

In Defense of Regulatory Peer Review

J.B. Ruhl and James Salzman

Editors' Summary: Profs. J.B. Ruhl and James Salzman suggest that random peer reviews be conducted of regulatory agencies' reliance on scientific information in order to better inform regulators and the public of the nature of regulatory decisionmaking. Brian Mannix responds that the laws directing regulatory decisions often create distinctions that are too sharp and that the laws should either allow agencies more decisionmaking discretion or that discretion should be retained for Congress once agencies have conducted fact-finding. Rick Melberth and Gary Bass caution against overreliance on peer review, but acknowledge that the system suggested in the main article may help to collect useful data on existing agency practices.

I. Introduction

On June 29, 2001, just outside Klamath Falls, Oregon, an angry mob of farmers took actions into their own hands. Massing around the closed headgates of a federally operated irrigation ditch, the crowd defied federal government orders, burst open the headgate locks, and returned the flow of water to the thirsty soils of their croplands.¹ The mob stayed put and made camp for the next few days, challenging federal officials time after time by unlocking the gates as soon as they had been closed. The crowd finally was dispersed under the stern direction of U.S. Marshals. The battle lines could not have been more clearly drawn.

The standoff had been building ever since two local species of sucker fish found in the lake and a population of coho salmon found in the river below the dam had been listed for protection under the Endangered Species Act (ESA).² This placed the fish under the watchful protection of the federal government. The farmers cried for relief from

dry irrigation ditches and the specter of failed crops. The federal government stood firm: the gates had to stay shut and farmlands go dry in order to save endangered fish dependent on the water stored in Upper Klamath Lake and flowing in the Klamath River.

The following March, however, amidst the flash of news cameras, the Secretary of Agriculture and Secretary of the Interior quite publicly opened the very same headgates.³ This saga, popularly known as “the Klamath,” made headlines around the nation and served as a rallying call for many communities in the western United States concerned about the future in the face of “their water” being dedicated to endangered species protection.⁴ What made the first liberation of water an act of civil disobedience and the latter a high-profile case of wise federal governance? Probably, the answer came from a room full of scientists and a practice called peer review. Despite how closely the popular press followed the Klamath story, it completely missed the consequence we believe to be most significant—the rise of regulatory peer review.

Following the Klamath saga, the National Research Council (NRC) convened a committee of experts, known as the Klamath Committee, to conduct a peer review of the agencies' decisions—the first ever conducted of an agency decision of this magnitude under the ESA.⁵ The initial re-

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1. For an account of the events described in this paragraph, see Ted Williams, *Salmon Stakes*, 105 AUDUBON 42 (2003), available at <http://magazine.audubon.org/incite/incite0303.html>. For a comprehensive history of the Klamath River Basin and the events involving the “crisis of 2001,” see Holly Doremus & A. Dan Tarlock, *Fish, Farms, and the Clash of Cultures in the Klamath Basin*, 20 ECOLOGY L.Q. 279 (2003).
2. Pub. L. No. 93-205, 87 Stat. 884 (1973) (codified as amended at 16 U.S.C. §136, 16 U.S.C. §§1531–1544, ELR STAT. ESA §§2-18, and in other scattered sections of 16 U.S.C.).

3. See Doremus & Tarlock, *supra* note 1, at 334-35.

4. See *id.* at 336-39.

5. J.B. Ruhl was a member of the Klamath Committee. The Klamath Committee provided a report thoroughly studying the area's land use and water management history. See COMMITTEE ON ENDANGERED & THREATENED FISHES IN THE KLAMATH RIVER BASIN, NRC, ENDANGERED AND THREATENED FISHES IN THE KLAMATH RIVER BASIN: CAUSES OF DECLINE AND STRATEGIES FOR RECOVERY 46-94 (2004) [hereinafter KLAMATH COMMITTEE FINAL REPORT]. The Klamath Committee also provided detail in an interim report. See COMMITTEE ON ENDANGERED & THREATENED FISHES IN THE KLAMATH RIVER BASIN, NRC, SCIENTIFIC EVALUATION OF BIO-

sults of the Klamath Committee's peer review sparked a firestorm of controversy.⁶ Reviewing the information available to the federal agencies responsible for managing the fish at the time of their respective decisions, the experts found that "no substantial scientific foundation" existed for the agencies' conclusions.⁷ In other words, the conclusions that further reducing river flows would harm the salmon could not be justified based on the available data. Releasing irrigation waters might harm the endangered fish, or it might not—science was too uncertain to say. Although the agencies said that science got them from point A to point B, the Klamath Committee's peer review concluded it did not. Many observers began to ask whether peer review should guide decisions in *other* regulatory settings. Indeed, since the Klamath controversy, strong, insistent calls for improving agency decisions based on science have been heard from the White House⁸ and from Congress.⁹ This self-proclaimed "sound science" movement argues that procedural safeguards to ensure better use of scientific data will improve agency decisions.¹⁰

LOGICAL OPINIONS ON ENDANGERED AND THREATENED FISHES IN THE KLAMATH RIVER BASIN: INTERIM REPORT (2002) [hereinafter KLAMATH COMMITTEE INTERIM REPORT]. Additional background and analysis of the events surrounding the Klamath can be found in Reed D. Benson, *Giving Suckers (and Salmon) an Even Break: Klamath Basin Water and the Endangered Species Act*, 15 TUL. ENVTL. L.J. 197 (2002); Marcilynn A. Burke, *Klamath Farmers and Cappuccino Cowboys: The Rhetoric of the Endangered Species Act and Why It (Still) Matters*, 14 DUKE ENVTL. L. & POL'Y F. 441 (2004); Doremus & Tarlock, *supra* note 1; Julia Muedeking, *Taking the Heart of the Klamath Basin: Is It Free?*, 8 DRAKE J. AGRIC. L. 217 (2003); Cori S. Parobek, *Of Farmers' Takes and Fishes' Takings: Fifth Amendment Compensation Claims When the Endangered Species Act and Western Water Rights Collide*, 27 HARV. ENVTL. L. REV. 177 (2003).

6. See Doremus & Tarlock, *supra* note 1, at 326.
7. *Id.* at 324 (finding no scientific evidence supporting requirement of increased take levels or increased stream flow).
8. The Bush Administration has aggressively advanced this agenda through means such as prescribing standards for agency data quality control. See, e.g., Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies, 67 Fed. Reg. 8452 (Feb. 22, 2002). See generally U.S. Environmental Protection Agency, *Summary of Fiscal Year 2004 Budget Request*, 34 Env't Rep. (BNA) S-17, 112-21 (Feb. 3, 2003) (including "Goal 8," which the Agency described as "Sound Science, Improved Understanding of Environmental Risk, and Greater Innovation to Address Environmental Problems").
9. Legislative proposals routinely use the "sound science" label to gain support. See, e.g., Sound Science for Endangered Species Act Planning Act of 2003, H.R. 1662, 108th Cong. (2003); Sound Science for Endangered Species Act Planning Act of 2002, H.R. 4840, 107th Cong. (2002).
10. See David E. Adelman, *Scientific Activism and Restraint: The Interplay of Statistics, Judgment, and Procedure in Environmental Law*, 79 NOTRE DAME L. REV. 497, 498 (2004) ("[S]chisms exist over how science is used in setting environmental policy. For most critics of environmental regulation, broad reliance on science is viewed as progress towards increased rationality and objectivity."). A comprehensive overview of the sound science debate is found in Thomas O. McGarity, *Our Science Is Sound Science and Their Science Is Junk Science: Science-Based Strategies for Avoiding Accountability and Responsibility for Risk-Producing Products and Activities*, 52 U. KAN. L. REV. 897 (2004). A more entertaining, though studiously documented account is available in CHRIS MOONEY, *THE REPUBLICAN WAR ON SCIENCE* (2005). The discussion and debate regarding the use of "sound science" in environmental law is pervasive—we found over 39,000 websites through a Google® search of "sound science" AND "environmental law." For a historical perspective on the use of science in environmental law, referencing a wealth of literature on the topic and suggesting several "cautionary tales" about the promotion of using more "good science," see Oliver Houck, *Tales*

Scientific peer review is a rigorous review and critique of a study's methods, results, and findings that is conducted by others in the relevant field who have the requisite training and expertise, who have no pecuniary or other disqualifying bias with respect to the topic, and who are independent of the persons who performed the study.¹¹ 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.

Regulatory peer review refers to the outside evaluation of an administrative agency's compilation, selection, or use of scientific data to support a proposed regulatory decision such as a rule, standard, permit, or other policy. Like scientific peer review, the review and critique would be conducted prior to the agency's final decision by qualified, independent experts who have no pecuniary or other conflict of interest in the outcome of the agency's decision. To make sense of the debate over regulatory peer review, three fundamental questions need to be answered: The first is *how many Klamaths are there?* Second, even if the Klamath experience is widespread, and even if agencies frequently fail to adequately justify policy decisions on scientific grounds, *are these actually poor policy decisions?* 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.¹² It just was not justified on scientific grounds alone.¹³ Finally, even if there necessarily is cause for concern when agencies explicitly base their policy decisions on inadequate scientific foundations, does regulatory peer review provide an effective safeguard? Put differently, will it avoid more Klamaths in the future? This Article addresses these questions directly, grounding the debate over the use of regulatory peer review in agency decisionmaking and charting a productive route forward.

Part II of the Article briefly discusses scientific peer review in journal publications and also touches on the agency regulatory applications. The next two sections of the Article address the current debate over regulatory peer review, setting out the arguments in favor of its use in Part III and their critiques in Part IV. To provide an empirical basis for our

From a Troubled Marriage: Science and Law in Environmental Policy, 302 SCIENCE 1926, 1926 (2003). Prof. Wendy Wagner has produced the most extensive body of work examining the claim for using more and better science in environmental law. See Wendy E. Wagner, *The "Bad Science" Fiction: Reclaiming the Debate Over the Role of Science in Public Health and Environmental Regulation*, LAW & CONTEMP. PROBS., Autumn 2003, at 63 [hereinafter Wagner, *Bad Science*]; Wendy E. Wagner, *Congress, Science, and Environmental Policy*, 1999 U. ILL. L. REV. 181; Wendy E. Wagner, *The Science Charade in Toxic Risk Regulation*, 95 COLUM. L. REV. 1613 (1995).

11. NRC ET AL., PEER REVIEW IN ENVIRONMENTAL TECHNOLOGY DEVELOPMENT PROGRAMS: THE DEPARTMENT OF ENERGY'S OFFICE OF SCIENCE & TECHNOLOGY 2 (1998). A peer is "a person having technical expertise in the subject matter to be reviewed (or a subset of the subject matter to be reviewed) to a degree at least equivalent to that needed for the original work." *Id.* at 28. "The peer's independence from the work being reviewed means that the peer, a) was not involved as a participant, supervisor, technical reviewer, or advisor in the work being reviewed, and b) to the extent practical, has sufficient freedom from funding considerations to assure the work is impartially reviewed." *Id.*
12. See KLAMATH COMMITTEE FINAL REPORT, *supra* note 5, at 34-35.
13. *Id.* at 35.

evaluation, we conducted a nationwide survey of environmental lawyers to reveal the perceptions of practitioners. In Part V of the Article we reassess the role of peer review in the regulatory process. We believe regulatory peer review is most effective when focusing on how agencies apply science in support of their regulatory decisions. We also believe that regulatory peer review can help inform the public about where an agency's use of science in support of a proposed decision ends and where its use of professional judgment and normative policy choices begins. Finally, in Part VI of the Article we propose a new diagnostic approach, through the use of mandatory "randomized peer review" by agencies to assist policymakers in assessing the problem of agencies' reliance on science in regulatory decisions, if there is one.

II. What Is Peer Review and Where Is It Used?

Using science is not the same thing as doing science. To assess whether the practice of peer review makes sense in regulatory settings, we must first acknowledge the use and benefits of peer review in science and how transferable these are.

A. Conventional Applications of Scientific Peer Review¹⁴

Peer review is most strongly associated with scientific journal publication decisions, in which it has been in use for over 300 years.¹⁵ Within science, peer review is widely considered "essential to the integrity of scientific and scholarly communication."¹⁶ Indeed, for many scientists, peer review "does not merely reflect the scientific method; it *is* the scientific method."¹⁷ The procedures seek to ensure "a documented, critical review performed by peers . . . who are independent of the work being reviewed."¹⁸ The quality of the reviewers is central to any peer review. Ideally, one selects reviewers who have demonstrated relevant expertise, independence, and freedom from conflicts of interest.¹⁹

Substantively, the peer review process is not a *de novo* review, to borrow from a legal model, but rather more like appellate review because there is no independent research to verify whether the data are accurate. One benefit of "appellate style" peer review is that it serves as a filter, ensuring quality control and allowing editors and grant makers to rank articles and proposals.²⁰

B. Extending Peer Review to Regulation

Although peer review is employed by a number of federal agencies that have primarily science-based missions, the use of peer review is more limited for agencies when exercising *regulatory* responsibilities. Using peer review in a regulatory context would require adapting conventional scientific peer review in three respects. First, regulatory peer review will need to address how the agency incorporated preexisting scientific knowledge into its own decision processes. Second, since agencies will not always necessarily rely on peer-reviewed data,²¹ regulatory peer review will need to provide some assessment of the agency's choices over which data to use in the form of an evaluation. Finally, regulatory peer review would have to be mindful that in getting from point A to point B, an agency may have the discretion or the mandate to rely on an integration of science and other policy factors, whereas the peer review must be limited to the science alone.

III. The Case for Peer Review

Despite any disagreement over mandating regulatory peer review, both sides agree on the overall goal—regulatory agencies that make decisions based, in whole or in part, on scientific research should seek to ensure their decisions accurately interpret and employ the research results.

Faced with competing versions of what the available science means, a court is in no position to conduct a reliable peer review and would thus lean decidedly toward deferring to the agency's version, as it must under the Administrative Procedure Act (APA). Regulatory peer review therefore may have something to offer in such cases, which, given the scientific uncertainty present in many regulatory decisions, may be quite common.

Peer review, however, is neither mandated by most environmental laws nor required through the default administrative law doctrines of the APA.

Peer review offers substantive and procedural benefits to regulatory decisionmaking that other procedural safeguards do not. Advocates argue that providing independent expert feedback will generally improve the quality of regulatory decisions.²² Proponents also argue that the use of independent, outside experts in regulatory peer review should enhance the legitimacy of the regulatory *process* by reducing the appearance of agency bias and conflict of interest.²³

A. Institutional Theory

A key assumption underlying regulatory peer review proposals is that there is a problem that needs to be fixed. Agencies often, perhaps systematically, present scientific data as supporting a policy decision more than is justified. Political science theory suggests why one might be concerned over agency use of science. The theory of agency mission focus, for example, asserts that single-mission agencies tend zealously to further their statutory missions in

14. For a longer discussion of the use and perception of peer review in science, see J.B. Ruhl, *Prescribing the Right Dose of Peer Review for the Endangered Species Act*, 83 NEB. L. REV. 398, 407-09.

15. See ANN C. WELLER, EDITORIAL PEER REVIEW: ITS STRENGTHS AND WEAKNESSES 1-7 (2001).

16. *Id.* at 322.

17. Lars Noah, *Scientific "Republicanism": Expert Peer Review and the Quest for Regulatory Deliberation*, 49 EMORY L.J. 1033, 1045 (2000).

18. NRC ET AL., *supra* note 11 and accompanying text.

19. WELLER, *supra* note 15, at 207. Of course, even reviewers who meet these criteria may have personal biases about approaches to or disputes in the particular scientific discipline, and there is no objective way of de-biasing review panels from this effect. See Robert J. MacCoun, *Biases in the Interpretation and Use of Research Results*, 49 ANN. REV. PSYCHOL. 259, 277 (1998).

20. There is some empirical evidence in support of this belief. See WELLER, *supra* note 15, at 51, 53.

21. Indeed, as Professor Wagner points out, case-specific regulatory decisions usually rely, at least in part, on "unvalidated industry science." Wagner, *Bad Science*, *supra* note 10, at 73.

22. See Lars Noah, *Peer Review and Regulatory Reform*, 30 ELR 10606, 10608 (Aug. 2000).

23. Proposed Bulletin on Peer Review and Information Quality, 68 Fed. Reg. 54023, 54024 (Sept. 15, 2003).

a single-minded fashion.²⁴ Personal bias can also play a significant role. For example, biologists may care personally about the work they devoted their careers to, which may impact their neutrality. Finally, and perhaps most important, agencies work in an environment of serious resource and time constraints.

B. Empirical Analysis: Faith, Perceptions, and Demand

We know of no comprehensive empirical study comparing regulatory decisions with and without peer review, attempting to reevaluate past regulatory decisions using peer review methods, or estimating the costs of broad-based regulatory peer review. Beyond political theory, in other words, the case for regulatory peer review is based largely on faith, faith in the gospel that agencies do in fact overstate how far their science carries them.

Faith, however, is a powerful force when shared by a multitude. Our survey shows that if enough of those who share these beliefs are experienced in administrative law and pol-

icy can claim to have practical experience with agency regulatory practices then the public is less likely to demand an empirical study of the issue before supporting proposals to put regulatory peer review in place.

The survey was designed to elicit respondents' perceptions about the performance of regulatory agencies, the merits of regulatory peer review, and the design of regulatory peer review.²⁵ With respect to agency performance, the survey posed a general question and many detailed ones relating to different attributes of agency use of science. Responses indicated a significant background level of concern over agency use of science among experienced practitioners.²⁶ Indeed, in more detailed questions, respondents revealed a deep mistrust of agency behavior. Figure 1 shows the percentage of responses to specific aspects of agency use of science. We asked respondents to indicate the extent to which they agree or disagree that the following statements describe agency resources and practices. Figures show percent of respondents in each category.

Figure 1

	Strongly Agree	Somewhat Agree	No Opinion	Somewhat Disagree	Strongly Disagree
a. Agencies generally have sufficient time to conduct adequate searches for and analyses of scientific data relevant to their decisions.	8	40	4	37	11
b. Agencies generally have sufficient budgets to conduct adequate searches for and analyses of scientific data relevant to their decisions.	3	23	7	36	31
c. Agencies generally have sufficient expertise to conduct adequate searches for and analyses of scientific data relevant to their decisions.	8	33	6	40	13
d. Agencies generally place an adequate priority on searching for scientific data relevant to their decisions.	9	31	12	34	14
e. Agencies usually select data that have adequate scientific reliability.	7	42	8	35	8
f. Agencies generally place appropriate reliance on scientific data that support their preferred decisions.	11	36	12	36	5
g. Agencies generally give appropriate recognition to scientifically reliable data that contradict their preferred decisions.	2	18	9	51	20
h. Agencies usually employ adequate scientific analysis when using the data they present as supporting their final decisions.	6	25	13	48	8

24. See RICHARD J. PIERCE JR. ET AL., *ADMINISTRATIVE LAW AND PROCESS* §1.9 (3d ed. 1999).

25. The complete survey is available on request from the authors. We provided respondents the following definition of regulatory peer review:

Regulatory Peer Review is the outside evaluation of an administrative agency's search, selection, or use of scientific data used to support a proposed regulatory decision (rule, permit, or other policy). The evaluation is conducted prior to the agency's final decision by one or more experts in the relevant field who are independent of the agency and have no pecuniary or other conflict of interest with respect to the outcome of the agency's decision.

We sent the survey to 900 randomly selected members of the American Bar Association's Section of the Environment, Energy, and Resources (SEER), of whom 158 responded with usable surveys. We chose SEER because the leading edge of the regulatory peer review debate has focused on environmental law and SEER is a prominent forum for practitioners of environmental law in private practice, government, academic, and other practice settings. The survey was voluntary and responses were anonymous. We greatly appreciate SEER's cooperation in providing the member names and their contact information (SEER did not commission, direct, or in any other way influence the design or implementation of the survey). All funding for the survey and the data analysis was provided by Florida State University (FSU) College of Law. We thank FSU Department of Statistics Prof. Kai-Sheng Song and graduate student Han Yu for their assistance in compiling and analyzing the survey data.

26. The general question asked respondents to state their level of agreement or disagreement with the statement that "based on my experience, administrative agencies usually employ adequate procedures for the search, selection, and use of scientific data in regulatory decision making." Although 41% of respondents stated some level of agreement with the statement, 51% somewhat or strongly disagreed.

Unsurprisingly, and consistent with the institutional theory reviewed above, many respondents indicated they believe that agencies face significant time and resource constraints in their use of science (questions a through c). More troublesome was the level of concern respondents revealed about how agencies prioritize their search for data and about how they select and rely on data in support of their decisions: almost one-half of the respondents expressed negative perceptions of agency behavior (questions d through f).

Most startling, however, were the responses to the final two questions in the series (questions g and h). Over 70% of respondents disagreed, 20% strongly so, with the statement that agencies generally give appropriate recognition to scientifically reliable data that contradict their preferred decisions; 56% of respondents disagreed with the statement that agencies usually employ adequate scientific analysis when using the data they present as supporting their final decisions.

The overall picture these responses paint is that many experienced practitioners understand that agencies face time and resource constraints in their use of science, but even more believe agencies make poor use of what science they have at their disposal, which leads to the potential overstatement of the scientific support for their regulatory decisions.

Of course, not all respondents felt this way, and the difference of opinion is starkest when the backgrounds of respondents are considered.²⁷ Not surprisingly, respondents who indicated federal or state agency government employment as their primary career experience, which made up 15% of the respondent pool, were far more likely to hold favorable views of agency use of science than were respondents with primarily private law firm or in-house careers representing corporations, which accounted for 73% of respondents. For example, government respondents were over four times more likely than industry respondents to agree with the general statement that agencies usually employ adequate procedures.²⁸ Ironically, agency attorneys revealed less concern than did industry attorneys about the adequacy of agency

time and resources. With respect to agency behavior, however, agency attorneys fell in line with institutional theory in expressing tremendous support for agency performance, far more so than did the industry attorneys. Moreover, with government attorneys accounting for most of the favorable opinion of agency performance (notwithstanding their lower representation numbers in the survey), the negative perception of agency use of science among industry attorneys was remarkably deep and broadly shared.

To determine the extent to which practitioners of environmental law view regulatory peer review as an answer to the perceived misuse of science by agencies, we asked respondents to indicate the extent to which they agree or disagree with statements about the potential effects of applying regulatory peer review to proposed regulatory decisions. The perception that regulatory peer review is the answer to agency misuse of science appears to be overwhelming, with well over 65% agreeing that it will improve the quality of agency decisions, expose flaws in agency use of science, and improve public confidence in agencies, and only 20% or less disagreeing that each of those expected benefits will accrue. We were not surprised to find that government and industry attorneys had different expectations about the effects of regulatory peer review, though we were shocked by the degree of disagreement.

Government attorneys, according to our results, simply do not buy into the idea that regulatory peer review has anything salutary to offer their work. But with industry attorneys *12 times* more likely than agency attorneys to believe regulatory peer review will expose flaws in agency procedures, *20 times* more likely to believe it will improve public confidence in agencies, and *33 times* more likely to believe it will improve the quality of agency decisions, can agencies afford to ignore the magnitude of pro-peer-review sentiment that appears to have taken hold among those who practice before them?

IV. The Case Against Peer Review

Critics of mandating regulatory peer review have advanced two positions: First, evidence that agencies frequently overstate the extent to which science supports a regulatory decision is insufficient. Second, absent such evidence, even if there is a problem, they argue, peer review is not the solution but rather a practice to be avoided at all costs.

One concern is that advocates of regulatory peer review promise too much and thus distort the public's expectations of agency practices. This concern is particularly acute in regulatory settings in which the best available science is likely to prove inconclusive, forcing the agency to rely on professional judgment to interpret the data and then, when

27. One of the underlying premises of proposals for regulatory peer review is that there is, or at least may be, a prevalence of regulatory decisions that are not adequately grounded in scientific support. We suspected that private-sector attorneys may be more likely than public-sector attorneys to believe there is such a problem, and thus we grouped the respondent population based on whether the respondent had practiced primarily in the private or public sector over the course of his or her career. We designed our survey questions to obtain respondents' perceptions about a variety of topics that any experienced environmental lawyer could find controversial and aligned with particular political and economic interests. As such, we recognize that responses may be affected by factors such as whether the respondent represents industry or government, believes in strong government or libertarian principles, and so on. Lawyers that represent industry might have rushed to condemn agencies' use of science in their responses, and lawyers representing government might have taken every opportunity to praise them. That is the nature of qualitative perception surveys. As we explain in Parts III and IV of the Article, as important as it is to know the actual performance of a regulatory agency in its use of science, we believe it is also vital to understand perceptions of the need for and efficacy of regulatory peer review, biased as they may be, because of the effect those perceptions will have on the demand for regulatory peer review and in dictating acceptance of the agency's decisions.

28. Since the responses called for in our survey are clearly ordinal in nature, we used the logistic regression method of statistical analysis for answering various questions of interest throughout our study. For example, to determine the influence of government work on perceptions of regulatory peer review, we treated the two practice setting categories as the explanatory variable X, and the responses to perceptions of regulatory peer review were coded on a scale from 1 to k; for example, 1-5, corresponding to strongly agree, somewhat agree,

no opinion, somewhat disagree, and strongly disagree. The score for each question was treated as the response variable Y and the k possible scores of Y are called the response categories. The principal objective of a statistical analysis is to investigate the relationship between the explanatory variable X and the response variable Y. The ordinal nature of the responses leads naturally to statistical models based on the cumulative response probabilities of observing response categories less than or equal to a given score j, when the covariate is X. More specifically, we are interested in investigating the influence of the explanatory variable X on the cumulative response probability up to and including category j. The logistic regression method of examining such relationships involves modeling the logarithm of the odds of the event of observing response categories up to and including category j as a function of the explanatory variable X through a linear regression equation.

permitted or required, to employ other policy considerations to reach a final decision. Regulatory peer review will not close the data gaps.²⁹ If advocates of regulatory peer review suggest otherwise, they oversell to the public what regulatory peer review really offers.

An added concern is that far from advocates' claims that peer review will eliminate bias from agency decisions, it may actually exacerbate these concerns by allowing agencies to mask their biases with the veneer of science. Agencies themselves can misuse peer review. This suggests that agencies may *systematically* tend to use peer review to support their decisions rather than as a critical outside check on the accuracy of their decisions. In its worst extremes, then, peer review can become a cynical exercise, allowing agencies to manipulate the process and rig outcomes to justify agency decisions that might not withstand legitimate peer scrutiny.

Overall, the arguments against regulatory peer review are supported by institutional theory and widely held perceptions among experienced practitioners of regulatory law.

V. Reconceiving the Role of Regulatory Peer Review

Since any discussion of regulatory peer review must be premised on theory and perception rather than empirical evidence, it is important to think clearly about how to balance countervailing concerns. In assessing any specific proposal, therefore, three overarching questions about regulatory peer review must be addressed: (1) what are its most important potential benefits?; (2) where in the regulatory process should it be applied to maximize these benefits?; and (3) under what conditions would it most likely substantially hinder or otherwise undermine agency process?

A. Defining Potential Benefits

Most of the fog surrounding regulatory peer review arises from the proclivity of almost everyone involved in the debate to conflate science and policy, as if agencies make one holistic conclusion about each particular regulatory decision. After the Klamath Committee issued its report, for example, one U.S. Fish and Wildlife Service (FWS) official concluded, accurately, that the committee "didn't say the science proves we were wrong; they just said there wasn't enough science to prove us right."³⁰ In science, of course, that is enough—one generally does not get published in scientific journals based on a claim that one's research did not prove *anything*. Yet, the FWS official clearly took solace in the peer review's finding a lack of scientific support for the agency's position rather than finding that scientific data actually refuted the agency's position.

The difference, for regulatory decisions at least, is grounded in the policy component of administrative decisions. In fact, Congress rarely commands that an agency decision be based solely on scientific evidence conclusively proving the decision correct. The problem is that agencies might not make explicit the policy-based preferences or

findings underlying their decisions. Hence one benefit, perhaps the chief benefit, that could reasonably be expected to derive from the use of regulatory peer review is that it would encourage agencies to provide sharper delineations between scientific and policy bases for decisions.

It is important that agencies not overstate, either by commission or omission, the role science plays in justifying their decisions relative to non-scientific, policy-driven bases. The public ought to know how far science takes the agency in support of its decision, and what beyond science fills any gaps. Indeed, even in its scientific applications, peer review is not expected to prove any research wrong, but rather to identify flaws and deficiencies in a particular research effort that may call into question whether the researcher's conclusions are justified.³¹

B. Mapping Peer Review Onto Regulation

Opponents of the "sound science" movement frequently (and we believe accurately) point out that the movement's primary aim seems to be to increase the quantity rather than the quality of the agencies' science, i.e., to impose on agencies the duty to *do* science more often rather than to *use* science more carefully.³²

Peer review, however, is quality control, not quantity control. Defined as such, peer review actually maps onto the regulatory process in a straightforward manner. Using the components of scientific peer review introduced above, the following model compares scientific peer review to the four stages where science is used in regulatory decisionmaking: (1) the search for scientific data; (2) the selection of data (found through the search) for use in the decision; (3) the interpretation of the selected data in terms relevant to the decision; and (4) the integration of that interpretation with whatever other factors the agency must or may consider in order to reach a final decision.

Figure 2

Stage	Scientific Peer Review	Regulatory Peer Review
Search	What was the quality of the research design and data collection procedures?	Did the agency consult appropriate sources of data and scientific research on the issue for decision?
Selection	Were the methods for testing the hypothesis appropriate and robust?	Did the agency appropriately select data and research identified in the search?
Interpretation	To what extent are the conclusions supported by the analysis of the data?	Did the agency draw appropriate scientific conclusions from the data and research it selected?
Integration	Not relevant—science is the exclusive source of the conclusions drawn in scientific research.	Not applied—although the agency might use other sources to reach its regulatory decision, regulatory peer review stops at evaluation of the agency's interpretation of the selected data and research.

29. Indeed, as we point out in Part V, if anything, regulatory peer review will expose the data gaps and sharpen the differentiation between science and policy as the bases for agency decisions, which we consider the strongest reason to use it.

30. Michael Grunwald, *Scientific Report Roils a Salmon War*, WASH. POST, Feb. 4, 2002, at A1.

31. See *supra* Part II.A.

32. See Burke, *supra* note 5, at 512-14; Wagner, *Bad Science*, *supra* note 10, at 109-32.

Regulatory peer review, as we suggest it should be constructed, would engage in the following kinds of inquiry:

Figure 3

Peer Review Focus	Scope of Peer Review Inquiry
Agency's search for data and research	What steps did the agency take to locate available scientific data and research? Did the agency perform a literature survey of relevant journal publications? Did the agency solicit information from researchers with relevant expertise at universities, other agencies, and private research sources? Was the scope of the search appropriate, e.g., if information about question is limited, did the agency search for available data and research?
Agency's selection of data and research identified in its search	How did the agency evaluate the quality of available data? Did the agency employ appropriate methods for determining the relative quality of the data and research sources identified in its search? Did the agency exclude any data or research for inappropriate reasons? Did the agency rely on data or research of questionable reliability?
Agency's interpretation of data and research selected	Are the agency's scientific conclusions justified based on the peer reviewer's assessment of the data and research the agency should have selected? Did the agency make appropriate conclusions about what were the determinable aspects of each of the relevant scientific inquiries?

These questions, if rigorously pursued, would likely lead reviewers to detect cases in which an agency attempted to oversell what its scientific case supports, and thus would be likely to encourage agencies to be more careful in their search for, selection, and interpretation of scientific data and research. Scientific peer review, in other words, maps quite nicely onto the regulatory process to produce regulatory peer review.

C. Avoiding Drag

And what of the legitimate concern over making agencies jump through more hoops? Our formulation of regulatory peer review focuses on the quality of the agency's use of science, not the quantity of how much science it conducts. If an agency presents any of its work as scientific in quality, there is a minimum standard it must meet to do so credibly. Asking agencies to substantiate their scientific claims ought not strike anyone as repugnant to appropriate administrative procedures. As to the concern that regulatory peer review imposes unrealistic burdens of proof, that also is not the case under our formulation of the process. Rather, regulatory peer review imports the standards of proof prescribed in the relevant statutory program.

Finally, as to the concern that regulatory peer review will unduly impede and interfere with agencies' policy deliberations, that is the least likely effect under the formulation we propose. Indeed, if regulatory peer review produces any improvement in the quality of agencies' use of science, which we believe it would, it should only improve agencies' policy deliberations by providing more confidence in the scientific

input and more explicit delineation between what is science and what is policy in the justification the agency presents for its final decision. We do recognize that regulatory peer review must be conducted properly if it is to be conducted at all.

VI. A Proposed Model of Randomized Peer Review

The policy question underlying our proposal is: how can we capture the benefits of regulatory peer review at lowest cost to improve overall agency decision quality? To craft a peer review policy, we need to be clear about what the most significant benefits of peer review are. Our proposal for regulatory peer review offers a potential benefit that no one has talked about, its diagnostic function. Neither advocates nor critics of regulatory peer review can intelligently assess the merits of requiring it—whether restricted to major decisions, decisions that create precedent, or decisions that protect species—without first having a clear sense of whether none, a few, or many of these decisions would benefit from peer review. 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.³³

To capture the benefits outlined above, we propose a model of randomized peer review with three discrete stages:

Stage One: Target Decisions

First identify classes of regulatory decisions that would likely benefit from peer review. This would include types of agency decisions that rely on scientific data and scientific judgments. Within this broad class of decisions, randomly select a subset of specific regulatory decisions within a six-month period. To commence, we would suggest following the U.S. Internal Revenue Service (IRS) audit practice of selecting roughly 1-2% of the eligible decisions.³⁴

Stage Two: Peer Review Decisions

The peer review of the science underpinning these decisions would be conducted by groups of three experts selected from standing panels established by the NRC. Peer reviewers would be compensated in order to attract competent experts and encourage timely performance, vetted for potential bias by the NRC through its standard practice, appointed for a limited term, and kept anonymous to the decision-making agency except in cases in which the reviewers' desire to conduct field investigation and

33. Holly Doremus & A. Dan Tarlock, *Science, Judgment, and Controversy in Natural Resources Regulation*, 26 PUB. LAND & RESOURCES L. REV. 1, 33 (2005). Profs. Holly Doremus and A. Dan Tarlock recognize that "[e]ffective outside reviews can also spur learning, by inspiring new thinking, demanding accountability, and highlighting gaps in the existing data base that could be filled." *Id.* We are suggesting that peer review also spurs learning about the quality of agency practices in general.

34. As regulators well know, deterrent effects can be realized even when compliance inspections are conducted less than 100% of the time for fewer than 100% of the regulated facilities. The number of reviews, of course, could not exceed the review budget, which would ultimately determine the percent used.

interviews precludes anonymity.³⁵ The peer review committees would not be asked to conduct a de novo review of the agency's entire record and decision. Rather, the committee would be asked to evaluate the agency's protocol for identifying relevant scientific data and research, its rationale for selecting and prioritizing data and research from the identified pool, and its interpretation of this body of science. When necessary, the peer reviewers could request important data compilations or research reports relied upon by the agency in making these evaluations. The peer review would be completed in no more than 90 days and would not be subject to the public meeting and other procedural requirements of the Federal Advisory Committee Act.³⁶

Stage Three: Disseminate and Analyze Reviews

The results of the peer review would be released to the agency and the public prior to the conclusion of any public notice-and-comment procedures applicable to the underlying decision. After a period of two years, and every two years thereafter, the overall results of the peer reviews conducted for a particular agency and regulatory program, e.g., designations of critical habitat, would be assessed to determine whether the audit rate is appropriate and, more generally, whether the agency's use of science warrants the mandatory or more intensive practice of regulatory peer review.

How well does this proposal capture the benefits yet minimize the costs of regulatory peer review? Based on the IRS

experience, the randomized aspect of the proposal seeks to create a general deterrent effect, ensuring agency officials understand that their decision may become subject to peer review. Through this approach, the benefits of regulatory peer review will be more institutional in nature than identifiable in discrete cases. In other words, if the audit rate is high enough, the prospect of peer review would inherently lead agencies to think twice about their use of science in making decisions. And, perhaps most importantly, it provides a way to empirically diagnose whether agency use of science really should be of concern and to finally answer how many Klamaths are out there.

But what of the downsides? As noted earlier, paralysis by analysis is a real concern for resource-strapped agencies working under tight deadlines. At some point, the quest for relevant, reliable, and reviewed data may add so much time to the decisionmaking process that the policy effectiveness of the decision is impeded. Our proposal has costs, but they are significantly less than those of other proposals. If a 1-2% audit rate can serve as a meaningful general deterrent and provide an accurate sample for analysis, the most important benefits of more comprehensive review requirements can be satisfied at a fraction of the cost.³⁷ Appropriating funds for the NRC rather than the target agencies to pay for the reviews would also ensure that agencies are not forced to sacrifice other activities in order to carry out reviews.

And what about concerns that the peer review process will become politicized or captured? Our proposal represents a measured approach that enhances regulatory peer review but puts the decision about whether to use it and how to conduct it outside of the agencies' control and in the hands of a generally respected neutral player.

VII. Conclusion

We have sought to show that regulatory peer review can meaningfully improve agency decisions that rely on the use or interpretation of scientific information. We propose randomized peer review to shift the debate to an empirically grounded vantage from which we can more intelligently assess the proper role for this process in agency settings.

35. The NRC peer review policy, under which the Klamath Committee was formed, provides:

The Research Council does not permit governmental agencies that sponsor projects to select committee members because of the institution's commitment to ensuring independence and objectivity in carrying out its work. However, sponsors can and often do suggest nominees, some of whom may be selected. Such a selection could be made when the individuals nominated by a sponsor have the expertise, knowledge, and stature required and can be expected to participate in a committee's work without being subjected to undue influence or pressure from the sponsoring agency.

National Academies, *The National Research Council Process*, <http://www.nationalacademies.org/about/faq4.html> (last visited June 23, 2008).

36. 5 U.S.C. app. §§1-11 (2000).

37. In order to make these decisions, more information would be needed on the likely costs and number of reviews. It is worth noting that for a fraction of its \$650,000 total budget, the Klamath Committee was able within 90 days to conclude its initial peer review of the agency decisions.