decision may or may not have been justified on policy grounds. It just was not justified on scientific grounds alone.”<sup>6</sup> One can think of many examples where science might not justify taking action, but the public demands action. Think of the many actions the federal government took with respect to anthrax right after 9/11.

Yet the reverse is not true: when science conclusively shows a need for regulation, government, at least under the Bush Administration, has been prone to ignore the evidence. For example, two congressionally funded National Academy of Science reports supported links between certain workplace risk factors and recognized injuries.<sup>7</sup> However, the Bush Administration took action to kill ergonomic regulations, ignoring studies and peer review by a preeminent research body. Thus, it appears science can be ignored on policy grounds. This adds to our skepticism about the utility of peer review in a highly politicized environment.

The “in defense” portion of the authors’ argument is that peer review is the right tool to use to analyze how science is incorporated into agency decisionmaking and whether that science leads directly to the decisions made. They cite the generally accepted notion that peer review “is commonplace, indeed, fundamental, to the practice of science. It is the gold standard for determining publication and general acceptance of scientific research.”<sup>8</sup>

We urge three cautions to accepting peer review. First, as Prof. David Michaels points out, the widespread acceptance of peer review for editorial purposes is only a mid-20th century phenomenon, and there is not a single, predominant model accepted for use.<sup>9</sup> Although used since the 18th cen-

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1. J.B. Ruhl & James Salzman, *In Defense of Regulatory Peer Review*, 38 ELR (ENV’T L. & POL’Y ANN. REV.) 10553 (Aug. 2008) (a longer version of this article was originally published at 84 WASH. U. L. REV. 1 (2006)).
2. See generally OMB Watch, *Homepage*, <http://www.ombwatch.org> (last visited June 23, 2008).
3. See generally UNION OF CONCERNED SCIENTISTS, FEDERAL SCIENCE AND THE PUBLIC GOOD: SECURING THE INTEGRITY OF SCIENCE IN POLICY MAKING (2008), available at [http://www.ucsusa.org/assets/documents/scientific\\_integrity/Federal-Science-and-the-Public-Good.pdf](http://www.ucsusa.org/assets/documents/scientific_integrity/Federal-Science-and-the-Public-Good.pdf).
4. Final Information Quality Bulletin for Peer Review, 70 Fed. Reg. 2664 (Jan. 14, 2005).

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5. Ruhl & Salzman, *supra* note 1, at 10559.

6. *Id.* at 10554.

7. See NRC, WORK-RELATED MUSCULOSKELETAL DISORDERS: REPORT, WORKSHOP SUMMARY, AND WORKSHOP PAPERS (1999); NRC & INSTITUTE OF MEDICINE, MUSCULOSKELETAL DISORDERS AND THE WORKPLACE: LOW BACK AND UPPER EXTREMITIES (2001).

8. Ruhl & Salzman, *supra* note 1, at 10554.

9. David Michaels, *Politicizing Peer Review: The Scientific Perspective*, in RESCUING SCIENCE FROM POLITICS 219 (Wendy Wagner & Rena Steinzor eds., 2006).

tury, prepublication review was long the exception, not the rule, in publishing scientific articles.

Peer review procedures used to consider financial support for scientific research developed prior to its use in publishing and developed independently. Thus, the two arenas where peer review is widely accepted do not share common approaches and models to provide a road map for its use in regulatory peer review.

In addition, Professor Michaels notes that within editorial peer review, there are limitations to its effectiveness. “Perhaps the most widely recognized failing of peer review is its inability to ensure the identification of high-quality work.”<sup>10</sup> Professor Michaels cites two studies in which peer review processes used by medical journals were systematically studied. The conclusions were that editors did not know how to measure peer review effects or processes, and that peer review is a “largely untested” tool.<sup>11</sup>

The second caution revolves around the possibility of alternatives to peer review. The authors acknowledge that legal scholars generally oppose the use of regulatory peer review, but Ruhl and Salzman argue for it based on its use by the Klamath Committee in its review of agency decisions under the Endangered Species Act (ESA). We would like to see scientific, policy, and legal scholars’ work on advancing alternatives like judicial review, policy evaluation, increased public participation, and the impacts of greater transparency in the decisionmaking process. Would full disclosure of the information in the rulemaking record created by agencies assist in understanding better how scientific (and social and economic) information is used? Would this disclosure, in turn, help answer the question of whether agency conclusions are based on the scientific evidence?

Ruhl and Salzman offer survey research to demonstrate the “perception that regulatory peer review is the answer to agency misuse of science . . . .”<sup>12</sup> The results more accurately suggest that many are unhappy with the regulatory process and are looking “on faith” for any answer to improve the process. It would have been interesting to ask the participants about competing approaches to peer review for improving agency decisionmaking such as the items we suggest above.

Third, we are very cautious about extending ideas that may work in one program area or agency and applying it across government. This one-size-fits-all approach simply does not work in our government; it is too vast and diversified. Additionally, we think decisions of this magnitude about the regulatory process should be considered in public fora by Congress and, if needed, enacted into law. As the authors note: “[P]eer review . . . is neither mandated by most environmental laws nor required through the default administrative law doctrines of the APA.”<sup>13</sup> Changes made by executive branch actors, such as OMB, could intrude upon existing laws agencies must follow or even subordinate power granted to the agencies by Congress.

These cautions notwithstanding, the authors’ proposal of a peer review mechanism, if conducted independently of the politics of the current regulatory environment, may help

document the use of science in agency decisionmaking. The authors set out the benefits they would expect from applying their peer review mechanism to a selection of agency decisions. Most important among them is the diagnostic function that may provide empirical data about how many agency decisions could benefit from peer review. As the authors state: “The greatest benefit of peer review may lie in providing empirical data on the scope of the problem that can then tell us whether broader or reduced use of peer review is warranted.”<sup>14</sup> Perhaps the authors’ goal would be better served by a pilot program to test the value of peer review as opposed to their broader proposal.

The proposed mechanism is for a randomized peer review, conducted by the NRC with three stages. The first stage would involve identifying classes of regulatory decisions “that would likely benefit from peer review,” i.e., those relying most heavily on scientific data and applying scientific judgment.<sup>15</sup> Prominent examples of these types of decisions are those required under the ESA but would also include the “types of agency decisions [throughout government] that rely on scientific data and scientific judgments.”<sup>16</sup> From this class of decisions, 1 or 2% of the decisions would be randomly selected for review initially.

Second, the decisions selected would be reviewed by three anonymous experts from NRC standing committees. The experts “would be asked to evaluate the agency’s protocol for identifying relevant scientific data and research,” the rationale for selecting the data, and its interpretation of the science.<sup>17</sup> Although not intended to be a *de novo* review, the experts could request to review research reports relied on by the agency. The reviews would be completed in 90 days or less.

As the authors note: “The quality of the reviewers is central to any peer review.”<sup>18</sup> Yet the authors give scant attention to this issue in their proposal. We believe the NRC would resist political manipulation. However, the pool of experts to conduct peer reviews is often very limited—and those most skilled and represented in peer review panels too often have ties to regulated interests. Disclosure of these connections is important but not an answer. Moreover, the authors’ decision to exclude the application of the Federal Advisory Committee Act, which may be appropriate, means there is no requirement to ensure that the committee is balanced.

Third, the results of the review would be released publicly and to the agency “prior to the conclusion of any public notice-and-comment procedures applicable to the underlying decision.”<sup>19</sup> Every two years, these peer reviews would be reviewed to determine if the agency’s use of science justifies extending regulatory peer review within the agency.

Although we are advocates for government openness, we have modest concerns about this transparency aspect. Oftentimes, the utility of peer review is in its anonymous nature. Hence, every effort must be taken to ensure anonymity, because a reviewer may work with the researcher in other capacities.

10. *Id.* at 224.

11. *Id.* at 225.

12. Ruhl & Salzman, *supra* note 1, at 10557.

13. *Id.* at 10555.

14. *Id.* at 10559.

15. *Id.*

16. *Id.*

17. *Id.* at 10560.

18. *Id.* at 10555.

19. *Id.* at 10560.

In its 2000 publication, *Strengthening Science at the U.S. Environmental Protection Agency: Research-Management and Peer-Review Practices*, NRC recommended that the U.S. Environmental Protection Agency's (EPA's) Science Policy Council use a similar randomized approach to review those work products already peer-reviewed.<sup>20</sup> In addition, however, it encouraged the review to include "the responses to review, and the cost, quality, timeliness, and impact of the review."<sup>21</sup> Tracking these variables through the authors' peer review process would add even more potentially valuable information.

The authors point out, correctly we think, that this approach may have the advantages of removing peer review from both agency and OMB influence and not being as costly as more widespread applications of peer review within or across agencies. Furthermore, it may have the ef-

fect of making science-based agencies more careful about their uses of science in regulatory decisionmaking.

Its most valuable contribution, however, is that there would be data about how agencies apply scientific information, thus providing at least some evidence in the debate about scientific integrity in agency rulemaking. Focusing on the question of "how many Klamaths" is a valuable first step.

With this data in hand from independent reviews, it might be possible to support or refute some of the political impacts and biases the authors argue exist from their institutional theory framework. We have to leave it to the environmental, public health, and workplace safety experts to determine if this approach is as applicable to other scientific decisions mandated legislatively as it appears it is to ESA decisions.

Extending this randomized peer review approach across agencies will likely result in very different findings about how science is used in agencies with vastly different missions, programs, and research priorities. If so, those findings can be very useful in dispelling the notion that a one-size-fits-all approach to regulatory peer review and to the integration of scientific information in agency regulatory decisionmaking is appropriate or feasible.

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20. COMMITTEE ON RESEARCH & PEER REVIEW IN EPA ET AL., *STRENGTHENING SCIENCE AT THE U.S. ENVIRONMENTAL PROTECTION AGENCY: RESEARCH-MANAGEMENT AND PEER-REVIEW PRACTICES* (2000).

21. *Id.* at 21.